SECTION 2

SPECIFICATIONS AND REQUIREMENTS

FOR

**THE SUPPLY AND DELIVERY OF MEDICINAL PRODUCTS FOR BRUNEI ENGINEERING, LOGISTICS AND TRAINING SOLUTIONS SDN BHD ONE PLUS ONE (1+1) YEARS**

TENDER BATCH:

BELTS/MSC/PROC/MP/2024/10

The following information are required as part of **Technical Proposal submission**. Failure to comply with the requirement may cause unnecessary delay in processing for approval from the relevant authority.

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| **Technical Requirements** |
| 1. **Delivery Period**   Please indicate the lead-time for delivery period. The shortest or specific lead-time will be preferred.  **Not acceptable if** language used to describe lead time as *“Not more than 60-90 days upon confirmation, however subject to stocks availability upon receipt of purchase order”* would be regarded as unspecified lead time which therefore be considered as the longest lead-time |
| 1. **Samples**  * Must be submitted in untampered original pack including its package insert; * The sample should be labelled with tender reference number and listed item no.; * Must be submitted with Submission of Sample Form; and * Must be enclosed with a copy of Certificate of Analysis (COA) with the same batch number of product sample submitted (if available).   Tenderers are reminded to ensure the product sample match with their offer.  Upon approval of the said tender, samples submitted from unsuccessful tenderers will be returned.  (For Controlled drugs and Psychotropic drugs – if unable to supply physical sample, must submit artwork of original pack with digital picture; product package insert and COA). |
| 1. **Source of supply**   The source of the product should be stated (manufacturer or wholesaler). If source from wholesaler, please provide the following documents:   * Copy of Wholesaler License * Declaration letter stating that the sponsor/principal will be responsible to inform the regulatory authority of any issues related to product safety, quality and efficacy |
| 1. **Product Registration Status**   *Preference will be given to medicinal products:*   * *Registered with the BDMCA.* * *Submitted for registration with the BDMCA.*   **Registered with Brunei Darussalam Medicines Control Authority (BDMCA)**  Please enclosed a copy of Product Licence Certificate.  If not yet registered, please indicate its status e.g.   |  |  | | --- | --- | | **Status** | **Information/ document required** | | * Submitted for registration | LOA-P reference no | | * Committed for registration | A copy of Commitment letter to register with the proposed date for submission | | * Not classified as medicinal product | Relevant approval document from the regulatory authority e.g. cosmetic product notification no. |   **Registered with BDMCA but not the Product License Holder**  If tenderer is not the Product License holder, please provide one of the following documents:  5.2.1 Letter of authorisation issued by the Product License holder stating the following:   * authorising the tenderer to quote the product; and * Product License holder remains the importer and distributor of the product   5.2.2 If tenderer will be the importer, please submit a declaration letter that you are able to fulfil the *“Application to import a registered medicinal product by non-product license holder (on consignment basis)”.*  **Transfer of Product License Holder**  If the product in the process of transfer of Product License Holder to the tenderer, please indicate the variation application reference no. and submit a declaration letter that you are able to fulfil the *“Application to import a registered medicinal product by non-product license holder (on consignment basis)”*.  **If not registered with BDMCA,** Product registered by at least one drug regulatory agencies in any of the reference countries\* will be given preference  Please state product registration no. in any reference countries, if applicable.  **Note:**   * Refer to **Item c** for submission of Product information and Documents Required for Unregistered Drug.   *[****\*****The reference countries include Australia, Canada, France, Japan, South Korea, Malaysia, Singapore, Sweden, Switzerland, United Kingdom, European Union, and the United States of America]* |
| 1. **New Product**   It is considered ***new product*** if the product offered has never been supplied to the Ministry of Health, Brunei and the product is **not registered or never submitted technical document for registration with BDMCA**.  The followings detailed information of the product must be submitted (in soft-copy in the USB pen drive). The information required include, but not limited to, the followings:   1. Bioequivalence studies (Generic products) and / or Clinical studies; 2. Stability studies; 3. A copy of the Summary of Product Characteristics / Package Insert which, for parenteral preparations, must contain the following information (where applicable):  * Stability information once opened and after dilution / reconstitution * Incompatibilities with other injection or intravenous fluids * Reconstitution method * Mode of administration e.g. for only intravenous / intramuscular / subcutaneous etc.  1. Declaration of source of animal origin and alcohol content (if any).   Good Manufacturing Practice (GMP) certificate – *“Manufacturers with valid GMP certificates for medicinal Products will be given preference”* |
| 1. **Shelf life**   Minimum of 24 months on receipt; unless the item’s manufactured shelf life is less than 24 months; short expiry date items agreed to be accepted by BELTS with prior knowledge before delivery and with letter of undertaking provided.  Please indicate the product overall shelf-life.  Product with longer shelf-life will be given preference. |
| 1. **Storage condition**   The storage condition of the product should be labelled in accordance with ASEAN Guideline on Stability Study of Drug Product. Specific temperature for storage condition should be indicated.  **Not acceptable** by using these terms such as “ambient conditions”, “room temperature” or “does not require any special storage condition”; unless enclosed with stability study document. |
| 1. **Special Requirements**   Awarded Company must provide:   * **Cold chain items**   Records of temperature readings from manufacturer to point of delivery at State Medical Store, Brunei Darussalam.   * **Blood products**   **Batch Release Certificate** or **Certificate of Origin** for every batch and consignment delivered.   * **Animal content**   Please indicate yes or no if there is any part of the product is derived from animal source. If yes, please state the source. For any bovine source, the certificate of suitability or TSE/BSE certificate must be submitted.   * **Alcohol content**   Please indicate yes or no if there is any alcohol content. If yes, please state the name of alcohol and strength. |

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| **No.** | **Item Description** | **Units** | **Estimated Requirements** | **Buffer Stock (Units)** | **Packing / Presentation** | **Pack Size** | **Shelf Life** | **Delivery Period** |
| 1 | Insulin Aspart Biphasic 30/70 (30% Insulin Aspart And 70% Insulin Aspart Protamine) 100iu/Ml Injection In Prefilled Disposable Injection Device As Novomix 30 Flexpen X 3ml Or Its Equivalent With Compatible Needles According To The Number Of Doses Required For Each Patient.  Specifications Of Needles • Material: Sterile, Single Use Needle With Silicone Coating • Size: 0.23mm X 32g • Length – 4mm • Each Needle Comes In Its Own Antiseptic Peelback Ensuring Complete Sterility Up To Moment Of Use • Compatible With Product On Offer (I.E. Insulin) | Pen | 8,250 | 20% of Estimated Annual Usage | Prefilled pen in individual box preferred | 3ml preferred | Minimum of 2 years’ shelf life upon receipt. Any period less than 2 years to provide Letter of Undertaking | First order within 2 months upon receipt of purchase order, subsequent order ex-stock |
| 2 | Dupilumab 300mg/2ml Solution For Injection In Prefilled Syringe | Pen | 80 | 20% of Estimated Annual Usage | Prefilled pen of 2's per box preferred | 2’s | Minimum of 2 years’ shelf life upon receipt. Any period less than 2 years to provide Letter of Undertaking | First order within 2 months upon receipt of purchase order, subsequent order ex-stock |
| 3 | Denosumab 60mg/ml Solution for Injection Pre-filled Syringe | Syringe | 200 | 20% of Estimated Annual Usage | Prefilled syringe in individual box preferred | 1's | Minimum of 2 years’ shelf life upon receipt. Any period less than 2 years to provide Letter of Undertaking | First order within 2 months upon receipt of purchase order, subsequent order ex-stock |
| 4 | Golimumab 50mg/4ml for Intraveneous Infusion | Vial | 70 | 20% of Estimated Annual Usage | Vial in individual box preferred | - | Minimum of 2 years’ shelf life upon receipt. Any period less than 2 years to provide Letter of Undertaking | First order within 2 months upon receipt of purchase order, subsequent order ex-stock |

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| 5 | Antithymocyte 25mg Immunoglobulin (Rabbit) Intravenous Infusion As Thymoglobuline Or Its Equivalent | Vial | 200 | 20% of Estimated Annual Usage | Vial in individual box preferred | - | Minimum of 2 years’ shelf life upon receipt. Any period less than 2 years to provide Letter of Undertaking | First order within 2 months upon receipt of purchase order, subsequent order ex-stock |
| 6 | Sorafenib (As Tosylate) 200mg Oral Solid Preparation Preferably Scored Tablet | Tablet | 2,100 | 20% of Estimated Annual Usage | Blister pack with 10’s per strip preferred Preference will be given to suppliers quoting item where the name and strength of the product appears over each blister pocket or be oriented centrally | Box of 60 tablets preferred | Minimum of 2 years’ shelf life upon receipt. Any period less than 2 years to provide Letter of Undertaking | First order within 2 months upon receipt of purchase order, subsequent order ex-stock |
| 7 | Glecaprevir 100mg & Pibrentasvir 40mg Oral Solid Preparation Preferably Scored Tablet As Maviret Or Its Equivalent | Tablet | 5,040 | 20% of Estimated Annual Usage | Blister pack of 10’s per strip preferred. Preference will be given to suppliers quoting item where the name and strength of the product appears over each blister pocket or be oriented centrally | Box of 84 tablets preferred | Minimum of 2 years’ shelf life upon receipt. Any period less than 2 years to provide Letter of Undertaking | First order within 2 months upon receipt of purchase order, subsequent order ex-stock |
| 8 | Ruxolitinib (As Phosphate) 15mg Oral Solid Preparation Preferably Scored Tablet | Tablet | 2,240 | 20% of Estimated Annual Usage | Blister pack with 10’s per strip preferred Preference will be given to suppliers quoting item where the name and strength of the product appears over each blister pocket or be oriented centrally | Box of 30 tablets preferred | Minimum of 2 years’ shelf life upon receipt. Any period less than 2 years to provide Letter of Undertaking | First order within 2 months upon receipt of purchase order, subsequent order ex-stock |
| 9 | Upadacitinib 15mg Modified Release Oral Solid Preparation Preferably Tablet | Tablet | 5,600 | 20% of Estimated Annual Usage | Blister pack of 10’s per strip preferred. Preference will be given to suppliers quoting item where the name and strength of the product appears over each blister pocket or be oriented centrally | Box of 28 tablets preferred | Minimum of 2 years’ shelf life upon receipt. Any period less than 2 years to provide Letter of Undertaking | First order within 2 months upon receipt of purchase order, subsequent order ex-stock |
| 10 | Lenalidomide 10mg Oral Solid Preparation Preferably Scored Tablet | Tablet | 5,040 | 20% of Estimated Annual Usage | Blister pack with 21’s per strip preferred Preference will be given to suppliers quoting item where the name and strength of the product appears over each blister pocket or be oriented centrally | Box of 21 tablets preferred | Minimum of 2 years’ shelf life upon receipt. Any period less than 2 years to provide Letter of Undertaking | First order within 2 months upon receipt of purchase order, subsequent order ex-stock |
| 11 | Deferasirox 90mg Oral Solid Preparation Preferably Tablet | Tablet | 48,000 | 20% of Estimated Annual Usage | Blister pack with 10’s per strip preferred. Preference will be given to suppliers quoting item where the name and strength of the product appears over each blister pocket or be oriented centrally | Box of 100 tablets preferred | Minimum of 2 years’ shelf life upon receipt. Any period less than 2 years to provide Letter of Undertaking | First order within 2 months upon receipt of purchase order, subsequent order ex-stock |
| 12 | Sacubitril 24mg & Valsartan 26mg Oral Solid Preparation Preferably Tablet As Entresto 24/26mg or Its Equivalent | Tablet | 154,050 | 20% of Estimated Annual Usage | Blister pack with 10’s per strip preferred Preference will be given to suppliers quoting item where the name and strength of the product appears over each blister pocket or be oriented centrally | Box of 30 tablets preferred | Minimum of 2 years’ shelf life upon receipt. Any period less than 2 years to provide Letter of Undertaking | First order within 2 months upon receipt of purchase order, subsequent order ex-stock |
| 13 | Dabigatran 150mg Oral Solid Preparation Preferably Scored Tablet | Tablet | 420,000 | 20% of Estimated Annual Usage | Blister pack with 10’s per strip preferred. Preference will be given to suppliers quoting item where the name and strength of the product appears over each blister pocket or be oriented centrally | Box of 30 tablets preferred | Minimum of 2 years’ shelf life upon receipt. Any period less than 2 years to provide Letter of Undertaking | First order within 2 months upon receipt of purchase order, subsequent order ex-stock |
| 14 | Dabigatran 110mg Oral Solid Preparation Preferably Scored Tablet | Tablet | 489,000 | 20% of Estimated Annual Usage | Blister pack with 10’s per strip preferred. Preference will be given to suppliers quoting item where the name and strength of the product appears over each blister pocket or be oriented centrally | Box of 30 tablets preferred | Minimum of 2 years’ shelf life upon receipt. Any period less than 2 years to provide Letter of Undertaking | First order within 2 months upon receipt of purchase order, subsequent order ex-stock |
| 15 | Sacubitril 49mg & Valsartan 51mg Oral Solid Preparation Preferably Tablet As Entresto 49/51mg or Its Equivalent | Tablet | 300,000 | 20% of Estimated Annual Usage | Preference Will Be Given To Suppliers Quoting Item | Box of 60 tablets preferred | Minimum of 2 years’ shelf life upon receipt. Any period less than 2 years to provide Letter of Undertaking | First order within 2 months upon receipt of purchase order, subsequent order ex-stock |
| 16 | Sacubitril 97mg & Valsartan 103mg Tablet Oral Solid Preparation Preferably Tablet As Entresto 97/103mg or Its Equivalent | Tablet | 489,000 | 20% of Estimated Annual Usage | Where The Name And Strength Of The Product | Box of 60 tablets preferred | Minimum of 2 years’ shelf life upon receipt. Any period less than 2 years to provide Letter of Undertaking | First order within 2 months upon receipt of purchase order, subsequent order ex-stock |
| 17 | Deferasirox 360mg Oral Solid Preparation Preferably Tablet | Tablet | 90,000 | 20% of Estimated Annual Usage | Blister pack with 10’s per strip preferred. Preference will be given to suppliers quoting item where the name and strength of the product appears over each blister pocket or be oriented centrally | Box of 100 tablets preferred | Minimum of 2 years’ shelf life upon receipt. Any period less than 2 years to provide Letter of Undertaking | First order within 2 months upon receipt of purchase order, subsequent order ex-stock |