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Request for Participation **for the Provision of Third-Party Temperature Controlled Cold Storage Facility** **of Pharmaceuticals between 2°C and 8°C for the Central Procurement and** **Supplies Unit (MFH)**

The Central Procurement and Supplies Unit within the Ministry for Health (MfH) wishes to identify economic operators interested in providing 100 to 300 Euro Pallets of third-party temperature-controlled storage facility of Pharmaceuticals between 2°C and 8°C. Economic Operators who can provide less than 100 Pallets should still submit a Request to Participate.

1. Aims of this Procurement Process and Background

- 1.1 The Ministry for Health is in continuous process to adapt its logistic operations, in view of the exponential increase in the demand affecting the CPSU's cold storage capacity which has become saturated. Through this request for participation, the Government intends to identify and enter into an agreement with interested licensed economical operators willing to receive CPSU Stores cold items from several appointed suppliers, stock the goods and prepare the orders for collection to the various entities/ sites as determined by the Contracting Authority. Please note that these services are required for cold chain medicinal products only.
- 1.2 The request for the provision of third party, cold storage facilities has also been taking into consideration, the potential emanating from the Brexit, COVID19 factors etc. Such factors have made CPSU MfH vigilant and more proactive to ensure that the provision of cold medicinal stock will not suffer any abnormal shortages from such situation. Therefore, an increase in the stock holding of all cold medicines has been imposed as a directive by the MfH.
- 1.3 Therefore the above scenario in 1.2 will require additional buffer cold storage facilities to maintain for any additional stock holding of government cold medicines.
- 1.4 The provision of this contract shall be for a period of 3 years extendable by a further period of another 1 year.

2. Requirements

- 2.1 The following requirements are considered as compulsory and must be accepted by the economic operators as all inclusive;

2.2 Leasing of cold storage space for cold-chain medicinal products with controlled temperatures ranging between 2 °C and 8 °C.

The storage facilities space must be temperature controlled (between 2 to 8 Degrees Celsius) normally distributed. The storage facilities must include the necessary plastic pallets on which items are to be stored, lifting equipment to move the pallets around and other machinery needed to keep the storage facilities clean and tidy. The economic operator would be responsible for the upkeep of the storage facilities which is to include cleaning services and maintenance of the cold storage facilities. The cold storage facilities must also be protected and insured against breakdown, theft and fire.

There will be no obligations for use of plastic pallets during delivery of cold chain medicinal products but goods must be stored on plastic pallets at the third-party temperature controlled cold storage facility as this is a requirement by the Medicines Authority Inspectorate for storage of cold chain medicinal products.

3. General Technical Conditions for the Storage of Cold Pharmaceutical items

3.1 The following general technical conditions apply for the receipt, holding and distribution of cold chain medicinal products by the Economic Operator.

3.2 The Economic Operator must hold a valid Wholesale dealer license and Certificate of GDP compliance of wholesale distributor issued by the Medicines Authority for the storage and distribution of cold-chain medicinal products according to Art 83 of 2001/83/EC.

3.3 The Economic operator means the third-party licensed logistics provider that will receive, store and prepare for dispatch cold-chain medicinal products owned by the Contracting Authority.

3.4 The Economic Operator ensures that the warehousing activities are carried out in accordance with the recognized pharmaceutical regulations as well as the requirements of the local authorities and the requirements of the GDP Guidelines as outlined in 2013/C 343/01 and its subsequent amendments.

3.5 The Contracting Authority and the Economic Operator shall provide each other with all relevant, current licenses/certificates issued by the relevant competent authority (with certified translation in English, if necessary).

3.6 The Economic Operator must declare that it is in possession of the wholesale dealer's licence for cold chain medicinal products to carry out the warehousing activities during the complete term of this contract.

3.7 The Economic Operator shall not subcontract in full or any part of the wholesale dealing activity without the approval of the Contracting Authority, where in such case the Economic Operator will remain fully responsible of any full or part subcontracted wholesale activities.

3.8 The Economic Operator must note that apart from the temperature control key factor for cold chain medicinal products, segregation of medicinal products from the rest of other stock is also a key factor.

4. The Contracting Authority Responsibilities

4.1 The Contracting Authority shall advise the Economic Operator of the need for storage of cold chain medicinal products as early as possible and shall give an estimate of quantities and types of products to be stored.

- 4.2 The Contracting Authority shall advise the Economic Operator when deliveries include penicillin containing products, hormones, cephalosporins, and/or cytotoxic drugs.
- 4.3 Radiopharmaceuticals and controlled drugs under the current Malta Dangerous Drug Ordinance **do not** make part of this contract.
- 4.4 The Contracting Authority shall provide the Economic operator with a packing list before any delivery or collection of goods.
- 4.5 All consignments to the Economic Operator shall be labelled. The Economic Operator shall ensure that the pallets contain the following information: name of product, dosage form, strength, pack size, batch number, expiry date and quantity
- 4.6 Furthermore, the Contracting Authority Responsible Person/s will direct the Economic Operator Responsible Person/s to label any specific batch/es of cold medicinal product/s as Quarantine, Released or Not-to-be-used.

The Receiving Section CPSU shall be labelling the cold stock before sending it to third-party cold room.

- 4.7 Both the Economic Operator and the Contracting Authority shall maintain an inventory of all cold-chain medicinal products stored at the Economic Operator storage facilities and shall update this inventory whenever new stock is delivered or stock is issued from the Economic operator's cold facility. The Inventory shall include the following information - name of product, dosage form, strength, pack size, batch number, expiry date and quantity in packs and quantity in units. The Contracting Authority shall supply the Economic Operator with a copy of this inventory whenever it is updated.
- 4.8 The Contracting Authority will be managing all the transport involved and will be responsible of the handling stock from the Contracting Authority stores to loading bay at the Economic Operator's off site storage facility loading bay.

5. The Economic Operator Responsibilities

- 5.1 On delivery of stock of cold-chain medicinal products, the Economic Operator Employee shall check the quantities of each product received against delivery note. On successful completion of these checks, a goods received note or equivalent document shall be signed off by the Economic Operator employee.
- 5.2 Throughout the duration of this contract, the Economic Operator shall store all cold products under suitable physical conditions, according to their specification and in a secure manner.
- 5.3 The Economic Operator Responsible Person/s shall inform the Contracting Authority in a timely manner of any temperature excursions (defined as temperature values falling outside the documented temperature limits and periods set by the Quality Management System) existing at the off-site third party controlled-temperature cold storage facilities.
- 5.4 The Economic Operator will assume the responsibility of implementing and maintaining the required Environmental Health and Safety regulations as per current Maltese legislation.

5.5 Cold-chain medicinal products shall be stored appropriately separated from other cold products of other companies, in a clearly marked area of the Economic Operator's licensed premises.

5.6 The Economic Operator must provide a report including monthly stock take and all stock movement to the Contracting Authority of all cold-chain medicinal products stored at the Economic Operator storage facilities.

6. Other Responsibilities - Collection of Cold Pharmaceutical Products from the Economic Operator's Cold Storage Facility

6.1 The Contracting Authority shall inform the Economic Operator of the intention to collect stock of cold medicinal products at least 24 hours in advance and shall provide the Economic Operator with a packing list containing details of the goods to be collected.

As a general rule, stock will be delivered and collected in Pallets. The average collection frequency is difficult to say at this point, as every item has relatively different Customer Demand thus stock turnover varies.

6.2 When the cold-chain medicinal products are to be collected, the delivery note shall be signed off by a representative of the Contracting Authority on receipt of goods.

6.3 The responsibility of the Economic Operator for the storage of the products shall end once the representative of the Contracting Authority accepts goods and signs the delivery note as evidence of receipt of goods from the Economic Operator storage facility.

6.4 The Contracting Authority is responsible to update the inventory.

6.5 The Economic Operator shall abide by delivery and/or collection dates/times agreed upon by both parties.

7. Terms and Conditions Under the GDP for Pharmaceutical Items

7.1 The Contracting Authority shall be responsible for all the GDP activities related to the cold pharmaceutical products being stored at the Economic Operator apart from the storage function. All such activities shall be carried out by the Contracting Authority employees.

7.2 Such activities include, but are not limited to

- All the Contracting Authority GDP documentation
- The printing of relevant delivery note
- Receipt, handling and distribution of products as per Contracting Authority GDP procedures
- Handling of complaints, adverse events and pharmacovigilance issues related to the Contracting Authority products.
- Communications with the relevant MAHs and regulatory bodies regarding the contract warehousing arrangement.

7.3 As long as adequate prior notification is given, authorised Contracting Authority employees shall be granted access to the Contracting Authority products stored at the Economic Operator warehouse during working

hours. When in the Economic Operator warehouse, the Contracting Authority employees shall be accompanied by an Economic Operator employee at all times.

7.4 Any other GDP function that the Contracting Authority requires the Economic Operator to perform apart from storage shall be listed in Appendix 1 of this Contract.

8. Complaints

8.1 The Economic Operator shall assist in the handling of all complaints received by the Contracting Authority where the potential root cause may be directly or indirectly related to the contract warehousing activities described in this contract.

9. Product Recall

9.1 Initiation of a product recall is the sole responsibility of the Contracting Authority. The Economic Operator shall provide the Contracting Authority with technical assistance necessary with regards to the contract warehousing operations carried out by the Economic Operator.

9.2 The Contracting Authority shall have a procedure in place for the carrying out of recalls.

9.3 In the case of a recall affecting products stored at the Economic Operator, the Contracting Authority shall inform the Economic Operator in the shortest time possible.

9.4 The Economic Operator shall ensure that affected batches are stored safely and segregated from other products until they are returned to the Contracting Authority or disposed of. The Contracting Authority shall instruct the Economic Operator on the disposal or return of the recalled product in the shortest time possible.

9.5 Any transportation and/or destruction costs are to be borne to the Contracting Authority unless root cause of the recall has been established as arising from the contract warehousing activities described in this Contract.

10. Audits

10.1 The Economic Operator shall conduct and document self-inspections to assess its quality systems. The Economic Operator shall notify the Contracting Authority of any inspections or actions by the regulatory authority that may potentially impact the warehousing activity or the license of the Economic Operator.

10.2 If any deficiency noted during an inspection by a regulatory body relates to or impacts the warehousing of products covered by this contract, the Economic Operator shall be advised immediately.

10.3 The Economic Operator shall allow the Contracting Authority to audit its facilities; the Contracting Authority must notify the Economic Operator at least 2 weeks prior to the date of the planned audit. Following any audit, the Contracting Authority must provide the Economic Operator with a written report. The Economic Operator shall remedy any gaps identified during the audit within a timescale agreed upon by both parties.

11. Expired Goods

11.1 It is the responsibility of the Contracting Authority to collect expired goods stored at the Economic Operator or to instruct the Economic Operator to dispose of expired goods no later than two months after expiry.

12. Damages

12.1 If the Economic Operator discovers any damages and/or discrepancies at any point following the preliminary check, the Economic Operator shall inform the Contracting Authority immediately, and shall provide photos where applicable.

13. Secrecy

13.1 The Economic Operator shall not divulge any information about the Contracting Authority and Contracting Authority products received from the Contracting Authority in connection with the contract warehousing.

13.2 Furthermore, the Contracting Authority operates in line with the Data Protection Act (Chapter 586) and the General Data Protection Regulations (EU GDPR 2016/679). This document may contain confidential, proprietary or legally privileged information and it is intended only for the person or entity to which it is addressed. Anyone who is not the intended recipient should not use it. Any dissemination, distribution, copying, and/or alteration of this document for any purpose without the sender's express authorisation is strictly prohibited.

14. Validity

14.1 This Contract shall be binding on both parties. Any deviation here from must first be communicated between and approved in writing by both the Economic Operator and the Contracting Authority.

14.2 This agreement enters into effect on the date of award of this contract and remains valid until the termination of this contract.

14.3 Anyone of the parties wishing to terminate this contract during the validity period may do so by giving a thirty (30) days written notice to the other party.

15. Other General Conditions

15.1 It is understood that for the purpose of this contract, the working hours of the Economic Operator shall be notified to the Contracting Authority at least three (3) weeks in advance.

15.2 The Economic Operator will be liable for the cost of damaged goods only if and when products are damaged and/or made unsaleable as well as any shortages during the storage of the products at the premises of the Economic Operator.

15.3 The Economic Operator shall keep the original of all records generated by the contract warehousing operations for at least a year after the expiry date of the products, or for five years, whichever is the longest period of time. These records shall be stored securely.

15.4 In cases that the Contracting Authority requires to use the Economic Operator for emergency purposes as part of a contingency plan due to *for majeure*, the Contracting Authority has to contact the Economic

Operator to check for the available space at that point in time before moving any goods from the premises to the Economic Operator premises.

16. General Upkeep and Environmental Conditions of the Storage Facilities

16.1 The Economic Operator will be responsible for the upkeep, safety and security of the Cold Storage Facilities offered to the Contracting Authority.

16.2 In view of the above, the Economic Operator must provide evidence that the Cold Storage Facilities are covered by Cleaning Services.

16.2.1 The Economic Operator is responsible for the maintenance and upkeep of the cold facilities.

16.2.2 The Economic Operator is to ensure that the cold storage facilities are equipped with 24 hour temperature monitoring and off-site alarm system in case of any temperature excursions outside the set limits of 2 and 8 degrees Centigrade.

16.2.3 The Economic Operator must provide evidence as to what contingency measures are in place for the cold facilities in case of breakdown.

16.2.4 Nonetheless, the Economic Operator must provide evidence that the Cold Storage Facilities are temperature controlled by a cooling system which must be connected with a stand by generator in case of a power cut downtime by the Main Power Grid.

17. Minimum Requirements for Proper Stock Handling and Storage Systems

17.1 The Economic Operator must ensure to have proficient employees to handle the Contracting Authority stocks.

17.2 The Economic Operator must also ensure to have the appropriate lifting equipment to handle heavy stocks or when storing stock in elevated storage rack in order to avoid any damages or fatigue by the Economic Operator employees during the handling of the Contracting Authority Stocks.

17.3 The Economic Operator must ensure that handling of the cold stock within the stores will be carried out by his operators.

17.4 It is highly recommended that Economic Operator shall ensure that the stock will be stored on plastic pallets and not directly on the floor especially where Pharmaceutical products are involved.

17.5 The Economic Operator is also advised to store any cold stock which respects the FEFO principle in or order to facilitate the collection of the same stocks when required by the Contracting Authority.

17.6 The Cold Storage Facilities for cold Pharmaceutical items must be temperature controlled between 2°C to 8°C.

18. Insurances and Protection Policy of the Off-Site Storage Facilities.

18.1 The Economic Operator must submit evidence which clearly shows that the Cold Storage Facilities offered for the storage of the cold stocks pertaining to the Contracting Authority is covered by the following insurance policies;

- Pilfering
- Fire
- Accidental damage

19. Contract Duration and Payment Terms

- 19.1 The tender duration is for three years extendable for another year.
- 19.2 This is a multiple award tender based on price ranks, rate per pallet and pay per use.

20. Payment Terms

- 20.1 Each month invoice must include stock take report which must tally to effect endorsement by the Contracting Authority. These invoices will be sent to the Contracting Authority representatives, Mr Saviour Pace and Mr Josef Borg for their attention and eventual endorsement and payment.
- 20.2 Payment terms are sixty (60) days from the date of invoices.

21. Penalties

- 21.1 The Ministry for Health reserves the right to impose penalties as per Term of Reference and Conditions included in this tender document.

22. Taxes and Duties

- 22.1 All taxes (other than Value Added Tax), duties, levies, registration fees, stamp duties, customs duties, fines, tolls, social insurance contributions or other impositions levied on the Contractor or the Contractor's personnel or any of its subcontractors for activities related to the Contract Works, and which are attributable to the Contractor, shall be borne and paid exclusively by the Contractor, who shall be deemed to have included such taxes in the Contractor's rates during the submission of the bid.
- 22.2 Evidence of such payments shall be submitted to the CPSU upon request. In case of failure of the Contractor to produce such evidence of payment due, the Client shall have the right to deduct from any payment due to the Contractor such amounts as may be necessary to discharge the Contractor's liability and the Contractor shall forthwith indemnify and save harmless the CPSU against any such taxes, duties or any other similar expenses.

24. Additional Information

- 24.1 Please note that there will be no minimum number of pallet spaces guaranteed to be used for each economic operator that is awarded hits call.
- 24.2 The date of initiation of contract will be as soon as call is awarded.
- 24.3 The time between notice of award and commencement of use will be a maximum of TWO weeks.
- 24.4

23. Interested Economic Operators are to submit a technical proposal. No Financial Offer is to be submitted at this point.

The technical proposal must include:

Item	Description	Tick if submitted
1	Wholesale dealer license issued by the Medicines Authority for the storage and distribution of cold chain medicinal products according to Art 83 of 2001/83/EC.	
2	Certificate of GDP compliance of wholesale distributor issued by the Medicines Authority for the storage and distribution of cold chain medicinal products according to Art 83 of 2001/83/EC	
3	All relevant, current licenses/certificates issued by the relevant competent authority (with certified translation in English, if necessary)	
4.	Evidence of 24-hour temperature control and off-site alarm system	
5.	Evidence of engineering maintenance and upkeep agreement for the cold facilities and records of maintenance	
6.	Evidence of contingency measures in case of breakdown or power cut	

Clarification Period:

Economic Operators may submit any clarifications or request additional information from the Contracting Authority by not later than **7th October 2020 at 12.00pm (noon)**. Any requests for clarifications are to be submitted by email on negotiation.cpsu@gov.mt clearly indicating the reference number of this call in the subject of the email.

The last date on which additional information can be issued by the Contracting Authority is **12th October 2020 at 12.00 pm (noon)**. Any clarifications and additional information will be uploaded on the CPSU website in the section 'Request for Negotiation Procedure'.

Clarification notes will constitute an integral part of the original published procurement documentation, and it is the responsibility of the Economic Operators to visit the website and be aware of the latest information published online prior to submitting their Request for Participation.

Submission of Request to Participate:

Requests to Participate are to be submitted through email **by not later than 10.00 hrs on 20th October 2020** to be sent to negotiation.cpsu@gov.mt. The reference number of the call MUST be clearly indicated in the Subject field of the Email. **The maximum size of the email (including attachments) is NOT to exceed 20 MB.** If the offer consists of multiple emails, please include the Part number (Part 1, Part 2, etc) in the subject field of the email together with the reference number.

Submissions shall, **at least** include the following information:

- Full name of Service Provider;

- Address of Service Provider;
- Full name of contact person;
- Contact Telephone Number / Mobile Number & Fax Number;
- E-mail Address;
- VAT number.
- All the information, technical documentation and Certification as requested in the previous section of this call.

No links are to be provided for Technical Specifications.

Please note that ALL submissions/documentation must include the Reference number. In cases, where this information is not included, the Contracting Authority reserves the right NOT to consider the offer.

Offers submitted that do not conform to specifications and conditions will not be considered.

Please note that it is entirely the Economic Operator's responsibility to ascertain that the submission is received BEFORE the deadline for submission of Request for Participation.

Any submissions received after this date and time will be automatically rejected.

The Economic Operator is required to provide the number of pallets offered.

All Requests for Participation should be submitted **only** through email by not later than 10.00 hrs on 20th October 2020 sent to negotiation.cpsu@gov.mt. The maximum size of the email including ALL attachments must not exceed 20 MB.

The reference number of this call is to be clearly indicated in the Subject field of the Email.

ANY SUBMISSIONS AFTER THIS DATE AND TIME WILL BE AUTOMATICALLY REJECTED.