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Request for Participation (Negotiated) for the Supply of Nitrous Oxide Gas for Medical use to be refilled in Cylinders

The Central Procurement and Supplies Unit within the Ministry for Health wishes to identify economic operators interested in supplying Nitrous Oxide Gas for Medical use to be refilled in cylinders.

1.1 Aims of this Procurement Process and Background

Through this Request for Participation the Ministry for Health intends to identify and enter into an agreement with eligible Economic Operators that are able to provide the cheapest-priced supply of Nitrous Oxide Gas to be refilled into cylinders.

1.2 Site Visits

No Site Visits are needed

1.3 Technical Requirements

Conditions of the contract

1. This contract shall run for a period of three (3) years extendable by an additional period of one (1) year with the same terms and conditions at the sole discretion of the Contracting Authority;
2. The supplier must be in a position to supply the cylinders awarded through this contract from the date of the award;
3. The supplier is responsible for all deliveries of the cylinders to the government sites as requested by GHPS
4. All requests for the medical gas must be honoured within 24 hours from request by the respective government entity;
5. The supplier must provide a 24/7 emergency service. On award of the contract, the supplier must provide the contact details for this emergency service.

Specifications of Nitrous Oxide Gas for Medicinal Use

The supply of nitrous oxide gas for medicinal use, containing not less than 98.0% v/v nitrous oxide in the gaseous phase, supplied on loan by the contractor, according to MHEC requirements for hospitals, health centres and other sites as indicated by the Government Health Procurement Services. Any other cylinders belonging to the Dept. of Health are also to be refilled according to MHEC requirements. The successful tenderer shall be bound to confirm that the nitrous oxide delivered conforms to Ph. Eur. standards.

Each delivery must be accompanied by the following documents:

1. A certificate of conformance signed by the Qualified Person, whereby s/he declares that the nitrous oxide for medicinal use was manufactured and tested in compliance with the manufacturer's licence issued by the competent authority of the country in which the gas was manufactured.

2. A certificate of analysis which contains the following information:

    a. Title of document
    b. Manufacturer's name
    c. Manufacturer's complete address
    d. Manufacturer's contact details
    e. Manufacturer's trading details
    f. Identity of the gas
    g. Market Authorisation Nº.
    h. Date of certification
    i. Batch number
    j. Batch Size
    k. Date of manufacture
    l. Date of expiry
    m. Analytical results for full testing as per Table 1 below:

Table 1: Purity of medical gas mixture

Parameter being tested	**Ph. Eur. Value**	**Actual analytical result**
Nitrous Oxide	Value as indicated in the most current Ph. Eur.	
Allowable Impurities	**Ph. Eur. Value**	**Actual analytical result**
Impurities according to the most current Ph. Eur.	Values according to the most current Ph. Eur.	

    o. Name of Qualified Person, signature of Qualified Person and date.

3. A separate, clearly legible invoice must be generated for each different size of cylinder delivered. The invoice shall have the following minimum information.

    a. Title of document
    b. Supplier's name
    c. Supplier's complete address
    d. Supplier's contact details
    e. Supplier's trading details
    f. Customer's name and account number
    g. GHPS file number and VAT number
    h. Page number and total number of pages (in case of multiple number of pages)
    i. Invoice number
    j. Date of invoice
    k. Delivery note number (if applicable)
    l. Item description
    m. For each cylinder size delivered, the invoice must include:
        i. Water capacity of the cylinders (Litres)

ii. Volume (m^3) of gas in the cylinder
iii. Quantity of cylinders delivered
iv. Cylinder numbers
v. Batch number of the medical gas mixture filled in a particular cylinder next to the cylinder number
vi. Filling pressure
vii. Unit price in Euros per cylinder delivered (volume delivered in brackets)
viii. Total price in Euros **excluding** VAT for quantity of cylinders delivered
ix. VAT rate and amount charged
x. Total price in Euros **including** VAT for quantity of cylinders delivered

n. Name and signature of authorised personnel issuing the invoice from the supplier

Specifications for cylinders

All medical nitrous oxide cylinders supplied must have:

a. A bar code incorporating the respective serial number of that cylinder. Bar codes will be affixed to the medical gas cylinders as a metal plate.
b. Cylinder serial no. engraved on the cylinder shoulder
c. Batch label affixed onto the shoulder/body of cylinder
d. Product Identification and Instructions for Use labels affixed onto the shoulder of the cylinder.

The cylinder shall be oxygen cleaned (which implies that the cylinder shall be free of oils and other impurities that can react with oxygen) and shall be suitable for the Nitrous Oxide medicinal gas.

The supplier must ensure that all the guards fitted on the delivered cylinders must allow for the proper fit of all pin-index yokes, not just those fitted on flowmeters but also on manifolds' tailpipes. Detailed specifications for the cylinders required are shown in Table 2.

Table 2: The various types of cylinders required

Item no.	Minimum qty of cylinders	Indicative nominal weight full (kg)	Valve Type	Indicative space available to receive cylinder + valve assembly (length mm x diameter mm)	Valve protection Cap/Guard	Comments	Location	Specific Requirements – To Fit:
1	42	5	Pin Index	520 x 105	Cap or easily removable Guard	Steel	ITU	Ohmeda Anaesthetic Machine
2		5	Pin Index	550 x 110	Cap or easily removable Guard	Steel	MOT	Datex Ohmeda Aestiva 5 Anaesthetic machine
3		51.53	Pin Index	550 x 110	Cap or easily removable Guard	Steel	MOT	Datex Ohmeda Aespire S/5 Anaesthetic machine (Space available)
4		5	Pin Index	480 x 120	Cap or easily removable Guard	Steel	MOT	Portable anaesthetic machine
5		5	Pin Index	550 x 110	Cap or easily removable Guard	Steel	CCS	Datex Ohmeda Anaesthetic Machine
6		5	Pin Index	450 x 120	Cap or easily removable Guard	Steel	DENTAL	Matrx Stand
7		5	Pin Index	550 x 140	Cap or easily removable Guard	Steel	DENTAL	Matrx Stand
8		5	Pin Index	480 x 120	Cap or easily removable Guard	Steel	DENTAL	Matrx Stand
9		5	Pin Index	550 x 110	Cap or easily removable Guard	Steel	DENTAL	Matrx Stand
10		5	Pin Index	550 x 110	Cap or easily removable Guard	Steel	ENDOSCOPY	Dragger Julian Anaesthetic machine
11	10	5	Pin Index	480 x 120	Cap or easily removable Guard	Aluminium	MEDICAL IMAGING	Datex Ohmeda Aestiva / 5
12		5	Pin Index	450 x 120	Cap or easily removable Guard	Aluminium	DENTAL	Matrx Stand
13		5	Pin Index	450 x 120	Cap or easily removable Guard	Aluminium	MEDICAL IMAGING	Sims Pneu Pac 880
14		5	Pin Index	550 x 110	Cap or easily removable Guard	Aluminium	MEDICAL IMAGING	Datex Ohmeda Aespire / 5
15	23	9	Pin Index	840 x 110	Cap or easily removable Guard	Steel	MOT	Datex Ohmeda Aestiva 5 Anaesthetic machine
16		9	Pin Index	840 x 110	Cap or easily removable Guard	Steel	CCS	Ohmeda Anaesthetic Machine
17	42	52	Thread connection 11/16" x 20 TPI rh	1290 x 180	Guard	Steel	MOT	Carrier supplying ERBE ERBOKRYO AE
18		52	Thread connection 11/16" x 20 TPI rh	1290 x 180	Guard	Steel	F1 AREA MANIFOLD	Manifold

The product supplied to the Government Pharmaceutical Services is to comply with all the tests shown on the BP/EP/USP/BPC monographs. A certificate to this effect is to be supplied with each consignment of product supplied.

General Conditions for the Supply of Medical Gases in cylinders

These conditions shall apply to all medical gas cylinders:

Contractor shall:

1. Ensure that no cylinder is overfilled and/or over pressurized and that the filling pressures/ratios are applicable to local environmental conditions. The filling pressure must be certified with each consignment. Unless otherwise specified, as for the air transport incubator, Oxygen and Medical Air cylinders *shall have filling pressures of 150* bars; N2O 60bar and N2O/O2 50/50% 137bar. For the case of the mixture 79% He with 21% O2 the pressure *shall* be 137 bar.

2. Be bound to immediately (i.e. within one hour of notice), render safe any cylinder anywhere, covered by this contract which is deemed to be dangerous by a Department of Health Officer. This condition shall be in force for 24 hours 365/6 days a year for the duration of the contract. Contractor shall therefore make available emergency contact telephone numbers and responsible persons for this purpose immediately on the issue of the contract award.

3. Ensure that all valves; valve guards/caps and cylinders, shall comply as applicable with the requirements of:

EN ISO 11117:2008 – Gas cylinders. Valve protection caps and valve guards. Design, construction and tests.

MSA EN 850: 2000 (Pin Indexing);

Legal Notice LN331/2002;

and shall conform to any other Maltese and European regulations that may be applicable and withdraw from service any valve/cylinder not conforming. Replacement cylinders must be made available immediately any cylinder is withdrawn.

If not otherwise specified, flat bottomed cylinders are preferred.

N.B.: MSA EN 850: 2000 has been replaced by ISO 407: 2004.
Existing Pin Indexed connections however comply with the MSA EN 850 standards. ISO 407: 2004 compliant connections can be used only insofar as the latter standard is compatible to existing Pin Indexed connections without any hazard to the user. It is the responsibility of the contractor to ensure this.

4. Prospective tenderers are required to make available to the Health Department, at tendering stage; a declaration signed by the company's warranted engineer that the cylinders and valves which will be used in this

contract will be within the scope and compliant to LN 331/2002 and any other Maltese and European regulations that may be applicable. The declaration shall include the full name; identity card number and engineering warrant number of the signatory.

5. Ensure that each cylinder shall bear: Stampmarking according to MSA EN ISO 13769:2009; Precautionary labels according to MSA EN ISO 7225:2007; Colour coding according MSA 1089-3:2004 or equivalent standards.

6. Ensure that for the case of the 32.4 kg N2O cylinders only (large size), the valve connection shall be 11/16 inch BSW Male Right Hand thread, 20 threads per inch in accordance with the requirements of BS 341 Part 1 of 1962.

7. Ensure that before refilling, all cylinders are properly marked with a serial number, recorded in the contractor's records and properly covered by test records. Copies of these records shall be submitted to the Client upon request.

8. Inspect and test the cylinders, including those owned by the Department of Health, as applicable, to different types of cylinders and also for permanent expansion. For the Department of Health cylinders, a certificate is to be provided. Test periods shall normally be 5 years unless the contractor provides proof that longer periods are applicable to his case.

9. Withdraw from service any cylinder which requires repairs.

10. Ensure that cylinder valves fitted to the cylinders are safely functional. They shall be free from leaks, jamming, worn out parts, loose parts and broken parts. Valve knobs fitted shall be with knurled or otherwise easily hand operated.. Valves needing spindle keys to operate are not acceptable

11. Take full responsibility to guarantee that the gas cylinder, valve, valve guard/caps and gas are safe for their intended use provided that they are not mishandled and/or misused

12. Notify the Department of Health in writing of any cylinders nearing the due date for the next tests and maintenance as specified above. This notification shall be at least two calendar months in advance and staggered.

13. Ensure that each cylinder supplied shall:

    a) Be clearly colour coded according to international standards
    b) Have a batch label to include a unique batch number, product name, filling date and expiry date;
    c) Have a product identification label which includes:
        i. the Marketing Authorization number

ii. the name and chemical symbol of the gas or gas mixture contained in the cylinder. Additionally, in the case of gas mixtures, the proportion of constituent gases must be shown
iii. a hazard warning sign
iv. specific product and cylinder handling precautions
v. particular instructions to the user where necessary
vi. safety information.

c) An easily readable bar code incorporating the respective serial number of that cylinder
d) Be conspicuously marked "use no oil or grease" or equivalent symbol

14. Depending on the gas, deliveries to MDH shall be either to the Medical Gas Storage rooms in K1, Hyperbaric or the un/loading bay. Deliveries at Gozo General Hospital shall be at the Main Plant room, Hyper Baric unit and Male Geriatrics Plant room.

15. Ensure that each delivered cylinder shall be:

a) carried out and delivered to site by competent personnel
b) supplied capped or with a valve protection guard to protect their valves from damage (Refer to table of cylinder sizes)
c) provided with new medical gas compatible washers as applicable at the valve delivery connection interface.
d) fitted with a tamper-evident seal which has to be removed prior to usage.
e) clean and free from dust and rust scale; paintwork must be in a condition enabling easy identification from the colour code.

16. Also be asked to supply other sizes/volumes of cylinders according to the requirements of the Department of Health as they evolve.

17. Ensure that the offered cylinders are fit for purpose. For this reason, prospective tenders shall, arrange with the Department of Health, to come on site before the closing date of the tender call, to take any measurements required. However, the Department of Health reserve the right to ask for a sample of the cylinders complete with valve and valve protection, as applicable, being offered during the evaluation of the offer.

18. Note that, in the event of an award the Department of Health reserves the right to carry out audit/s on the successful tenderer's cylinders and valves and valve protection guards/caps and if non compliance to specifications is established the Department of Health will have the right and authority to terminate the contract and take any necessary remedial action to safeguard the continued uninterrupted provision of this vital service.

19. Ensure that all invoices supplied to the Department of Health include both the filling pressure and the water capacity of the cylinders in litres.

List of documents to be supplied by tenderer at tendering stage with the tender documents subject to Article 9 of the Special Conditions:

- Copy of Summary of Product Characteristics/Product Data sheet
- A copy of the marketing authorisation, where applicable
- A copy of the manufacturer's licence
- A copy of the wholesale dealer's licence
- Sample of certificate of conformance
- Sample of certificate of analysis of invoice
- A declaration signed be the company's warranted engineer as per Clause 4 of the General Conditions for the Supply of Medical Gases in Cylinders

Statement of Compliance by Tenderer

This is to confirm that for the duration of this contract,
(Name of tendering Company) will use and supply cylinders to service the Department of Health that comply with all the specified:

TECHNICAL SPECIFICATIONS AND GENERAL CONDITIONS FOR THE SUPPLY OF MEDICAL GASES IN CYLINDERS.

SIGNATURE	
NAME IN FULL	
IDENTITY CARD NUMBER	

ANY Non-Compliance shall be listed below and countersigned.

Item no.	Indicative nominal Weight full (kg)	Valve Type	Indicative space available to receive cylinder + valve assembly (length mm x diameter mm)	Valve protection Cap/Guard	Comments	Location	Specific Requirements – To Fit:	Unit Price € (carried forward to Tender Form)
1	5	Pin Index	520 x 105	Cap or easily removable Guard	Steel	ITU	Ohmeda Anaesthetic Machine	
2	5	Pin Index	550 x 110	Cap or easily removable Guard	Steel	MOT	Datex Ohmeda Aestiva 5 Anaesthetic machine	
3	5	Pin Index	550 x 110	Cap or easily removable Guard	Steel	MOT	Datex Ohmeda Aespire S/5 Anaesthetic machine (Space available)	
4	5	Pin Index	480 x 120	Cap or easily removable Guard	Steel	MOT	Portable anaesthetic machine	
5	5	Pin Index	550 x 110	Cap or easily removable Guard	Steel	CCS	Datex Ohmeda Anaesthetic Machine	
6	5	Pin Index	450 x 120	Cap or easily removable Guard	Steel	DENTAL	Matrx Stand	
7	5	Pin Index	550 x 140	Cap or easily removable Guard	Steel	DENTAL	Matrx Stand	
8	5	Pin Index	480 x 120	Cap or easily removable Guard	Steel	DENTAL	Matrx Stand	
9	5	Pin Index	550 x 110	Cap or easily removable Guard	Steel	DENTAL	Matrx Stand	
10	5	Pin Index	550 x 110	Cap or easily removable Guard	Steel	ENDOSCOPY	Dragger Julian Anaesthetic machine	
11	5	Pin Index	480 x 120	Cap or easily removable Guard	Aluminium	MEDICAL IMAGING	Datex Ohmeda Aestiva / 5	
12	5	Pin Index	450 x 120	Cap or easily removable Guard	Aluminium	DENTAL	Matrx Stand	
13	5	Pin Index	450 x 120	Cap or easily removable Guard	Aluminium	MEDICAL IMAGING	Sims Pneu Pac 880	
14	5	Pin Index	550 x 110	Cap or easily removable Guard	Aluminium	MEDICAL IMAGING	Datex Ohmeda Aespire / 5	
15	9	Pin Index	840 x 110	Cap or easily removable Guard	Steel	MOT	Datex Ohmeda Aestiva 5 Anaesthetic machine	
16	9	Pin Index	840 x 110	Cap or easily removable Guard	Steel	CCS	Ohmeda Anaesthetic Machine	
17	52	Thread connection 11/16" x 20 TPI rh	1290 x 180	Guard	Steel	MOT	Carrier supplying ERBE ERBOKRYO AE	
18	52	Thread connection 11/16" x 20 TPI rh	1290 x 180	Guard	Steel	F1 AREA MANIFOLD	Manifold	
* Applicable as indicated on Contract Agreement								

Literature List

Description	Reference in Technical Specifications Section 4
Original/true copy of the Summary of Product Characteristics (for medicinal products)	2
Original/true copy of the marketing authorisation (for medicinal product)	2
Sample of a valid manufacturer's licence and wholesale dealer's licence	2
Sample of certificate of conformance and certificate of analysis	2
Declaration by company warranted engineer to verify that cylinders being supplied complies with clauses 3, 4 and 5 of the general conditions for the supply of Medical Gases in cylinders	General Conditions 3, 4 & 5

2.1 Eligibility

The successful bidder should have a valid wholesale dealer's license and should be in a position that all personel and equipment are duly certified/licensed that will allow the performance of the contract to be in line with all the applicable legislation.

2.2 Award Criteria

Contract will be awarded to the Economic Operator submitting a technically compliant offer with the cheapest overall cost.

2.3 Special Conditions

These conditions amplify and supplement, if necessary, the General Conditions governing the contract. Unless the Special Conditions provide otherwise, those General Conditions remain fully applicable. The numbering of the Articles of the Special Conditions is not consecutive but follows the numbering of the Articles of the General Conditions. Other Special Conditions should be indicated afterwards.

Article 2: Law Applicable

2.1 The laws of Malta shall apply in all matters not covered by the provisions of the contract.

2.2 The language used shall be English.

Article 4: Communications

All communications following the award of the contract are to be addressed to

The Managing Director,
Sourcing & Supply Chain Management – MfH,
Central Procurement & Supplies Unit,
UB002, Industrial Estate,
San Gwann, SGN 3000.

Article 7: Supply of Documents

Further to the General Conditions, please refer to table in Section 4.1 of this document.

Article 8: Assistance with Local Regulations

As per General Conditions.

Article 9: The Contractor's Obligations

9.6 Sub-Article 9.6 is not applicable for Malta Funds.

9.7 ***Medicinal Products***
It is the responsibility of the Responsible Person/Qualified Person to make available the batch specific Quality Control Certificate upon request by the Central Procurement and Supplies Unit (CPSU).

9.8 ***Medical material & devices, food supplements, dietary foods for special medical purposes, chemicals, cosmetics and disinfectants***

The necessary documentation as determined by the competent authority in Malta is to be submitted by the contractor upon request by the Central Procurement and Supplies Unit (CPSU).

9.9 **Summary of Product Characteristics (*Medicinal Products*)**

The Contractor must ensure that a copy of the latest approved Summary of Product Characteristics (SPC) intended for the use of healthcare professionals is kept at all times by the contractor.

The contractor must make the Summary of Product Characteristics (SPC) available without delay when requested by CPSU. When the SPC is updated or revised during the period of validity of the contract, the contractor must provide CPSU with a copy of the updated or revised SPC.

9.10 **Pharmaceutical Wholesale Dealer *(Medicinal Products)***

A contractor must be duly licensed as a pharmaceutical wholesale dealer by the appropriate competent authority of the country where the contractor is registered.

The Responsible Person/Qualified Person must inform the Central Procurement and Supplies Unit (MfH) of any changes including renewal, variation, suspension or revocation of the pharmaceutical wholesale dealer/importation license as issued by the competent authority.

The Licensee and the Responsible Person/Qualified Person of the local pharmaceutical wholesale dealer/importer must ensure that Maltese legislation, conditions of license and other requirements that may be issued from time to time by the Superintendent of Public Health or the competent authority in Malta are abided with within the definitions of their individual responsibilities.

9.11 **Registration of Medicinal Products**

The Responsible Person/Qualified Person must inform the Central Procurement and Supplies Unit (Ministry for Health) of any changes to the registration status of the medicinal product issued by the competent authority during the validity period of the contract.

For a centrally authorised medicinal product, a copy of the delegated responsibility as issued by the Marketing Authorisation Holder (MAH) is to be submitted with the first consignment. The Responsible Person/Qualified Person must inform the Central Procurement and Supplies Unit (Ministry for Health) of any changes to delegated responsibility granted by the Market Authorisation Holder to place the product on the Maltese market during the validity period of the contract.

For a medicinal product granted a temporary authorisation by the Superintendent for Public Health in accordance with Article 20 of the Medicines Act, once the product is registered, the contractor is required to submit a copy of the registration certificate as issued by the local regulatory authority (MA).

For 'special medicine' or where the medicinal products supplied is licensed in a third country, the Responsible Person of the contractor must submit a batch specific certificate of analysis or conformance (as applicable) with every batch delivered to Central Procurement & Supplies Unit (Ministry for Health)

For medicinal products registered by the contractor following the signing of the contract, a copy of the registration certificate issued by the Licensing Authority of Malta must be submitted to CPSU within 90 days from signing of the contract. If the product is not registered within the stipulated timeframe, the Contracting Authority will reserve the right to:

either:

a) purchase the product on the account of the defaulting contractor until such time that the product is registered

or:

b) register the product on behalf of the contractor at a onetime registration fee of €1,000 and an annual fee as applicable by the Licensing Authority of Malta. Furthermore, the Contracting

Authority shall also charge an annual administration fee of Eur500 per year. All the above fees shall be payable by the contractor. The registration shall conform to the procedures and policies applicable by the Licensing Authority of Malta

Article 10: Origin

10.1 No derogation is applicable.

Article 11: Performance Guarantee

11.1 The Contractor shall, within 15 calendar days of receipt of the contract, sign and date the contract and return it together with a copy of the Performance Guarantee. The Contractor is further obliged to forward the original performance guarantee to the Contracting Authority. The Contracting Authority will not affect any payment to the contractor until the performance guarantee is submitted. The amount of the guarantee shall not exceed 4% where the amount of the total contract value is between €10,000 and €500,000 ex VAT, and 10% where the amount of the total contract value is €500,001 or above.

In the case where the contract is for a period of more than one year, the performance guarantee is to be calculated on the average value of one year (the total value of the recommended offer divided by the number of years). Performance Guarantees are to be valid for a period of 12 months, renewable every year in accordance with the duration of the Contract Agreement.

11.3 The performance guarantee shall be in the format given in Section 5 and shall be provided in the form of a bank guarantee.

11.7 As per General Conditions.

Article 12: Insurance

12.1 Supplies shall be insured against all damages at all times including during any operation, during and after delivery. The contractor shall be responsible for all damages or loss in transit up to the delivery site. For marine cargo, the contractor is to ensure that deliveries to Central Procurement and Supplies Unit (CPSU) are adequately insured.

Article 13: Performance Programme (Timetable)

1. This contract shall run for a period of three (3) years. The contract may be extended by a further period of up to one (1) year at the sole discretion of the Contracting Authority. Such extension would be subject to the same price rates and all the original contract conditions;
2. The supplier must be in a position to supply the cylinders awarded through this contract from the date of the award;
3. The supplier is responsible for all deliveries of the cylinders to the government sites as requested by GHPS
4. All requests for the medical gas must be honoured within 24 hours from request by the respective government entity;
5. The supplier must provide a 24/7 emergency service. On award of the contract, the supplier must provide the contact details for this emergency service.

Article 14: Contractor's Drawings

As per General Conditions.

Article 15: Tender Prices

15.1 As per General Conditions.

Article 16: Tax and customs arrangements

16.1 No derogation applies.
16.2 No derogation applies.

Article 17: Patents and Licences

17.1 As per General Conditions.

Article 18: Commencement Order

18.1 The Contract will come into force from the last date of the signature of the Contract, unless indicated otherwise in the Contract.

Delivery of supplies shall be carried out in accordance with the instructions issued by the Contracting Authority in terms of Article 13. The first instruction issued by the Contracting Authority in terms of Article 13 shall be deemed to be the commencement order.

Article 19: Period of Execution of Tasks

19.1 This contract shall run for a period of thirty-six (36) months from commencement date. Supplies are to be delivered within the stipulated delivery periods and in quantities instructed by the Contracting Authority in terms of Article 13.

Article 21: Delays in Execution

21.1 The contractor acknowledges that performance of his obligations within the stipulated time limit(s) is crucial for the purposes of ensuring that the Contracting Authority maintains an adequate stock of supplies. Accordingly, the contractor agrees that if the contractor fails to deliver any or all of the supplies within the time limit(s) specified in the contract and as a result of such failure by the contractor, the Contracting Authority shall, without formal notice and without prejudice to its other remedies under the contract, be entitled, for every day which shall elapse between the expiry of the time limit(s) for supply and the actual date of supply, to liquidated damages equal to 5/1000 of the value of the undelivered supplies to a maximum of 15% of the total value of the contract.

In the event that the Contractor is in delay in providing any supplies to the Contracting Authority, then the Contracting Authority shall, without prejudice to and in addition to its right to claim liquidated damages set forth in the above clause, be entitled to purchase supplies from a third party and to charge to the contractor any additional costs and expenses incurred by the Contracting Authority as a result of its purchases from the third party.

Article 22: Modification to the Contract

22.1 Subject to the provisions of the Public Procurement Regulations, contracting Authority reserves the right to vary the repetition of supplies up to 100% of the contract value. The unit price used in the tender shall be applicable to the quantities procured under the modification.

The prerogative to order such additional supplies shall be at the discretion of the Contracting Authority and if not used the Contractor shall have no claim against Government.

Article 24: Quality of Supplies

24.1 In the case when the contractor delivers to the Central Procurement and Supplies Unit (CPSU) and on its part CPSU receives items that have shelf life conditions different to those listed above, the contractor shall notify in writing CPSU with the alternative shelf life conditions of the items on date of delivery of the said items. Any expired stock delivered to CPSU as aforesaid, shall be collected by the contractor in the case that the said stock expires and CPSU shall receive a credit equivalent to the price of the expired stock. CPSU shall notify the contractor in writing with a list of items supplied by the contractor that expired and the contractor is to collect the said stock within seven (7) working days from date when the list of expired items is notified to the Contractor. If the expired items are not collected within the seven (7) day period, CPSU shall debit the Contractor's account to credit transaction equivalent to the cost of the expired stock and dispose of the expired items. All costs including the cost of disposal shall be charged to the Contractor's account.

Any infringement in this respect will render the contractor liable to a penalty of 5% of the value of the consignment. CPSU – Ministry for Health also reserves the right to purchase from third parties and charge the difference to the contractor's account.

24.2 As per General Conditions.

24.4 It shall be lawful for the Head of Department to reject without the necessity of prior legal proceedings any consignment or part thereof, which in his/her opinion does not possess the qualities required under the contract and to obtain it elsewhere, at any price, and the difference in price charged on the contractor's account, should the latter fail to replace the articles rejected within the time allowed for the purpose by the Head of Department.

24.5 **Monographs - Medicinal Products**
The Department reserves the right to request a true copy of the company in-house monograph.

24.6 ***Medicinal products***
The Responsible Person/Qualified Person must inform the Central Procurement and Supplies Unit (CPSU), within 12 hours of having come into possession, of any information concerning batch defects and withdrawal of the product from the market. The Responsible Person/Qualified Person must inform in writing the Central Procurement and Supplies Unit of any suspension or withdrawal of the authorization to place the product on the market by the Superintendent of Public Health or the competent authority in Malta. The Responsible Person/Qualified Person of the Contractor must also provide any relevant support and documentation, as necessary, for the Responsible Person CPSU to ensure the safe use of medicinal stocks.

24.7 ***Medical material & devices, food supplements, dietary foods for special medical purposes, chemicals, cosmetics and disinfectants***
The contractor must inform the Central Procurement and Supplies Unit (CPSU), within 12 hours of having come into possession, of any information concerning batch defects and withdrawal of the product from the market. The contractor must also provide any relevant support and documentation, as necessary, for CPSU to ensure the safe use of medical products.

24.8 ***Non-Medicinal Products***
All non-medicinal products that are required for pharmaceutical purposes must comply with the respective standards listed in Ph. Eur. / B.P. / B.P.C. / U.S.P., where applicable and must be accompanied

by a complete and detailed quality control analysis report by a certified body. The contractor must also provide any relevant support and documentation, as necessary, for CPSU - Ministry for Health to ensure the safe use of non-medicinal products.

Article 25: Inspection and Testing

25.2 As per General Conditions.

Article 26: Methods of Payment

26.1 Payments will be made in Euro.

Payments shall be authorized by the Contracting Authority or any other entity as delegated by CPSU, and paid by the Treasury Department.

26.3 Further to the General Conditions, payment shall be effected within 60 days from the date of the Contractor's request for payment, provided that it is tied:

a) to the actual date of the 'physical receipt/acceptance' of the ordered goods and,

b) shall be subject to conformity in all respects to all contractual obligations, specifications and conditions on the date of the 'physical receipt/acceptance' of the ordered goods to the satisfaction of the Head of Department or his/her representative.

Payment request is to be submitted by the contractor once the patient is certified to have been successfully cured based on the positive results of tests that are carried out in line with the stipulated procedure as set up by the Department of Health.

26.5 Not applicable.

26.7 Further to the General Conditions, for supplies not covered by a warranty period, the conditions to which final payments are subject, shall be as stated in Clause 26.3.

26.9 No revision of prices is allowed.

Article 28: Delayed Payments

28.1 The Contracting Authority shall pay the contractor sums due within 60 days of the date on which an admissible payment is registered, in accordance with Article 26 of these Special Conditions. This period shall begin to run from the approval of these documents by the competent department referred to in Article 26.1 of these Special Conditions. These documents shall be approved either expressly or tacitly, in the absence of any written reaction in the 30 days following their receipt accompanied by the requisite documents.

28.2 Once the deadline laid down in Article 28.1 has expired:
the contractor may, within two months of late payment, claim late-payment interest: meaning simple interest for late payment at a rate which is equal to the sum of the reference rate and at least eight percent (8%); on the first day of the month in which the deadline expired. The late-payment interest shall apply to the time which elapses between the date of the payment 'deadline (exclusive) and the date on which the Contracting Authority's account is debited (inclusive).

Article 29: Delivery

29.1 The contractor shall bear all risks relating to the goods until provisional acceptance at destination. The supplies shall be packaged so as to prevent their damage or deterioration in transit to their destination.

Deliveries must comply with Good Distribution Practice Guidelines currently in force.

29.2 As per General Conditions unless any special requirements are included in the product specifications. All packaging, marking and documentation inside and outside the packages must comply with Maltese legislation currently in force.

29.5/6 ***Medicinal Products, Medical material & devices, food supplements, dietary foods for special medical purposes, chemicals, cosmetics and disinfectants***
All products delivered to Central Procurement and Supplies Unit (CPSU) - Ministry for Health must comply with Maltese legislation currently in force.

29.8 Consignments of goods must be strictly delivered in boxes that are appropriately packed to withstand transport and handling**.**

Products requiring controlled storage temperature
The actual date and time of arrival of such products must be notified in advance, thus enabling proper arrangements for their storage. Such products must be appropriately packed and must include specific storage instructions that are clearly indicated on the bulk packaging.
A temperature logger or any other validated system acceptable to RP CPSU that demonstrates that the storage status for such products has been maintained throughout the delivery should be used. The Central Procurement and Supplies Unit (CPSU) reserves the right to refuse consignments not abiding with the above conditions at the expense of the tenderer.

Delivery of consignments on pallets must be made on Euro pallets.

The Central Procurement and Supplies Unit (CPSU) reserves the right to make any claims on discrepancies in the quantity of items delivered within 48 hours of receipt of goods at the stores.

When consignments are to be delivered via containers, the contractor should inform in writing the relative stores of the date of delivery and the number of consignments a minimum of one week in advance. The Central Procurement and Supplies Unit (CPSU) reserves the right to refuse such consignments if prior notification is not effected. Expenses and responsibility for refused items shall be borne by the contractor.

29.9 For medicinal products which are not to be delivered to CPSU stores such as, but not limited to, radioactive medicinal products, a technical agreement between Responsible Person - CPSU and Responsible Person/Qualified Person of contractor delineating duties and responsibilities of both parties shall be agreed prior to signing of the Contract Agreement (CA).

Article 31: Provisional Acceptance

As per General Conditions.

Article 32: Warranty

32.1 As per General Conditions.

Article 33: After-Sales Service

33.1 Contractor is entirely responsible for maintenance of all systems installed by him.

Article 35: Breach of Contract

35.3 Without prejudice to the Government's right to dissolve 'ipso jure' the contract in the case of infringement of any condition thereunder and apart from the deduction established for delay in delivery, any such infringement shall render the contractor, in each case, liable to a deduction by way of damages of 5 per cent of the value of the contract, unless the Government elects, with regard to each particular infringement, but not necessarily with regard to all infringements, to claim actual damages incurred.

Article 41: Dispute Settlement by Litigation

If no settlement is reached within 120 days of the start of the amicable dispute-settlement procedure, each Party may seek:

a) either a ruling from a national court, or
b) an arbitration ruling, in the case where the parties, that is, the Contracting authority and the Contractor, by agreement decide to refer the matter to arbitration.

3.0 Extracts from the Public Procurement Regulations

*Part **IX** of the Public Procurement Regulations*

Appeals from decisions taken after the closing date for the submissions of an offer

270. Where the estimated value of the public contract meets or exceeds five thousand euro (€5,000) any tenderer or candidate concerned, or any person, having or having had an interest or who has been harmed or risks being harmed by an alleged infringement or by any decision taken including a proposed award in obtaining a contract, a rejection of a tender or a cancellation of a call for tender after the lapse of the publication period, may file an appeal by means of an objection before the Public Contracts Review Board, which shall contain in a very clear manner the reasons for their complaints.

271. The objection shall be filed within ten calendar days following the date on which the contracting authority or the authority responsible for the tendering process has by fax or other electronic means sent its proposed award decision or the rejection of a tender or the cancellation of the call for tenders after the lapse of the publication period.

272. The communication to each tenderer or candidate concerned of the proposed award or of the cancellation of the call for tenders shall be accompanied by a summary of the relevant reasons relating to the rejection of the tender as set out in regulation 242 or the reasons why the call for tenders is being cancelled after the lapse of the publication period, and by a precise statement of the exact standstill period.

273. The objection shall only be valid if accompanied by a deposit equivalent to 0.50 per cent of the estimated value set by the contracting authority of the whole tender or if the tender is divided into lots according to the estimated value of the tender set by the contracting authority for each lot submitted by the tenderer, provided that in no case shall the deposit be less than four hundred euro (€400) or more than fifty thousand euro (€50,000) which may be refunded as the Public Contracts Review Board may decide in its decision.

274. The Secretary of the Public Contracts Review Board shall immediately notify the Director, the Ministerial Procurement Unit and, or the contracting authority, as the case may be, that an objection had been filed with his authority thereby immediately suspending the award procedure.

275. The Department of Contracts, the Ministerial Procurement Unit or the contracting authority involved, as the case may be, shall be precluded from concluding the contract during the period of ten calendar days allowed for the submission of appeals. The award process shall be completely suspended if an appeal is eventually submitted.

276. The procedure to be followed in submitting and determining appeals as well as the conditions under which such appeals may be filed shall be the following:

(a) any decision by the General Contracts Committee, the Ministerial Procurement Unit or the Special Contracts Committee or by the contracting authority, shall be made public by affixing it to the notice-board of the Department of Contracts, the Ministerial Procurement Unit or of the office of the contracting authority, as the case may be, or by uploading it on government's e-procurement platform prior to the award of the contract if the call for tenders is administered by the Department of Contracts;

(b) the appeal of the complainant shall also be affixed to the notice-board of the Public Contracts Review Board and shall be communicated by fax or by other electronic means to all participating tenderers;

(c) the contracting authority and any interested party may, within ten calendar days from the day on which the appeal is affixed to the notice board of the Review Board and uploaded where applicable on the government's e-procurement platform, file a written reply to the appeal. These replies shall also be affixed to the notice board of the Review Board and where applicable they shall also be uploaded on the government's eProcurement platform;

(d) the authority responsible for the tendering process shall within ten days forward to the chairman of the Public Contracts Review Board all documentation pertaining to the call for tenders in question including files and tenders submitted;

(e) the secretary of the Review Board shall inform all the participants of the call for tenders, the Department of Contracts, the Ministerial Procurement Unit and the contracting authority of the date or dates, as the case may be, when the appeal will be heard;

(f) when the oral hearing is concluded, the Public Contracts Review Board, if it does not deliver the decision on the same day, shall reserve decision for the earliest possible date to be fixed for the purpose, but not later than six weeks from the day of the oral hearing:

Provided that for serious and justified reasons expressed in writing by means of an order notified to all the parties, the Public Contracts Review Board may postpone the judgment for a later period;

(g) the secretary of the Review Board shall keep a record of the grounds of each adjournment and of everything done in each sitting;

(h) after evaluating all the evidence and after considering all submissions put forward by the parties, the Public Contracts Review Board shall decide whether to accede or reject the appeal or even cancel the call if it appears to it that this is best in the circumstances of the case.

4.1 Documents required to be submitted for Participation

Interested Economic Operators are to submit a technical proposal and financial offer.

4.2 Instructions to Interested parties

Clarification Period:
Economic Operators may submit any clarifications or request additional information from the Contracting Authority by not later than **7th November 2020 at 12.00pm.** 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 **13th November 2020 at 12.00pm**. 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 in sealed envelopes **by not later than 10.00 hrs on 19th November 2020** in the **Purple** tender box located at the Reception Area, **CPSU Offices, UB002, Industrial Estate, San Gwann - SGN 3000**. The reference number of the call should be clearly indicated on the sealed envelope.

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 after this date and time will be automatically rejected.

All Requests for Participation should be submitted **only** in sealed envelopes
by not later than 10.00 hrs on 19th November 2020 in the **Purple** tender box
located at the Reception Area, **CPSU Offices,**
UB002, Industrial Estate, San Gwann - SGN 3000.

The reference number of this call is to be clearly indicated on the outside of the envelope.

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