**CPSU File Reference:** **CPSU02132N20AF**

**RfP Publication Ref:** **021-6101/20**

# Request for Participation for the supply of Remodulin® (Treprostinil) 2.5mg/ml Vials, Cleo 90 infusion set and I-Life: I-jet pump syringes

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| **Date Published:** | **27/10/2020** | |
| **Deadline for Submission:** | **24/11/2020** | **at 10:00am CET/CEST** |

# IMPORTANT

**Clarifications shall be uploaded and will be available to view/download from CPSU Portal.**

*Requests for participation are to be submitted in English on negotiation.cpsu@gov.mt, by closing date and time as specified above. Late submissions or interests submitted by any other means will not be considered.*

Please consider your environmental responsibility before printing.

**Central Procurement and Supplies Unit (CPSU)**
**UB002, San Gwann Industrial Estate, San Ġwann, SGN3000, Malta.**
**Tel: (356) 2540 4000 Email: info.cpsu@gov.mt**

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## SECTION 1 – INSTRUCTIONS TO TENDERERS

### *1. General Instructions*

**1.1 In submitting the proposal, the candidate accepts in full and in its entirety, the content of this procurement document, including subsequent Clarifications issued by CPSU, whatever his own corresponding conditions may be, which he hereby waives. Candidates are expected to examine carefully and comply with all instructions, forms, contract provisions and specifications contained in this tender document. Where applicable, these Instructions to Tenderers complement the General Rules Governing Tenders. *Part IX of the Public Procurement Regulations – S.L. 601.03* applies in case that any Economic Operator wishes to file a remedy before the closing date of the call for competition or Appeals from decisions taken after the closing date for the submissions of an offer.**

1.2 The place of acceptance of the supplies shall be as and where directed by the Department of Health, the time-limits for the execution of the contract shall be as specified in the Special Conditions of this document, and the INCOTERM[2010] applicable shall be Delivery Duty Paid (DDP).

1.3 This is a unit-price contract.

1.4 The Contracting Authority for this tender is the Central Procurement and Supplies Unit – Ministry for Health.

### *2. Variant Solutions*

2.1 No variant solutions will be accepted. Tenderers must submit a tender in accordance with the requirements of the tender document.

### *3. Financing*

3.1 The project is financed from local budget funds.

### *4. Selection and Award Requirements*

4.1 In order to be considered eligible for the award of the contract, candidates must provide evidence that they meet or exceed certain minimum criteria described hereunder.

**(A) Eligibility Criteria (Form B – Eligibility and Administrative information)**

(i) Declare agreement, conformity and compliance with the General Rules Governing Tendering.
(ii) Declare agreement, conformity and compliance with the provisions of the Tender's Declaration.
(iii) Declare agreement, conformity and compliance with the provisions of the Statement on Conditions of Employment.
(iv) Declaration concerning exclusion grounds including blacklisting

**(B) Technical Specifications**

(i) Technical Offer in response to specifications is to be submitted through **Form C – Technical Offer Form** attached with this Document.

Technical Documentation listed in Section 3 of this document.

(ii) Literature as per 'Literature List' in Section 5 of this document.

(iii) **If samples are required, these will be requested during the adjudication stage and will need to be submitted within 10 working days of being notified to do so.**

**(C) Financial Offer**

(i) No financial offer is to be submitted at this stage. Economic Operators will be notified to submit a financial offer in the second stage of the process.

### *5. Criteria for Award*

5.1 The aim of this procurement process is to determine whether there is only one source of supply. If more than one submission is found to be technically compliant, this RFP Process will be cancelled and an open procurement cycle will be issued.

## 6. Process for Submission of Clarifications and Requests for Participation

### 6.1 Submission of Clarifications

Economic Operators may submit any clarifications or request additional information from the Contracting Authority by not later than 11th November, 2020 **at 12.00pm.** Any requests for clarifications are to be submitted by email on **negotiation.cpsu@gov.mt**

The last date on which additional information can be issued by the Contracting Authority is 16th 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.

### 6.2 Submission of Request to Participate

Requests to participate are to be submitted through **negotiation.cpsu@gov.mt** by not later than 10.00 hrs on 24th November, 2020 and shall, at least include the following information:

- Duly filled-in forms that are attached with this document
  - A. Company Contact Details
  - B. Eligibility and Administrative Information
  - C. Technical Offer Form

- All the information, technical documentation and Certification requested in Section 3 of this document.

- The documentation listed in the "List of Literate" in Section 5 of this document.

Submissions must be provided in Word, Excel, pdf or jpg formats. No links are to be provided for Technical Specifications. These should be attached with the offer. Other formats will NOT be considered.

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.

All Requests for Participation should be sent **only** by email on
**negotiation.cpsu@gov.mt**
clearly indicating the reference number of this call in the subject of the email.

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

# SECTION 2 – 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 and Language of the Contract***

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 3: Order of Precedence of Contract Documents***

3.1 The contract is made up of the following documents, in order of precedence:

(a) the Contract;
(b) the Special Conditions;
(c) the General Conditions;
(d) the Contracting Authority's technical specifications and design documentation;
(e) the Contractor's technical offer, and the design documentation (drawings);
(f) the financial bid form (after arithmetical corrections)/breakdown;
(g) the tender declarations in the submitted documents;
(h) any other documents forming part of the contract.

Addenda have the order of precedence of the document they are modifying.

***Article 4: Communications***

4.1 Further to what is stated in the General Conditions, any communication should be made on:

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

E-mail: info.cpsu@gov.mt

***Article 7: Supply of Documents***

7.4 Not applicable.

***Article 8: Assistance with Local Regulations***

8.3 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 copy of the Performance Guarantee forwarded to the Central Government Authority is to be endorsed by the Contracting Authority prior to submission. The contract will not be endorsed by the Contracting Authority/Central Government Authority until the performance guarantee is submitted. The Contractor is therefore obliged to forward the original Performance Guarantee to the Contracting Authority. The amount of the guarantee shall be 4% where the amount of the total contract value is between €10,000 and €500,000 exclusive of VAT, and 10% where the amount of the total contract value is €500,000 or above. Where the contract is a Framework Contract, or when a contract is awarded to one contractor over a period of years for recurrent supplies, the Performance Guarantee may cover the yearly/annual total contract value, which means that the performance guarantee is calculated on the total contract value, and then divided by the number of years covered by the contract. Performance Guarantees are to be valid for a period of 12 months, renewable every year in accordance with the duration of the Contract Agreement.

If a Procurement Procedure was published with lots and subsequently awarded accordingly, each lot shall be regarded as a separate contract, even if the same contractor wins more than one (1) lot. As a result, the amount of the Performance Guarantee shall be calculated per lot.

Economic Operators have the possibility to provide the Contracting Authority with a Single Bond covering the performance guarantees for all the contracts with the same Contracting Authority. If an additional contract is awarded to a given contractor, which results in an economic operator's current cumulative contracts value to go beyond the contract value range currently covered by the Single Bond, the contractor is to be requested to; either submit a separate Performance Guarantee for the additional contract; or else submit a new Single Bond to cover the new total contracts value or submit an amendment to the original Single Bond specifying the new amount. If an Economic Operator chooses to make use of the Single Bond, he must submit a letter from the respective Contracting Authority specifying that the amount of the Single Bond covers the new Contract, otherwise the new Contract Agreement would not be signed.

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. 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)***

The contractor agrees to make first delivery of supplies within 6-8 weeks from the date of commencement order (Confirmation of Order). On the same Confirmation of Order there shall also be stipulated a number of monthly deliveries (that are to commence four (4) weeks after the first delivery) which must be abided with by the contractor. Subsequent confirmation of orders for deliveries of supplies shall also be issued as necessary (first delivery of 4 weeks) and monthly deliveries shall also be stipulated accordingly. The contractor must acknowledge that the Contracting Authority is unable to forecast with precision its monthly requirements for the duration of the contract, consequently it must be ensured that delivery of supplies is made in accordance with the exigencies of the Contracting Authority.

The delivery of supplies in terms of this contract shall be made by the contractor in the quantities and on the dates specified by the Contracting Authority in accordance with this Article. For the purposes of assisting the contractor to plan the delivery of supplies, should there be a change in the quantity required for monthly delivery/deliveries from that stipulated in the Confirmation of Order, the Contracting Authority shall by the first day of each calendar month submit in writing to the Contractor the volume of supplies required. These shall be delivered by no later than the stipulated period.

In case of staggered orders with delivery dates that go beyond the contract period, the contract terms and conditions shall remain valid for the duration of the consignment period or the contract date (as stipulated in Article 19.1 of the Special Conditions), whichever comes latest.

The Contracting Authority reserves the right that, notwithstanding having instructed the Contractor to make delivery of supplies during any particular month, be permitted to instruct the contractor not to make the delivery of supplies, in whole or in part, or to instruct the contractor to delay the delivery of supplies. The Contracting Authority shall not be liable for any damages, costs or expenses incurred by the contractor as a result of any instruction issued to the contractor not to make the delivery of supplies, in whole or in part, or to delay the delivery of supplies.

The Contracting Authority also reserves the right, notwithstanding having instructed the contractor to make a delivery of supplies during any particular month, to subsequently instruct the contractor to deliver additional supplies, which shall be delivered according to the delivery period indicated above.

The contractor is also responsible to accept (and maintain as per instructions above) multiple Confirmation of Orders for the same product, from various sites/locations as indicated by the Contracting Authority.

The contractor shall perform multiple deliveries ofthe product/s, without any additional cost, directly to any healthcare entity as may be directed from time to time by CPSU or an appointed representatives.

The contractor undertakes and is bound to maintain a stockpile of the product/s, which stockpile shall not be of an amount less than the amount required for a period of three months. The contractor undertakes to deliver the stockpile within 24 hours in case of urgency.

No minimum pre-determined order quantities shall be allowed.

***Article 14: Contractor's Drawings/Diagrams***

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 as specified in Section 3 of this Procurement Document. Supplies are to be delivered within the stipulated delivery periods and in quantities instructed by the Contracting Authority in terms of Article 13.

The Contracting Authority is bringing to the attention of the Contractor that this Contract can be utilised by any entity falling under the Department of Health, following written notification by CPSU. Given that orders and payments may be undertaken directly by these respective healthcare entities, it is important that the contract value is in no way exceeded without the written prior authorisation by CPSU. In this regards, the Economical Operator is being held accountable to inform CPSU, once the thresholds of 75% and 100%, of the total contract value, are reached.

No payment will be made for suppliers, services or works should the threshold of 100% be exceeded without prior written authorisation by CPSU.

19.2 As per General Conditions.

***Article 21: Delays in Execution***

21.1 The contractor acknowledges that performance of his/her 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 CPSU's stock of supplies is entirely depleted, the Contracting Authority shall, without further 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 of €23 daily 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 - whether it is a new or continuation of supply - and, as a result of such delay, the level of supply at CPSU main warehouse is below four weeks (based on the most recent customer demand), then the Contracting Authority shall, without prejudice to and in addition to its right to claim liquidated damages set forth in the above clause, reserves the right 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, the CGA/CA reserves the right to vary the quantities specified.

22.11 No modifications are allowed.

22.12 No modifications are allowed.

***Article 24: Quality of Supplies***

24.1 Further to Article 24.1 of the General Conditions, Product shelf life should be as follows:

**either**

Products having a shelf life as per SPC or other documentation of 24 months or more, must not be more than $^1/_3$ rd expired upon delivery to Stores.

Products having a shelf life as per SPC or other documentation which is less than 24 months must not be more than $^1/_6$ th expired upon delivery to Stores.

In cases where the Marketing Authorisation Holder (MAH) / Manufacturer submits written evidence in the quote that lead time prior to release is 2 months or more, the product must not be more than $^1/_3$ rd expired upon delivery to Stores.

**or**

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 authorised by the Contracting Authority, 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.

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 (2) months of late payment, claim late-payment interest:

a) 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%);
b) 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 Further to the provisions of the General Conditions, the Contractor shall bear all risks relating to the supplies until provisional acceptance at destination. The supplies shall be packaged so as to prevent their damage or deterioration in transit to their destination.

Delivery shall be in accordance with the instructions given by the Contracting Authority in terms of Article 13. Delivery is to be effected to CPSU or any other sites/locations as requested by the Contracting Authority on the Confirmation of Order and must also comply to Article 29.9. The contractor shall perform multiple deliveries of the product/s, without any additional cost, directly to any healthcare entities or community pharmacies (as stipulated in Article 13 of these Special Conditions) as may be directed from time to time by CPSU or an appointed representatives.

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. Furthermore, all packaging, marking and documentation inside and outside the packages must comply with Maltese legislation currently in force.

29.3 The packaging shall become the property of the recipient subject to respect for the environment.

29.5 / 29.6 ***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.

**DH markings**

Each unit container or pack is to be marked 'DH'. Markings are to be printed in an indelible medium on the outer packaging of each item and must be clearly legible, otherwise the products will be rejected upon delivery. Expenses and responsibility for refused items shall be borne by the contractor.

When the packaging of a consignment is opened to place DH markings on unit containers or packs, the goods must be re-packaged again in the same manner as the original packaging of the manufacturer or supplier.

**Batch Numbers**

Each consignment delivered to the Central Procurement and Supplies Unit (CPSU) must be physically segregated according to batch numbers and must be clearly documented. ***Each bulk packaging (carton box) must be labelled with the batch number and quantity of items contained therein***.

The Central Procurement and Supplies Unit (CPSU) reserves the right to refuse any consignment delivered comprising more than two different batch numbers.

**GS1 standards for the identification and marking of healthcare products**
The requirement to use GS1 standards is applicable to Secondary packaging for products supplied either directly or via local distributors to CPSU. The requirement applicable should conform to the FMD (Falsified Medicines Directive (FMD) 2011/62/EU) which comes into effect in February 2019.

Brand owners, Importers and distributors who are responsible for labelling products will need to ensure this requirement is met.

Each product requires the following details:

| |
|---|
| Global Trade Item Number (GTIN)<br>(Issued in full compliance with GS1 standards) |
| Batch/lot number |
| Expiry date |
| Serial Number |

For secondary level packaging of pharmaceutical products, the GS1 DataMatrix barcode is recommended.

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 The contractor shall provide and secure the provision of reliable and regular after-sales for a period as specified in the Technical Specifications (if applicable).

***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 i.e. the contracting Authority and the Contractor, by agreement decide to refer the matter to arbitration.

***Article 45: Other conditions for the supply of Blood products/derivates (if applicable)***

The contractor shall ensure that:

a) the blood products requiring refrigerated storage are transported at a temperature of 2°C - 8°C at all times, including the delivery of these products to the Central Procurement and Supplies Unit (CPSU) or any other sites/locations as required.
b) each consignment delivered is to be accompanied by an Original Declaration stating that the specific batch numbers delivered are manufactured from plasma originating from the type of donors as specified in original quote.
c) products delivered must be accompanied by an independent Certificate of Analysis from an accredited laboratory.
d) manufacturer is to keep contractor, and consequently the Department, informed of any changes in the product during the contract period.

The conditions set out in the tender should not in any way be interpreted as exonerating the Fractionation Centre, Supplier, Manufacturer from ensuring that the best possible precautions available are used to ensure that the products are in no way contaminated and safe for use on patients.

# SECTION 3 –TECHNICAL SPECIFICATIONS

## 1.1. Product specifications

**Remodulin® (treprostinil) 2.5mg/ml Vials**

Remodulin® (Treprostinil) 2.5mg/ml supplied in 20ml multidose vials

Cleo 90 infusion set (6mm sub-cutaneous applicator + 31in/79cm lines)

I-Life: I-jet pump syringes (3ml)

### 1.1.1 Estimated Consumption:

Remodulin® (treprostinil) 2.5mg/ml Vials - 55

Cleo 90 infusion set (6mm sub-cutaneous applicator + 31in/79cm lines) - 600

I-Life: I-jet pump syringes (3ml) - 600

### 1.1.2 **Estimated Duration** for this contract (subject to further agreement at negotiation stage):

**24 months**

## 1.2 Other technical specifications

### 1.2.1 Medicinal products and food supplements

i) In case of solid oral dosage forms (tablets/capsules), medicinal products and food supplements must be supplied in the following containers and these will considered in the following sequence order as follows:

a) Pack size of 120 units or less in blister packs

b) Pack size of 120 units or less in any other container type

c) Pack size of 120 units or less, in blister packs repackaged from a larger pack size, provided that the re-packaged product is registered as per clause 9.11 [Registration with Medicines Authority (Medicinal Products)] of the Special Conditions in this tender dossier.

d) Pack size of 120 units or less in any other container type, repackaged from a larger pack size, provided that the re-packaged product is registered as per clause 9.11 (Registration of Medicinal Products) of the Special Conditions in Section 3 of this tender dossier.

In the case that none of the offers received are in line or within the Last Purchased Price through open tender procedure, other pack sizes may be considered.

ii) If the medicinal product being offered is not registered locally, it is hereby confirmed that product/s shall be registered within 90 days from award of Contract. Failure of this, the Contracting Authority reserves the right, at its own discretion:

to purchase registered product on the account of the defaulting contractor until the product is locally registered, or

otherwise the product shall be registered by the Contracting Authority on behalf of the Contractor at a onetime registration fee of €1,000 and an annual fee as applicable by the Medicines Authority. In the latter case the Contracting Authority shall also be charging an annual administration fee of €500 per year. Such registration shall abide to the procedures and policies as applicable by the Maltese Medicines Authority.

The Contracting Authority reserves the right to still consider other offers that are not locally or centrally registered to ensure availability of such medication.

For medicinal products that are not locally or centrally registered, the Contracting Authority reserves the right to request the Responsible Person (RP) of the economic operator to complete and submit an unlicensed form. In the absence of the economic operator's compliance to the above, offer may be rejected.

**1.2.2 Medical materials and devices**

All tenderers submitting surgical equipment and/or medical devices which require reprocessing and sterilisation should provide:

1. Declaration that the surgical instrument can safely undergo, with no damage:
   i. washing with alkaline enzymatic detergent at a pH ≥ 10
   ii. thermal disinfection at 90°C for 1 minute
   iii. steam sterilization at 134°C for 3.5 min
2. Certification that the medical device/s can undergo cleaning within washer disinfectors and/or immersion in ultrasonic baths, thermal disinfection and sterilization. If instruments are unable to withstand any of these processes, information about alternative washing/cleaning/drying/sterilisation methods must be provided at the tendering stage.
3. Confirmation that instruments will fit flat in the existing washing trolleys whose maximum dimensions are: length 50cm x width 25cm and height 12cm.
4. Indication of the expected life time of the device under normal use, including the maximum permitted number of processing cycles during the lifetime of the device.
5. Statement of any chemicals that are incompatible with the device or could cause deterioration or damage.

In addition, in case of award, the tenderer should:

6. Include - at no extra cost - any attachments, restraining devices and/or containers that are necessary for the instruments/equipment to be washed safely in the washer disinfectors, without damage occurring.
7. Ensure (if the instruments are provided in a set) that the total weight of the set will not exceed 10kgs. If this is not the case, the set should be split into separate mesh trays. The mesh tray should include anchoring accessories to keep the instruments secure and safe from damage. It should also have a flat surface on both sides, where bar codes can be fixed. The bottom of each mesh tray should be flat, with no studs and also be free from any sharp edges.
8. Make available a complete processing manual, including a full instrument list as well as pictorial cleaning and packing instructions together with the device/set. This should include instructions on correct dismantling of the instrument, where relevant, as well as instrument inspection, care and handling during reprocessing. In addition, a representative of the supplier will be required to give an appropriate demonstration to CSSD at a date/s and time/s indicated by the CSSD manager, showing how it needs to cleaned (including any dis/assembly) and packed. All this should be undertaken at no additional cost.
9. If the device requires any consumables for regular maintenance (e.g. lubrication), provide enough of these materials for the duration of the contract, at no extra cost together with a maintenance manual showing the procedures that need to be done and their frequency.

MDH reserves the right to reject the purchase of any medical devices, even if the cheapest, which are incompatible with the reprocessing methods, and/or which fail to comply with these requirements.

**1.2.3 Requirements for GS1 standards for the identification and marking of healthcare products**

The requirement to use GS1 standards is applicable to Secondary packaging for products that will be supplied either directly or via local distributors to the Contracting Authority. The requirement applicable should conform to the FMD (Falsified Medicines Directive (FMD) 2011/62/EU) which came into effect in February 2019.

Brand owners, Importers and distributors who are responsible for labelling products will need to ensure this requirement is met for any supplies that will be delivered through this tender.

Each product requires the following details:

| |
|---|
| Global Trade Item Number (GTIN)<br>(Issued in full compliance with GS1 standards) |
| Batch/lot number |
| Expiry date |
| Serial Number |

For secondary level packaging of pharmaceutical products, the GS1 DataMatrix barcode is recommended.

For more information about the use of GS1 standards for the identification and marking of healthcare products refer to the AIDC Implementation Guideline for Healthcare (www.gs1.org/docs/healthcare/GS1_Healthcare_Implementation_Guideline.pdf) and the GS1 General Specifications (www.gs1.org/docs/barcodes/GS1_General_Specifications.pdf).

## 1.3 Other specifications for the Supply of Blood Products/Derivatives (if applicable)

Original declarations from the manufacturer, in reply to the following queries, are to be submitted with each offer unless the product is registered in Malta and/or another EU country or EMA:

1. indicate the countries in which the product is in use.
2. indicate whether the product is in use in the country of origin.
3. indicate whether the product is manufactured from the same donor pool and source plasma used for residents of the country of origin.
4. indicate whether the donors are voluntary or not, and whether they are paid or reimbursed; preference will be given to source plasma from voluntary and non-paid donors.
5. state whether products from same batch of source plasma are used in the country of manufacture.
6. state whether each plasma donor has been tested and found negative for HBsAg, Anti-HIV 1, 2 and subtype O, Anti-HCV, and other tests which might be implemented as routine screening test for donors in the future.

   **Note:** only batches derived from plasma pools tested and found non-reactive for HCV RNA by GAT, using validated test methods of suitable sensitivity and specificity, should be batch released by the Marketing Authorisation holder (as from 01/01/99).
7. indicate the source of origin of the plasma stating specifically the exact country/ies of origin of the plasma source. Plasma derived products from countries with very low BSE prevalence will be given preference.
8. state the expiry date of the product, which must have a shelf-life of at least two years and ideally four years, when delivered.
9. supply documentation regarding details and number of methods used to sterilise and virally inactivate the blood products, as well as documents on their efficacy. Documents must also

state that the normal therapeutic properties of this product are retained. The Department reserves the right to accept only the blood product which it considers to be the most appropriate on the grounds of safety.

10. state whether sero conversions for HIV 1, 2 and subtype O, Hepatitis B, Hepatitis C are known to have occurred in patients receiving this product and when. If no sero conversions are known to have occurred, the tenderer is to make clear statement to this effect.
11. supply 3 vials of the product for local clinical trial, with full descriptive literature.
12. clearly state and indicate that products supplied are also in conformity with the latest European Pharmacopoeia standards for blood products.
13. supply certificate of Good Manufacturing Practice and Free Sales Certificates from Health Authority of the country of origin.
14. ensure that the products supplied by them are as safe as the best scientific state of the art can make them. Their falling short of these standards could also make suppliers liable to pay any sums in damages which any such action or non-action might have caused the Maltese Government to pay.
15. ensure that the blood products requiring refrigerated storage are transported at a temperature of 2°C - 8°C at all times, including the delivery of these products to the Central Procurement and Supplies Unit (CPSU) or any other sites/locations as required.
16. genetically engineered products may be preferred to products which are derived from human plasma or to products which contain human derivatives as an excipient.

The tenderer must clearly state and confirm that the product complies with each of the above specifications, as otherwise the offer may not even be considered.

The conditions set out in the tender should not in any way be interpreted as exonerating the Fractionation Centre, Supplier, Manufacturer from ensuring that the best possible precautions available are used to ensure that the products are in no way contaminated and safe for use on patients.

## 2 Further technical documentation that needs to be submitted with the RfP proposal

### 2.1 Medicinal Products

The following technical documentation is to be submitted with the RfP proposal:

i. Summary of Product Characteristics (SPC) of product being offered in one of the official languages of Malta (Applicable for medicinal products excluding 'Special Medicines').

### 2.2 Food supplements, dietary foods for special medical purposes, chemicals, cosmetics and disinfectants

The following technical documentation is to be submitted with the RfP proposal:

i. Detailed product technical documentation, including outer labeling, of product being offered. In case of dietary foods for special medical purposes documentation should be as specified in Subsidiary Legislation 449.29 [as per requirements of LN309/2001, LN241/2007 and LN284/2013] as amended.

ii. Materials Safety Data Sheet (MSDS) for the product being offered (if applicable).

### 2.3 Medical materials & devices

The following technical documentation is to be submitted with the RfP proposal:

i. Detailed product technical document/datasheet for product being offered.

ii. A valid Declaration of Conformity for product being offered and references to the relevant harmonized standards used (applicable if product falls under the medical device directive).

For products that do not fall under the medical device directive, a declaration is to be submitted confirming the classification of the product, together with certificate of compliance with the applicable legislation (as applicable).

# 3 Standards

**3.1.1 Medicinal Products**

All medicinal products should meet those standards laid down in the latest edition of European Pharmacopoeia (Ph.Eur.) or, in the absence of which, other pharmacopoeia acceptable to the Superintendent of Public Health. In the event that neither of the above is available, an in-house company monograph may be considered.

**3.1.2 Medical material and devices**

Medical devices should, where applicable, bear the CE mark and must meet those standards established by Maltese legislation or standards acceptable to the appropriate competent authority in Malta.

**3.1.3 Food supplements, dietary foods for special medical purposes, chemicals, cosmetics and disinfectants**

Food supplements, dietary foods for special medical purposes, chemicals, cosmetics and disinfectants must meet those standards established by Maltese legislation or standards acceptable to the appropriate competent authority in Malta, where applicable.

**3.2 Legal Classification**

**3.2.1** The Department shall accept the classification of the product being offered as determined by the competent authority in Malta.

# SECTION 4 – SUPPLEMENTARY DOCUMENTATION

## *5.1 – Draft Contract Form*

This is available to view and download from the 'Resources Section' at: www.etenders.gov.mt

## *5.2 – Glossary*

This is available to view and download from the 'Resources Section' at: www.etenders.gov.mt

**Further Definitions:**

***Accessory of medical device: accessory of a medical device as follows:***

**"Accessory"** means an article which whilst not being a (medical) device is intended specifically by its manufacturer to be used together with a device to enable it to be used in accordance with the use of the device intended by the manufacturer of the device. (MDD Article 1(2) b)

***Common name:*** means the international non-proprietary name recommended by the World Health Organisation, or if one does not exist, the usual common name.

***Cosmetic:*** The European Union Cosmetics Directive defines a cosmetic as "any substance or preparation intended to be placed in contact with the various external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance and/or correcting body odours and/or protecting them or keeping them in good condition."

***Food supplements:*** means foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination,marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities; (Directive 2002/46/EC)

***Nutrients:*** means the following substances:(i) vitamins,(ii) minerals (Directive 2002/46/EC)

***Immediate packaging:*** means the container or other form of packaging immediately in contact with the medicinal product.

***Marketing Authorization (MA):*** is the licence for medicinal products to be placed on the market in Malta granted by the Medicines Authority in accordance with the Medicines Act, 2003 (Act No III of 2003 and subsidiary legislation) and for Centrally Authorized products, by the European Medicines Agency (EMA). Currently the three main types of procedures recognized for the granting of a marketing authorization and to place a product on the market in Malta are the National Procedures, European Procedures (Mutual Recognition and Decentralized Procedures), and Centralized Procedure.

***Marketing authorisation holder:*** means the person responsible for placing the medicinal product on the market.

***Medical device***: "Any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:
- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means;" (MDD Article 1(2))

***Medicinal product***: means a) any substance or combination of substances presented for treating or preventing disease in human beings, b) any substance or combination of substances which may be

administered to human beings with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings.

***Name of the medicinal product:*** means the name given to a medicinal product, which may be an invented, common or scientific name together with a trademark or the manufacturer's name; the invented name shall not be liable to confusion with the common name.

***Outer packaging:*** means the packaging into which is placed the immediate packaging.

***Parallel Importation (PI):*** is the importation from an EU Member State or a country within the EEA of a medicinal product, which is already authorised on the Maltese-market, by an importer who is someone other than the importer, appointed by the marketing authorisation holder of the product on the Maltese-market. The medicinal product may then be parallel imported in Malta provided that the importer obtains a licence to market the product.

***Parallel distribution (PL):*** Parallel distribution is the distribution of a centrally authorised medicinal product from one Member State to another by a pharmaceutical company independent of the marketing-authorisation holder. The task of the European Medicines Agency (EMA) is to check compliance of products distributed in parallel with the conditions laid down in Community legislation on medicinal products and in the marketing authorisation of the product

***Qualified Licence (QL):*** may be granted in the absence of a marketing authorization for a medicinal product, whereby the Licensing Authority may authorize the placing of that medicinal product on the market in Malta, provided that the said product is authorized in another Member State (EU/EEA country). An MA is thus granted in accordance with Regulation 4(2) of the Medicines (Marketing Authorization) Regulations, under the Medicines Act, 2003, in accordance with article 126(a) of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code relating to medicinal products for human use, as amended by Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004].

***Qualified person:*** means a person performing duties as specified in the Medicines Act especially with respect to importation of medicinal products coming from outside the EU/EEA.

***Responsible person:*** means a person registered as a pharmacist with the Pharmacy Council and recognised as suitable by the Medicines Authority since such person possesses adequate knowledge of the conditions required for the storage and distribution of medicinal products in order to avoid their deterioration or damage, has adequate knowledge of the regulations concerning the distribution of medicinal products, and has knowledge and understanding of good distribution practice.

***Representative of the marketing authorisation holder***: the person commonly known as local representative, designated by the marketing authorisation holder to represent him in the Member State concerned.

***Special Medicines:*** These are unlicensed medicinal products, which may be needed to treat patients with special clinical needs that cannot be met by other medicinal products. They do not have a marketing authorisation in the country where they are manufactured but they are produced by a Manufacturer holding a "specials" licence.

***Third Country:*** A country that is not an EU Member State or within the EEA.

***Total Shelf Life:*** means shelf life of product as stated in the Summary of Product Characteristics.

### *5.3 – Specimen Performance Guarantee*

This is available to view and download from the 'Resources Section' at: www.etenders.gov.mt

### *5.4 – General Conditions of Contract*

The full set of General Conditions for Supplies Contracts (applicable on date of publication) can be viewed/downloaded from the 'Resources Section' at: www.etenders.gov.mt

It is hereby construed that the tenderers have availed themselves of these general conditions, and have read and accepted in full and without reservation the conditions outlined therein, and are therefore waiving any standard terms and conditions which they may have.

These general conditions will form an integral part of the contract that will be signed with the successful tenderer/s.

### *5.5 – General Rules Governing Tendering*

The contents of this procurement document complement the latest version of the General Rules Governing Tenders applicable on the date of the publication of this tender, the Terms of Use and the Manual for Economic Operators applicable to Government's e-Procurement Platform (available from the Resources section of www.etenders.gov.mt).

# SECTION 5 – LITERATURE LIST

List of Literature to be submitted with the offer.

Supporting documents and printed manufacturer's technical literature furnished by the tenderer may be in another language, provided they are accompanied by an accurate translation into English. For the purposes of interpretation of the tender, the English language will prevail.

ALL BIDDERS ARE TO NOTE THAT PHOTOS SUBMITTED AS MANUFACTURER'S TECHNICAL LITERATURE **SHALL NOT SUFFICE** AND ACCORDINGLY THESE **MUST BE DULY ACCOMPANIED BY THE RESPECTIVE DETAILED MANUFACTURER'S TECHNICAL LITERATURE.**

The submission shall be in a structured form and is to be in the same sequence as listed hereunder for ease of reference and evaluation.

| Item No. | Description | Reference in Technical Specifications |
|---|---|---|
| **1.1** | Further technical literature as requested in Clause 1.1 of Section 3, such as, but not limited to, user manuals, studies on product use, etc. for products being offered. (*applicable for medical materials and devices as required in Clause 1.1 – Section 3*) | Clause 1.1 – Section 3 |
| **1.2** | A clear and legible copy of the packaging including the labelling of the product being offered. (*applicable for medical materials and devices*) | Clause 1.1 – Section 3 |
| **1.3** | Declaration/s required (refer to Clause 1.2.2) regarding reprocessing and/or sterilisation at Sterile Services Departments (*if applicable*). | Clause 1.1 and 1.2.2 – Section 3 |
| **1.4** | Evidence of notification of dietary food for special medical purposes as per requirements of LN309/2001 as amended by LN241/2007 and LN 284/2013 may be requested. (*applicable for dietary foods for special medical purposes*) | Clause 1.1 and 3.1.3 – Section 3 |
| **1.5** | If product contains blood products/derivatives (even in excipients), a copy of certificate and declaration stating whether the product conforms to the special conditions for the purchase of blood products, unless the product is registered in Malta and/or another EU country or European Medicines Agency (EMA) (refer to Clause 1.3 Section 3 – Technical Specifications). | Clause 1.1 and 1.3 – Section 3 |
| **1.6** | | |