AVVIZ TAS-SERVIZZI FARMACEWTICI TAL-GVERN
GOVERNMENT PHARMACEUTICAL SERVICES NOTICE MST 559/08

GOVT. PHARMACUETICAL SERVICES,
ST. LUKE'S SQUARE
G'MANGIA,MALTA
Phone Nos: 21 245795; 21 231321
Fax No.: 21 243163

1. Dan l- Ufficju jircievi offerti maghluqin u miktubin fuq formula maghmula ghalhekk, u skond kif specifikat fil- formoli u fil-kundizzjonijiet mehmuza ma' l-istess formola sal – 10 ta' fil-ghodu ta' 6-Oct-08

1. Sealed tenders on the prescribed form, and in accordance with the specifications and conditions attached thereto, will be received at this office, by 10.00 a.m. on 6-Oct-08

2. MA TITQIES EBDA OFFERTA JEKK:

a. Ma' tintefax fil-kaxxa l-kannella fid-Dipartiment tas-Servizzi Farmacewtici tal-Gvern, jew tintbaghat bil-*fax*, sal-gurnata u l-hin imsemmijin hawn fuq ;

b. ma tkunx miktuba fuq formola maghmula ghalhekk;

c. fil-kaz ta' kumpannija b'responsabbilita' limitata,
i. ma tkunx iffirmata minn persuna/i awtorizzata/i li jiffirmaw ghan-nom tal-kumpannija;

c. fil-kazijiet l-ohra kollha, ma jkunx iffirmat minn
ii. min jaghmel l-offerta;

d. ma jissemmewx fl-offerta, l-indirizz postali u l-eta' ta' min jaghmel l-offerta – dan fejn japplika;

3. Kull min jaghmel offerta, ma jistax ireggaghha lura jew jirtiraha fiz-zmien imsemmi fil-formola relattiva ta' l-offerta. Matul dan iz-zmien, li jibda jghodd mid-data li fiha jkun ghalaq iz-zmien li jinxtehtu l-offerti, dawn l-offerti jibqghu jghoddu u jistghu jintlaqghu f'kull zmien;

4. Il-Gvern izomm id-dritt li jilqa' jew jirrofta, kollha kemm huma, jew parti mill-offerti li jaslulu, jew li jaqsam l-appalt bejn zewg kuntratturi jew izjed;

5. Il-formoli ta' l-offerti, bil-hlas tal-prezz iffissat, fejn applikabbli, u kull taghrif iehor dwar il-kundizzjonijiet tal-kuntratt, jistghu jinkisbu minn dan l-Ufficju, f'kull gurnata ta' xoghol, bejn it-08.30 ta' fil-ghodu u nofs in nhar;

6. Il-konferma ta' l-accettazzjoni tista' l-ewwel tinghata bil-fomm lil min ikun ha l-offerta; jew b'telegramma, b'telefax jew b'ittra. L-accettazzjoni formali tigi mibghuta fi zmien ghaxart ijiem (10), fost granet tax-xoghol mid-data ta' l-ewwel konferma;

2. NO TENDER SHALL BE CONSIDERED UNLESS:

a. It is dropped in the brown box at the Government Pharmaceutical Services, or faxed, on or before the date and time established above;

b. it is made on the prescribed form;

c. in the case of a limited liability Company, it is
i. signed by a person or persons duly authorised to act on behalf of the company;

c. in all other cases, it is signed by the party
ii. tendering;

d. the postal address and age of the bidder – where applicable – are stated in the offer;

3. Bidders shall not retract or withdraw their offers for the period specified in the relative form of tender. During this period which shall commence from the expiration date of the time fixed for the presentation of tenders, the tenders shall remain binding and may be accepted at any time.

4. Government reserves the right to accept or to reject, in the whole or in part, any of the tenders received, or to divide the service among two or more contractors;

5. Forms of tenders, against payment, of the prescribed fees – where applicable, and any further information regarding the conditions of the contract, may be obtained on application at this Office, on any working day between 08.30 and 12.00 noon;

6. Confirmation of acceptance may, initially be verbally communicated to the successful bidder, or else by cable, telex, telefax, letter or any other available means. In any such case, the formal letter of acceptance will be dispatched within a further ten (10) working days from such confirmation.

DIRETTUR GENERALI TAS-SAHHA

DIRECTOR GENERAL, HEALTH

Tender Form

1. With reference to Notice No. **MST 559/08** published in the Government Gazette by the Director General Health, Malta on the **5/9/08** and in terms of the Conditions therein mentioned and therto attached;

   I/We _____offer to:
   (Name of individual or firm making the tender, are to be entered in block letters)

i. Supply and deliver to the designated site, or

ii. Assemble complete, hand over in working condition, and thereafter maintain, as directed by the Director Government Pharmaceutical Services, all charges paid, including vat, customs import duty and levy, if
any, and insured against all risks, the articles enumerated on the attached schedule at the prices stated on same.

2. I/We further offer to undertake to perform the above within the delivery period stated on the attached documents from the date of receipt of the Letter of Acceptance and or the relative requisition.

3. I/We undertake that this tender shall not be retracted or withdrawn for a period of three (3) calendar months from the date of the expiration of the period fixed for its delivery, inclusively, but shall remain binding, and may be accepted by the government, at any time during the said period of three (3) calendar months, even by a verbal communication of the acceptance.

4. Should the above tender be accepted, I/We undertake to provide within the stipulated period (07 days for local bidders, 15 days for overseas bidders), starting from the date of the Letter of Acceptance the Approved Bank Guarantee by a local Bank, as detailed in clause 31 of the General Conditions of Contract, to the extent of ten (10) per cent of the value of this contract. Should at any time, in the course of such contract, the value be increased by the allocation of extra or additional orders in terms of Clause 06 of the General Conditions of Contract, then the amount of this guarantee shall, if so required, be adjusted proportionately by the Bank concerned.

Signature:_____ Date:_____

VAT Registration No._____ Validity Date: _____

Registration Date: _____ P. Code: _____

Address:_____

_____

_____

Age: _____ Tel No. _____TeleFax No. _____ Telex No. _____

a/. Applicable only to tenders for contracts exceeding Euros 9317.50 (LM4,000) in value.

GOVERNMENT PHARMACEUTICAL SERVICES
Medical Stores, Guardamangia MSD 09 MALTA
Telephone: 21 245795; 21 231321 Fax: 21 243163

Specifications & Conditions

FOR THE SUPPLY OF:
AZTREONAM 2G INJECTIONS

ITEM: **AZTREONAM 2G INJECTIONS CPV 24451100-1**

Description: Aztreonam 2g injections for I.M. and I.V. use presented as a powder for reconstitution in vials each containing 2g of the active ingredient.

Label: Pertinent storage conditions are to be clearly indicated on the label of the outer pack. All vials should be labelled accordingly.

The batch / lot number and expiry date must be printed on each individual vial.

Each unit pack is to be marked D.H.

A complete and detailed quality control analysis report showing that the consignment/s being supplied comply with the B.P./B.P.C./E.P./U.S.P. standards [or a quality control analysis report acceptable to the Director of Public Health, if the former is not available] is to be submitted with each consignment.

Present Annual Consumption:359 vials

The Contract shall run for a period of 36 months commencing from the date of the relative Letter of Acceptance. Tenderers are advised to carefully note all relevant conditions and to proceed by submitting the information requested hereunder.

1. The quantity indicated above is the actual quantity utilised over the last 12 months. It is therefore to be clearly understood that the quantity purchased by Government during the contract period may vary according to the needs of the Department depending on the actual consumption of the item.

2. Goods are to be supplied in consignments as requested by the Director Government Pharmaceutical Services, in the quantities stated on each requisition. In this case, delivery is to be effected within 3 to 4 weeks from the date of the order. However, the department reserves the right to request any quantity in one single consignment, the delivery period remaining that stated in the above paragraph unless otherwise stated by the GPS.

3. The tenderer shall quote separate unit prices as stipulated on the schedule attached for the 1st,2nd and 3rd year respectively from the date stipulated in the L.A. Adjudication of offers will be based on the total of these three prices. The Director Government Pharmaceutical Services reserves the right to award the tender for the 1st. year only, or for the 1st. and 2nd. year, or for the 1st., 2nd. and 3rd. year, from the date of the L.A.

4. In instances where the Department deems fit, the Director, Government Pharmaceutical Services may, with the consent of the contractor, extend the contract period by a further six (6) months at the same price rates and under all the original contract conditions.

5. Delivery is to be effected to G.P.S. - Guardamangia
Deliveries to "FIS Floriana" (ONLY) are to be effected to the "In Patient Dispensary" at St. Luke's Hospital after normal office hours.

6. Tenderers are requested to submit samples of the item, as well as Literature/ Documentation/ Package/ insert and labelling (as applicable) in English. Otherwise offers may not be considered.

7. Interpretation or Correction of Tender Documents

a. Tenderers shall promptly notify the Director Pharmaceutical Services of any ambiguity in or discrepancy between any of the tender documents which they may discover upon examination of the tender documents.

b. Tenderers requiring clarification or interpretations of the tender documents shall make a written request which shall reach the Director Government Pharmaceutical Services at least sixteen (16) days prior to the date of receipt of tenders. Any request after this date will not be accepted.

c. Any interpretations, corrections or changes to the tender documents by the Director Government Pharmaceutical Services will be made by an official addenda. Interpretations, corrections or changes made in any other manner will not be valid, and tenderers shall not rely upon such interpretations, corrections and changes.

8. Addenda

a. Addenda will be telefaxed and confirmed by mail to the tenderers.

b. No addenda will be issued later than six (6) days prior to the date of receipt of tenders except an addendum postponing the date of receipt of tenders or withdrawing the request for tenders.

Each tenderer shall ascertain, prior to submitting his tender, that he has received all addenda issued and shall acknowledge their receipt in his tender.

9. Appeals Board

This tender is being published and awarded subject to the appeals procedure as set forth in the Financial Administration and Audit Act (Cap 174), Legal Notice No. 177, Public Contracts Regulations 2005 published in the Government Gazette No. 17775 dated 3rd June 2005. A copy of the relevant Regulations 20 of these regulations is being attached with this tender document.

10. Data Protection Clause

The information collected on this form shall be processed in accordance to the Data Protection Act 2001. The contents of this document are confidential and intended solely for the use of this organisation, and will not be disclosed or copied without your consent to anyone outside the Government Pharmaceutical Services unless the law permits us to.

11. Ownership of tenders

The contracting Authority retains ownership of all tenders received under this tendering procedure. Consequently, tenderers have no right to have their tenders returned to them.

12. Confidentiality

The entire evaluation procedure is confidential. The Evaluation Committee's decisions are collective and its deliberations are held in closed session. The members of the Evaluation Committee are bound to secrecy. The evaluation reports and written records, in particular, are for official use only and may be communicated neither to the tenderers nor to any party.

13. Participation

Participation in tendering is open on equal terms to all natural and legal persons of the Member States of the European Union, the beneficiary country and any other country. All works, supplies and services must originate in one or more of these countries.

These terms refer to all nationals of the said states and to all legal entities, companies or partnerships constituted under, and governed by, the civil, commercial or public law of such states and having their statutory office, central administration or principal place of business there. A legal entity, company or partnership having only its statutory office there, must be engaged in an activity which has an effective and continuous link with the economy of the state concerned. Tenderers must provide evidence of their status.

In this regard tenderers must fully complete and submit with their offer the attached statement shown at ANNEX I.

These rules apply to:
a) tenderers
b) members of a consortium
c) any subcontractors

Natural persons, companies or undertakings for whom the conditions set out in Article 49 of the Public Contracts Regulations, 2005 apply, may be excluded from participation in and the award of contracts.

Tenderers or candidates who have been guilty of making false declarations will also incur financial penalties representing 10% of the total value of the contract being awarded. That rate may be increased to 20% in the even of a repeat offence within five years of the first infringement.

To be eligible for participation in this tender procedure, tenderers must prove to the satisfaction of the Contracting Authority that they comply with the necessary legal, technical and financial requirements and have the wherewithal to carry out the contract effectively.

14 Rates

Tenderers are required to submit their offer in Euro and rates should include VAT, Eco-Contribution and all other charges / taxes as may be applicable on the closing date of the tendering period, as well as any other expenses. The tendered rates shall be fixed and no allowance will be made for any fluctuation or for any increase or decrease in the cost of labour and / or any other expenses.

However, and unless otherwise specified in the tender documentation, any tenderer may submit a bid in any other freely convertible currency. In such cases, the overall price shall, for evaluation purposes, be converted to Euro at the rate of exchange established by the Central Bank of Malta as applicable on the closing date of the tendering period. In the event that the bidder is awarded the contract, any payments deriving from the award will be honoured in the currency that is legal tender at the time of payment. Payments may also be made in the same currency quoted in the bid, provided that this is specifically requested at the time of bidding by the tenderer and that all expenses related to the application of the relevant exchange rate at the time of payment shall be bourne by the successful tenderer.

15. Arbitration

Any Dispute, controversy or claim arising out of or relating to this contract, or the breach, termination or invalidity thereof, shall be settled by arbitration in accordance with the rules of the Malta Arbitration Centre as at present in force.

16. Late Delivery of goods

Besides the penalties for delay envisaged in these conditions and without prejudice to all his other liabilities arising out of the contract, the contractor shall also be liable for the additional costs and damages caused by his failure. In this regard, the Head of Department may enter in a contract with a third party for the provision of supplies

17. The attached "General & Technical Conditions" shall also apply as long as they are not inconsistent with the above.

ANNEX 1

STATEMENT ON EXCLUDING CIRCUMSTANCES OF ARTICLE 49 OF PUBLIC CONTRACTS REGULATIONS 2005.

This declaration, duly completed, must be submitted by all tenderers and returned with the tender submission.

Name of Tenderer: _____

Address: _____

_____

_____

Please tick Yes or No as appropriate to the following statements relating to the current status of your organization:

1. The tenderer is bankrupt or is being wound up; or whose affairs are being admininistered by the court, who has entered into arrangement with creditors or who has suspended business activities or who is in any analogous situation arising from a similar procedure under national law and regulations.

[YES] [NO]

2. The tenderer is the subject of proceedings for a declaration of bankruptcy, for an order for compulsory winding up or administration by the court for an arrangement with creditors or of any other similar proceedings under national laws or regulations.

[YES] [NO]

3. The tenderer has been convicted of an offence concerning professional conduct by a judgment which had the force of *res judicata* in accordance with the laws of Malta.

[YES] [NO]

4. The tenderer has been declared guilty of grave professional misconduct proven by any means which the contracting authorities can demonstrate.

[YES] [NO]

5. The tenderer has not fulfilled the obligations relating to the payment of social security contributions in accordance with the law of Malta or the country in which he is established.

[YES] [NO]

6. The tenderer has not fulfilled obligations relating to the payment of taxes in accordance with the legal provisions of Malta or the country in which he is established.

[YES] [NO]

7. The tenderer is guilty of serious misrepresentation in supplying the information required under these regulations or has not supplied such information.

[YES] [NO]

8. The tenderer is the subject of conviction by final judgment for one or more reasons listed below:

   (a) participation in a criminal organization, as defined in Article 2(1) of Council Joint Action 98/733/JHA;
   (b) corruption, as defined in Article 3 of the Council Act of 26 May 1997 and Article 3(1) of Council Joint Action 98/742/JHA respectively;
   (c) fraud within the meaning of Article 1 of the Convention relating to the protection of the financial interests of the European Communities;
   (d) money laundering, as defined in Article 1 of Council Directive 91/308/EEC of 10 June 1991 on prevention of the use of the financial system for the purpose of money laundering.

[YES] [NO]

I certify that the information provided above is accurate and complete to the best of my knowledge and belief. I understand that the provision of inaccurate or misleading information in this declaration may lead to my organization being excluded from participation in future tenders.

Tenderers who have been guilty of making false declarations will incur financial penalties representing 10% of the total value of the contract being awarded. The rate may increase to 20% in the event of a repeat offence within five years of the first infringement.

SIGNATURE: _____ **DATE:** _____

NAME: _____ **TEL:** _____

Regulation 20
Procedure for the right of Recourse

(1) Where the estimated value of the public contract exceeds Euros 11646 (Lm5,000) but not Euros 46587 (Lm20,000) and is issued by a Local Council by an authority listed in Schedule 2, any interested undertaking shall have a right to make a complaint to the general Contracts Committee in accordance with the procedure laid down in these regulations.

(2) The Contracting Authority shall be obliged to issue a notice and affix an advertisement, in a prominent place at its premises, indicating the warded public contract, the financial aspect of the award and the name of the successful tenderer.

(3) Any interested undertaking who may be aggrieved by the award shall, within three working days from the publication of the notice, file a letter of objection, together with a deposit of Euros 233 (Lm100), with the Contracting Authority, clearly setting forth any reason for his complaint.

The letter by the complaining tenderer shall be affixed on the notice board of the Contracting Authority and shall be brought to the attention of the recommended tenderer. The Contracting Authority shall be precluded from concluding the contract during the period allowed for the submission of appeals. The award process shall be completely suspended if an appeal is eventually submitted.

(4) After the expiry of the period allowed for the submission of a complaint, the contracting Authority shall deliver the letter of complaint, the deposit receipt and all documents relating to the public contract in question to the Director of Contracts.

(5) The Director of contracts shall refer the case to the General Contracts Committee which shall examine the matter in a fair and equitable manner and determine the complaint by upholding or rejecting it.

The written decision of the General Contracts Committee shall be affixed on the notice board of the Contracting Authority and copies thereof shall be forwarded to all the parties involved.

(6) In its deliberation the Committee shall have the authority to obtain in any manner it deems appropriate, any other information not already provided by the Contracting Authority. The General contracts Committee's decision shall be final and binding on the contracting Authority and the interested undertaking who shall not be afforded any further recourse.

(7) Tender documents issued in terms of this part of the regulations shall include a clause informing tenderers that the ward of the contract is subject to the right of recourse as provided for in this regulation, a copy of which should be reproduced in the documents.

(8) The Minister shall have the authority to order by legal notice, the recourse as provided in this regulation be made available also by Authorities listed in Schedule 3 and to prescribe the procedure by which such recourse is to be granted.

A. TECHNICAL CONDITIONS

1: Standards

1.1 Medicinal Products

All medicinal products (1) should meet those standards laid down in the latest edition of European Pharmacopoeia (Ph.Eur.) or, in the absence of which, other pharmacopoeiae acceptable to the Superintendent of Public Health. In the event that neither of the above are available, an in-house company monograph may be considered.

1.2 Medical 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.

2: Legal Classification

2.1

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

2.2

In the case of medicinal products, the Responsible Person (2)/Qualified Person (7) and the Licensee of the Wholesale Dealer and the Tenderer must complete Declaration Sheet for Medicinal Products A. The Tenderer must also complete Information Sheet C.

2.3

In the case of non-medicinals, the Tenderer must complete Declaration Sheet for Non-Medicinal Products - B, together with Information Sheet C declaring the classification of the product being offered.

The tenderer shall ensure that the appropriate Declaration Sheet A or B is completed depending on the classification of the product. Adjudication of offer will then be made according to the classification declared.

3: Packaging and Labelling

3.1 Medicinal Products

The following particulars shall appear on the ''outer packaging'' (3) of a medicinal product, or where there is no outer packaging on the "immediate packaging" (4) in one of the official languages of Malta.

(i) the "name of the medicinal product''(5), which must be followed by the "common name" (6) when the product contains only one active ingredient and if the name of the product is an invented name. If a product is available in more than a single pharmaceutical form and/or strength, the pharmaceutical form and/or strength must be included in the respective labelling.
(ii) a statement of the active ingredients expressed qualitatively and quantitatively per dosage unit or according to the form of administration for a given volume or weight using their common names.
(iii) the pharmaceutical form and contents by weight, by volume or by number of doses of the product.
(iv) the route/s of administration must be clearly shown.
(v) a special warning that the medicinal product must be stored out of reach of children, where appropriate.
(vi) a special warning, if this is necessary, for the medicinal product concerned.
(vii) the expiry date in clear terms by month and year.
(viii) the manufacturer's batch number.
(ix) special storage precautions / conditions.
(x) special precautions for disposal of unused medicinal products or waste material derived from such products, if appropriate.
(xi) the name and address of the manufacturer and/or marketing authorisation holder.
(xii) In the case of radiopharmaceuticals the outer carton and the container shall be labelled in accordance with the regulations for the safe transport of radioactive materials laid down by the International Atomic Agency. In addition the labelling on the shielding shall explain in full the codings used on the vial and shall indicate, where necessary, for a given time and date, the amount of radioactivity per dose or vial and the number of capsules, or for liquids, the number of millilitres in the container. The vial shall be labelled with the name or code of the product, including the name or chemical symbol of the radionuclide; the

batch identification and expiry date; the international symbol for radioactivity; the name of the manufacturer; and the amount of radioactivity.

Where appropriate, a package insert in one of the official languages of Malta must accompany each medicinal product.

3.2 Medical Devices

All medical devices offered must comply with Maltese legislation currently in force.

4: Monographs

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

5: Certificates

5.1 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 Government Pharmaceutical Services.

5.2 Medical Devices, Food Supplements, Chemicals and Disinfectants
The necessary documentation as determined by the competent authority in Malta is to be submitted by the tenderer.

6: Quality and Safety

6.1 Medicinal products
The Responsible Person/Qualified Person must inform the Government Pharmaceutical Services, within 12 hours of having come into possession, of any information concerning batch defects and withdrawal of the product from the market.

6.2 ***Medical Devices***
The tenderer must inform the Government Pharmaceutical Services, within 12 hours of having come into possession, of any information concerning batch defects and withdrawal of the product from the market.

7: Samples and Literature

All samples are to be submitted to the Director, Government Pharmaceutical Services, St Luke's Square, Guardamangia MSD07 by the closing time and date for the submission of tender.

7.1 Medicinal Products
The tenderer must ensure that the following is submitted with each offer:
(i) A true representative sample of the product in the pack size as offered, including the actual dosage form, otherwise the offer may not be considered. Only *present* suppliers at the time of offer need not submit a representative sample.
(ii) Original/true copy of the outer packaging and immediate packaging labelled in one of the official languages of Malta.
(iii) Original/true copy of the package insert in one of the official languages of Malta.

In the case of narcotic and psychotropic medicinal products under international control, radiopharmaceuticals and solid dosage forms of cytotoxic medicinal products – only (ii) and (iii) above are to be submitted. The Department reserves the right to request representative samples if required.

7.2 Medical Devices
The tenderer must ensure that a sample accompanies each offer.

8: Summary of Product Characteristics/Data Sheet

8.1 Medicinal Products

In case of an award of tender, the tenderer must ensure that a copy of the latest approved European Summary of Product Characteristics (SmPC) or a Product Data Sheet intended for the use of healthcare professionals is kept at all times by the tenderer, where such tenderer is established in Malta, or by the pharmaceutical wholesale dealer appointed as per Condition 9.1, when the tenderer is not established in Malta.

The tenderer or the appointed pharmaceutical wholesale dealer, as applicable, must make the SmPC or Data Sheet available without delay and on request to healthcare professionals in Government employment to permit appropriate use of the medicinal product offered. When the SmPC or Data Sheet is updated or revised during the period of validity of the contract, the tenderer or the appointed pharmaceutical wholesale dealer, as applicable, must make available to healthcare professionals already supplied with a SmPC or Data Sheet, a copy of the updated or revised SmPC or Data Sheet.

B. SPECIAL CONDITIONS

9: Pharmaceutical Wholesale Dealer

9.1 Medicinal Products

A tenderer established in Malta must be duly licensed as a pharmaceutical wholesale dealer by the competent authority in Malta. When the tenderer is not established in Malta he must appoint a pharmaceutical wholesale dealer duly licensed by the competent authority in Malta in order to act on his behalf to import the medicinal product into Malta and to deliver the product to the Government Pharmaceutical Services. In this respect, Part II and Part III of Form A are to be duly filled in.

The Licensee and the Responsible Person/Qualified Person of the local pharmaceutical wholesale dealer/importer must ensure that Maltese legislation, conditions of licence 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.

9.1.2 **In the event that at the closing date for the submission of the offer, the medicinal product being offered does not have**

a) **a valid** Provisional Marketing Authorisation, **or**
b) **a valid** Marketing Authorisation, **or**
c) a **valid** Parallel Import Licence, **or**
d) a Central Authorisation by E.M.E.A.

tenderers will be allowed an additional 6-week period from the closing date of the respective tender or from the date of request from Director General of Contracts/ Director GPS, **in order to be able to register the offered medicinal product in terms of prevailing Laws of Malta.**

In this respect clause 9 in Part I of Form "A" - "Declaration Sheet For Medicinal Products" **refers**.

However in respect of medicinal products already holding a valid Provisional Marketing Authorisation **or a valid** Marketing Authorisation **or** a **valid** Parallel Import Licence, **or** a Central Authorisation by E.M.E.A. **at the closing date for the submission of the offer, clause 9 in Part I of Form "A" -** "Declaration Sheet For Medicinal Products*" **is not* **applicable.**

10: Delivery

10.1 Delivery of goods

Consignments of goods must be strictly delivered in boxes that are appropriately packed to withstand transport and handling**.** Delivery of consignments on pallets must be made on Euro pallets.

The Government Pharmaceutical Services 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 tenderer 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 Government Pharmaceutical Services reserves the right to refuse such consignments if prior notification is not effected. Expenses and responsibility for refused items shall be borne by the tenderer.

10.2 Delivery Period

Preference will be given to those tenderers who fully abide by the GPS published delivery period (i.e. 3-4 weeks). If other delivery periods are quoted the span must not be in excess of 3 weeks.

10.3 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 tenderer.

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.

11: Shelf life

The shelf life of the product must be clearly indicated in the Tender documents submitted. When five-sixths of the total shelf-life is less than 2 years, the tenderer must clearly state this on the tender documents. Products with a longer shelf-life will be given preference.

Goods received at Government Pharmaceutical Services must not have their shelf-life expired by more than one-sixth of their total declared shelf-life. Any infringement in this respect will render the tenderer liable to a penalty of 5% of the value of the consignment, together with any other damages suffered by the Government Pharmaceutical Services.

The Government Pharmaceutical Services reserves the right to refuse any consignment which does not satisfy these conditions.

12: Batch Numbers

Each consignment delivered to the Government Pharmaceutical Services 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 Government Pharmaceutical Services reserves the right to refuse any consignment delivered comprising more than two different batch numbers.

13: Preparations requiring cold storage

The actual date and time of arrival of these preparations 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.

In case of medicinal products, a declaration must be submitted by the Responsible Person/Qualified Person stating that the storage status for such preparations has been maintained as required throughout the delivery. The Government Pharmaceutical Services reserves the right to refuse consignments not abiding with the above conditions at the expense of the tenderer.

14: Products purchased for the first time

The Department reserves the right to award contracts for a period of one year for those products that will be purchased for the first time and that have never been used within the Government Health Services. If the product supplied results to be satisfactory, the contract will be extended for another two years. However, if in practice, the product is found not to satisfy the quality, safety and efficacy criteria, the remaining stock at GPS will be returned at the expense of the contractor and payment for this quantity will not be effected. In addition the contract will be terminated.

C. OTHER CONDITIONS

15: Marine Cargo Insurance

All tenderers established in Malta are to ensure that in compiling and submitting their offer, they take into consideration and observe in full the directive as laid down in the press release issued by The Ministry of Finance on the 31st May, 1982. This press release concerns Marine Cargo Insurance. Unless these directives are compiled with, suppliers will inevitably face difficulties in securing any foreign exchange they may require to settle bills relating to insurance policies in respect of import on account of Government Contracts.

16: Communication

Any communication relative to the offer, whether to request information or for any other purpose must be made in writing.

17: Value Added Tax

Tenderers quoting on a delivered to store/site basis are to submit *prices* and/or *rates* INCLUSIVE of VALUE ADDED TAX (VAT), Customs Import Duty, Eco-Contribution (if any) and any other charges, as applicable. Moreover, the successful bidder shall be bound to conform to all respects, with all VALUE ADDED TAX (VAT) legislation and regulations.

18. Payment Terms

The payment terms referred to under the relative Clause of the General Conditions particular to this tender state that payment shall be effected within a reasonable period of time. This means that payment is to be effected within 150 days, provided that it is tied

(a) to the actual date of the 'physical receipt/acceptance' of the ordered goods (or services rendered) which

(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 (or services rendered) to the satisfaction of the Head of the Department or his/her representative.

In breach of this time limit, as qualified by provisos (a) and (b) here above, a Contractor would become entitled to the payment of 2% above the Central intervention rate as established by the Governor of the Central Bank of Malta in terms of the powers granted to him in part IIA of the Central Bank of Malta Act in force on the first calendar day of the half year during which interest become due.

19: Arbitration

Any dispute, controversy or claim arising out of or relating to this contract, or the breach, termination or invalidity thereof, shall be settled by arbitration in accordance with the rules of the Malta Arbitration Centre as at present in force.
Any reference in the attached General Conditions to other arbitration procedures shall not apply.

D. DEFINITIONS

1. "**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.

2. **"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.

3. "**outer packaging**" means the packaging into which is placed the immediate packaging.

4. "**immediate packaging**" means the container or other form of packaging immediately in contact with the medicinal product.

5. "**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.

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

7. **"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.

E. NOTICE

General Conditions of Contract for the Supply of Materials and Other Articles also apply in so far as they are not inconsistent with the above Conditions, in which case, the above Conditions shall be followed in preference to the General Conditions.

GOVERNMENT PHARMACEUTICAL SERVICES
ST LUKE`S SQUARE, GUARDAMANGIA MSD 07, MALTA
TEL. NOS: 21245795; 21231321 FAX: 21243163

DECLARATION SHEET FOR MEDICINAL PRODUCTS - A

Information to be submitted by Tenderer and by Responsible Person/Qualified Person and Licensee of Pharmaceutical Wholesale Dealer/Importer duly licensed in Malta. Where the Tenderer and the Pharmaceutical Wholesale Dealer/Importer are the same both Parts II and III must be completed. If this is not completed in ALL respects, where applicable, offer will not be considered.

PART I (to be completed by the Responsible Person/Qualified Person of the Pharmaceutical Wholesale Dealer/Importer)

1: Advert / MST NO: _____

2: Name of Medicinal Product: _____

Strength: _____

Pharmaceutical Form: _____

3a: Marketing Authorisation Holder in country of licensing: _____

3b. PMA/MA/EU No.:_____
(delete as applicable)

4: Country of licensing: _____

5: Pack size: _____

6: Product complies with the latest edition of :

Ph Eur: ☐ BP: ☐ USP: ☐ Company in-house Monograph: ☐

OTHERS (specify) : _____

N.B. Any variation from the published specifications, must be clearly specified.

7:a. Product contains blood products/derivatives (including excipients) Yes ☐ No ☐

7:b. If Yes in Point 7a, the product must comply with requirements in Document "Special Conditions for the Supply of Blood Products/Derivatives".

8: Samples submitted with offer: Yes ☐ No ☐

9. **In the event that the medicinal product being offered does not have a valid** Provisional Marketing Authorisation **or a valid** Marketing Authorisation, **or a valid** Parallel Importation Licence **or** a Central Authorisation by E.M.E.A. **at the closing date for the submission of the offer,** I, the **Responsible / Qualified** (*) **Person**, accept to undertake

i) to ascertain that the offered medicinal product is duly registered strictly within a 6-week period from the closing date of the respective tender, or otherwise

ii) to inform the Director General of Contracts / Director GPS in writing within one week from the closing date of tender, that the offered medicinal product will not be registered in terms of the prevailing Laws of Malta.

I, the Responsible Person/Qualified Person*, declare that the product to be supplied in respect of this offer (1) is classified as a medicinal product in Malta; (2) will be covered by a Certificate of Analysis for each specific batch in terms of the relative monograph. The Certificate of Analysis will be submitted upon request.

I hereby declare: (i) that the company for whom I am the responsible person/qualified person* is licensed by the competent authority in Malta to act as a wholesale dealer / importer* in the pharmaceutical business as related to this offer; (ii) to inform the Government Pharmaceutical Services of any changes including renewal, variation, suspension or revocation of the pharmaceutical wholesale dealer/importation* licence as issued by the competent authority; (iii) that the product being offered, and for which a sample is being submitted, is authorised under prevailing Laws of Malta to be placed on the market in Malta for wholesale distribution and for sale or supply by other means to patients. Moreover, this product complies in all respects to the specifications and technical conditions as published. Where the product does not comply in all requests to the published specifications I have indicated such deviations. I further undertake that the product will be released for use to the Government Pharmaceutical Services in accordance with all the obligations in my capacity as Responsible Person/Qualified Person* and as dictated by local legislation and European Directives.

**Delete whichever is not applicable*

I further declare that I shall inform in writing the Government Pharmaceutical Services of any suspension or withdrawal of the authorisation to place the product on the market by the Superintendent of Public Health or the competent authority in Malta or of any information concerning batch defects or recalls of the product.

…….. ……..

Signature of Responsible Person/Qualified Person* Name in Capital Letters

Telephone No.: …… Fax No.: ……

Pharmacy Board Registration Number: …… Date: …….

PART II (to be completed by the Licensee of the Pharmaceutical Wholesale Dealer/Importer)

I declare that I am aware of the undertaking made by the Responsible Person/Qualified Person*.

In case of an award of tender, the person to be contacted to provide a copy of the latest approved European Summary of Product Characteristics (SmPC) or Product Data Sheet as per Technical Condition 8.1 is:

Name of Contact Person in Capital Letters: ……..

Position: ……

Telephone No.: …… Fax No.: ……

I accept to be appointed as the pharmaceutical wholesale dealer/importer* on behalf of the tenderer shown below who is not established in Malta.#

Delete if tenderer is established in Malta

…… ……..

Signature of Licensee of Wholesale Dealer/Importer* Name in Capital Letters

Licence No. of Pharmaceutical Wholesale Dealer/Importer*: ……

……. Date: …….

Rubber Stamp or Company Name in Capital Letters

PART III (to be completed by the Tenderer)

I undertake to ensure that the above will be part of the Contractual obligations in the event of an award.

As a tenderer who is not established in Malta I hereby appoint the pharmaceutical wholesale dealer shown above to act on my behalf in order to import the medicinal product into Malta and to deliver the product to the Government Pharmaceutical Services.

I declare that Mr/Ms _____, Responsible Person/Qualified Person* of the pharmaceutical wholesale dealer/importer* _____ , will be assuming the responsibilities mentioned in Part I of Form A, regarding this tender.#

Delete if tenderer is established in Malta

…….. ……..

Signature of Tenderer Name in Capital Letters

……. Date: …….

Rubber Stamp or Company Name in Capital Letters

* *Delete whichever is not applicable*

GOVERNMENT PHARMACEUTICAL SERVICES
ST LUKE`S SQUARE, G' MANGIA MSD 07, MALTA
TEL. NOS: 21245795; 21231321 FAX: 21243163

DECLARATION SHEET FOR NON-MEDICINAL PRODUCTS - B

Information to be submitted by Tenderer.
If this is not completed in ALL respects, where applicable, offer will not be considered.

1: Advert / MST NO: _____

2: Product name (Brand): _____

3: Manufacturer and country of manufacturer: _____

4: Product conforms with regulations on CE marks: Yes ☐ No ☐

5: Package insert in English/Maltese language Yes ☐ No ☐

6: Pack size: _____

7: Samples submitted with offer: Yes ☐ No ☐

I undertake to ensure that the above will be part of the Contractual obligations in the event of an award.

…….. ……
Signature of Tenderer Name in Capital Letters

Tel No.: …… Fax No.: …….

……. Date: ……..
Rubber Stamp or Company Name in Capital Letters

GOVERNMENT PHARMACEUTICAL SERVICES
ST LUKE`S SQUARE, GUARDAMANGIA MSD 07, MALTA
TEL. NOS: 21245795 ; 21231321 FAX: 21243163

INFORMATION SHEET - C

Information to be submitted by Tenderer.
If this is not completed in ALL respects, where applicable,
and submitted with Declaration Sheet A or B, offer will not be considered.

Advert / MST No. _____

I hereby certify that the product offered is classified in Malta as:

Medicinal Product: ☐ Food: ☐ Medical Device: ☐

Others: _____ (to be stated).

1. Pack size: _____

2. Unit C.I.F. Price: * 1st YEAR *2ND YEAR *3RD YEAR

1. 3. Unit Price delivered to stores/site inclusive of VAT, CUSTOMS Duty & any other charges/taxes (if any):

*1st YEAR *2ND YEAR *3RD YEAR

(Prices must be worked out as requested, otherwise offer may not be considered)

4. Customs Tariff Number: _____

5. Customs Duty included in the total cost submitted at (3): _____% (rate):

6. Eco-Contribution (if any) included in the total cost submitted at (3): _____

7. VAT included in the total cost submitted at (3): _____ % (rate)

Country of Manufacture (Origin): _____

8. Delivery Period: _____ weeks (E.U Countries do not attract Customs Import Duty)

9. Shelf life:

10. Validity of Offer: Days:

11. Police / Trading License No.: Validity Date:

12. Signature of Tenderer: _____ Name in Capital Letters: _____ Tel/Fax No: _____

13. Vat Registration No.: Validity Date:

14. Rubber Stamp or Company Name in Capital Letters:

* Applicable as indicated on Letter of Acceptance

FORM B

GOVERNMENT PHARMACEUTIAL SERVICES, MALTA
DECLARATION ON SUPPLY OF A PHARMACEUTICAL PRODUCT
This form should be filled in by local and foreign suppliers.

I, the undersigned, as the responsible / qualified person* for

_____,
(name of wholesale dealer / manufacturer)*

declare that the product _____, is licensed in the
(*trade name of product)*
_____.
(name of country forming part of EC/EEA)

I also declare that this product meets the latest standards established by the British, European, and International Pharmacopoeia, or the British Pharmaceutical Codex or according to the finished product standards of the particular product being supplied, as registered in the licensing country.

I undertake to inform the Medicines Authority of Malta of any product recalls and changes in the licensing status concerning this product throughout the whole shelf-life of the product.

I accept in their entirety the conditions set out above.

I also undertake to inform the Government Pharmaceutical Services of any changes including renewal, variation, suspension or revocation of the pharmaceutical wholesale dealer's / wholesale dealer's (importation from non-EC/EEA countries) / manufacturer's licence as issued by the competent authority.

Signature of Responsible / Qualified* Person: _____

Name in full: _____

Name of company: _____

Wholesale Dealer's / Manufacturer's* License No: _____

Address: _____

_____

_____

Tel No: _____ Fax No: _____

Date: _____

** Delete whichever is not applicable*

SPECIAL CONDITIONS FOR THE SUPPLY OF BLOOD PRODUCTS/DERIVATIVES

Original declarations from the manufacturer, in reply to the following queries, are to be submitted with each offer:

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 form 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 Pharmacopoeial 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 are transported at a temperature of 4° C ± 2° C at all times, including the delivery of these products to the Government Pharmaceutical Services.
16. clearly state and confirm that the product complies with each of the above conditions, as otherwise the offer may not even be considered.
17. 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.
18. products delivered must be accompanied by an independent Certificate of Analysis from an accredited laboratory.
19. genetically engineered products may be preferred to products which are derived from human plasma or to products which contain human derivatives as an excipient.
20. manufacturer is to keep tenderer, 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.

GENERAL CONDITIONS OF CONTRACT FOR THE SUPPLY OF MATERIALS AND OTHER ARTICLES

1. In these conditions and in any specifications or special conditions annexed hereto:

(a) the word 'Government' shall mean the Government of Malta;

(b) the word 'Inspector' shall mean the engineer or other person or persons appointed by Government to inspect the work when the Government decides to have inspection;

(c) the words 'Head of Department' shall mean the Head of Government Department in Malta – by whom or on whose behalf the tender is being issued;

(d) the words 'Accountant General' shall mean the 'Director of Contracts' in Malta;

(e) the word 'contractor' shall mean any person whose tender for the work referred to shall be accepted by the Government;

(f) the word 'work' shall mean articles of every description and materials of every kind in every stage of their preparation;

(g) the word 'Malta' shall have the meaning assigned to it by Section 126 of the Constitution.

2. Local bidders, including the accredited local agents of overseas firms, are required to quote prices covering the total cost delivered to stores/site inclusive of VAT, Customs Duty and Levy if any. Overseas bidders who have no local agent are required to quote CIF prices on liner terms. All local and overseas bidders, including the accredited agents of overseas firms, shall have the option of quoting either in Maltese currency or else in British Pound Sterling, Euros and U.S. Dollars. Quotations in other currencies may be considered.

Clause 2(a) When local bidders opt to quote in foreign currency they should, when submitting their offer, specify whether: (i) they would prefer to be paid either at the rate of exchange ruling on the date of delivery or (ii) against presentation of the necessary documentary evidence from their bank, showing the date and the rate at which they transferred monies in respect of the relative Contracts to their principals abroad. If bidders fail to specify their preference beforehand, payment would then be made at the rate of exchange obtaining on the delivery date.

3. The contractor shall indemnify the Government against all claims at any time on account of patent rights of royalties, whether for manufacture or for use in Malta. In the event of any claims being made against the Government in respect of which the contractor is liable under this condition; the contractor shall be notified thereof and may at his own expense, conduct any litigation that may arise therefrom, or any negotiations for settlement.

4. The Government shall have the power to require reasonable alterations in the work or any of its details; and, if such alterations do not involve extra expense, no payment shall be made in respect of them.

5. The contractor shall not receive payment beyond the contract sum for any work which he may consider that payment should be made as an extra, unless suck work shall have been ordered as extra work, or unless the contractor, before commencing such work, shall have claimed in writing, that it should be paid for as an extra, and the Inspector of the Head of Department shall have certified in writing that the claim is reasonable and proper.

6. The Head of Department shall have power to order reasonable additions to, or deductions from the work, measurements, quantities, or weights specified, and such additions or deductions shall be allowed for at the contract rates. Such variations shall be sent in the form of written orders to the contractor.

7. In the event of additions being made, the Government may, if it thinks it necessary, extend the time for delivery for such period as it may consider reasonable and proper. The contractor shall be informed in writing of any such extension.

8. Should there by any discrepancy between the contract drawings and the specifications, or any inconsistency or omission in either of them, reference must be made to the Inspector or the Head of Department for any explanation and the contractor will be held responsible for any errors that may occur in the work through neglect of this precaution.

9. The contractor shall deliver the whole of the work, complete in all its parts and furnished with every necessary detail and fitting notwithstanding any omission or inconsistency in the contract drawings and specification.

10. Before proceeding to execute any work, the contractor shall obtain the Inspector's or the Head of Department's approval of the manner in which the contractor proposes to execute each portion of the work; and shall furnish such drawing or information as the Inspector or the Head of Department shall require.

11. The contractor shall take all risks of accident or damage to the work, from whatever cause arising. He shall be responsible for the sufficiency of all means used by him for the fulfilment of the contract. He shall not be relieved from such responsibility by any approval which may have been given by the Inspector or the Head of Department.

12. The materials and fittings of every kind used, are to be free from defects and, unless otherwise specified, are to be of the best description of their respective kinds. The workmanship is to be of first class character, and the degree of finish such as the Inspector or the Head of Department shall require.

13. The Inspector or the Head of Department may adopt any means he may think fit to satisfy himself that the materials specified are, actually used. He shall have power throughout the contract, either personally or by deputy, to inspect, without giving notice, the entire work, or any part thereof, at every stage of progress and wherever the work, or any part thereof may be in progress, to amend or alter anything he may think fit and to reject any parts of the work of which he may disapprove.

14. Should the contractor anticipate at any time during the execution of the contract that he will be unable to deliver the work within the contract time, he must at once give notice accordingly, in writing, to the Head of Department explaining the cause of the delay.

15. The contract time for delivery shall be the period or periods named in the letter of acceptance of tender, and shall be reckoned from the date of the receipt of the said letter.

16. Any drawings, tracings or descriptions specified must be furnished by the contractor with the first consignment of the work to which they refer. Payment will not be made by the Director of Contracts until such drawings, tracings, or descriptions have been furnished to the satisfaction of the Inspector or the Head of Department.

17. It shall not be lawful for the contractor to transfer or assign the contract, directly or indirectly or any part, share or interest in it, or any amount due by the Government thereof, to any person or persons whomsoever, or to sublet the contract or any part of it, or to allow any portion of the work to be done otherwise than in his own establishment, without the written consent of the Government.

18. Should there be any discrepancy between the General Conditions and any special conditions or specifications of any contract, the special conditions shall be followed in preference to the General Conditions.

19. Payment will be made by the Treasury in accordance with the terms of the Bond (Bank Guarantee) referred to at Clause 31, and within a reasonable time after delivery in Malta, to the satisfaction of the Head of Department. Payment will be subject to any deduction to which the contractor may have become liable under this contract.

20. (a) The work shall be delivered to store or site of works, at Malta, all charges paid, including VAT, Customs Import Duty and Levy, if any and insurance. The contractor shall be responsible for all damages or loss in transit from the contractor's work to the store or site or works at Malta, and shall replace, free of cost, all materials that may be broken, damaged or lost in transit as aforesaid.

(b) Delivery to store or site shall not apply in the case of overseas bidders referred to in condition (2) above.

(c) Vat, Customs Import Duty and Levy, if any, SHALL NOT BE REFUNDED.

21. Failure to deliver within he contract time shall, in addition to any other liabilities incurred by the contractor under this contract, render the contractor liable by way of penalty, to a deduction from the contract sum of one (1) per cent per week on the value of any work which may be in arrear, unless the Head of Department is of the opinion that such delay has arisen from causes which were unavoidable, and could not be foreseen or overcome by the contractor, in which case, the Government shall decide the extent, if any which deduction shall be remitted. Delays in the supply of materials to the contractor will not be admitted as a ground for the remission of deductions, except insofar as they may have arisen from strikes, or other causes which could not be foreseen or overcome by the manufacturers or vendors of such materials. Provided that in the latter event, and unless the contractor, within six (6) weeks from the due date of delivery, resumes supplies as provided for in these conditions, Government without prejudice to its rights under conditions 22 and 23 hereof, shall be entitled to hold, the contractor responsible for damages incurred by Government as a result of the delays referred to in these conditions.

22. Should the contractor fail to effect delivery in whole or in part, within one month from the expiration of the period stipulated in the contract without the previous permission of the Director of Contracts; the contract shall be deemed to have been abandoned, in which case the contractor shall be liable to pay a penalty of ten (10%) per cent of the value of the undelivered goods, calculated on the basis of the contract sum in addition to any compensation which may be due for damages.

23. Late delivery, or failure to effect delivery shall, at any time, entitle the Government to dissolve 'ipso jure' the contract and, in case of such dissolution, the liquidated damages which shall never exceed the full value of the contract shall be computed up to the date of the communication to the contractor of the Government's decision to terminate the contract.

24. Besides the penalties for delay envisaged in these conditions, and without prejudice to all his other liabilities arising out of the contract, the contractor shall also become liable to a penalty, if the rate of progress of the work throughout the contract period is not satisfactory. The contractor shall be considered to be in default if he fails to carry out every month, at least 70% of the estimated monthly average progress. For the purpose of assessing such average progress, the value of the contract shall be divided by the number of months stipulated in the contract period. Within each month, the contractor should complete works whose value is equivalent to the average progress obtained as above. Hence, in the case of contracts having a completion period of 6 or more months, no penalty shall be imposed in respect of the first month from the date of allocation of the contract. Should the contractor's progress fall below the minimum percentage progress, he will become liable to a penalty equivalent to two (2%) per cent of the value of the contract, in respect of every month during which, progress is below standard. If the contractor completes the whole contract within the stipulated periods, the Government may consider the refund of any penalties the contractor may have incurred for slow, monthly progress.

25. 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 opinion, does not possess the qualities required under the contract and to obtain it elsewhere, at any price, and on contractor's account; should the latter fail to replace the articles rejected, within the time allowed for the purpose by the Head of Department.

26. The name of address of the manufacturer and the country where the goods will be manufactured, shall be furnished. Failure to give this information may involve non-consideration of the tender. Full specifications of the product offered shall be submitted.

27. Without prejudice to the Government's right to dissolve 'ipso jure' the contract in the case of infringement of any conditions 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 five (5%) per cent of, the value of contract or the sum of Euros 23.29 (Lm 10)., whichever is the greater, unless the Government elects, with regard to each particular infringement, but not necessarily with regard to all infringements, to claim actual damages incurred.

28. The Government is not bound to accept the lower or any tender, and shall not give reasons for the acceptance or rejection of a particular tender.

29. The Government reserves the right of accepting any tender, wholly or in part, or of dividing the contract among two or more bidders.

30. The award of the contract does not exonerate the contractor from the obligation of obtaining any other permit and/or licence that may be required under any law, principal or subsidiary, in force in Malta, from time to time.

31. The contractor shall, within seven (7) days in the case of a local contractor, fifteen (15) days in the case of an overseas contractor – such periods to commence from the date of the Letter of Acceptance – furnish the Bank Guarantee by a local Bank, referred to in the "Form of Tender" amounting to ten (10%) per cent or fifteen (15%) per cent, according to the value of the contract.

32. This contract shall be, and be deemed to be a Maltese contract and shall be governed by, and construed according to the Laws of the time being in force in Malta. Notwithstanding any other agreement or condition to the contrary, in case of any disagreement or claims, the Maltese Courts shall have exclusive jurisdiction to hear and decide on the merits of the matter in dispute.

33. Notwithstanding anything contained herein or in the notice for tender, or in the 'Form of Tender', if a bidder happens to be a statutory body, having a distinct legal personality, and if a contract is awarded to such a body, a Bank Guarantee will not be required, and the provision of all clauses relating to the submission of a Bank Guarantee shall not apply; but the said body shall bind itself to indemnify the Government against any failure on the part of such body to comply with any of the conditions of the tender.

BOND

The Director of Contracts,

In connection with the agreement entered into between yourself on behalf f the Malta Government and

……

……

(Name and Address of Contractor)

referred to as "the Contractor" as per the latter's tender dated …….. and your Acceptance (Ref ……...) of the ……..……..

whereby the Contractor undertook to provide, supply, deliver to site/store, erect complete, hand over in working order and thereafter maintain* in accordance with the terms of Clause 31 of the General Conditions the work/services as mentioned, enumerated or referred to in the Specifications and/or Bills of Quantities forming part of the tender documents, we hereby guarantee to pay you on demand a maximum sum of (amount in words and figures) EUROS……. (Lm ……..) in case the obligations under the above-mentioned agreement are not duly performed by the Contractor.

It is understood that this guarantee will become payable on your first demand and that it shall not be incumbent upon us to verify whether such demand is justified.

For avoidance of doubt it is hereby declared that although this instrument gives rise to legal relations between the guarantor and Government, it is hereby specifically declared for all intents and purposes of law that this guarantee does not exempt the above-mentioned Contractor from any obligations, acts of performance or undertakings assumed under the tender documents as ratified in the Contract.

Any payments due to the Contractor in respect of the obligations entered into under the contract above referred to shall be made through this Bank.

This guarantee expires on the …….. and unless it is extended by us or returned to us for cancellation before that date, any demand made by you for payment must be received in writing not later than the aforementioned expiry date.

This document should be returned to us for cancellation on utilization or expiry or in the event of the guarantee being no longer required.

……

(Local Bank) Manager

……

Director of Contracts

I accept in their entirety the conditions set out above.

……

Contractor

* Delete where not applicable

GENERAL CONDITIONS GOVERNING THE EMPLOYMENT OF LABOUR IN CONNECTION WITH GOVERNMENT CONTRACTS

1. The following conditions shall apply to all contracts entered into by the Maltese government, the execution of which involves the employment of workers by the other party to the contract and expenditure of public funds of an amount exceeding £M500 being contracts for:-

a) the construction, alteration, repair or demolition of public works;
b) the manufacture, assembly, handling or shipment of material, supplies or equipment; or
c) the performance or supply of services.

2. The wages, hours of work and other conditions of labour of workers employed by a contractor shall be not less favourable than those established for work of the same character:-

a) by national laws and regulations as modified by collective agreement or other recognised machinery of negotiation between employers and workers representatives: respectively of substantial proportions of employers and workers in the trade or industry concerned or by voluntary settlement or arbitration award under the Conciliation and Arbitration Act affecting such employers and workers; or
b) failing such modifications described in (a) by the laws and regulations as modified by the general level observed by the employers in the trade or industry in which the contractor is engaged; or
c) failing the applicability of (a) and (b), then by collective agreements, voluntary settlement or arbitration award, or by the general level in the trade or industry.

3. On tendering for Government contracts, the contractor shall certify that to the best of his knowledge and belief the wages, hours of work and conditions of labour of workers employed by him in the trade or industry in which he is offering himself as a contractor are fair and reasonable having regard to the provisions of condition 2 above.

4. Any difference or dispute arising as to what wages ought to be paid, or what hours or other working conditions ought to be observed in accordance with the requirements of condition 2 shall, if not otherwise disposed of, be referred to the Malta Arbitration Tribunal for settlement by it.

5. The Contractor shall keep proper wages books and time sheets showing the wages paid to and the time worked by the workers in and about the execution of the contract, and he shall be bound, whenever required, to produce such wages books and time sheets for the inspection of any person authorised by the Head of the Department concerned or by the Head of the Department of Emigration Labour and Social Welfare.

6. The Contractor shall also, when required to do so furnish to the Department concerned or to the Department of Emigration, Labour and Social Welfare such further detailed information and evidence as the Head of the Department may deem necessary in order to be satisfied that these conditions have been complied with.

7. (1) A contractor shall not be entitled to payments of any money which would otherwise be payable under the terms of the contract in respect of the work and labour performed in the execution of the contract unless and until he shall have filed a statement, certified by him to be correct, showing:-

(i) the rates of wages and hours of labour of the various classes of workmen employed in the execution of the contract;
(ii) whether any wages in respect of the said work and labour remain in arrears; and
(iii) that all the labour conditions of the contract have been complied with.

(2) Where the works carried out by the Contractor extend over a period of six months or more, the contractor shall file such a statement every six months, even where he shall be entitled to payment only when the works have been completed.

8. If any worker employed in the execution of the contract files a claim in the Department of Emigration, Labour and Social Welfare that any payment in respect of wages due to him has not been made, the Director of Emigration, Labour and social Welfare may, if the claim is proved to his satisfaction and if the contractor fails to pay, arrange for the payment of such claim out of the monies at any time payable to the contractor under the said contract and the amount so paid shall be deemed a payment under the contract.

9. Any contractor who contravenes these conditions shall not be allowed to tender for Government contracts for such period as the Government may determine.

10. Contractors shall recognise the freedom of their workers to be members of registered trade unions.

11. It shall not be lawful for the contractor to transfer or assign the contract, directly or indirectly, or any part, share or interest in it or any amount due by the Government, therefore, to any person or persons whomsoever, without the written consent of the Government.

12. The contractor shall be held responsible for compliance with these conditions by sub-contractors, or by assignees of contracts or whose behalf application is made by the contractor in terms of the preceding paragraph of these conditions. The limit of £M500 shall not apply to sub-contractors and assignees of contracts.

13. These conditions shall not apply to employees of contractors occupying positions of management, or of a technical, professional or scientific character who do not ordinarily perform manual work.