PRE-BID CLARIFICATIONS / AMENDMENTS IN RESPONSE TO THE QUERIES RAISED BY PROSPECTIVE BIDDERS IN THE PRE-BID MEETING HELD ON 12.04.2018, 11:30 A.M. IN THE CONFERENCE HALL, OSMCL FOR THE RE-TENDER OF DRUGS & MEDICAL CONSUMABLES- 2017-18
[Bid Ref. No.: OSMCL/2017-18/DRUGS-DHS (Re-Tender-I)/11 & OSMCL/2017-18/DRUGS-DHS (Re-Tender-II)/12]

CORRIGENDUM

Corrigendum No : 5542/ 684 Date 19/04/218

Sl. No	Item Name/ Particulars	Details as mentioned in the tender document	Queries raised by the prospective bidders	Clarifications/ Amendments in response to the queries.
		Queries relating to General Terms and Conditions		
1	**Section-V** **Clause No. 5.2.1** Pre-qualification of bidders **Page no.- 23**	Bidder shall only be a manufacturer having valid own manufacturing license/loan license or Direct importer holding valid import license with product registration certificate issued by the Drugs Controller General of India. a) In case of manufacturer, it shall have a valid manufacturing drug license or duly acknowledged renewal application with old license issued by the State Licensing Authority / Central Licensing Approving Authority (wherever applicable). b) In case of importer, it should have a valid import license and product registration certificate issued by the Drugs Controller General of India.	It may be clarified whether a **bidder as a importer** can participate in the tender by submitting the copy of receipt of renewal for expired import license issued by CDSCO	***Clarification:*** *In case of **bidder as importer** at tender clause no. **5.2.1 (b),** it is clearly mentioned that it should have a valid import license and product registration certificate issued by the Drugs Controller General of India.* *However, for **manufacturer** Tender Clause No. **5.2.1 (a)** can be referred for clarification **along with the Notification issued by CDSCO vide Gazette Notification No. 1337(E) dt. 27.10.2017**.*
	Section- V Clause No. 5.2.6 **Page No. 24**	Bidder (manufacturer/ importer) shall have a minimum turnover of Rs. 15Crs or more in each of the year for last three financial years in India from Sl.No. 1 to Sl. No. 58, Rs. 10 Crs or more in each of the year for last three financial years in India from Sl. No. 59 to Sl. No. 86 & Rs. 2 Crs or more in each of the year for last three financial years in India from Sl. No. 87 to Sl. No. 92 for the items as per Section IV. Last three financial years means either for **2013-14, 2014-15 and 2015-16 or 2014-15, 2015-16 and 2016-17**. The proof of turnover is to be furnished in format T6 certified by the Chartered accountant & supported by audited annual statements / annual report with the turnover figure highlighted there.	•The minimum turnover criteria for Sl. No. 82 i.e. VDRL Rapid Test Kit, (RPR) Rapid Plasma Regime (S02053) is 10 crore may be reduced to Rs. 5 Crs or more. •Final audited statement of annual turnover certificate for years 2015-16, 2016-17, 2017-18 may be accepted.	***No Change*** **Clarification:** *The final audited statement of annual turnover certificate for the year 2017-18 may be accepted.*
2	**Section-V** **Clause No. 5.2.8 (a)** Pre-qualification of bidders **Page no.- 24**	Bidder / manufacturer who has been blacklisted / debarred/banned by any other State Government / Central Govt. Organization /State Medical Corporations/ Director Health Services (Odisha) and or convicted by any court of law due to (i) quality failure of the drug(s) supplied (NSQ/ Spurious/ Adulterated/ Misbranded etc.). (ii) Submission of fake or forged documents. (iii) Submission of incorrect information / Suppression of vital information & facts can't participate in the tender during the period of blacklisting / debarment/ Banned. Bidder / manufacturing unit which has been blacklisted / debarred/ banned by OSMC for any reasons can't participate in the tender during the period of blacklisting / debarment/ banned.	It can be clarified whether the firm/ manufacturer blacklisted by other state corporations for **default in supply** and **non-submission of agreement or LOI** can participate in the tender	**Clarification:** *Tender Clause No. 5.2.8(a) may be referred for selection of bid regarding blacklisting.*
3	**Section- V** Clause No. 5.2.9 **Page No. 25**	Bidder should have experience in supplying quoted item/Same Molecule of Similar Dosages form as per tender specification to the State or Central Government or Government Hospitals / Corporate Hospitals / PSU Hospitals / Municipal Hospitals / Pvt. Hospitals in India / UN agencies / Authorized agency of the State / Central Govt. / PSU/Open Market Supply as a manufacturer or otherwise during the last 3(three) years.	Supplies to the export market & bulk supplies to reputed resellers may be categorised under "**open market supply**".	**Clarification:** *As per tender Clause No. 5.2.9 A manufacturer supplying quoted item/Same Molecule of Similar Dosages form as per tender specification in the open*

				market supply during last three years is allowable.
4	**Section- VI** Clause No. 6.24.1 **Page No. 40**	The contract will be awarded to the lowest evaluated responsive bidder qualifying to the final round after scrutiny of the technical bids and sample verification of the item (s) if any, i.e. after price bid opening. However, for programme item (s) and other Bulk item (s) empanelment of **other technically qualified suppliers may be asked through negotiation to match with the L1 price for supply of the item** (s). Subsequently orders can be given to L1, L2 & L3 suppliers at L1 rate in the ratio of 50:30:20. In case of failure of any supplier, the non supply portion of the order can go to the suppliers who are on the panel for supplying and in the event L2 and L3 suppliers also failing, the orders can be placed on other qualified suppliers willing to supply at L1 rate**. MD, OSMCL reserves all rights regarding the decision of division of the total order quantity**.	If L1 bidder reduces its quoted price, then L2/L3 bidder who had matched the earlier L1 price has to further reduce its price or not.	**Clarification:** *Rate contract will be made with the L2/L3 bidder only after they match with L1 rate. If the L1 price of the L1 bidder is modified then the L2/L3 bidder has to again match with the modified L1 price for supply the item.*
Queries relating to Technical Specification for OSMCL/2017-18/DRUGS-DHS (Re-Tender-I)/11				
5	**Section – IV** Item Sl No. 02, D23016- Inj. Hepatitis B Immunoglobulin (HBIG) **Page No. 12**	**200IU/ 0.5ml or 1ml** Each unit packet shall contain the following: i) 1Vial/ (0.5ml or 1ml/Vial) ii) 1 Eclipse Needle (21G) All blood products should be Test Negative for HBsAg, HIV I and II, HCV Antibodies which will be printed on each unit packet.	1Vial/ (0.5ml or 1ml/Vial) may be changed to less than or equal to 0.5 ml.	**Amended** D23016- Inj. Hepatitis B Immunoglobulin (HBIG) **200IU in 0.5ml or less / 1ml** Each unit packet shall contain the following: i) 1Vial/ (0.5ml or 1ml/Vial) ii) 1 Eclipse Needle (21G) All blood products should be Test Negative for HBsAg, HIV I and II, HCV Antibodies which will be printed on each unit packet.
5	**Section – IV** Item Sl No. 07, D40002- Inj. Human Albumin IV **Page No. 13**	D40002- Inj. Human Albumin IV 20% 100ml/Bottle/Bag 20 Bottles or Bag/Box	•The strength of The item D40002- Inj. Human Albumin IV 20% may be amended to 25 %. •Pack size of 50 ml/ Bottle, may also be included.	***No Change***.
6	**Section – IV** Item Sl No. 41, D16048- Factor VII (Pre-filled Syringe) **Page No. 15**	D16048- Factor VII (Pre-filled Syringe) 1mg / PFS 20 PFS/Box	The dosage packing may be changed to 1 mg vial instead of PFS.	**Amended** D16048- Factor VII **1mg Powder/Vial** **Each unit packet shall contain the following:** **i) 1Vial / 1 mg** **ii) 1 Vial Sterilized required diluents** **iii) 1 Transfer / Filter Set** **iv) 1 Disposable Syringe : 5 ml** **v) 1 Disposable Needle** **vi) 1 Winged Infusion Set / Twin Set** **vii) Alcohol Swab**
7	Section – IV , Item Sl No. 82 S02053 – VDRL Rapid Test Kit, (RPR) Rapid Plasma Regime **Page No. 19**	S02053 – VDRL Rapid Test Kit, (RPR) Rapid Plasma Regime		Detailed Technical Specification of the mentioned item is mentioned at **Annexure-A.**
Queries relating to Technical Specification for OSMCL/2017-18/DRUGS-DHS (Re-Tender-II)/12				
8	**Section – IV** Item Sl No. 46, D16004-Inj. Heparin Sodium 5000 IU/ml	D16004-Inj. Heparin Sodium 5000 IU/ml **1ml/Amp or Vial** 20 Amps or Vials/Box	**1ml/Amp or Vial** may be changed to **5ml/Amp**	**Amended** D16004-Inj. Heparin Sodium 5000 IU. **5 ml or 1ml / Amp or Vial**

	Page No. 15			20 Amps or Vials/Box
9	**Section – IV** Column No. 5 Pack size of various drug items floated in tender	Column No. 5 Preferable Pack size of various drug items floated in tender	Pack size as specified in the tender document may be amended.	***Clarification:*** The pack size mentioned in Column No. 5 of Section IV is **Preferable Pack Size.** However, the items listed in the tender under Schedule **P1 of D & C Act 1940 & Rules 1945** as well as Govt. of India Programme items should be supplied in the primary packaging as per the prescribed norms

General Clarification on Price Bid

- The bidders have to quote the prices as per the Format mentioned in Price BOQ in the e—tender portal. The prices (Rates) are to be quoted per tab/ caps /bottle/amp./vial/PFS/tube/Kit/cylinder/jar/film/piece/lit./ kg./gm/test. etc(as the case may be) and not in unit pack, the quoted price includes packing, forwarding / transportation & Door Delivery and excludes GST.

N:B:- 1. The amendments mentioned above are to be treated as amendments in the technical specification(s) and term(s) and condition(s) of the above tender references. All other technical specifications and terms conditions remain unchanged.

2. Since any text in the price BOQ can't be changed in the e-tender portal, the amendments mentioned in the specifications above are to be treated as amendments in the price bid/ BOQ also.

Sd/

Managing Director

OSMC Ltd.,Odisha

Annexure - A

TECHNICAL SPECIFICATIONS

RPR TEST KITS FOR SYPHILIS DETECTION (S02053)

Bidders are required to mention "Comply"/ "Not comply" or specific information requested against each criteria of the following Technical Specification

PART A

Sl.	Specific Requirement:	Your Offer (Please fill-in) "Comply"/ "Not comply"
1.	A "Cold Chain indicator□ is to be supplied with the kits with the following specification:	
i.	A cumulative time/temperature indicator should indicate the exposure to temperature in the range of 2-8 0C	
ii.	The cumulative time-temperature indicator technology used should be prequalified by WHO	
iii.	The indicator should change color uniformly, irreversibly and the rate of reaction should be predictable by appropriate kinetic parameters.	
iv.	The color change should have a well-defined start point and end point that can be correlated to the heat stability of the kit.	
2.	Bar-coding details should be as mentioned in the tender document.	

Requirements	Your Offer (Please fill-in)
RPR test kits for Syphilis detection	"Comply"/ "Not comply"
1. The indigenous RPR (Rapid Plasma Reagin) kits should have been manufactured under manufacturing licence issued by the State Licensing Authority under the Drugs and Cosmetics Act. The imported kits should have been imported under Import Licence issued by the DCG(I) under the Drugs and Cosmetics Act.	
2. The assay should allow for qualitative and semi quantitative determination of reagin antibodies in serum or plasma for sero-diagnosis of syphilis based on flocculation principle using non treponemal antigens.	
3. The assay should be suitable to perform with either serum or plasma	
4. The assay should have sensitivity of 80% or more in primary syphilis and a specificity of 90% or more	
5. The assay should be calibrated to WHO reference serum and the same should be supported by statements in kit insert and certificate from manufacturer.	
6. The test should be able to yield results within 20 minutes.	
7. The pack size of RPR test kit should be 50 tests per kit	

8. The assay components should include positive and negative serum controls sufficient for conducting 20% of the tests (10% negative and 10% positive controls)	
9. The kit should have all essential accessories required for the test such as cards, droppers, applicator, etc. in adequate quantities for the number of tests to be performed.	
10. The kit should have more than 60% residual shelf-life or 10 months (whichever is more) at the time of dispatch to the consignee	
11. The kit should have a storage temperature of 2 0C to 8 0C and supplier/ local agent should have the facility to store kits at 2 0C to 8 0C	
12. Cumulative Time Temperature Indicator should be part of the kit as per specification defined in the terms and conditions.	
13. Literature, detailing the components, methodologies, validity criteria, performance characteristics, storage conditions, manufacturing and expiry dates should be provided with each kit.	

Quality Testing

Sl.	Our Requirements	Your Offer (Please fill-in)
	III Details of Quality Testing mentioned in the tender document.	"Comply"/ "Not comply"
	After receipt, the consignee shall draw samples at random from the consignment and get them retested to satisfy whether the lots conform to the laid down specifications. In the event of the product failing to conform to specifications, the consignee shall reject that batch of supply and inform the supplier for arranging replacement of the rejected batches at supplier's cost.	

PART B

TECHNICAL SPECIFICATION – GENERAL

Sl.	Our Minimum Requirements	Your Offer (Please fill-in)
	TECHNICAL SPECIFICATION – GENERAL	"Comply"/ "Not comply"

1.	Product and Package Specifications	
1.1.	The required packing standards and labeling must meet the requirements given	
1.2.	Not only the Goods but also the packaging components should also meet specifications suitable for use in a climate similar to that prevailing in the country of the Purchaser. All packaging must be properly sealed and tampered- proof.	
1.3.	All labeling and packaging inserts shall be in the language requested by the Purchaser or English if not otherwise stated	
1.4.	Goods requiring refrigeration or freezing for stability must specifically indicate storage requirements on labels and containers and be shipped in special containers to ensure stability in transit from point of shipment to port of entry.	
1.5.	Upon award, the successful Supplier shall, on demand, provide a translated version in the language of the bid of the prescriber's information for any specific goods the Purchaser may request	
2.	Product Information	
2.1.	The following information will be required for each pharmaceutical product offered by the Bidder: i) International Non-Proprietary Name (INN), if applicable; ii) Brand Name (if it appears on label); iii) Name and address of the manufacturer;	
2.2.	Upon award, the supplier shall, on demand, provide a translated version in English, of the prescriber's information for any specific product, the Purchaser may request.	
2.3.	Failure to include any of this information, at the discretion of the Purchaser, may render the bid non-responsive.	
3.	Expiration Date	
3.1.	All products must indicate the dates of manufacture and expiry. In addition, unless otherwise stated in Part A of these Specifications, all products must arrive at the final consignee point with a remaining shelf life of at least five- sixths (5/6ths) of the total stipulated shelf life at the time of manufacture.	
4.	Recalls	
4.1.	If products must be recalled because of problems with product quality as a result of quality check carried out during the life span of the drug or adverse reactions to the pharmaceutical, the supplier will be obligated to notify the purchaser providing full details about the reason leading to the recall and shall take steps to replace the product in question at its own cost with a fresh batch of acceptable pharmaceuticals, or withdraw and give a full refund if the product has been take off the market due to safety problems.	
5.	Labeling Instructions	

5.1	The label for each Goods shall include: (a) the Purchaser□s logo and code number and any specific color coding if required (b) content per pack (c) instructions for use (d) special storage requirements (e) batch number (f) date of manufacture and date of expiry (in clear language, not code) (g) name and address of manufacture with license number (h) any additional cautionary statement	
5.2.	The outer case or carton should also display the above information	
6.	Details of Packing/Cases	
6.1.	All cases should prominently indicate the following: i) The generic name of the product; ii) date of manufacture and expiry (in clear language not code); iii) batch number iv) quantity per case.	
6.2.	No case should contain drugs from more than one batch.	
7.	Unique Identifier	
7.1.	The Purchaser shall have the right to request the Supplier to imprint a logo on the containers used for packaging and in certain dosage forms such as tablets and this will be indicated in Part A of the Technical Specifications. The design of such logo shall be provided to the supplier at the time of Contract award.	

Sl.	Our Minimum Requirements	Your Offer (Please fill-in)
	TECHNICAL SPECIFICATION – GENERAL	"Comply"/
8.	Qualifications of Manufacturer	
8.1.	The bidder shall furnish a certificate from the competent FDRA that the manufacturer of the pharmaceutical or vaccine product covered by this Invitation for Bids is licensed to manufacture these products.	
9.	Standards and Quality Assurance Requirements	
9.1.	All products must:	
(a)	Meet the requirements of manufacturing legislation and regulation of pharmaceuticals or vaccines in the country of origin;	
(b)	Conform to all the specifications contained herein	
(c)	Must undergo strict raw material inspection, in process checks, appropriate material handling to eliminate cross contamination (of molecules) and final product testing to ensure quality and consistency of the products.	
9.2.	The Bidder is required to furnish to the Purchaser:	
(a)	With each consignment, a certificate of quality assurance test results concerning quantitative assay, chemical analysis and other tests, as applicable to the product being supplied and Part A of these Specifications.	
(b)	Assay methodology of any or all tests if requested.	
(c)	Evidence of basis for expiration dating and other stability data on the offered package (as per climatic conditions prevalent in India) concerning the commercial final package upon request.	
(d)	Package integrity test results.	
9.3.	The Bidder will also be required to provide the purchaser with access to its manufacturing facilities to inspect its facilities, quality control procedures for raw materials, test methods, in-process tests, and finished Goods.	

THE PRODUCTS OFFERED ARE IN ACCORDANCE WITH THE SPECIFICATIONS AND REQUIREMENTS

YES NO

ANY DEVIATION MUST BE LISTED BELOW:

PART C - SPECIAL INSTRUCTION

Sl.	Our Requirements	Your Offer (Please fill-in)
	SPECIAL INSTRUCTIONS	"Comply"/ "Not comply"
1.	Each packing, inner carton and nested cartons to have the following words printed in red ink with bold letters. "GOVT. OF ODISHA SUPPLY - NOT FOR SALE"	
2.	Life of the product, indicating the date of manufacture and date of expiry should be printed as per Drugs & Cosmetics Act-India	
3.	Equivalency of Standards & Codes Wherever reference is made in the Technical Specifications to specific standards and codes to be met by the Product to be furnished or tested, the provisions of the latest current edition or revision of the relevant standards or codes in effect shall apply, unless otherwise expressly stated in the Contract. Where such standards and codes are national or authoritative standards that ensure substantial equivalence to the standards and codes specified will be acceptable	
4.	Packing Packing Instruction: Each unit package will be marked on two sides with proper paint/indelible ink, the following ; i) Programme : ii) Purchase Order No. : iii) Country of origin of Goods : iv) Supplier's Name and : v) Packing list reference number :	

5.	Each outer packing containing the unit packing should have the following label printed in bold letters in large size. i) Purchaser's Name: HEALTH &FAMILY WELFARE, Govt. of Odisha. ii) Programme: National Rural Health Mission, Odisha iii) Purchase Order No : iv) Country of origin of Goods v) Supplier's Name	
6.	Any other labeling requirement which the purchaser may ask at the time of approving the labeling samples	