KEMH/EOI/642/2024

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Date: 19/08/2029

Expression of Interest

Subject – To Invite Expression of Interest from Original Manufacturer/ Vendor/ Distributor to supply medicines for patients of rare diseases through the NPRD (National Policy for Rare Disease)-2021 fund received in PBCF (Poor Box Charity Fund) Department of K.E.M Hospital.

King Edward Memorial Hospital is one of the leading public tertiary care hospitals in the metropolis of Mumbai, providing basic and specialised services to needy patients from all over the country. With a glorious legacy of 98 years and currently catering to over 1.8 million out patients and 85,000 in patients annually, the institute is among the top ranked medical institutes in India. KEM Hospital is one of the Centers of Excellence (CoE) under the NPRD-2021 and provides facilities for the diagnosis, prevention and treatment of rare diseases. Through the funds received under NPRD 2021, KEM Hospital wishes to purchase medicines for patients with rare diseases.

For purchase of the above drugs, it is proposed to invite EOI (Expression of Interest) from the Original Manufacturer/Vendors/Distributor, to supply the same to KEM Hospital. Original Manufacturer/Vendors/Distributor should submit the proposal with all the required documents on or before 30th August 2024 (by 4:00 pm) in the Department of Pediatrics Office, Outside Ward-2, Ground Floor, Old Hospital Building, KEM Hospital, Parel, Mumbai- 400012 in a three Packet System (i.e. Packet A - Administrative Documents, Packet B - Technical Documents & Packet C - Commercial Documents). Do not disclose the price other than in the commercial packet. All envelopes (Packet A, Packet B & Packet C) are to be packed in a single sealed envelope. All envelopes are to be submitted in a sealed form. The packet will be opened in front of KEM Hospital Rare Disease Committee as per schedule decided by the committee.

Specifications For Drug for Department of Pediatrics of KEM Hospital

	Description			
Name of	Inborn Errors of Metabolism			
Disease	Group 2 (a) Diseases requiring long term / lifelong treatment having relatively			
	lower cost of treatment and benefit has been documented in literature and			
	annual or more frequent surveillance is required:			
	Disorders managed with special dietary formulae or Food for special medica			
	purposes (FSMP)			
Name of Drug	Medical food or Food for Special Medical Purposes (FSMP)			
	1) Synthetic amino acid medical formulas for treatment of inborn			
	error of metabolism.			
	Di la la la Cara de la			
	a. Phenylalanine-free amino acid medical formula for infants & children			
	upto 3 years of age for treatment of Phenylketonuria.			
	b. Phenylalanine free amino acid medical formula for children and adults			
	more than 3 years of age for treatment of Phenylketonuria.			
	c. Leucine, isoleucin and valine free amino acid medical formula for			
	infants and children upto 3 years of age for treatment of Maple Syrup			
	Urine Disease.			
	d. Leucine, isoleucin and Valine free amino acid medical formula for			
	children and adults more than 3 years of age for treatment of Maple			
	Syrup Urine Disease.			
	e. Phenylalanine and tyrosine free amino acid medical formula for infants			
	and children upto 3 years of age for treatment of Tyrosinemia.			
	f. Phenylalanine and tyrosine free amino acid medical formula for children			
	and adults more than 3 years of age for treatment of Tyrosinemia.			
	g. Methionine free amino acid medical formula for infants and children			
	upto 3 years of age for treatment of Homocystinuria.			
	h. Methionine free amino acid medical formula for children and adults			
	more than 3 years of age for treatment of Homocystinuria.			
	i. Alanine, Arginine, Aspartate, Glutamate, Glycine, Proline Serine, Glutamine free amino acid medical formula for infants & children upto 3			
	years of age for treatment of Urea Cycle Defects.			
	j. Alanine, Arginine, Aspartate, Glutamate, Glycine, Proline Serine,			
	Glutamine free amino acid medical formula for children and adults more			
	than 3 years of age for treatment of Urea Cycle Defects.			
	k. Lysine and Tryptophan free amino acid medical formula for infants &			
	children upto 3 years of age for treatment of Glutaric Aciduria Type 1.			
	1. Lysine and Tryptophan free amino acid medical formula for children			
	and adults more than 3 years of age for treatment of Glutaric Aciduria			
	Type 1.			
	m. Isoleucine, Methionine, Threonine and Valine free amino acid medical			
	formula for infants and children upto 3 years of age for treatment of			

Methylmalonic Acidemia and Propionic Acidemia. n. Isoleucine, Methionine, Threonine and Valine free amino acid mediformula for children and adults more than 3 years of age for treatments.					
	Methylmalonic Acidemia and Propionic Acidemia. o. Leucine free amino acid medical formula for infants and children upto 3 years of age for treatment of Isovaleric Acidemia. p. Leucine free amino acid medical formula for children & adults more than 3 years of age for treatment of Isovaleric Acidemia.				
	2) Galactose free Medical formula for infants and children more than 1 year of age for treatment of Galactosemia.				
	3) Synthetic Amino Acid and Protein Free Medical Formula for treatment of Amino Acid Metabolic Disorders.				
	 a. Amino Acid and Protein free medical formula for infants and children upto 3 years of age for treatment of Amino Acid Metabolic Disorder. b. Amino Acid and Protein free medical formula for children and adults more than 3 years of age for treatment of Amino Acid Metabolic Disorder. 				
Specification of Drug	 Each TIN of 400gms one Carton box of 12 TINS. FSSAI Certified. 				
	Shelf life of 12 months.				
Quantity with Package	 37 TINS of Amino Acid and Protein free medical formula for children and adults more than 3 years of age for treatment of Amino Acid Metabolic Disorder. 89 TINS Alanine, Arginine, Aspartate, Glutamate, Glycine, Proline Serine, Glutamine free amino acid medical formula for children and adults more than 3 years of age for treatment of Urea Cycle Defects 				

DR. SUNIL KARANDE PROFESSOR & HEAD,

Dr. Sunil Karande EPARTMENT OF PEDIATRICS, Professor and Headeth G.S. MEDICAL COLLEGE & Department of Pediatribs HOSPITAL.

Seth GSMC & KEM Hospital MBAI - 400 012.

DEPARTMENT OF PEDIATRICS SETH G. S. MEDICAL COLLEGE & K.E.M. HOSPITAL,

Dr. Mamta Muranjan

Professor and In-charge of Genetic Clinic Department of Pediatrics Seth GSMC & KEM Hospital.

Specifications For Drug for Department of Pediatrics of KEM Hospital

	Description		
Name of Disease	Inborn Errors of Metabolism Group 2 (b) (vi) Diseases requiring long term / lifelong treatment having relatively lower cost of treatment and benefit has been documented in literature and annual or more frequent surveillance is required: Disorders that are amenable to other forms of therapy (hormone / specific drugs) Sodium Benzoate, arginine, citrulline, phenylacetate (Urea Cycle disorders), carbaglu, Megavitamin therapy (Organic acidemias, mitochondrial disorders)		
Name of Drug	 L-Lysine Powder L-Citrulline Powder L-Arginine Powder 		
Specification of Drug	1) L-Lysine Powder - each sachet containing 5gms of L-Lysine. - FSSAI Certified. - Shelf life of 12 months.		
	2) L-Citrulline Powder - each sachet containing 5gms of L-Citrulline. - FSSAI Certified. - Shelf life of 12 months.		
	3) L-Arginine Powder - each sachet containing 5gms of L-Arginine FSSAI Certified Shelf life of 12 months.		
Quantity with Package	 340 sachets of L - Lysine Powder 740 sachets of L - Citrulline Powder 730 sachets of L - Arginine Powder 		

Dr. Sunil Karande PARTMENT OF PEDIATRICS, Professor and Head TH G.S. MEDICAL COLLEGE &

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DEPARTMENT OF PEDIATRICS SETH G. S. MEDICAL COLLEGE & M. HOSPITAL, PAREL MUMBAI - 400 012.

Dr. Mamta Muranjan

Professor and In-charge of Genetic Clinic Department of Pediatrics Seth GSMC & KEM Hospital.

GENERAL REQUIRE MENTS:

Packet A :-

- A. Administrative Documents (Attested Copies)
- 1) EOI form
- 2) EOI form fee receipt (if applicable)
- 3) Signed & Stamp copy of EOI
- 4) Pan Card with Photograph as applicable
- 5) GST Registration certificate as applicable
- 6) Copy of Power of Attorney as applicable
- Copy of valid sales TAX/VAT/GST registration certificate (whichever is applicable)
- 8) Authority letter for appointment of Distributor (as applicable)
- 9) Photograph of individuals, proprietor of all partners as the case may be
- 10) Taxes bifurcation & HSN code mentioned on letterhead
- 11) Bidder's Profile

• Packet B :-

- B. Technical Documents (Attested Copies)
- 1) Valid Drug Manufacture License/Import License (Form 10)/Repacking License/Medical Devices License with approved product list issued by competent drug authority (as applicable)
- 2) Valid Drug Selling License issued by FDA (as applicable)
- 3) Valid Product wise WHO-GMP certificate with approved Product List or Certificate of Pharmaceutical Products (COPP) issued by FDA.
- 4) Quality Control Test Report /FDA approved Lab/ Govt. aided Lab/In house Test Report form manufacturer as per D & C Act.
- 5) Rate should be quoted per number (unit should specified)
- 6) Sample along with Test Report should be submitted as & when asked
- 7) FSSAI Certificate.

Packet C :-

C. Rate Envelop

The supplier should be submitting documents mention in check list attached herewith.

If any doubts or any query about above mentioned work, you can contact Department of Pediatrics Office, Outside Ward - 2, Ground Floor, Old Hospital Building, KEM Hospital, Parel, Mumbai - 400 012.

Dr. Sunil Karande R. SUNIL KARANDE
Professor and Head ROFESSOR & HEAD,
Department of Pediatrics TMENT OF PEDIATRICS, Seth GSMC & KENTHOSPITAL MEDICAL COLLEGE & Department of Pediames. MUMBAI - 400 012

K.E.M. HOSPITAL, PAREL, MUMBAI - 400 012. Dr. Mamta Muranian RTMENT OF PEDIATRICS Nodal Officer for Rare Disease MEDICAL COLLEGE & Professor and In-charge of Genetic Clinic

Seth GSMC & KEM Hospital.

Dr. Ajay Rana Deputy Dean

Seth GSMC & KEM Hospital

Dr. Sangeeta Rawat Dean (Chairperson)

Seth GSMC & KEM Hospital.

Dean, K.E.M.H. & Seth G.S.M.C. Parel, Mumbai - 400 012.

Check list of Documents to be submit with EOI form as per the order given below.

Sr. No	Administrative Documents	Sr. No.	Technical Documents
1	EOI Form	1	Valid Drug Manufacture License/Import License (Form 10)/Repacking License/Medical Devices License with approved product list issued by competent drug authority (as applicable)
2	EOI Form Fee Receipt (if applicable)	2	Valid Drug Selling License issued by FDA (as applicable)
3	Signed & Stamp copy of EOI	3	Valid Product wise WHO-GMP certificate with approved Product List or Certificate of Pharmaceutical Products (COPP) issued by FDA.
4	Pan Card with Photograph as applicable	4	Quality Control Test Report /FDA approved Lab/ Govt. aided Lab/In house Test Report form manufacturer as per D & C Act.
5	GST Registration certificate as applicable	5	Rate should be quoted per number (unit should specified)
6	Copy of Power of Attorney as applicable	6	Sample along with Test Report should be submitted as & when asked
7	Copy of valid sales TAX/VAT/GST registration certificate (whichever is applicable)		
8	Authority letter for appointment of Distributor (as applicable)		
9	Photograph of individuals, proprietor of all partners as the case may be		
10	Taxes bifurcation & HSN code mentioned on letterhead		
11	Bidder's Profile		

Authorised Signature of the Bidder With Official Seal & Address