UNITED NATIONS CHILDREN'S FUND (UNICEF) AFGHANISTAN COUNTRY OFFICE, KABUL, AFGHANISTAN <u>REQUEST FOR EXPRESSION OF INTEREST (REoI)</u> <u>FOR PHARMACEUTICAL PRODUCTS</u> <u>REOI-AFG-2024-002</u>

Date of Request for Expression of Interest (REoI): 11th June 2024

Closing date for receipt of REoI: Multiple windows of submissions due on 1st of every month open for 12 month starts on 1st July 2024 and ends on 1st June 2025.

There are multiple due dates for submission: 1st of July 2024, 1st Aug 2024, 1st Sep 2024, 1st Oct 2024, 1st Nov 2024, 1st Dec 2024, 1st Jan 2025, 1st Feb 2025, 1st Mar 2025, 1st April 2025, 1st May 2025 and final due date 1st June 2025.

UNICEF, Afghanistan Country Office, Kabul, Afghanistan is requesting Expressions of Interest from potential suppliers of pharmaceuticals from Afghanistan and its neighbouring countries (India, Iran, Pakistan, China, etc.) in preparation for a solicitation exercise for pharmaceutical products.

Interested suppliers or manufacturers of pharmaceuticals, please read below the requirements and submit your expression of interest (EoI) by filling in the forms along with the documentation requested.

Purpose of the REOI:

This REoI is addressed to suppliers and manufacturers of pharmaceuticals in the region for the supply of any of the listed pharmaceutical products.

Description of requirements:

- 1. Amoxicillin powder/oral suspension 125mg/5ml
- 2. Amoxicillin 250mg dispersible tablet
- 3. Amoxicillin 500mg tablet/capsule
- 4. Chlorhexidine Digluconate gel 7.1 % for cord care
- 5. Ciprofloxacin 250mg tablet
- 6. Erythromycin powder for oral suspension 125mg/5ml
- 7. Gentamicin eye drops 0.3%
- 8. Micronutrient tabs, used during pregnancy.
- 9. Salbutamol 2mg/5ml oral liquid
- 10. Salbutamol 4mg tablets... tablets
- 11. Salbutamol oral inhalation (aerosol) 0.1mg/ds 200ds
- 12. Compound Sodium Lactate 1L bag/bottle
- 13. Sodium Chloride 0.9 % w/v and Glucose 5% w/v solution, 500ml bag/bottle
- 14. Ampicillin powder for injection 500mg

For an itemised list of products per category, please refer to the accompanying Expression of Interest (EoI) form.

Historical procurement data (2022-2023):

3001			
1.	Amoxicillin powder/oral suspension 125mg/5ml	USD	1,000,000
2.	Amoxicillin 250mg dispersible tablet	USD	500,000
3.	Amoxicillin 500mg disp.tab/PAC-100	USD	1,500,000
4.	Chlorhexidine digluconate gel 7.1 %,3g tube for cord ca	reUSD	200,000
5.	Ciprofloxacin 250mg tablet	USD	200,000
6.	Erythromycin powder for oral suspension 125mg/5ml	USD	500,000
7.	Gentamicin eye drops 0.3%	USD	300,000
8.	Micronutrient tabs, used during pregnancy	USD	200,000
9.	Salbutamol 2mg/5ml oral liquid	USD	200,000
10	. Compound Sodium Lactate 1L bag	USD	1,000,000
11	. Sodium Chloride 0.9% w/v and Glucose 5%w/v, 500ml	USD	500,000

Potential suppliers/manufacturers:

UNICEF primarily globally purchases pharmaceuticals directly from manufacturers and/or their authorized representatives.

UNICEF Afghanistan is particularly interested in identifying GMP qualified manufacturers with a Good Manufacturing Practice (GMP) Certificate issued by any stringent regulatory authority, PICS member or any of the following agencies: WHO, UNICEF, MSF or ICRC and/or suppliers with a Good Distribution Licence (GDP) for Medicines who procure & distribute pharmaceuticals from GMP qualified manufacturers for the items listed below for Afghanistan.

Potential suppliers/manufacturers are to indicate for the products of interest, all the packaging types and pack sizes they have available in their portfolios.

To be considered for the planned tender it is preferable, but not a requirement, for potential suppliers to have a website providing access to the product information if available, and in addition to provide information as per Annex I and Annex II below.

Please also provide information on the registration status of the medicines specifically in Afghanistan in addition to the other countries of registration of such as India, Pakistan, China, United Kingdom, European Union, United States of America, Australia or Canada etc.

Procedure for submission of EoI:

Interested suppliers/manufacturers are encouraged to indicate their interest by duly completing the Expression of Interest (EoI) form (Annex I) and the <u>Additional template for REOI-HER (Annex II)</u> and submit via email to: <u>afghanistanetendering@unicef.org</u> with the subject **Expression of Interest (EoI) for Pharmaceutical products.**

Please note:

(a) Prices are not required at this stage.

(b) Questions from manufacturers/suppliers on any aspects of their products included in the submission will not be entertained.

(c) This REoI does not constitute a solicitation. Submitting an EoI does not automatically guarantee receipt of the solicitation document when it will eventually be issued.

(d) UNICEF reserves the right, when issuing the final solicitation document, to request from the interested manufacturers/supplier's compliance to additional conditions.

UNICEF reserves the following rights:

(a) to seek additional information deemed as appropriate for evaluation of the EoIs.

(b) to accept any submission for this expression of interest, in whole or in part; to reject any or all

submissions for this expression of interest; or to cancel this EoI process in its entirety.

(c) to verify any information contained in the EoI response (and the submitter will provide UNICEF with its reasonable cooperation with such verification).

(c) to invalidate any submission to this EoI that, in UNICEF's sole opinion, fails to meet the requirements and instructions as stated in this Request for Expression of Interest.

(e) UNICEF is not liable for any costs/expenses or loss incurred by interested suppliers and manufacturers in connection with responding to this Request for Expression of Interest

Registration on the United Nations Global Marketplace (UNGM)

Interested manufacturers/suppliers are encouraged to register on the United Nations Global Market Place (UNGM) website through the link https://www.ungm.org/ to receive various tender alerts issued by United Nations.

(Please check the appropriate boxes and return to UNICEF)

A - GENERAL INFORMATION

Supplier's full name:			
Type of company	Manufacturer 🗌	Wholesaler 🗌	Other(specify)
Address:			
Country:			
Email address (company):			
Website address:			
Telephone:			
Fax:			
Contact person:			
E-mail address for contact			
person:			

B – INTEREST / CAPACITY TO SUPPLY THE FOLLOWING CATEGORIES

Please see link to UNICEF technical requirements for Pharmaceutical and Nutrition Products: <u>UNICEF_Technical_Requirements_for_pharmaceuticals_5th_edition_2017_____for_additional_information</u>

Medicine	Yes	No	 In this column, please specify following: Packaging type and pack size you would like to offer.
1- Name of medicine			
2- Name of medicine			
3- Name of medicine			
4- Name of medicine			
5- Name of medicine			
6- Name of medicine			
7- Name of medicine			
8- Name of medicine			
9- Name of medicine			
10- Name of medicine			
11- Name of medicine			
12- Name of medicine			

C - GEOGRAPHICAL COVERAGE

	Yes	No	Any limitation, please explain
Ability to supply to UNICEF Afghanistan			
Are you authorized by AFDA to supply medicines and			
pharmaceutical products in Afghanistan			
Do you have an authorized representative approved			
by AFDA to supply medicines and pharmaceutical			
products in Afghanistan			

D - COMPLIANCE WITH INTERNATIONAL QUALITY STANDARDS

Quality Management System (company):	Yes	No	Comments
Valid GMP certificate issued by regulatory authority as per WHO Good Manufacturing Practice (GMP) Guidelines (please indicate name of			
regulatory authority) https://www.who.int/publications/m/item/trs986-annex2			
mtps.//www.who.mt/publications/m/item/trs960-annex2			
GMP inspection by Stringent Regulatory Authority in the last 5 years			
<u>https://cdn.who.int/media/docs/default-</u> source/medicines/norms-and-			
standards/guidelines/pregualification/trs986-			
annex5.pdf?sfvrsn=8aae767d_2			

GMP inspection by PICS member in the last 5 years Members (picscheme.org) Please indicate name of PICs member (s)		
GMP inspections/audits by MSF, ICRC, UNICEF in the last 5 years Please indicate name of Agency(s)		
Others-specify		

E – ACCESS TO PRODUCT INFORMATION

	Yes	No	
Product information (SmPC) available on-line			If Yes, specify web address:
Product catalogue available on-line			If Yes, specify web address:
Any other ways of providing access to product			If Yes, specify which way(s):
information			

F- ADDITIONAL INFORMATION

	Yes	No		Yes	No
Registered with UNGM? (<u>www.ungm.org</u>)			UNGM number		
UNICEF vendor			UNICEF vendor number		

G – COMMITMENT TO SUSTAINABILITY IN PROCUREMENT SDG GOAL 12 AND ITS TARGET 12.7 Please provide company policy as applicable for below criteria

#	Criteria	Indicators
1	Prevention of pollution	Corporate environmental policy or an environmental management system (ISO 14001 or equivalent)
2	Sustainable resource use	Company policy on design and production to use recycled, recyclable, biodegradable, re-used, reusable, renewable or compostable materials
3	Social inclusion of persons with disabilities	The requirement has been reviewed and potentially adapted to ensure accessibility for persons with disabilities
4	Human rights and Gender issues	Company policy on human rights issues and reserved procurement opportunities (lot, subcontract, or entire tender) open to vendors qualifying as women-owned businesses, i.e. an entity at least 51% owned, managed and controlled by one or more women
5	Social health and well-being	 Avoidance of chemicals potentially hazardous to users of the product, like volatile organic compounds (VOCs) etc. Require labelling of included/used hazardous chemicals

On completion, please return this form to UNICEF including the Summary of Pharmaceutical Characteristics (SPC) for each item offered by email to <u>afghanistanetendering@unicef.org</u> starting from 1st day of each month beginning of July 2024.

ANNEX II: ADDITIONAL TEMPLATE FOR REOI-HER				
UNICEF SUPPLY DIVISION				
REQUEST FOR EXPRESSION OF INTEREST				
Pharmaceuticals				
(Complete one form for each separate product)				
Date				
Name of company				
Type of Company (manufacturer/Importer/Wholesaler)				
Contact detail of person filling this form				
Name				
Title				
Email address				
Phone number				
General information about the product				
Full INN/Generic name of the product				
Brand/trade name (If any)				
Pharmaceutical form				
Strength (per dosage unit)				
Pack type and sizes				
Storage temperature	-			
Transport temperature (if different from storage temperatures)				
Product shelf life				
In use Shelf life if applicable (Specify at what storage conditions)				
Language of label/Patient information leaflet (PIL)				
Full name of the FPP manufacturer				
FPP Manufacturing site (Physical address - not P O Box)				
Technical criteria	Yes/No			
WHO prequalification				
Product approval by Stringent Regulatory Authority (SRA)				

If above conditions are not met then is the product manufactured at a site that is compliant with all standards of Good Manufacturing Practice (GMP) that apply to the relevant product formulation, as verified after inspection by the WHO Prequalification Programme OR an SRA OR UNICEF or a regulatory authority participating to the Pharmaceutical Inspection Cooperation Scheme (PIC/S) https://www.picscheme.org/en/members Bioequivalence studies or Comparative dissolution studies carried out against an approved comparator product		
studies carried out against an approved comparator product Others specify anything related to certification or approval Market approval and product quality references Product complies with WHO guidelines (Y/N) https://extranet.who.int/prequal/content/WHOguidanc e-documents Product quality assurance in accordance with ICH quality guidelines (Y/N) http://www.ich.org/products/guidelines/quality/article /quality-guidelines.html Compliance to BP, USP, Ph.Int, Ph.Eur for FPP and API (Specify) Product dossier available in appropriate format e.g. CTD (Y/N) Marketing Authorization Reference from country of origin/manufacture (Number, agency and country) Marketing Authorization Reference from other countries (Number, agency and country) The product registered in other countries (number, agency) Others (Specify) Documents to submit Summary of Product Characteristics Artwork of packaging and label or pictures of the commercial product showing all sides-both primary and secondary pack. GMP certificate issued by regulatory authority for the manufacturer of this product	manufactured at a site that is compliant with all standards of Good Manufacturing Practice (GMP) that apply to the relevant product formulation, as verified after inspection by the WHO Prequalification Programme OR an SRA OR UNICEF or a regulatory authority participating to the Pharmaceutical Inspection Cooperation Scheme (PIC/S) <u>https://www.picscheme.org/en/members</u>	
approval Market approval and product quality references Product complies with WHO guidelines (Y/N) https://extranet.who.int/prequal/content/WHOguidanc e-documents Product quality assurance in accordance with ICH quality guidelines (Y/N) http://www.ich.org/products/guidelines/quality/article /quality-guidelines.html Compliance to BP, USP, Ph.Int, Ph.Eur for FPP and API (Specify) Product dossier available in appropriate format e.g. CTD (Y/N) Marketing Authorization Reference from country of origin/manufacture (Number, agency and country) Marketing Authorization Reference from other countries (Number, agency and country) The product registered in other countries (number, agency) Others (Specify) Documents to submit Summary of Product Characteristics Artwork of packaging and label or pictures of the commercial product showing all sides-both primary and secondary pack. GMP certificate issued by regulatory authority for the manufacture of this product	studies carried out against an approved comparator	
Product complies with WHO guidelines (Y/N) https://extranet.who.int/prequal/content/WHOguidanc e-documents Product quality assurance in accordance with ICH quality guidelines (Y/N) http://www.ich.org/products/guidelines/quality/article /quality-guidelines.html Compliance to BP, USP, Ph.Int, Ph.Eur for FPP and API (Specify) Product dossier available in appropriate format e.g. CTD (Y/N) Marketing Authorization Reference from country of origin/manufacture (Number, agency and country) Marketing Authorization Reference from other countries (Number, agency and country) The product registered in other countries (number, agency) Others (Specify) Documents to submit Summary of Product Characteristics Artwork of packaging and label or pictures of the commercial product showing all sides-both primary and secondary pack. GMP certificate issued by regulatory authority for the manufacturer of this product		
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product showing all sides-both primary and secondary pack.GMP certificate issued by regulatory authority for the manufacturer of this productPlease attach	Summary of Product Characteristics	Please attach
manufacturer of this product		Not mandatory at this stage but useful
Market authorization certificates Please attach		Please attach
	Market authorization certificates	Please attach