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Government of Nepal
Ministry of Health and Population
Department of Drug Administration

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Invitation to manufacturers in Nepal to submit an Expression of Interest (EOI) for Technical Assistance

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To support national and global efforts to increase access to the affordable quality assured products for Maternal, Neonatal and Child Health (MNCH) and Family Planning (FP), the Department of Drug Administration (DDA), with technical assistance from the Promoting the Quality of Medicines Plus (PQM+) program implemented by **United States Pharmacopeia (USP)** and with funding from the **U.S. Agency for International Development (USAID)**, invites Nepali pharmaceutical manufacturers to submit an Expression of Interest (EOI) for evaluation of their manufacturing sites to assess compliance with Good Manufacturing Practices (GMP) for production of essential medicines for MNCH and FP products to attain the WHO Prequalification requirement.

1. PROCEDURE FOR THIS INVITATION TO SUBMIT EOI

The current invitation is published in accordance with the provision of Drug Act 2035 to prevent the misuse or abuse of drugs and allied pharmaceutical substances and false or misleading information relating to the efficacy and use of drugs and to control the production, sale, distribution, export, import, storage and consumption of those drugs which are not safe for public consumption, efficacious and of standard quality.

The assessment of manufacturers under this invitation will include inspection of manufacturing site, review of product data, and information of current manufacturer and comparison of the data and information to internationally accepted standards such as the World Health Organization (WHO) GMP and National GMP requirements. In collaboration with the DDA, PQM+ program will provide the needed technical assistance to address the areas of improvement within the mandate and period of performance of PQM+ program.

Interested manufacturers in Nepal are therefore encouraged to submit their expression of interest for technical assistance to manufacture products listed under item 2 below.

2. PRODUCTS INCLUDED IN THIS INVITATION

The purpose of this invitation is to invite manufacturers to participate in the technical assistance program to increase the supply of quality assured essential medicines to meet WHO-recommended quality standards. Following list of finished products is selected based on The Treatment of Diarrhoea-A manual for physicians and other senior health workers (WHO), National list of essential medicines of Nepal and on the basis of their benefits and appropriateness for use in the treatment of child and maternal health problems. The products of interest are:

2.1. Amoxicillin tablet (scored), 125mg, 250mg
2.2. Oxytocin injection, 5/10 IU
2.3. Zinc sulfate dispersible tablet, 10 mg, 20mg
2.4. Azithromycin tablet 500 mg

3. QUALITY ASSESSMENT PROCEDURE FOLLOWING SUBMISSION OF AN EXPRESSION OF INTEREST BY MANUFACTURER

The assessment in response to the EOI will be conducted to determine whether the pharmaceutical product manufacturers of products listed above meet the quality standards recommended by WHO and is manufactured in compliance with GMP norms. The procedure for evaluation will include:

a. Evaluate the production and quality control status of the manufacturer
b. Assess product data and information on safety, efficacy and quality submitted by the manufacturer including the product formulation, manufacturing and testing data and results
c. Assess the manufacturing site's compliance status with GMP norms, consistency in production and quality control of starting materials, packaging materials with specific emphasis on active pharmaceutical ingredient(s) and finished product.
d. Sample and test the products.

4. TECHNICAL ASSISTANCE TO MANUFACTURERS OF SELECTED PHARMACEUTICAL PRODUCTS FOLLOWING SUBMISSION OF AN EXPRESSION OF INTEREST

After assessment of manufacturing site by PQM+, a review of product data and information will be conducted comparing the data and information to internationally accepted standards such as WHO-GMP and National GMP requirements. In partnership with PQM+, DDA will provide the needed technical assistance to address any discovered deficiencies in order to ensure the quality of products meeting the internationally accepted quality standards.

PQM+, in collaboration with DDA, reserves the right to prioritize the manufacturers to receive technical assistance based on the assessment and existing compliance level to ensure effective support to those selected pharmaceutical companies.

5. DEADLINE AND SUBMISSION PROCEDURE FOR EOI

A covering letter expressing the manufacturer's interest in receiving technical assistance for the manufacture of selected finished pharmaceutical products should be submitted to PQM+ within on or before March 08, 2021 (5:00 PM) to PQM+ Nepal, House no 405, Prasuti Griha Marga, Ward no 11, Babarmahal, Kathmandu, Nepal or via e-mail at usp.nepal@usp.org

A preliminary assessment questionnaire will be sent to interested manufacturer upon request. The filled questionnaire should be submitted along with the expression of Interest.