Invitation to pharmaceutical manufacturers to submit an Expression of Interest (EOI) for technical assistance related to market expansion of tranexamic acid (TXA) and misoprostol

(July 2024)

Title: Request for submission of EOI by manufacturers of maternal health drug products toward expansion of markets into low- and middle-income countries

Issue Date: 25 July 2024; deadlines revised on 26 August 2024

Closing Date: ~~30 August 2024~~; 30 September 2024

Summary of deadlines:

Invitation for EOI released	25 July 2024
Open period for submission of questions related to EOI	19 August 2024
Final response by PATH to fact-finding questions	~~23 August 2024~~ 20 September 2024
EOI due	~~30 August 2024~~ 30 September 2024
Notification of shortlisted manufacturers	~~13 September 2024~~ 14 October 2024

Background and rationale

Postpartum haemorrhage (PPH) is the leading cause of maternal mortality worldwide. The risk of PPH and PPH-related morbidity and mortality disproportionately affects women in low- and middle-income countries, especially those who lack access to quality care due to poverty, geography, and/or cultural barriers. Oxytocin, which is recommended by the World Health Organization (WHO) as the first-line medicine for preventing and treating PPH, requires cold chain for transport and storage to maintain required potency. Many resource-limited settings fail to meet this requirement, resulting in uncertain quality of oxytocin at point of use.

WHO has recently recommended new or newer medicines and delivery approaches critical to reducing PPH-related mortality and morbidity in these settings. These include tranexamic acid (TXA) for the treatment of PPH, and advanced distribution of misoprostol to prevent PPH during community-based births. Ensuring these medicines are quality assured and registered in countries, integrated into national clinical guidelines and health systems, consistently available where women deliver, and trusted by providers for use in real-world settings will help to end the needless deaths of women from PPH.

The Unitaid-funded Accelerating Measurable Progress and Leveraging Investments for Postpartum Haemorrhage Impact (AMPLI-PPHI) project (August 2022–July 2026)

aims to dramatically reduce maternal mortality and morbidity from PPH. Jhpiego is leading AMPLI-PPHI in partnership with PATH and the International Federation of Gynaecology and Obstetrics (FIGO). Working hand in hand with governments from the Democratic Republic of the Congo, Guinea, India, and Kenya, AMPLI-PPHI will support countries to ensure that the right PPH medications are available at the right time, in the right place, for the right indication, and for the right patient across health systems, ultimately reducing maternal morbidity and mortality.

Scope of activities

The AMPLI-PPHI project seeks to increase the availability of TXA and misoprostol that are quality-assured (either by World Health Organization prequalification or stringent regulatory authority approval) at affordable prices in low- and middle-income countries (LMICs). To that end, **PATH and Jhpiego jointly invite interested manufacturers to submit an expression of interest (EOI) application to receive technical support toward market expansion in LMICs.**

Interested manufacturers are encouraged to submit documentation for recommended dosage forms and strengths, as specified below, of medicinal products in the following categories:

1. Treatment of postpartum hemorrhage
   - TXA, injection 500 mg/5 mL in vial or ampoule

2. Uterotonics
   - misoprostol, 200 mg tablet

PATH, on behalf of the AMPLI-PPHI project, will engage with eligible manufacturers to provide the latest market intelligence on demand estimations and benchmark pricing and define mutually agreeable terms that maximize access to quality assured products of the aforementioned medicines. These access terms include competitive and sustainable pricing, commitment to register in LMICs, and/or commitment to supply to LMICs. PATH will provide technical assistance toward LMIC market expansion to the manufacturer that offers access terms that are approved by Unitaid.

The technical assistance will enable:

- Co-development of a go-to-market strategy for expanding product access and availability in LMICs
- Targeted go-to-market strategy will be:
  - customized for selected manufacturer,
  - include current demand estimations for the target markets

Please note that a separate expression of interest, with a broader scope for potential technical assistance for manufacturers, has been launched by Unitaid. For more information see: https://unitaid.org/news-blog/call-for-expression-of-interest-eoi-strengthening-sustainable-regional-manufacturing-of-therapeutics-for-maternal-health-malaria-and-hiv-programmatic-priorities-in-africa/#en.

Technical evaluation criteria

The selection of a manufacturer is based on technical evaluation of the following criteria and submission of supporting documentation described below.

Selection criteria include:

- ➔ Current regulatory approval by stringent regulatory authorities and/or WHO Listed Authority (WLA) and/or WHO prequalification for one or both of the medicinal products mentioned above or actively pursuing stringent regulatory approval or WHO prequalification.
- ➔ Appropriate Quality Management Systems (QMS) in place.
- ➔ Sales and distribution capabilities in LMICs.
- ➔ Commitment to access terms, which can include competitive and sustainable pricing, commitment to register in LMICs, and/or commitment to supply to LMICs.

EOI submission requirements

1. Cover letter, in English, expressing interest in exploring collaboration with the AMPLI-PPHI project, and confirming that the information submitted in the product dossiers is complete and correct
2. Company overview document (e.g., ownership, structure (main business units), revenue, distribution network)
3. Product dossier, in English, describing product data and information related to current sales, by volume and geography (e.g., list of countries where manufacturer has obtained market authorization including the authorization number, and geographies where market authorization is currently pending, sales volume, etc.)
4. Documentation/evidence of quality assurance (i.e. WLA/ SRA approval or WHO Prequalification (PQ) or dossier submission to either; CE certificate
5. Current manufacturing capacity (current and planned monthly capacity for relevant products, minimum batch requirements)
6. Quality Management Systems including ISO certificate for QMS or equivalent
7. A certificate of analysis issued for a batch produced after 1 January 2024.

Fact-finding questions

Fact-finding questions may be submitted on a rolling basis through ~~August 19, 2024~~. September 20, 2024. All questions should be sent to the contacts listed below. Fact-finding questions received after this deadline may not be accommodated. It is advisable that any fact-finding questions be aggregated rather than sent individually.

PATH will post responses to fact-finding questions within two days of receipt at this Google document link:

https://docs.google.com/document/d/16MIYjOyCg6kTJ1l0BnKwqPFiYSKzKLij3LUa0iCnMA8/edit?usp=sharing

In line with transparency principles, all fact-finding questions and all responses from PATH to these questions will be shared with all those who confirmed their interest in this opportunity. Questions will be anonymized and answered if PATH reasonably determines that such fact-finding questions do not disadvantage any potential interested manufacturer and are not commercially in confidence. If such are commercially in confidence, they shall be handled in line with PATH policy on information and data.

How to submit an EOI

Interested manufacturers should provide the required information with supporting documents by ~~August 30, 2024~~ September 30, 2024, to pcoffey@path.org and mruffo@path.org. Manufacturers may submit an EOI for one or both products.

PATH statement of business

PATH is a global nonprofit organization dedicated to achieving health equity. With more than 40 years of experience forging multisector partnerships, and with expertise in science, economics, technology, advocacy, and dozens of other specialties, PATH develops and scales up innovative solutions to the world's most pressing health challenges. Learn more at www.path.org.

Jhpiego statement of business

Jhpiego, a Johns Hopkins University affiliate, is a nonprofit organization that creates and delivers transformative health care solutions that save lives. In partnership with national governments, health experts and local communities, Jhpiego builds health providers' skills and develops systems that save lives now and guarantee healthier futures for women and their families. Learn more at www.jhpiego.org.

Disclaimer notice and confidentiality

This EOI is issued by JHPIEGO/PATH solely for the purpose of identifying manufacturers that might be interested in receiving technical assistance as

described above. This EOI is not related to any procurement; it should not be regarded as a Request for Proposal. Any information submitted in response to this EOI is provided to JHPIEGO/PATH on a voluntary basis. JHPIEGO/PATH may use the information provided by respondents to this EOI to support strategic decisions and planning or for its own internal purposes, including but not limited to, the design of future Request for Proposal or other solicitations.

Further information

For further information on the AMPLI-PPHI project, see:
https://www.jhpiego.org/pph-unitaid/