Terms of Reference

To carry out a rapid assessment of surveillance system of Medical abortion (MA) drugs in Nepal

1. Background:

The WHO Country Office (WCO) Nepal is committed to provide technical assistance to Ministry of Health and Population (MoHP) Nepal, in achieving universal coverage to Sexual and Reproductive Health and Rights (SRHR) in the country. In this endeavour, a time-bound project, encompassing the Health System Strengthening (HSS) approach, is being implemented to ensure access to comprehensive package of SRHR by the women and girls in the country. The comprehensive package of SRHR services includes quality services for family planning, safe abortion (as per the national law) and post abortion care (including post-abortion family planning and management of the consequences of abortion).

The overall goal of this project is to support the Ministry of Health and Population (MoHP) in achieving universal access to sexual and reproductive health care services (SDG 3.7); to achieve universal access to sexual and reproductive rights (SDG 5.6); and to reduce maternal mortality (SDG 3.1) in Nepal.

It is envisaged to achieve the project objectives by strengthening different building blocks of the Health System (HS) including service delivery, health workforce, Health Information System (HIS), access to quality medical abortion drugs and streamlining policy and guidelines in the federal context.

This Expression of Interest is being circulated to carry out a desk review / rapid assessment of the surveillance of MA drugs in Nepal.

2. Rationale:

Medical abortion care plays a crucial role in providing access to safe, effective and acceptable abortion care in both high- and low-resource settings. Many interventions in medical abortion care, particularly those in early pregnancy, can be provided at the primary-care level and on an outpatient basis, which further increases access to care. Medical abortion care reduces the need for skilled surgical abortion providers and offers a non-invasive and highly acceptable option to pregnant individuals.

In 2009, Mifepristone and Misoprostol for Medical Abortion (MA) was approved by the Department of Drug Administration (DDA), MoHP, Nepal. It was recommended to be made available in the market on prescription from accredited health care providers and clinics. ANMs working in the public sector who are trained as SBAs are authorized to provide medical abortions in Nepal for the termination of pregnancies till 9 weeks of gestational age. Studies suggest that MA is the commonly used method for terminating the pregnancies and constitute over 50% of all abortions in Nepal (1).

As per the 2016 SAS guidelines, combi-packs of Mifepristone and Misoprostol, manufactured by the USFDA or UKMHRA or having WHO GMP and approved and registered by the Department of Drug Administration (DDA), Nepal, are legalized to be sold in the market. So far, only 4 brands (Medabon, MTP kit, Mistol, and Pregno) are registered to be sold in the Nepal on prescription from accredited health care providers and clinics. Off-label or over-the-counter sale of MA tablets by pharmacies is not permitted. However, the studies conducted by CREPHA and PSI in the year 2015 and 2018 respectively, reported that there are 18 and 17 different brands of MA drugs available in the Nepal market. The unregistered brands of MA drugs enter into the Nepalese market from India due to the open border and were generally sold at cheaper prices than the registered brands (2). Besides, ineffective ayurvedic (eg. Mensure), homeopathic (eg. Mensolex) and other indigenous medicines that are purported to be abortifacient were also reported to be in practice for inducing abortion (3).

As per the recently released guidelines by WHO, medical methods of abortion have contributed to task shifting and sharing and more efficient use of resources in both high and low resource settings and provides evidence-based information on how individuals can play a role in managing some of the components of MA themselves, outside a health care facility.

Government of Nepal enacted the “Safe Motherhood and Reproductive Health Rights Act, 2075”, which recognizes the access to abortion services as one of the fundamental rights of women in Nepal. To meet the vision of this act, it is proposed to review the existing mechanism of surveillance and regulation of MA drugs in the country and align them in the light of international updates and national evidence.

It is expected that streamlining the manufacturing, procurement, distribution, retail and other regulations regarding MA drugs would be helpful in improving the access of good quality and legal abortion services by the women and help in exercising their right to reproductive health in Nepal.

3. Objectives:

3.1 General Objective:

The main objectives of this rapid assessment are to review the existing policies and guidelines on MA drugs procurement, distribution and surveillance systems and identify factors impeding availability of registered MA drugs in the market.

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2 PSI 2018; CREPHA 2015
3 Tamang A, 2005
3.2 Specific objectives:

The specific objectives are to assess:

- The existing policies and directives for manufacture, procurements, distributions, surveillance, as well as prescribing and dispensing practices of MA drugs and the extent of compliance to them at various level;
- Market availability of registered and unregistered MA drugs and factors influencing market inundation with unregistered MA drugs;
- Providers’ compliance to protocols for quality assurance of MA drugs and barriers thereof;
- Registered MA drugs procurement process adopted by public health facilities, NGO clinics and private sector MA clinics accredited for safe MA service provision;
- MA drugs dispensing practices of private chemists and pharmacy workers;
- To propose solutions based on the report findings and the good practices around the world
- To propose a policy brief in the current federal context of the country to ensure availability of quality MA drugs and rational use of these drugs.

4. Scope of the work:

The research agency will follow a statistically robust method to carry out the study. The study protocol including design, methodology and the tools will be finalized in consultation with the WCO Nepal and the Task Force for strengthening surveillance of MA drugs.

This assessment will comprise of - i) Desk review and ii) Rapid Assessment.

Desk review:

The contractual partner is required to carry out a thorough Desk Review of existing government policies and guidelines, regulatory mechanism, relevant published articles/papers and grey literatures/reports to identify policy and pragmatic gaps in provision, quality control and surveillance system of medical methods of abortion.

Rapid assessment:

A rapid assessment will be done to gather relevant data from the field. A representative sample (covering 2-3 districts) can be chosen to cover and compare both the hilly and Terai region of the country. The study is also supposed to assess the roles of local government (municipalities) in MA drug procurement if this task of MA drug procurement and quality assurance are mandated to them. Interviewing key stakeholders such as officials and managers of DDA, DPHO and DCDA, MA Distributors, retailers/pharmacy workers to be planned in the methodology.

4 Task Force - WHO is facilitating the formation of a task force, comprising of 13-15 members and co-chaired by the Director General of the Department of Drug Administration (DDA/MoHP) and Director, Family Welfare Division (FWD/MoHP) to provide necessary guidance to strengthen surveillance of MA drugs in Nepal.
The Assessment tools:

Different tools (semi-structured questions and in-depth interview tools) are supposed to be designed to interview different stakeholders to address the research objectives.

5. Timeline

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<tr>
<th>Activities</th>
<th>Timeline</th>
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<tr>
<td>Sharing the study protocol including design, methodology and tools with the WCO team/ task force</td>
<td>Within 2 weeks of signing the contract</td>
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<td>Desk review and field work (2-3 districts)</td>
<td>3 weeks</td>
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<td>Compilation &amp; Report writing</td>
<td>2 weeks</td>
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<tr>
<td>Presentation of preliminary findings and draft report with WCO team/Task force</td>
<td>Within 8 weeks of signing the contract</td>
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<td>Submission of final report, data (raw data, tables, statistical analysis etc) and SoE</td>
<td>10 weeks of initiating the contract</td>
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<td>Total duration</td>
<td>10 weeks</td>
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6. Deliverables:

- Study protocol
- Draft report
- Presentation on the key findings of the study
- Final report
- Raw data, analytical tables and interpretations

7. Institutional competency and experts

The service provider institution should have:

- Good understanding and proven experience of carrying out public health research;
- Good understanding of SRHR related issues in the international, national and local context;
- Excellent understanding of political and social complexities related to abortion care in the local context;
- Understanding and experience of working within the federal governance and service delivery structure of the health system;
- Roster of experts;
- Experienced team leader;
- Readiness to take responsibility of viability, feasibility and applicability of the recommendations;
Service provider institution should have a team lead having excellent academic background and sufficient relevant experience. A mix of professionals is needed for the work due to cross-cutting nature of the work extending from public health, drugs regulations, marketing environment, public policy and socio-economic factors influencing peoples’ choices. Following are the minimum categories of team members needed to accomplish the work.

- Public Health Expert
- SRHR expert
- Research expert
- Statistician
- Field work

8. Budget and Payment modalities

The payment will be done in three instalments. First instalment of 25% will be provided upon sharing of study design, methodology and tools with the WCO team/task force. Second payment of 50% will be done after the presentation of preliminary findings and submission of draft report with WCO team/Task force. Last payment of 25% will be made when final report is received upon submission of final report, and submission of SoE.

9. Evaluation Criteria

An evaluation team in WHO country office will evaluate the technical and financial proposal based on ToR, other specific criteria and the following documents;

Technical Evaluation:

- Organization profile with the copy of certificate of company registration, certificate of affiliation with Social Welfare Council, Registration with Permanent Account No., Tax clearances and other legal documents as applicable etc.
- Institutional experience
- Study methodology and design
- Team mobilization plan
- Qualification and experience of the professionals including team lead
- CVs of all personnel proposed

Financial Evaluation

- Professional fees
- Cost of the field work
- Total cost (taxes separately mentioned)
- Mode of payment

Other terms and conditions are applied as per terms of reference and WHO’s rules and regulations.