Safe Abortion Breakout Session Joint WHO-UNICEF-UNFPA Manufacturers Meeting

4 December 2019 Reproductive Health Supplies Coalition







Safe Abortion Supplies

- Medical abortion (MA)
- Manual vacuum aspiration (MVA)

Due to time constraints and the wishes of event organizers, we focused in this session on MA and specifically on the relationship between MA manufacturers and international quality assurance standards

Quality-Assured MA

Medicine	WHO-PQ Products	SRA-Approved Products
Mifepristone	3	1
Misoprostol	3	9
Co-packaged	1	2

WHO-PQ: WHO-Prequalification

SRA: Stringent Regulatory Authority (WHO-Listed Authority)

Discussion Participants

2 MA Manufacturers 1 Social Marketing Organization

WHO

UNFPA

3 Global Health Organizations / Consultants

Key Questions for Small Group Discussions

How to increase number of quality-assured MA manufacturers

How to support the related business case for manufacturers

How to assist manufacturers in seeking QA approvals

Structure of Discussions

- Small group discussions
- Encouraged the generation of creative ideas
- Did not critique ideas

Outcomes of Discussions







Benefits May Not Exceed the Costs

Benefits don't now clearly outweigh costs for MA manufacturers in considering WHO-PQ or SRA approval.

- Significant costs are incurred by manufacturers in seeking WHO-PQ
- Uncertainty exists in time, staff effort, and expense to achieve WHO-PQ or SRA approval
- If MA manufacturer's costs (and selling price) increase, they may lose future business
- Many customers focus on lowest price and do not limit procurement to quality-assured MA
- Can market shaping activities help to ensure that the benefits gained by achieving the QA standard will exceed potential business lost in the long run?

Business Case Can Be Strengthened

Manufacturers may be encouraged to pursue WHO-PQ or SRA approval by the following.

- Clear forecasting and procurement plans are needed from procurers
- Supportive laws and regulations are critical for safe abortion services and markets in countries
- Comprehensive, disseminated national safe abortion guidelines are very valuable
- Manufacturers need to know that the market will bear a greater price
- Pursuit of SRA approval, rather than WHO-PQ, may be perceived by manufacturers as unlocking more opportunities

Manufacturers Value Integrated Approach to MA in Countries

A comprehensive approach toward integration of MA in tools and procedures is valuable. Can it be strengthened?

- Include MA combi-packs in national essential medicines list (EML)
- Include MA in standard clinical protocols
- Can governments be convinced to prioritize QA approvals in procurements?
- Can WHO Collaborative Registration Procedure (CRP) be used in more countries to efficiently register PQ-ed MA?
- Can UNFPA catalog be used by governments to procure MA combi-packs?
- If so, can governments be persuaded to use it (instead of using public tenders)?
- Is there value in including MA as part of a procurement package of women's health products (with contraceptives)?

Shifting Advocacy Approach for Safe Abortion and Related Supplies

As everyone is aware, advocacy for safe abortion is critical. Can shifts in advocacy strategies add value?

- Focus on women's health, with safe abortion as part of that (product) portfolio
- Emphasize how many lives can be saved by preventing unsafe abortions
- UNFPA's abortion stance was noted, "UNFPA does not promote abortion.
 Rather, it accords the highest priority to voluntary family planning to
 prevent unintended pregnancies in order to eliminate recourse to
 abortion." It was suggested that UNFPA and partners transform their own
 stance on abortion: promote safe abortion when a woman chooses that
 path.
- Could actions by organizations in shifting their stances on abortion help reduce stigma?

Need an Aligned Approach among Stakeholders

Alignment of stakeholder actions is needed to increase the number of quality-assured MA manufacturers.

- Actions are needed from stakeholders including: manufacturers, advocates, procurers, governments, and regulators.
- Limited value will be derived from independent stakeholder actions. A coherent framework of stakeholder actions is needed.
- Consider an approach such as that of "global goods". A "good", which would be of benefit globally, will not be produced or disseminated if left to the markets, because of a lack of incentive to each individual actor.
- Can the community benefit from applying a version of the "global goods" approach, used previously by WHO?

Thank you





