

Contribution of the non-profit sector to medical abortion

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- Research and development
- Evidence-based policy and guidelines
- Making quality product available at an affordable price
- Appropriate approaches to product introduction

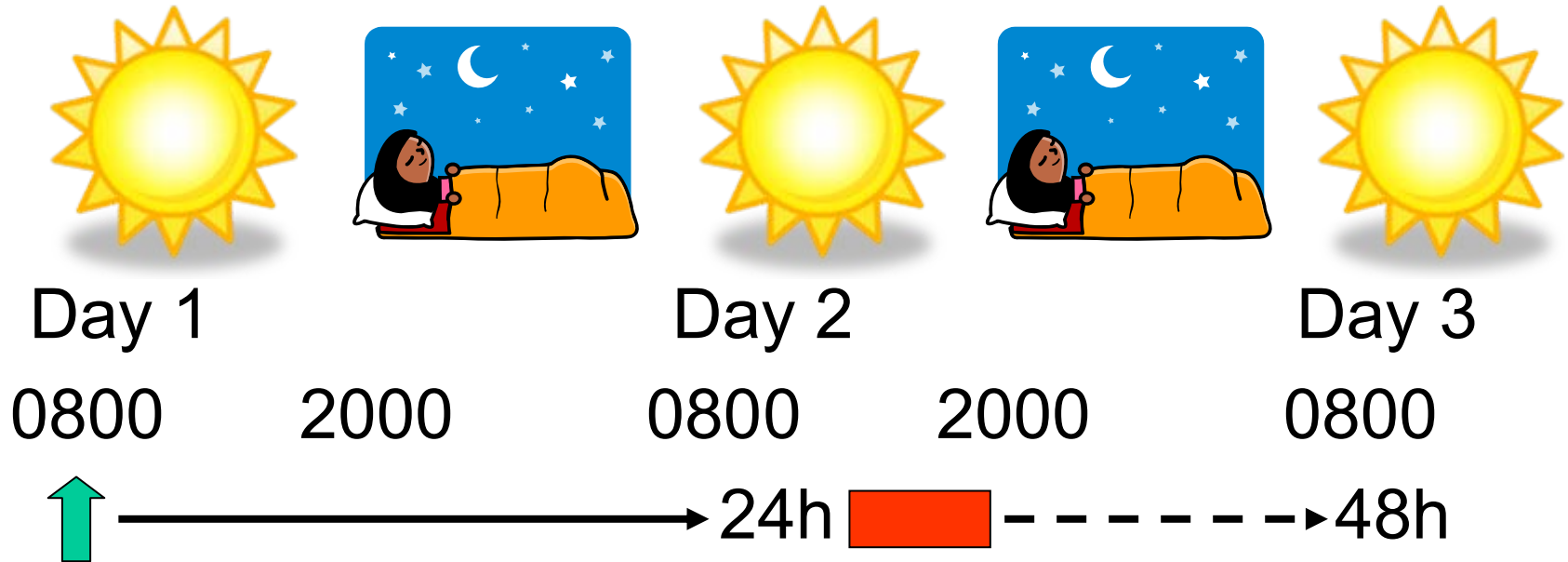
Research and development

- Roussel-Uclaf synthesized and patented RU-486 (mifepristone) in 1980.
- In 1983, Karolinska Institute funded by WHO showed increased efficacy when used with a PG
- Roussel-Uclaf began commercialization in western Europe, rights taken over by Exelgyn.
- R&D continued by non-profit sector, in particular by WHO and the Population Council and then Gynuity, as well as other research by Ipas, Ibis and others.

Selected research findings from WHO

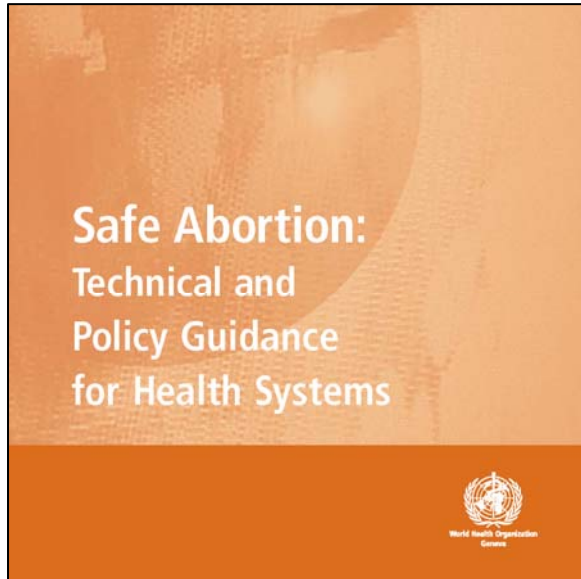
- 200mg of mifepristone is as effective as 600mg (recent data shows that even 100mg is as effective) up to 63 days LMP.
- When 200mg of mifepristone followed 36-48 hours later by 800µg of vaginal misoprostol, 95%-98% have complete abortion. Misoprostol is more effective and better tolerated when administered vaginally rather than orally. Efficacy with oral administration decreases >49 days LMP and if administered <36 hours post-mifepristone.
- Recent research has shown that even higher efficacy when misoprostol is administered sublingually, although higher incidence of side-effects.

Evidence now shows 24 hours is adequate

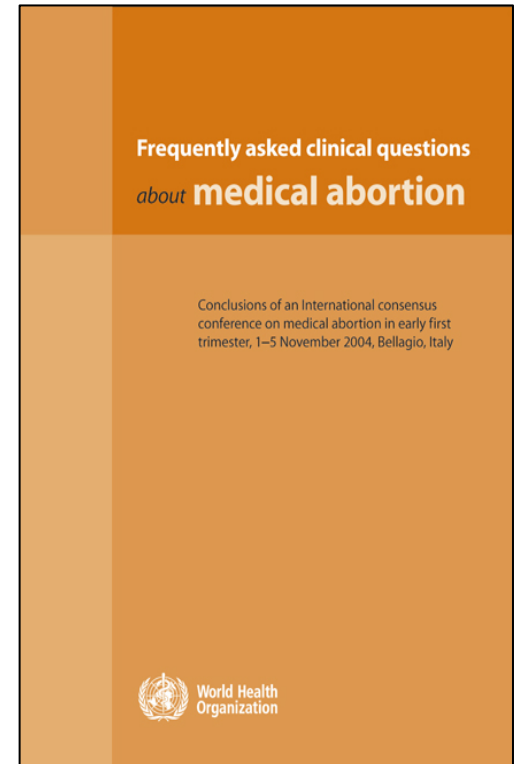


Evidence from WHO studies show the efficacy of the mifepristone-misoprostol regimen to be similar for intervals from 24-48 hours post-mifepristone, when misoprostol is given vaginally. Is similar with sublingual administration. A major advantage to women and health services.

Evidence-based information for providers and policy makers



Safe Abortion: Technical and Policy Guidance for Health Systems. World Health Organization, Geneva 2003
www.who.int/reproductive-health/publications/safe_abortion/index.html



Frequently asked clinical questions about medical abortion. World Health Organization, Geneva 2006
www.who.int/reproductive-health/publications/medical_abortion/index.html

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Getting from research to product

- Price – Co-packaged product with preferential price to public sector, making it affordable to many more women.
- Quality - Manufactured in USFDA/EMEA compliant facility, meeting international current Good Manufacturing Practice (cGMP).
- Regulatory issues – Misoprostol used “off-label” (except France and India), regulatory agencies welcome formal registration of misoprostol for use in medical abortion; clinical part of registration dossier based on WHO clinical trials.
- Ease of use – co-packaged product easier for both provider and woman.

What does Concept Foundation do?

- Concept Foundation is a not-for-profit organization, based in Thailand, with the goal to:
“Provide access to products for reproductive health of assured quality to the public sector of lower and middle income countries at the lowest possible price.”
- This goal is met through design and implementation of Access-to-Medicines (ATM) programmes for selected products for reproductive health, through the establishment and support of: Public-Private Partnerships (PPPs) with pharmaceutical companies.

What does a PPP need to achieve?

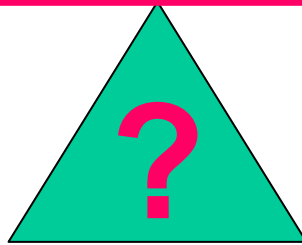
Private enterprises need to generate financial success

Public sector needs access to low cost drugs of assured quality



Financial support from donors allows funding:

Technology transfer, cGMP protocols, GCP-compliant clinical research, ICH-compliant regulatory documentation, regulatory dossier submissions



Benefit to public sector:

In return, the commercial partner makes investment and agrees to serve public sector in developing countries with products of assured quality at the lowest possible cost.

What has the PPP for drugs for medical abortion achieved?

A collaborative agreement with WHO; creation of a PPP with a major Indian pharmaceutical company; and funding by governmental and foundation donors, has allowed development and introduction of an affordable product of assured quality:

Medabon®

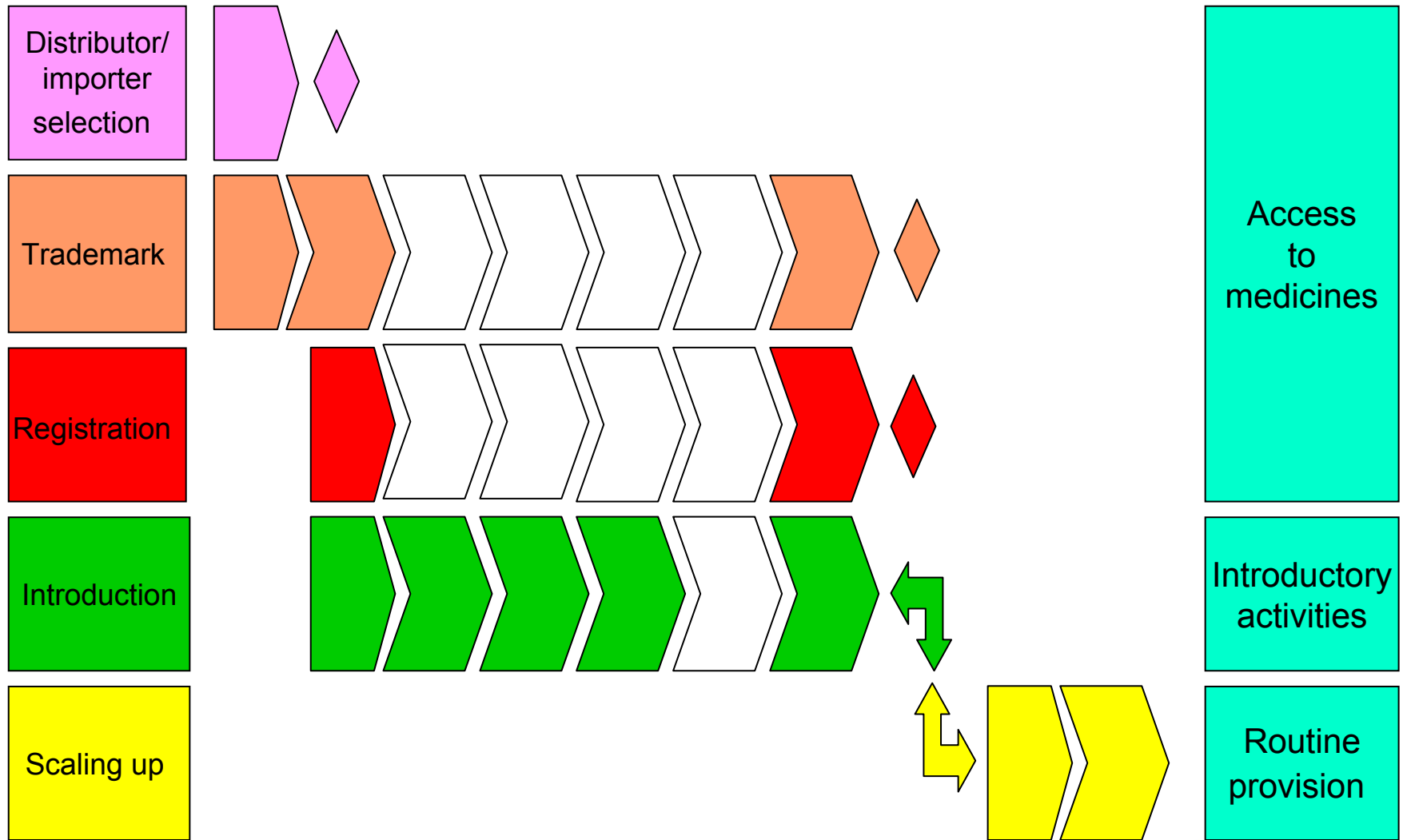


An access-to-medicines programme for drugs for medical abortion

- The Access-to-Medicines (ATM) programme for Medabon® is designed to ensure that it is available to those who require it, at an affordable price.
- But it necessitates appropriate use, initially through introduction into a supportive health system.
- Drugs for medical abortion can be provided by trained mid-level providers. But, in the few cases of incomplete abortion or excessive bleeding, there is need for access to referral services, in particular, access to a provider trained in the use of manual vacuum aspiration (MVA).
- The health system must be prepared to provide training of all levels of health care providers and, if necessary, values clarification with providers.

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Making medical abortion available - ideal

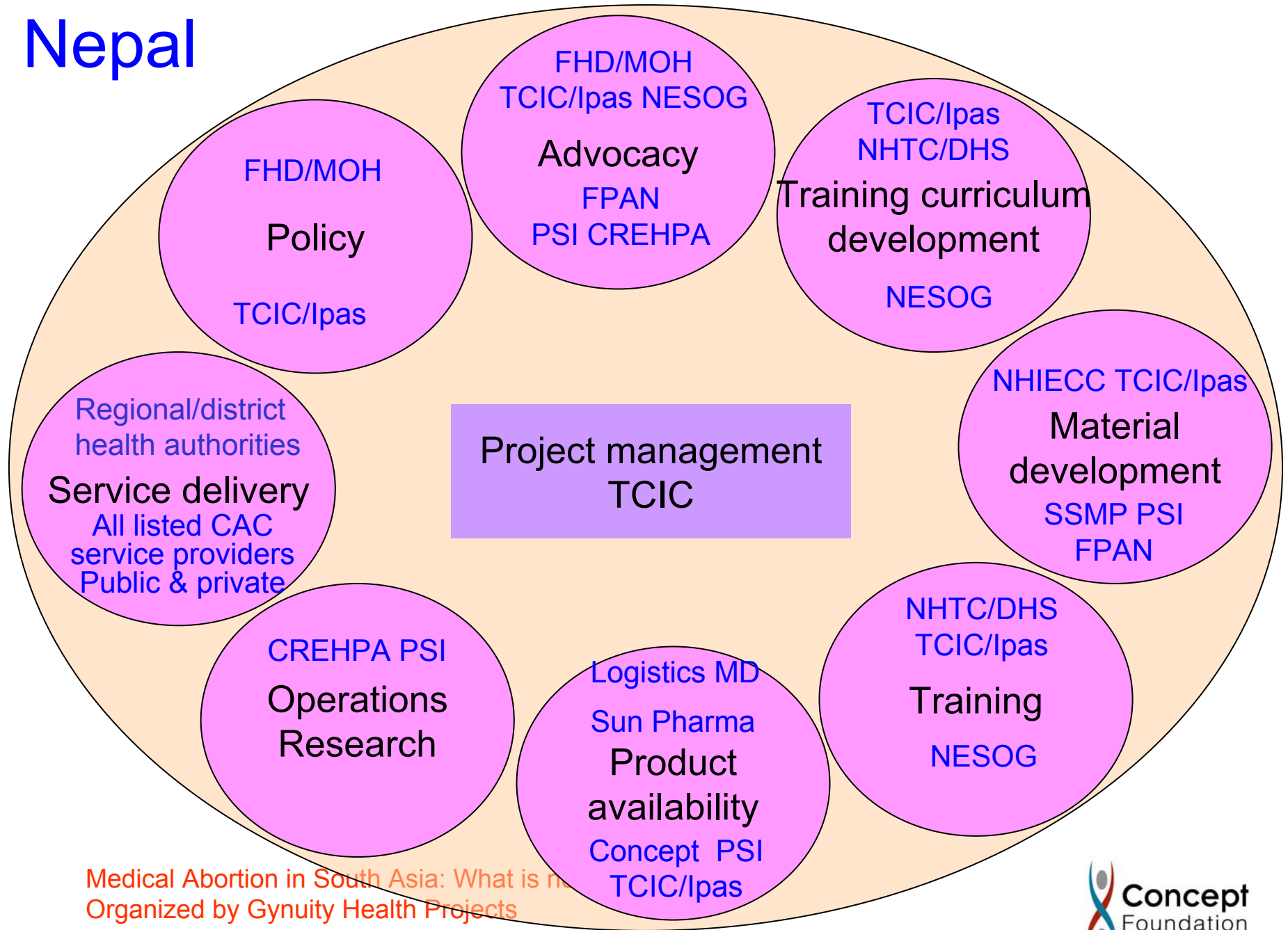


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Objectives of an introductory strategy

- Provision of medical abortion in the context of CAC in all facilities meeting the requirements of the national guidelines. The initial phase is undertaken in selected healthcare facilities.
- Development of a training curriculum, based on Ipas training modules, for the provision of comprehensive abortion care.
- Development of IEC materials for professionals and users.
- Development of an advocacy strategy for CAC.
- Implementation of operations research to allow planning for scaling up to other health care facilities.

Nepal



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