



Ensuring Access to Medical Abortion Drugs

**An overview of the Medabon pricing
model**

PDP Access Meeting, Divonne-les-Bains

Introduction

- Medabon® is a co-packaged drug for early medical abortion containing 200mg of mifepristone and 800µg of misoprostol
- The issue of abortion is often highly controversial – sensitive, emotive and with significant socio cultural and moral dynamics
- Branded product with full legal protection through comprehensive PLI
 - Creating brand equity – yes,
 - Not to de-medicalize, but to de-mystify, provide identity and reduce apprehension

Introduction

- Medabon® has been developed through a public-private partnership between Concept Foundation and industry, utilizing clinical studies and data from WHO/HRP under a formal collaborative agreement
- Scheduled for introduction in 26 lower and middle income countries

Where is Medabon being registered?

Registered	In process	Preparation	Planned
Nepal	Ethiopia	Viet Nam	<i>Cuba</i>
India	Ghana	Tunisia	<i>Georgia</i>
Cambodia	Mozambique	Moldova	<i>Guyana</i>
Zambia	Colombia	Benin	<i>Kazakhstan</i>
	Mongolia	Burkina Faso	<i>Tajikistan</i>
	South Africa	Turkey	<i>Uzbekistan</i>
	15 countries		<i>Armenia</i>
	In EU		<i>Macedonia</i>
			<i>Kyrgyzstan</i>
			<i>Brazil</i>

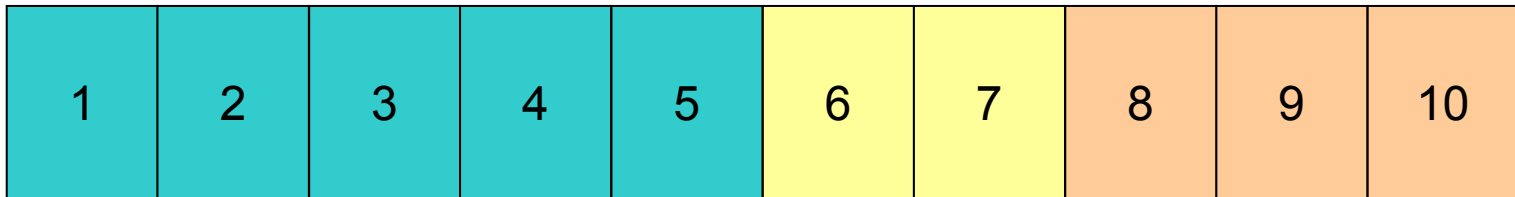
How does Concept access IP?

- Has 5 license agreements under a general collaboration agreement with WHO in reproductive health – including combi mife/miso
- Used WHO and own research results to develop a product for those who access medicines through the public sector of developing countries.
- Undertook bioequivalence and additional genotoxicity studies to generate complete datasets
- Usually not involved in patents or patented products but uses its access to clinical and preclinical data as its IP.

What role does Concept play?

- Managed technology transfer and key components of pharmaceutical manufacturing.
- Acts as “guardian” of product quality and access to public sector agencies at an affordable price, through specific agreement on quality, availability and pricing with the manufacturer.
- Names licensee in its Lloyds liability insurance.
- Participates in pricing modelling and monitors how public sector price agreements are implemented in each country.
- Co-develops protocols for pharmacovigilance and PMS

Steps from discovery to widespread availability of a medicine

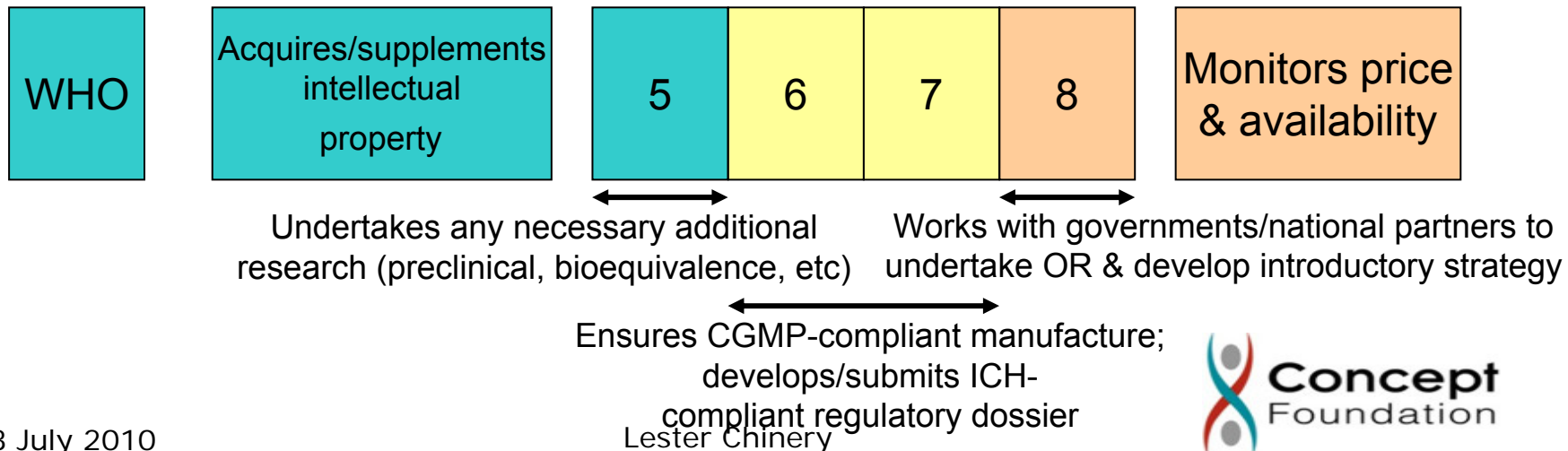


Discovery, preclinical and clinical research

Establish CGMP manufacturing facility; develop/submit ICH-compliant regulatory dossier

Undertake operations research; develop introductory strategy; scale-up availability; ensure importation, distribution and marketing

What steps Concept covers in its Public-Private Partnerships for access-to-medicines



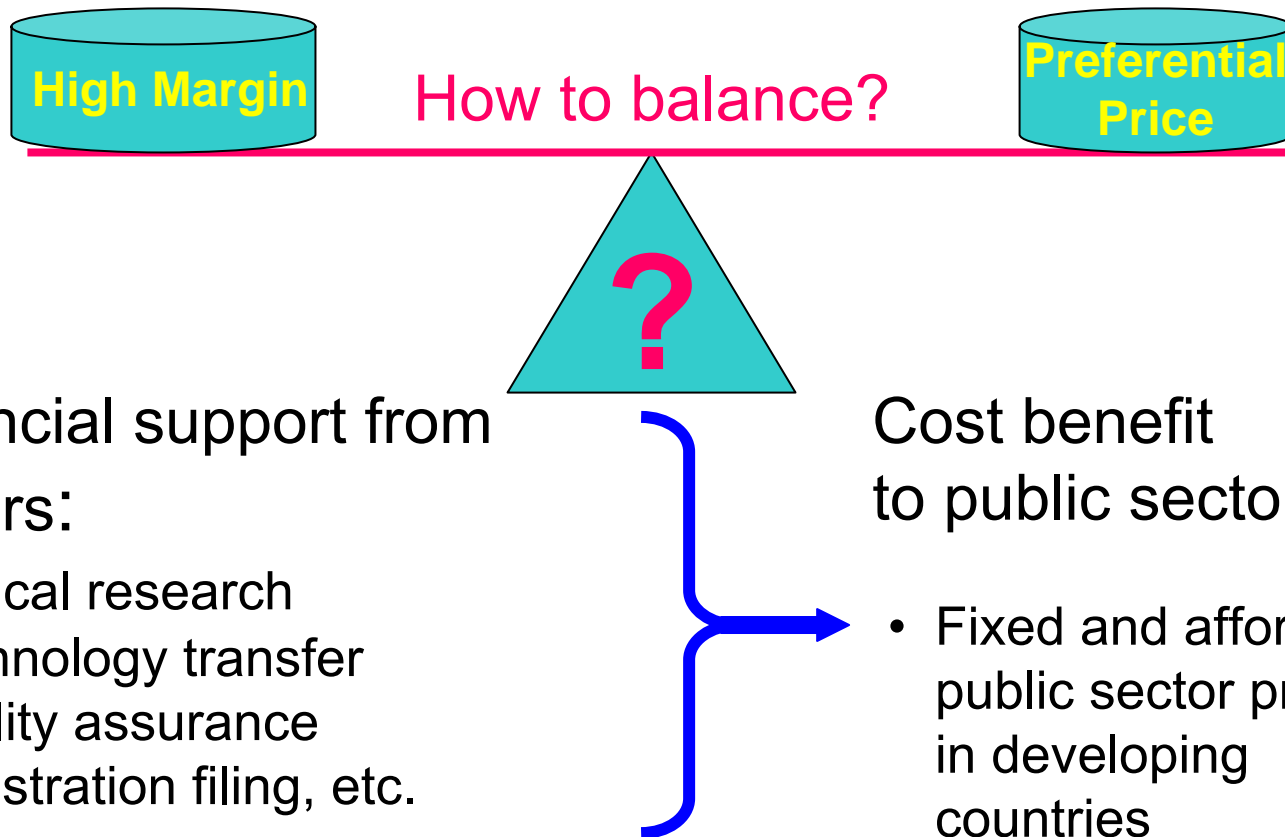
How is this implemented?

- Concept undertook and managed: technology transfer, cGMP protocols, data from pivotal clinical studies, GCP-compliant clinical research, ICH-compliant regulatory documentation, regulatory dossier submissions, and identifying country-based importers and distributors.
- Undertakes and provides baseline market analysis data and segmentation for target countries
- Commercial partner manufactures product of assured quality and serves under-developed and unprofitable markets with products at the lowest possible cost = cost +

What does the programme need to achieve?

Private enterprises need to generate financial success

Public sector needs access to low cost drugs of assured quality



Commercial proposition

- Permitted to market in developed markets with high revenue potential – Europe etc
- Can market commercially through private sector segments of lower and middle income countries

Partner selection

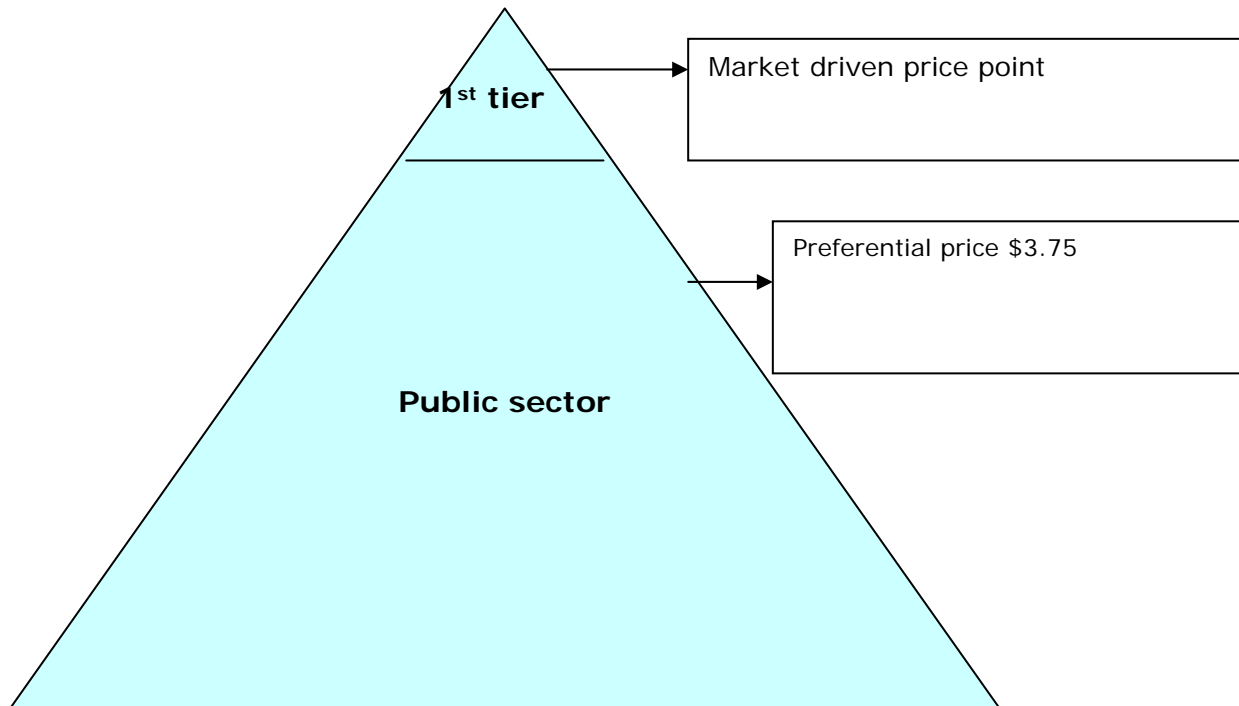
- Initial round of reviews based on quality assurance capabilities
- A global survey of manufacturers of mifepristone identified five potential candidate companies in China and India. Of these, only the three Indian companies had manufacturing facilities that met cGMP.
- Second round negotiations based on terms of license agreement.
 - Company A did not accept the public sector oriented goals of the project;
 - company B opted out after a lengthy period of negotiation;
 - Eventually, agreement was reached with the third, Sun Pharma and a formal licence agreement established

Basic price key – low/middle income

Public Sector*	Private Sector
Preferential public sector price US\$3.75 FOB	Market pricing determined by manufacturer

*Public sector – Government entity or local service provider who will deliver the product without adding a margin – at cost (or lower).

Market segmentation



Distribution

- Even when legal obstacles are overcome and acceptance criteria completed, often channels of distribution will be low-profile, more covert – it is likely that actors other than Government will play a key role in providing access at country level.
 - National NGOs
 - SMOs
 - Commercial distributors
- Specific nature of the product and channels impact upon financing and pricing structures
- In less developed countries 60% of RH products are provided through non-public channels

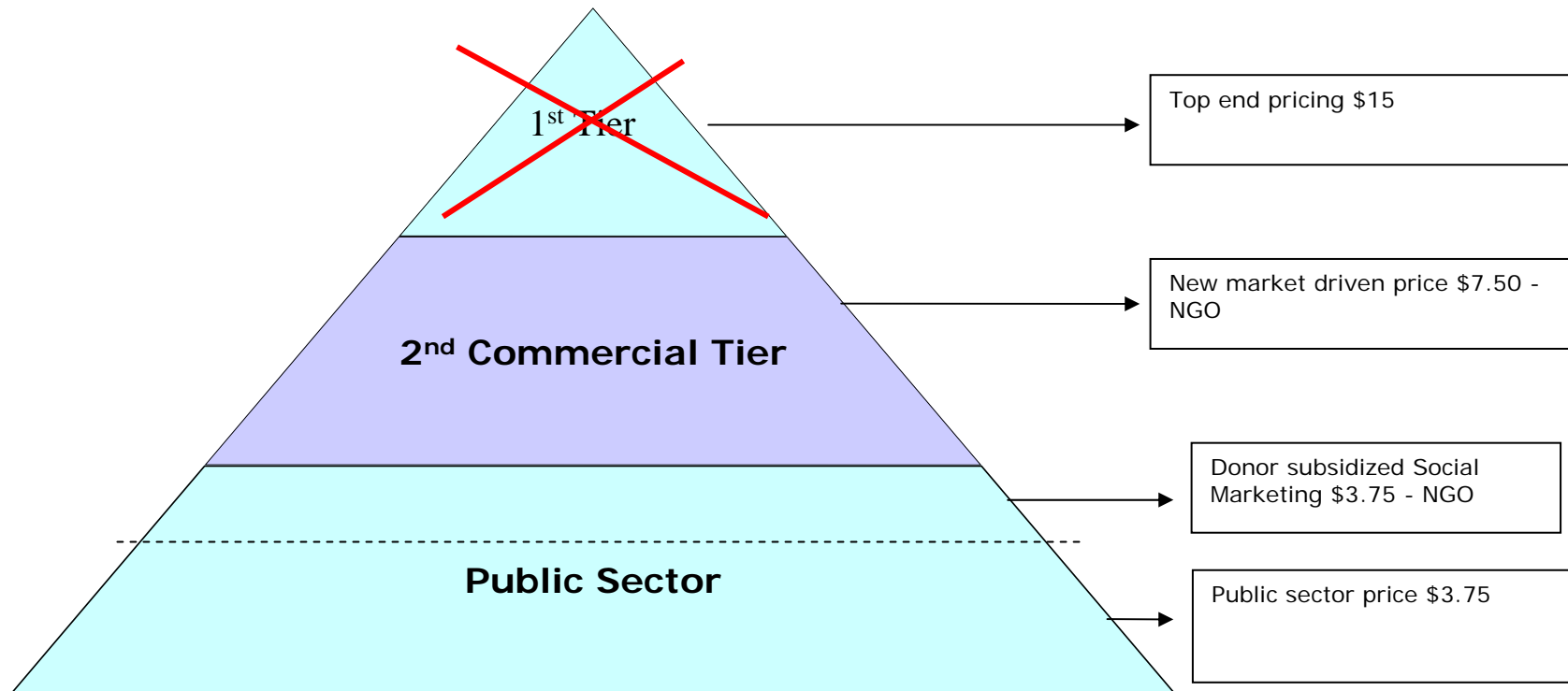
Price key impact

Public Sector*	Private Sector
Preferential public sector price US\$3.75 FOB	Market volumes/pricing negotiated with NGOs
Donor subsidized social marketing US\$3.75	Market pricing determined by manufacturer

Total market segmentation

Broader access

Competition



Conclusions

- Country driven public sector supply doesn't necessarily mean traditional public procurement mechanisms
- Significance and importance of pre-determined monitoring mechanism for price monitoring at country level
- Upfront detailed definitions of potential customer profiles (in relation to pricing) required – in particular eligibility for PPSP.
- Pricing often necessarily complex, is based upon individual market dynamics and constantly evolves
- One size doesn't fit all but, is more resource intensive
- Involvement in the last mile has resulted in increased access to medical abortion!