



International Campaign for Women's Right to Safe Abortion

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Pharmacy Access to Medical Abortion in India: Reality, Necessity & Potential

by Dr Nozer Shariar

Past Secretary General & Chairperson, MTP Committee,
Federation of Obstetric & Gynecological Societies of India (FOGSI);

Past President, Mumbai Obstetric & Gynecological Society;

Member, Technical Expert Committee,
Ministry of Health & Family Welfare,
Government of India;

Member, Board of Directors, Ipas & C3 India

Member, Medical Advisory Panel, Family Planning Association of India

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Point

Obtaining medical abortion without prescription from pharmacies is illegal, risky & condemned by the establishment.

Counterpoint

Obtaining medical abortion without prescription from pharmacies is a reality, a practical necessity & is used widely by women.

Traditional demand for medical methods

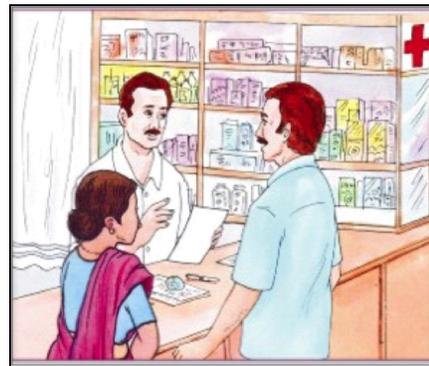
- Attempts at terminating pregnancy documented in 495 successive women
- Pharmacy access of simpler remedies in 32%
 - Tablets 65%
 - Decoctions 33%
 - Injections 8%

(Iyengar & Iyengar, RHM 2002)



Retail pharmaceutical distribution in India

- All India distribution
 - Pharmacies - 550000
 - Doctors - 936000
- Retail outlets
 - Lax oversight
 - Wide spread non-prescription dispensing
 - Grassroots provision
 - First point of contact
 - Cost savings



(Langer & Kelkar, Biopharm Int, India Today, 2008

Nadda, Quoted in Ind Med Times, 2015)

Mifepristone availability in India

Year	Mifepristone 200mg	Combi-packs introduced: mifepristone + misoprostol	
2002	1.24 million tablets		
2009	15.25 million tablets		
2010	16.29 million tablets	2010	1.1 million
2011	13.76 million tablets	2011	3.8 million
2012	14.32 million tablets	2012	6.8 million
2013	11.82 million tablets	2013	8.3 million
2014	11.29 million tablets		

Mifepristone availability - spoilt for choice

Availability & competitive pricing from 20-24 manufacturers

- MTPill
- Unwanted
- Mifegest
- Mifeprin
- T Pill
- Mifty
- Undo
- Mifemed
- Terpreg
- Contrapill
- Mifepreg
- Antipreg
- Mefnil
- Empri
- Mifyron
- Rimover
- Privc
- Eject
- Mifepill

Provision of abortion by FOGSI members

- FOGSI membership in 2015 - 31,282 members
- If responsible for the over 12 million abortions annually
- Would demand an impossible 366 abortions from every estimated FOGSI member-provider annually

Introduction of medical abortion in India

Date of approval - February 13, 2002

- Indication - For medical termination of pregnancy through 49 days of pregnancy
- To be sold by retail outlets on the prescription of a gynaecologist only
- To be used only under supervision of an expert & in a hospital where back up facilities are available for blood transfusion & MTP

(Drug Controller of India, Govt of India, 2002)

Local market availability of medical abortion

- Interviewed 591 pharmacists in 60 local markets
- Returned to 359 pharmacists with undercover patients
 - Pharmacists reported sales in 83.3% & undercover patients availability in 86.7% local markets
 - Availability was almost universal in city & town areas but lower in rural areas
 - Medical abortion dominated by combination packs
 - Traditional or alternative drugs offered to 20.6%
- Median price of combination packs was Rs. 350 (\$ 5.60)
 - Highest in town areas - median Rs. 397 (\$ 6.60)
 - Lowest in rural areas - median Rs.150 (\$ 2.50)

(Powell Jackson et al, PLoS One, 10(3): e0120637, 2015)

Gap between knowledge & practice among pharmacists

- Pharmacists (67.3%) knew to ask the timing of the LMP
 - But only 38.5% did so in practice
- Pharmacists (35.3%) knew to ask for a prescription
 - But only 13.8% did so in practice
- Pharmacists (90.9%) knew heavy bleeding was a warning
 - But only 49.5% gave advice on this matter
- Pharmacists (68.0%) knew how to use a combination pack
 - But only 35.3% offered the correct advice in practice
- Pharmacists (96.7%) knew where to get care for complications
 - But only 28.4% gave such advice

(Powell Jackson et al, PLoS One, 10(3): e0120637, 2015)

Why the market for medical abortion is so vibrant

- Supply side
 - Regulation of pharmacists & medical abortion is weakly enforced
 - Few pharmacists requested to see a prescription
- Demand side
 - High proportion of women want an abortion by the time they reach age 30
 - Strong preference for aborting at home
 - Cost of medical abortion is lower than surgical procedures.

(Powell Jackson et al, PLoS One, 10(3): e0120637, 2015)

Self-medication with abortion pills: a critique

- Retrospective observational study - 128 cases
 - Self-administered of medication in 40 (31.25%)
- Presentation
 - Excessive bleeding in 31 (77.5%)
 - Severe anaemia in 5 (12.5%) & shock in 2 (5%)
 - Incomplete abortion in 26 (62.5%) & failed abortion in 9 (22.5%)
- Management
 - Evacuation in 27 (67.5%) & transfusion in 5 (12.5%)
- Strict legislation to monitor & restrict the sales over the counter with access only through approved centres.

(Niveditha & Shanthini, J Clin Diag Res. 9(1), Epub 2015)

Pathways to unsafe abortion

Study of 1,565 abortion-related cases

Complications in 29%, with half having self-medicated

Provider type	First visit	Second visit	Third visit
Private doctor	23 %	37 %	58 %
Government doctor	9 %	14 %	33 %
Nurse ANM	8 %	10 %	8 %
Chemist shop	47 %	12 %	-

Total cost of treating complications of surgical abortion four times higher than the cost for medical abortion.

Targeting retail outlets & pharmacies to stop sex selective abortions - and the response

CHEMISTS IN CITY REFUSE TO STOCK ABORTION PILLS

Prachi Pinglay
prachi.pinglay@hindustantimes.com

MUMBAI: When a four-month pregnant 21-year-old went for a routine sonography to a civic hospital two weeks ago, the foetus was diagnosed with anencephaly, a condition where the brain does not develop. The doctor recommended an abortion and prescribed an abortion pill, which the woman could take at home.

She visited chemists in Andheri but was told they did not stock the pills. "I finally referred her to KEM Hospital, which has a civic-run dispensary" said the doctor, who treated the woman.

Gynaecologists in the city claim that following a crackdown by the Food and Drug Administration (FDA) on illegal sale of abortion pills to curb sex-selective abortions, chemists are reluctant to stock the pills, especially those prescribed to terminate a second trimester (between 12 and 20 weeks) pregnancy. The sex of a foetus can be determined during the second trimester.

Doctors said the pill is a better option than surgical abortion as it is closer to the natural process and recovery is faster.

"Abortion pills are off the market. I have heard patients are going from chemist to chemist," said Dr Nozer Sheriar, secretary general, Federation of Obstetric and Gynaecological Societies of

65% drop in sale of MTP kits/pills in city
FDA Drive Against Pregnancy Termination

Curbs on Abortion Pills Shock Women

Uproar over Maharashtra FDA crackdown on docs, chemists

The Forbidden Pill
Sale of MTP kits in the last 4 months (in Cr)

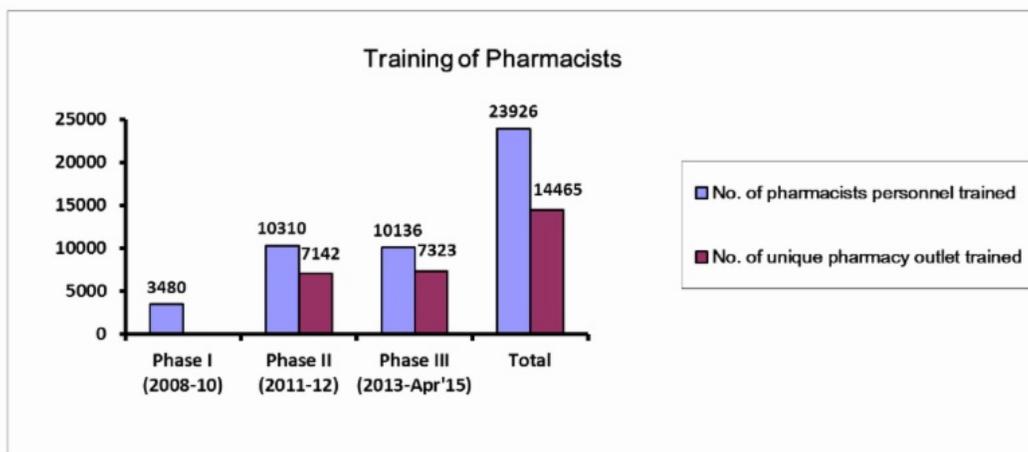
Feb-13	39.33
Mar	36.98
Apr	38.16
May	34.06
Jun	31.19
Jul	32.57

DIVYARAJGOPAL MUMBAI
A crackdown on female foeticide in Maharashtra has driven chemists and doctors across the state up the wall, triggering a severe shortage of medicines used to terminate unwanted pregnancies and complaints about high-handed and insensitive behaviour. The state Food & Drug Administration (FDA) has in recent weeks cracked down on doctors and chemists prescribing and selling medical termination of pregnancy kits commonly called MTP kits, raiding premises and filing cases against them for not recording details of women who have bought these drugs. In some cases, chemists say FDA officials have even asked them to provide addresses and phone numbers of women who purchased the drugs, displaying a lack of sensitivity on a deeply personal matter. "Facing harassment by officials, we have returned MTP drugs to companies," says Dilip Mehta, president of the Pharmacists' Wholesale Association in Mumbai. "The element of fear is so intense that not only dealers, even manufacturers are apprehensive and have withdrawn or are planning to withdraw drugs." While the FDA's actions appear aimed at curbing illegal sex determination and female foeticide, doctors said the way it was going about it risked criminalising abortions, a legal right of women, and increasing health risks for women. "All the abortions that are done in India are not after sex determination," says Dr Nozer Sheriar, secretary general of the Federation of Obstetric and Gynaecological Societies of India. Maharashtra FDA is Going Back in Time >>>

Maharashtra Food and Drug Admin is Going Back in Time

- Responses**
- Engage authority – meetings with Indian Food & Drug Administration Commissioner
 - Highlight legal discrepancies between the abortion law and the one on Food, Drugs & Cosmetic Acts
 - Collate illustrative cases of women deprived or denied abortion.
 - Media coverage – placement smart & responsive

Working at the grassroots: a FOGSI/PSI partnership



- Information regarding legalities
 - Medical abortion is prescription based drug
 - Women's needs - counselling & screening
- Information regarding use
 - Drug dosage & route of administration
 - Side effects and warning signs after use
 - Linkages to certified providers
- Access to toll free helplines



(PSI India 2015)

Pehel Project: Mystery client survey

	Aggregate across three states (DL, Raj, UP)	Range
Asked for doctor's prescription	38%	21-64%
Confirmed eligibility of women for medical abortion	94%	92-96%
Suggested correct dosage of medical abortion pills	44%	34-54%
Suggested correct route of administration	43%	26-51%

(PSI India 2015)

Role of pharmacists in expanding access

- Many pharmacists are willing to provide something to help a woman with an unwanted pregnancy.
- Women (many unable or unwilling to seek care from trained providers) already seek medicines from pharmacists.
- The specific roles of pharmacists in medical abortion will depend on a country's legal & policy context.
- Approaches that successfully improve pharmacists' ability & willingness to provide information as well as referrals to other healthcare providers can help & benefit women.

Orient and sensitise pharmacists

Working strategies that are both legally compliant & situationally realistic:

- Work with pharmacists' associations
- Impress pharmacists about their important role in supporting women's health
- Familiarise them with the legal as well as medical issues
- Pharmacists have a responsibility to be aware of drug use
- Not wise to advocate regulatory change at this time.

User-friendly package inserts to encourage & reiterate appropriate use

- Reiteration of appropriate dosage
- Pictorial display of mode of administration
- Assists in the early recognition of complications

Safe Abort Kit

CAUTION:

- Medical Abortion tablets should be taken under supervision of a doctor approved under the MTP Act
- Before taking Medical Abortion tablets any Intrauterine Contraceptive Device- IUD (like Copper T) must be removed
- Once started, the full course of tablets must be taken
- Once Medical Abortion tablets are started, the pregnancy should not be continued due to risk of deformities in baby caused by the abortion tablets
- In a few cases, if bleeding is excessive or abortion remains incomplete after taking the tablets, a surgical evacuation may be needed to complete the abortion
- **The SAFE ABORT KIT SHOULD NOT BE USED AFTER 9 WEEKS OF PREGNANCY** (63 days, counting from the first day of last menstrual period)

This Safe Abort Kit contains:
1 tablet of Mifepristone 200 mg (red circle), and 4 tablets of Misoprostol, of 200 mcg each (blue box)

How should you use the Safe Abort kit?

When to take tablet/s	How to take tablet/s	What should you expect? (Routine effects of tablets)
Day 1 1 tablet Mifepristone (to be taken on day 1)	Take the tablet by mouth with water. If you vomit within half an hour, take the same tablet again.	Some vaginal bleeding and lower abdominal cramping pain may start after taking this tablet.
ON DAY 3 (counting from Day 1) 4 tablets Misoprostol (oval tablets shown by blue box).	48 hours after taking Mifepristone (round tablet shown by red circle). Take 4 tablets Misoprostol (shown by blue box) using any of the following methods: Method 1- Keep the 4 tablets under your tongue OR in your cheek pocket	The bleeding and cramping pain will increase. This will seem like a heavier and more painful menstrual period. You may have to take painkillers like Ibuprofen to make the pain less. You will pass blood clots and may have some vomiting, loose motions, slight fever with chills, headache and dizziness. You should drink lots of fluids and rest as much as you can.

When to take tablet/s **How to take tablet/s** **What should you expect? (Routine effects of tablets)**

Wait for 20 minutes before swallowing, if possible. **OR** **Method 2 -** Insert the 4 tablets deep inside the vagina. Lie down for half an hour, if possible.

After the blood clots are expelled, the pain and bleeding will become less, but bleeding may continue up to two weeks.

Most women abort within 4 to 6 hours of Misoprostol use. The rest usually abort later on the same day and a few within the next 5 days.

ON DAY 15 (counting from Day 1) **You must visit a doctor** (14 days after taking first tablet) to confirm that your abortion is complete.

Your doctor will provide family planning advice and services, if you want.

Important:

- Do not have sexual intercourse till vaginal bleeding stops
- If you do have sexual intercourse before the bleeding stops then do use a condom to prevent infection

Warning signals:
Contact your doctor immediately if you experience any of the following:

- Heavy bleeding (Two thick sanitary pads soaked with blood in 1 hour-2 hours consecutively, i.e. you have to use four pads in two hours)
- Severe/unbearable pain in lower abdomen
- Very frequent diarrhea and vomiting
- High fever above 100°F for more than 4 hours after using the tablets on day 3

You will know that abortion process is complete if: Bleeding and pain become less after products of conception (i.e. large clot like structures) are passed. Bleeding decreases gradually and becomes minimal in about two weeks time.
If there is no or only slight bleeding even after a day of taking the second medicine (Misoprostol) and you continue to have symptoms of pregnancy, then you should contact the doctor immediately.

After Medical Abortion: You can become pregnant almost immediately. Consult your doctor early to discuss about the family planning method suitable for you.

You should not use Medical Abortion if you

- Do not have easy or quick access to a medical facility in an emergency
- Are unwilling to undergo a surgical abortion if Medical Abortion fails or bleeding is very heavy
- Are allergic to Mifepristone or Misoprostol
- Are using oral or injectable steroids for a long time
- Are on blood thinning medication

STAY CONNECTED

