



AVAILABILITY OF MEDICAL ABORTION DRUGS

IN THE MARKETS OF SIX INDIAN STATES

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About FRHS India

Foundation for Reproductive Health Services (FRHS) India is the No. 1 non-government provider of clinical family planning services. FRHS India works in 77 districts of the states of Bihar, Rajasthan and Uttar Pradesh in India. FRHS India has been working since 2009 to enable women and girls to exercise their reproductive rights and choice. FRHS India provides a range of contraception choices and safe abortion services to women from economically, socially and geographically marginalised communities through various service delivery channels. FRHS India works on the belief that women should have the right to choose whether, when and how many children to have. In 2019, FRHS India served 1,61,361 clients with a range of family planning and safe abortion services, which resulted in 1,843,726 couple years of protection and led to 82,464 unintended pregnancies, 29,406 unsafe abortions and 65 maternal deaths being averted. FRHS India also hosts the secretariat of Pratigya Campaign for Gender Equality and Safe Abortion which advocates for women's access to safe abortion in India.

www.frhsi.org.in

About Pratigya Campaign

Pratigya Campaign for Gender Equality and Safe Abortion is a network of individuals and organisations working towards protecting and advancing women's rights and their access to safe abortion care in India. The campaign advocates with governments, organisations and media at the national and state levels on issues of women's empowerment and women's access to healthcare services. Foundation for Reproductive Health Services India hosts the secretariat and a dedicated eight member Campaign Advisory Group guides and offers strategic direction to the coalition and its advocacy efforts.

www.pratigyacampaign.org

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Acronyms

- ANM Auxiliary Nurse Midwife
 ASHA Accredited Social Health Activist
- B. Pharma Bachelor of Pharmacy
- C CAC Comprehensive Abortion Care
 CDSCO Central Drugs Standard Control Organisation
 CMS Centre for Media Studies
- D D. Pharma Diploma in Pharmacy
 - DCC Drugs Consultative Committee
 - DCGI Drug Controller General of India
 - DTAB Drugs Technical Advisory Board
- E ECP Emergency Contraceptive Pills
- F FRHSI Foundation for Reproductive Health Services India
- G GYN Gynaecologist
- I ID Identification
 - IEC Information Education Communication
 - INR Indian Rupee
 - IRB Institutional Review Board
 - IUD Intrauterine Device
 - MA Medical Abortion
- M MBBS Bachelor of Medicine and Bachelor of Surgery
 - MoHFW Ministry of Health and Family Welfare
 - MP Madhya Pradesh
 - M. Pharma Master of Pharmacy
 - MRP Maximum Retail Price
 - MTP Medical Termination of Pregnancy
- N NGO Non-Governmental Organisation
 - **OB** Obstetrician
- O OTC Over the Counter
- P PCPNDT Pre-Conception and Pre-Natal Diagnostics Techniques
 PPIUCD Postpartum Intrauterine Contraceptive Device
- T TN Tamil Nadu
- U USG Ultra Sonography
- W WHO World Health Organisation

Chapter 1 Study Background and Methodology

Chapter 2 Key Findings from Chemist's Survey



Chapter 1 Study Background and Methodology

1.1. Study Background

Pratigya Campaign for Gender Equality and Safe Abortion carried out a research in 2019 on the 'Availability of Medical Abortion (MA) Drugs in Four States of India' which revealed a stark shortage of the drugs among chemists in two of the four states - Rajasthan and Maharashtra. **The main reason for the shortage as pointed out by a majority of chemists was legal barriers around stocking of MA drugs**.¹ 56% of all chemists across the four states reported that MA drugs are overregulated as compared to other Schedule H drugs. Organisations marketing MA drugs have indicated that they are facing barriers in distribution and sale of MA drugs in other states too.

Abortion done using a recommended method like MA drugs, even without medical supervision, is classified as less safe and not unsafe, by WHO.³ The primary requirement for this is the easy availability of MA drugs. If MA drugs are not easily available, women would be forced to seek abortions from unqualified providers who use methods that are not recommended, risking their health and life. To understand the situation in key states, Foundation for Reproductive Health Services India, a Pratigya Campaign partner undertook the second phase of the study in six states - Assam, Delhi, Haryana, Madhya Pradesh, Punjab and Tamil Nadu. This report highlights the key findings of the second phase of research, articulates the implications and proposes recommendations to address the issues concerning medical abortion access in India.

Abortion Incidence in India





73% are MA outside the facility.²

1.2. Purpose and Objectives of the Study

The study aims to understand the availability of MA drugs in the context of on-going efforts to address gender-biased sex-selection and overregulation of MA drugs in the market. The research involved an assessment of MA drugs availability among a sample of chemists (retail pharmacies) in urban areas of the six states.

The objectives of the study were:

- To verify and understand the current status of availability of MA drugs in the market
- To understand the key reasons for stocking/not stocking of MA drugs
- To assess chemists' knowledge on the product (primary use, Drugs and Cosmetics Act and Rules on dispensing etc.) and actual practice related to the MA drugs sales
- To understand chemists' experiences/interactions with the state & district drug authorities related to sales & distribution of medical abortion drugs in their outlet

1.3. Study Methodology

The quantitative cross-sectional survey was conducted by **Centre for Media Studies**, among a sample of chemist outlets located in the markets of five cities in each of the states of Assam, Delhi, Haryana, Punjab, Madhya Pradesh and Tamil Nadu. The study was conducted from **January to March 2020**.

1.3.1. Study Area

The study was carried out in six states of India namely Assam, Delhi, Haryana, Punjab, Madhya Pradesh and Tamil Nadu. In each state, five cities were covered while in Delhi, the study was conducted in five sub-districts. The five most populated cities/sub-districts were selected from each state using the Census Population Enumeration Data 2011. The cities/sub-districts, which were part of the study are listed in Table 1.

States	Cities/Sub-districts Covered					
Assam	Dibrugarh, Guwahati, Jorhat, Nagaon and Silchar					
Delhi	Hauz Khas, Najafgarh, Narela, Patel Nagar and Seelampur					
Haryana	Ambala, Faridabad, Gurugram, Panipat and Yamuna Nagar					
Madhya Pradesh	Bhopal, Gwalior, Indore, Jabalpur and Ujjain					
Punjab	Amritsar, Bathinda, Jalandhar, Ludhiana and Patiala					
Tamil Nadu	Chennai, Coimbatore, Madurai, Tiruchirappalli and Tiruppur					

Table 1: States and Cities covered under the study

1.3.2. Sampling Approach

To select the sample, each city/sub-district was divided into five zones, East, West, North, South and Centre. From each zone, 8-10 chemists were covered. Chemists covered in each city/sub-district were spread across the municipal corporation area of the city/sub-district. Representation of chemists from low, middle and upper-class localities in different geographical directions within the city was ensured to capture the variation among the responses. While selecting the chemists, different areas were approached such as residential colonies, commercial areas, localities near colleges and hospitals/clinics etc. A distance of at least 500 metres between two shops was kept while approaching chemists in a particular zone. In total, **1500 chemists** were covered under the study.

During the initial days of data collection in four states, namely, Haryana, Madhya Pradesh, Punjab and Tamil Nadu, the study team came across a scenario where almost all sample chemists reported not stocking MA drugs. To investigate further, the mystery shopping approach was used among a sub-set sample of chemists.

The **mystery shopping method** has been successfully used in many countries to evaluate the practices of chemists. Literature provides insights into the wide range of activities for which mystery shopping methodology can be used, including assessment of chemist-client interaction, patient counselling, feedback to pharmacists etc. In the study, this approach was employed to understand the stocking and sales of medical abortion drugs by chemists and the advice they give to clients on their use.

As the mystery shopping approach was introduced after the initiation of data collection, it was conducted without a doctor's prescription i.e., the mystery client approached the chemist to seek information without a doctor's prescription. In each city of the four 'problem' states, 20% sample (10 chemists) was covered through the mystery shopping method. State-wise sample details are given below in Table 2.



Chemists covered by administering the survey questionnaire.



Chemists covered under the mystery shopping category.

		Sample Covered						Sample Covered				
States	Cities	Chemists under survey method	Total chemists under survey method	Chemists under mystery shopping	Total chemists under mystery shopping							
Assam	Dibrugarh Guwahati Jorhat Nagaon Silchar	50 50 50 50 50	250									
Delhi	Hauz Khas Narela Najafgarh Patel Nagar Seelampur	50 50 50 50 50 50	250									
Haryana	Ambala Faridabad Gurugram Panipat Yamuna Nagar	40 40 40 40 40	200	10 10 10 10 10	50							
Madhya Pradesh	Bhopal Gwalior Indore Jabalpur Ujjain	40 40 40 40 40	200	10 10 10 10 10	50							
Punjab	Amritsar Bathinda Jalandhar Ludhiana Patiala	40 40 40 40 40	200	10 10 10 10 10	50							
Tamil Nadu	Chennai Coimbatore Madurai Tiruchirappalli Tiruppur	40 40 40 40 40	200	10 10 10 10 10	50							
То	tal	1300 200		00								

Table 2: Sample covered under the study

A pre-test of the research instruments was carried out in Delhi and Chennai where a total of 19 chemists were interviewed.

1.3.3. Areas of Enquiry

Face-to-face interviews were conducted with chemists in their shops/establishments. A questionnaire was developed for chemists to understand the following:

- Current availability of MA drugs
- Reasons for not stocking MA drugs
- Awareness on abortion and MA drugs
- Information source for MA drugs
- Chemist-Client interaction
- · Purchasing pattern and client experience
- Regulatory issues

Under the mystery shopping category, chemists were asked about the availability of abortion drugs. Based on the chemist-client interaction, the following information was observed and sought:

- Reasons for not stocking MA drugs
- · Various brands stocked
- · Questions asked by the chemists to the clients while selling MA drugs
- Advice given on routes of administration, side effects etc.

1.4. Ethical Considerations

The research protocol including research instruments was approved by the CMS-Institutional Review Board (CMS-IRB) prior to the initiation of the survey. CMS-IRB is an internationally accredited institutional review board which reviews ethical issues in research involving human subjects.



Chapter 2 Key Findings from Chemist's Survey

The key findings of the research are as follows:

2.1. Availability of MA Drugs (N=1300)



2.2. Reasons for not stocking MA Drugs (N=1018)

More than half (53.4%) of all chemists cited legal issues/barriers such as strict regulations, specific communication not to sell MA drugs by the local drug authority and government ban as reasons for not stocking MA drugs. 30.8% reported that low demand for these drugs was a deterrent. 43.9% in Madhya Pradesh and 38.2% in Delhi reported "too much paperwork /documentation requirement" as a reason for not stocking MA drugs. 36.8% of chemists in Assam who were not selling MA drugs at the time of the survey reasoned that these drugs are harmful for women's health.

2.3. Awareness on Abortion (N=1300)

78% of the chemists reported abortion is legal in India, with Madhya Pradesh reporting the highest at 92.5% followed by Haryana at 86.5%. Among those who said it was legal, around 80% mentioned that abortion is legal only under certain conditions. 21% chemists were not aware that abortion is legal in India.

2.4. Awareness on Gestational Limits for Abortion (N=1025)

Only half of the chemists were aware that abortion is legal up to 20 weeks gestation in India. 20.7% chemists reported that abortion can be done only up till 12 weeks gestation. Awareness was highest in Punjab (71.4%) followed by Assam (70.1%), Delhi (54%), Haryana (40.6%) and Madhya Pradesh (36.9%) while awareness was lowest at 29.5% in Tamil Nadu.

2.5. Awareness on Gestational Limits for Combi-pack MA (N=1025)

42.7% of all chemists reported a nine weeks' limit for Combi-pack MA drugs' use; an equal 42% reported a seven weeks' limit.

2.6. Purchasing Pattern (N=282)

The chemists who stocked MA drugs were asked about prescription and who buys the MA drugs, for the last 10 clients.



Clients who visited the chemists with a prescription



However, in the case of four states other than Assam and Delhi, the percentage of chemists who reported stocking MA drugs was very low to draw a conclusion on the trend of client purchasing pattern.

2.7. Interaction between Chemists and Clients (N=282)

Chemists stocking MA drugs asked about the following from the clients:

- **85.8%** reported asking about the doctor's prescription.
- **68.7%** asked about the duration of pregnancy.
- **55.2%** reported asking about their last menstrual period.
- **24.6%** reportedly asked the age of pregnant women.

Around 90% chemists reported advising the clients on how to take the pills and 64.3% on the routes of administration. When asked about different routes of administration for MA drugs to understand their awareness, an overwhelming percentage of chemists, who stock MA drugs, mentioned oral (94%) followed by (38.7 %) sublingual and (16.3%) buccal.

2.8. Perceptions on Abortion (N=1300)

The chemists across the six states had conflicting views on abortion.

65% of all chemists interviewed reported that the availability of MA has increased the number of abortions in India.

51.5% Chemists stated MA drugs are not useful for women.

16.2%

Chemists considered MA drugs to be useful for women.

9.8% of the respondents reported that MA can be used for gender-biased sex-selection.

Significantly, **35.5%** of respondents in Tamil Nadu reported that MA drugs can be used for gender-biased sex-selection, a misconception since MA drugs are only approved for use up to nine weeks gestation, when sex determination, using the most common and affordable method – Ultra Sonography, is not possible.

2.9. Communication received from Drug Inspectors (N=282)

Around 40% of chemists reported receiving some form of communication on MA from drug authorities. The major form of communication was oral and a majority of these chemists (43.8%) were advised to sell these drugs on prescription.

2.10. Perception on Overregulation of MA Drugs (N=1300)

54.8% chemists reported that MA drugs are overregulated as compared to other Schedule H drugs.

No difference in perception was observed between chemists, who stock MA drugs (55%) and those who don't stock (54.8%). However, more than 40% of the chemists reported that overregulation is required to avoid misuse or health complications from these drugs.

2.11. Availability of Contraceptives (N=1300)

97% of chemists interviewed reported stocking contraceptives. The most stocked contraceptives are:



Condoms

(99%)



Oral Contraceptive Pills (88%)



Emergency Contraceptive Pills (ECP) (70%)

Tamil Nadu was an outlier as far as stocking of Emergency Contraceptive Pills is concerned. Only 3% reported stocking ECPs. 90% of chemists in Tamil Nadu reported that ECPs are banned, which is incorrect. It appears that drug regulatory authorities have imposed barriers resulting in ECP not being stocked or believed to be banned.

2.12. Mystery Shopper Finding (N=200)

The mystery shopping method was carried out **among 50 chemists in each of the four states (Haryana, Punjab, Madhya Pradesh and Tamil Nadu)** which had the lowest MA stocking percentage. The findings for Haryana and Tamil Nadu were consistent with the survey findings. None of the chemists were stocking MA drugs in Haryana while only 8% in Tamil Nadu were doing so. Findings for Madhya Pradesh and Punjab were different from the survey findings, with 56% chemists stocking MA drugs in MP and 22% in Punjab.

Status of Emergency Contraceptive Pills stocking in Tamil Nadu

While the objective of the study was to understand the availability of MA drugs, we found that the stocking of Emergency Contraceptive Pills in Tamil Nadu was also very poor. Only six chemists out of the total sample (200) in Tamil Nadu reported stocking Emergency Contraceptive Pills and 90% of those not stocking had the misconception that these pills are banned in the state. As a state, Tamil Nadu is highly dependent on sterilisations (94% of all acceptors of contraceptives adopt this method) and there is limited use of spacing methods. In such a situation there is a greater need for ECPs to be easily accessible for women so that they don't end up with an unwanted pregnancy. The State Drug Control authorities should clarify the situation and ensure that this important drug is stocked by chemists and is easily available in the state.

Chapter 3 Detailed Findings from Chemist's Survey

Chapter 4 Findings from Mystery Shopping



Chapter 3 Detailed Findings from Chemist's Survey

3.1. Respondents' Profile (N=1300)

In total, **1300 chemists** participated in the survey. All chemists were dealing directly with the clients and on an average were working for more than ten years at their pharmacies. Two out of three chemists were shop owners while 20% were working as employees. Respondents (other than the owner of the shop) were working for an average of 12 years at the pharmacy. Table 3 shows the education profile of chemists across the six study states.

States	Assam	Delhi	Haryana	MP	Punjab	TN	Total
Highest level of education	n=250	n=250	n=200	n=200	n=200	n=200	n=1300
D. Pharma	6.0	40.8	47.5	21.0	51.0	38.5	33.3
B. Pharma	9.6	25.2	21.0	34.5	7.5	6.0	17.3
M. Pharma	0.8	0.4	2.0	3.0	1.5	0.0	1.2
Graduate	40.8	18.4	21.0	26.5	25.0	35.5	28.0
Senior Secondary	24.8	12.4	7.5	7.0	11.0	18.5	13.9
Secondary	16.0	2.8	0.5	6.5	4.0	1.5	5.5
Post Graduate	2.0	0.0	0.5	1.5	0.0	0.0	0.7

Table 3: Education profile of respondents (in %)

More than half of the respondents had a professional degree in pharmacy.

Respondents reported holding a qualification in pharmacy (masters/bachelors/diploma):



3.2. Drug Availability (N=1300)

3.2.1. Stocking of Contraceptives

Almost all chemists were stocking contraceptives for preventing and spacing of pregnancy. Most of them reported stocking of:



Very few chemists were stocking IUD/Copper-T or injectable contraceptive. In Tamil Nadu, only six chemists out of the total sample (n=200) were stocking emergency contraceptive pills (ECP), 90% of those not stocking ECP reported that these pills are banned in the state.

3.2.2. Clients seeking Information on MA Drugs

Chemists were asked whether clients come to seek information on termination of pregnancy and 78% chemists reported that such clients do come to their pharmacy for advice or information. In Assam 91% reported so, while in Punjab, the corresponding figure was 42%. In Assam, three-fourth respondents reported that they give abortion drugs to the clients in such situations.

In other states, chemists reported that they refer such clients to medical facilities. Most of the chemists reported, referring the clients to other pharmacies or health facilities as they do not stock these drugs.

20% of the respondents (11% from Tamil Nadu, 5% from Haryana and 3% from Delhi) informed that they are not allowed to stock or sell abortion drugs or give advice to such clients.

3.2.3. Stocking of MA Drugs

Only 22% of all chemists reported stocking MA drugs. Notable variation was found among the states. 70% reported stocking in Assam, followed by Delhi at 34%.

The reported availability of MA drugs was strikingly low in Madhya Pradesh, Tamil Nadu, Haryana and Punjab where the respondents refused when asked if they were dealing with abortion drugs. On an average, chemists were selling these drugs for six years. State-wise variation was observed. On an average, chemists were selling these drugs since the last two years in Haryana, three years in Madhya Pradesh, four years in Punjab, five years in Tamil Nadu, six years in Assam and eight years in Delhi.



Among those who were not selling the drugs, 13% revealed that they used to at some point, but stopped stocking them eventually. In Tamil Nadu, one-fourth of all respondents who were not stocking these drugs at the time of the survey mentioned that they used to earlier.

		-					
States	Assam	Delhi	Haryana	MP	Punjab	TN	
Ever stocked these drugs*	n=76	n=165	n=196	n=187	n=198	n=196	
Yes	5.3	10.3	8.7	7.0	15.7	25.5	
Reasons for not stocking MA drugs [#]	n=76	n=165	n=196	n=187	n=198	n=196	
Legal issues/barriers	5.3	24.8	62.8	40.1	74.2	78.6	
Not in demand	73.7	60.0	17.3	30.5	16.7	17.9	
Too much of paperwork/ documentation requirements	15.8	38.2	16.3	43.9	12.1	2.0	
Likely to invite trouble from drug inspectors	2.6	10.9	10.2	19.3	11.1	4.1	
Harmful for women's health	36.8	6.1	0.5	0.5	0.5	0.0	
Others	21.1	7.9	6.6	4.3	0.0	0.0	
*n=Chemists who currently do not stock medical abortion drugs							
[#] Total percentages may add to more than 100.0 because multiple reasons were accepted							

Table 4: Reasons stated	by chemists for not stocking	MA Drugs	(in %)
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Chart 3: Reasons for not stocking MA Drugs (in %) (N=1018)



Across the six states, chemists who were not stocking MA drugs (n=1018) were asked about the reasons for not stocking and multiple responses were accepted.

- **53%** Reported legal/regulatory issues as a common reason.
- 31% Reported not stocking due to low demand.
- 21% Cited too much paperwork/documentation requirements.
- 19% of respondents in MP reported that drug inspectors trouble chemists who stock and sell MA drugs.
- **37%** of respondents in Assam shared that they do not stock as the drugs are harmful for women.
- **79%** of respondents in Tamil Nadu, who had stopped stocking shared that the state government has banned these drugs.

Overall, it can be concluded that 79% chemists no longer stock MA drugs to avoid legal issues and documentation work.

Among chemists reporting excessive documentation requirements, 88% explained that they have to keep a copy of the doctor's prescription and 79% reported that they have to maintain separate registers for MA drugs, wherein they record the name of doctors as well as that of the clients with their contact details or a photocopy of any government ID if the client is not willing to share their contact details. 84% of chemists who reported that stocking MA drugs could invite trouble from drug inspector shared that the drug inspector could impose a fine, 82% mentioned that their license could be cancelled.

3.3. Price at which the Drugs are sold (N=282)

32% of all chemists selling MA drugs reported offering a discount on the maximum retail price (MRP) to the clients while 44.7% reported selling the drugs on MRP. 23.4% reported selling some on MRP and some on discount. Average discount provided by the chemists was 10%. Most commonly stocked brand as reported by 73% chemists was Mankind Unwanted Kit which is priced at INR 385.89.

States	Assam	Delhi	Haryana	MP	Punjab	TN	Total
	n=174	n=85	n=4*	n=13*	n=2*	n=4*	n=282
Mankind Unwanted Kit	64.9	84.7	4	12	1	4	73.0
Aristo Mifty Kit	51.1	28.2	0	0	0	0	40.1
Cadila Mifegest Kit	41.4	14.1	0	1	2	0	30.9
*in number as n is less than 30							

Table 5: Major brands of MA Drugs stocked

3.4. Stocking and Sales (N=282)

On an average, four MTP kits/MA Combi-packs are sold by the chemists per month. State-wise, in Assam, three units were sold in the month preceding the survey while in Delhi, four units were sold during the same time period. On an average seven units of MA drugs were kept in stock at a time by the chemists. Almost all chemists store these drugs on the shelf (in open/room temperature).

3.4.1. Supply of the Drugs (N=282)

In Assam, almost all chemists get the supply of MA drugs from the wholesalers, while in Delhi, 54% and 48% chemists get MA drugs from company stockists and wholesalers respectively.

99% chemists across all states reported that they always get invoice/bill from wholesaler/stockist when MA drugs are delivered to them.

3.5. Client Purchasing Pattern (N=282)

Questions on client purchasing pattern were asked to understand the role of prescriptions and the gender distribution of clients coming to buy MA drugs from the chemists.

3.5.1. Who visits to buy - Woman or Partner?

Except for Assam and Delhi, other study states had very few chemists stocking and selling MA drugs so their findings are not discussed below.





In Assam and Delhi, on an average, of the last 10 clients for MA drugs, six were men and four were women.

3.5.2. Role of prescription in MA Drugs sales

Chemists were asked about the proportion of clients who came with a prescription, out of the last 10 who requested for MA drugs. Out of 2820 clients, 77% of clients came with a prescription while 33% came without a prescription. 84% and 71% clients in Delhi and Assam respectively came with a prescription to purchase MA drugs. 246 out of 282 chemists reported that five or more out of the last 10 clients came with a prescription.



Chemists who reported at least one client coming without prescription out of the last 10 MA clients, (n=168), were requested to explain how they were asked about MA drugs. Six out of 10 chemists mentioned that clients without prescription would ask for details about the different brands of MA drugs. Remaining chemists shared that the clients without prescription would simply seek advice on drugs that can be taken to terminate a pregnancy. Chemists seeing clients come without a prescription were asked about what they'd do in such situations. 46% shared that they would provide the drugs while 36% mentioned that they would ask the client to come back with a prescription.

3.5.3. How far do Clients come from?

The average distance travelled by clients (who came to buy MA drugs) to reach the pharmacy in Assam, Haryana and MP was 3 km each while in Delhi and Punjab, chemists had clients come from up to 6 km distance. In Tamil Nadu, the average distance travelled by the clients was 4 km.

3.6. Interaction between the Chemist and the Client (N=282)

3.6.1. Questions asked by Chemists

Almost all respondents (95%) reported that they ask some questions to the clients before selling MA drugs. The most commonly sought information by the chemist was on:



In Assam, 28% of chemists reportedly enquire about the age of the pregnant woman and 26% enquire about her marital status. Other responses included last use of contraception, number of living children and place of residence.

States	Assam	Delhi	Haryana	MP	Punjab	TN	Total
Information sought by Chemists [#]	n=174	n=74	n=3*	n=12*	n=1*	n=4*	n=268
Doctor's prescription	90.2	71.6	3	12	1	4	85.8
Duration of pregnancy/ gestational period	85.1	40.5	1	2	0	3	68.7
Last menstrual period	70.7	27.0	2	1	0	2	55.2
Age of pregnant woman	28.2	14.9	2	1	1	2	24.6
Marital status	26.4	6.8	0	2	0	1	20.1
Last use of contraception	8.0	12.2	0	1	0	0	9.0
Number of living children	8.0	10.8	0	1	0	0	8.6
Place of residence	10.9	4.1	0	0	0	0	8.2
Photo ID of client	5.2	0.0	0	0	0	0	3.4
n=Chemists who stock MA drugs *in number because n is less than 30 #Total percentages may add to more than 100.0 because multiple answers were allowed							

Table 6: Questions asked by the chemists while selling MA Drugs (in %)

3.6.2. Questions asked by Clients to the Chemists

96.5% of respondents reported that clients (women/partners) ask questions while purchasing MA drugs like:

Sequence of use of the drugs 89.3%

Routes of administration 64.3%

Side effects 44.1%

A notable number of respondents (32%) also reported that the clients ask about the signs of complications.

States	Assam	Delhi	Haryana	MP	Punjab	TN	Total
Information sought by Clients [#]	n=173	n=80	n=3*	n=11*	n=2*	n=3*	n=272
How to take MA drugs (dosage and when to take)	93.1	78.8	3	11	2	3	89.3
Routes of administration	60.1	66.3	3	10	2	3	64.3
Expected side effects	38.2	56.3	3	4	1	1	44.1
Signs of possible complications	34.1	25.0	1	6	0	0	31.6
How to know if the process is complete	6.9	15.0	2	3	0	2	11.4
n=Chemists who stock MA drugs *in number because n is less than 30 [#] Total percentages may add to more than 100.0 because multiple answers were allowed							

Table 7: Questions asked by the client during purchase of MA Drugs (in %)

3.6.3. Advice given by the Chemists

Sequence of Drugs use:

Three-fourths of all respondents advised the clients correctly on how to take the drugs (day one Mifepristone followed by Misoprostol after 24-48 hours). In Assam, almost all chemists (98%) advised correctly. In Delhi, less than half of all respondents had correct knowledge. Around 14% of all chemists shared that they ask clients to speak to the doctor while 4% reported that they do not give any advice to clients on the sequence of taking the drugs.

States	Assam	Delhi	Haryana	MP	Punjab	TN	Total
Advice on sequence of drugs use	n=174	n=85	n=4*	n=13*	n=2*	n=4*	n=282
Mifepristone followed by Misoprostol after 24-48 hours	97.7	47.1	0	0	1	2	75.5
Both Mifepristone and Misoprostol together	0.6	1.2	0	0	0	0	0.7
Mifepristone in the morning, Misoprostol at night	0.0	21.2	0	0	0	0	6.4
I tell them to speak to a doctor	1.7	22.4	2	11	1	2	13.5
I don't give them any advice	0.0	8.2	2	2	0	0	3.9
n=Chemists who stock MA drugs *in number because n is less than 30							

Table 8: Advice to clients by chemists on sequence of Drugs use (in %)

Routes of Administration (N=282):

Chemists were asked about the route of administering MA drugs. Most (94%) of the chemists spontaneously mentioned that such drugs should be administered orally, 39% responded sublingual and 16% responded buccal.

States	Assam	Delhi	Haryana	MP	Punjab	TN	Total
Routes of Administration [#]	n=174	n=85	n=4*	n=13*	n=2*	n=4*	n=282
Oral	97.1	90.6	1	12	2	4	94.0
Sublingual	40.8	36.5	4	3	0	0	38.7
Buccal	3.4	41.2	3	2	0	0	16.3
Vaginal	0.0	7.1	1	1	0	0	2.8
Don't Know/Can't Say	0.0	1.2	0	0	0	0	0.4
#Total percentages may add to more than 100.0 because multiple answers were allowed n=Chemists who were stocking MA drugs *in numbers where n is less than 30							

Table 9: Chemists' knowledge on routes of administration (in %)

What to expect during the MA Process:

In Assam, nearly half of the chemists reported that they tell clients that bleeding is part of the process. In Delhi, 53% chemists reported that they advise clients to speak to a doctor to understand the process of medical abortion and what to expect. Few respondents (14.5%) across all states also shared that they tell clients about the side effects of MA drugs such as nausea, vomiting etc.

Fable 10: Advice to clients by chemis	ts on what to expect durir	ig the MA process (in %)
---------------------------------------	----------------------------	--------------------------

States	Assam	Delhi	Harvana	MP	Puniab	TN	Total
Advice on what to expect during the MA process	n=174	n=85	5 n=4* n=13*		n=2*	n=4*	n=282
Bleeding is a part of the process	49.4	29.4	1	3	0	0	40.8
There will be certain side effects such as nausea, vomiting	20.1	5.9	0	0	0	1	14.5
Cramping is part of the process and usually begins after taking Misoprostol	5.2	4.7	0	0	0	1	5.0
I tell them to speak to the doctor	25.3	52.9	3	10	2	1	37.2
I don't give them any advice	0.0	7.1	0	0	0	1	2.5
n=Chemists who stock MA dru *in number because n is less th	gs nan 30						

Completion of MA Process:

Chemists were asked about the advice they give to clients on how to determine the completion of the MA process. In Assam, nearly half of the respondents reported that they advise clients to check with a pregnancy kit while in other states, the majority of chemists reported advising the clients to speak to a doctor.

States	Assam	Delhi	Haryana	MP	Punjab	TN	Total
Advice on completion of MA process	n=174	174 n=85 n=4* n=13*		n=2* n=4*		n=282	
I tell them to check with a pregnancy test/give them a pregnancy kit	49.4	16.5	2	1	1	0	36.9
I tell them to get an ultrasound done	39.7	9.4	0	0	0	0	27.3
I tell them to speak to the doctor	10.9	71.8	2	11	1	4	34.8
I tell them that the bleeding will stop in a few days	0.0	2.4	0	1	0	0	1.1
n=Chemists who stock MA dr *in number because n is less	ugs than 30	-					

Table 11: Advice to clients by chemists on completion of the MA process (in %)

3.7. What would the Chemists do if a young unmarried woman asked for MA Drugs? (N=282)

To explore chemists' attitude on MA, those stocking the drugs were asked what they would do if a young unmarried woman visited them to purchase MA drugs.

Chemists who said they will provide MA drugs to the woman.



Chemists who said they will not give MA drugs to the woman.





Chemists across all states said they would refer the woman to a healthcare facility or a doctor.

Assam

30.5%

Chemists responded that they would ask the woman for a prescription.

Chart 6: What would you do if a young unmarried woman visits your pharmacy for MA Drugs? (N=282)



Table 12: What would you do if a young unmarried woman asks for MA Drugs?

States	Assam Delhi Haryana M		MP	Punjab	TN	Total				
Reasons for not providing MA drugs	n=144	n=82	n=4*	n=13*	n=1*	n=4*	n=248			
She does not have a prescription	81.3	80.5	4	12	1	4	82.3			
She looked very young	7.6	13.4	0	0	0	0	8.9			
She looked unmarried	11.1	6.1	0	1	0	0	8.9			
*in number because n is less than 30 n=Chemists who were stocking MA drugs										

All chemists other than those who said they would provide MA drugs were asked about the **reasons** for not dispensing the drugs to 'a young unmarried woman'.



Chemists reasoned that they won't sell to the woman if she comes without a prescription.

8.9%

would refuse to attend to her request if she is below 18 years of age.

Chemists said they

8.9%

Chemists explained that if the woman was unmarried, they would not sell her the drugs.

3.8. Client Experience

Chemists were asked whether the clients who purchase MA drugs come back and their reasons for returning.

3.8.1. Do Clients come back?

55% of the chemists who keep MA drugs mentioned that a few clients do come back after purchasing MA drugs. Around two-third chemists in Assam and 42% chemists in Delhi reported so. Less than two out of every 10 clients return to the pharmacy. Out of the last 2820 clients who visited the pharmacies, only 12% of clients came back.

3.8.2. Reasons why Clients come back and Chemist's advice

It appears that 93% of last 10 clients (2820), who purchased MA drugs from chemists had a positive outcome. Only 7% of the total clients came back because of issues with drugs. 28% of clients who returned, came for advice on post-abortion contraception, 15% visited to provide some feedback on the drugs. Of 199 who came back with issues with the drugs, 84% reported heavy bleeding and 56% reported continued pain. In a situation where clients came back with issues associated with the drugs, eight out of 10 chemists shared that they suggested clients to consult a doctor or visit a health facility, a third of the chemists reportedly gave assurance to the clients.

Issue with the drugs	199
To seek advice on post-abortion contraception	82
To provide feedback on drugs	52
Returned with relatives/friends to purchase the same drugs	29
Multiple responses were allowed	

Table 13: Reasons why clients return to the chemists (N=338)

3.9. Regulatory Issues (N=282)

To understand if chemists face any regulatory issues, they were asked about visits by drug inspectors to their pharmacies.



During visits, the inspector usually checks the bill book, stock registers, Schedule H register and expiry of medicines.





Visits by drug inspectors specifically for MA drugs were reported to be low in the study states. Only 5.7% chemists (16 out of 282) who were stocking MA drugs reported specific visits by drug inspectors. In Delhi, 12 out of 85 chemists (14.1%) reported so. During these specific visits, officials check the stock of MA drugs, stock register, purchase register and expiry date of the drugs. 15 out of 16 chemists shared that drug inspector sees documentation related to MA drugs. When asked about the types of documentation, copies of prescription were reported followed by name and contact details of the doctor who prescribed MA drugs.

While overall, 40% chemists (n=282) reported receiving any form of communication from the drug authorities on MA and its sale, in Delhi, it was 56.5%.



Chart 8: Chemists who received communication

Chart 9: Form of communication (N=112) (in %)



Majority of these chemists received verbal communication; only 7% received a written communication related to the sale of MA drugs. A large number of chemists in Delhi (71%) shared that they were advised to sell the drugs only on prescription. 31% of chemists in Assam were being told to keep women's details such as name, address, mobile number etc. before selling MA drugs.

Table 14: Content of communication received from drug controller/inspector (in %)

States	Assam	Delhi	Total
Content of Communication [#]	n=58	n=48	n=112
MA drugs can be sold only on prescription	17.2	70.8	43.8
Keep a copy of doctor's prescription	12.1	35.4	26.8
Keep women's details such as name, address, mobile number	31.0	22.9	25.9
Maintain all registers of MA drugs	25.9	2.1	14.3
Provide abortion drugs to women up to 7 weeks of pregnancy	22.4	4.2	13.4
n=Chemists who received communication * in number because n is less than 30	from drugs inspe	ector	were allowed

I otal percentages may add to more than 100.0 because multiple answers were allowed Total contain all chemists who received communication from drug controller/inspector

3.10. Awareness on Abortion and MA Drugs (N=1300)

3.10.1. Legality of Abortion in India

Chemists were asked about the legality of abortion in India. Those who said abortion is legal were further asked whether all pregnant women can avail abortion service or abortion can be done only under certain circumstances. Their responses were captured under three categories, 'legal', 'legal under certain conditions' and 'not legal'.



Chart 10: Chemists' awareness on legality of abortion in India (in %)

79% of chemists reported that abortion is legal in India under certain circumstances. 21% of chemists across all the six states stated that abortion is not legal in the country. In Delhi, 72% of chemists stated abortion is permitted for certain conditions, while 15.6% responded that abortion is not allowed at all. Awareness level amongst those stocking and those not stocking did not vary much. 63.5% chemists stocking MA drugs said abortion is legal under certain conditions, while 61.6% of chemists not stocking these drugs reported so.

3.10.2. Gestational Limit of Abortion (N=1025)

Except those who said abortion is illegal, others were further asked about the gestational limit for abortion. Half of the chemists responded accurately (20 weeks), while about 20% reported that abortion can be done only until 12 weeks gestation. Among chemists stocking MA drugs (n=249), 72.3% responded 20 weeks, 14.9% mentioned 24 weeks, 6.4% reported 12 weeks and 4.0% did not know the gestational limit for abortion. In comparison, 42.8% chemists not stocking the drugs (n=776) correctly responded as '20 weeks'.



3.10.3. Gestational Limit for MA Combi-pack (N=1025)

Respondents who knew that abortion is legal were asked about the gestational limit for MA Combi-pack. 42.7% of all respondents answered nine weeks, while an equal number of chemists responded seven weeks as the gestational limit for medical abortion. Amongst respondents keeping MA drugs, 49% responded nine weeks, while 40.7% chemists not stocking MA drugs gave the same response.



Chart 13: Chemists who were aware of the nine week gestational limit for MA Combi-pack (in %)

3.10.4. Who can prescribe MA Drugs? (N=1109)

85% of chemists believe that abortion drugs are legal in India. Among these:



Reported that MA drugs can be prescribed by Ob/Gyn.



Mentioned that it can be prescribed by MTP certified general physicians.

In Assam, 6.5% reported that chemists/pharmacists can prescribe these drugs. According to 16.8% chemists in Punjab, ANMs/trained midwives are also authorised to prescribe drugs for medical abortion.

States	Assam	Delhi	Haryana	MP	Punjab	TN	Total
MA drugs can be prescribed by [#]	n=216	n=200	n=172	n=184	n=155	n=182	n=1109
Ob/Gyn	99.5	97.5	99.4	98.9	98.1	98.4	98.6
General Physician	65.3	17.0	5.8	4.3	76.1	7.1	29.2
MTP Certified General Physician	13.0	32.5	21.5	21.2	9.7	7.1	17.8
ANM/Trained midwife	1.9	4.5	0.6	6.5	16.8	1.1	4.9
Chemist/Pharmacist	6.5	1.0	1.2	0.0	0.0	0.0	1.6
ASHA	3.2	1.0	0.0	0.0	1.9	0.0	1.1
*Total percentages may add to n is number of chemists who the	more than	100.0 bed n drugs a	cause multiple re legal in Ind	e answers ia	were allowe	ed	

Table 15	5: Who	can	prescribe	MA	Drugs?	(in	%)
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3.10.5. Side effects and complications of MA Drugs (N=282)

Heavy vaginal bleeding, which is a part of the medical abortion process, was identified as a side effect of MA drugs across all six study states.



Chemists reported bleeding.



Chemists reported nausea/ vomiting/diarrhoea.



Chemists reported dizziness/fatigue.

States	Assam	Delhi	Haryana	MP	Punjab	TN	Total			
Side effects of MA drugs [#]	n=174	n=85	n=4*	n=13*	n=2*	n=4*	n=282			
Bleeding	94.3	94.3 81.2 4		11	0	3	89.0			
Nausea/Vomiting/ Diarrhoea	63.8	62.4	4	11	1	2	64.5			
Dizziness/Fatigue	23.0	31.8	2	9	1	2	28.7			
Feeling of warmth and chills	12.6	31.8	1	8	1	0	20.9			
Headache	15.5	29.4	0	1	1	1	19.5			
Others (abdominal pain, low blood pressure, weakness etc.)	17.2	3.5	0	0	0	0	11.7			
Don't know/Can't say	0	0	0	1	0	1	0.7			
[#] Total percentages may add to more than 100.0 because multiple answers were allowed n=Chemists who were stocking MA drugs *in numbers where n is less than 30										

Table 16: Side effects of MA Drugs (in %)

Chemists were also asked about the possible complication(s) of MA drugs. Seven out of every 10 respondents mentioned that 'heavy bleeding' is a complication which women can face after taking abortion drugs. 58% of chemists reported incomplete abortion as a complication in Assam. In Delhi, 56.5% reported persistent pain as a possible complication.

States	Assam Delhi Haryana MP			Punjab	TN	Total					
Possible complications of MA drugs [#]	n=174	n=85	n=4*	n=13*	n=2*	n=4*	n=282				
Heavy bleeding	61.5	84.7	4	11	1	1	69.5				
Incomplete abortion	58.0	18.8	2	1	0	0	42.6				
Persistent pain	29.3	56.5	2	4	1	2	38.3				
Don't know/Can't say	0.0	4.7	0	2	1	1	2.8				
"Total percentages may add to n=Chemists who were stockir *in numbers where n is less th	*Total percentages may add to more than 100.0 because multiple answers were allowed n=Chemists who were stocking MA drugs *in numbers where n is less than 30										

Table 17: Possible Complications due to use of MA Drugs (in %)

Chemists who reported heavy bleeding as one of the complications were asked to define heavy bleeding. The majority (74%) of them mentioned that excessive and continued bleeding for long is heavy bleeding. Soaking of more than two sanitary pads in an hour (13.3%) or changing cloth frequently (12.8%) were also reported within the scope of heavy bleeding by some.

3.10.6. Difference between MA Drugs and Emergency Contraceptive Pills (N=1300)

Almost all retailers (98%) differentiated between MA drugs and Emergency Contraceptive Pills (ECP). They mentioned that ECP is taken to avoid conceiving while MA drugs are taken to terminate pregnancy/after conceiving.

Chart 14: Perceived benefits of MA over Surgical method (in %) (N=267)



3.11. Perceived benefits of MA Drugs over Surgical Abortion (N=282)

Chemists, who were stocking MA drugs, were asked about the perceived benefits of medical abortion over the surgical method. 5% of the respondents did not consider medical abortion better than surgical method. Among those who consider it beneficial (n=267), 84% reported that MA is an easy method and 67.8% opined that abortion through MA drugs is less costly. Other top benefits of MA as cited by the chemists included 'saves time' (41.6%), natural method (38.2%) and 'ensures privacy' (38.2%).

3.12. Effectiveness of MA Drugs (N=282)

Percentage of chemists who reported MA drugs are:



Table 18: Effectiveness of MA Drugs (in %)

States	Assam	Delhi	Haryana	MP	Punjab	TN
Effectiveness of MA drugs	n=174	n=85	n=4*	n=13*	n=2*	n=4*
Very effective	39.7	56.5	3	11	2	1
Sometimes effective	51.1	43.5	1	2	0	3
Rarely effective	7.5	0	0	0	0	0
Not effective	1.7	0	0	0	0	0
n=Chemists who we *in numbers where n	re stockir is less th	ig MA d nan 30	rugs			



Chart 15: Effectiveness of MA Drugs (N=282)



3.13. Information on MA Drugs (N=282)

Most of the chemists (90%) shared that they get information on MA drugs from medical representatives, (63.8%) wholesaler/stockist and (54.3%) medical officer/doctor. In Delhi, 31.8% and 28.2% of respondents identified internet and training/workshop/seminar/meeting as sources of information on MA respectively. In Assam, 20% of chemists reported that they received information from other medical shops/chemists. 5.7% of all chemists reported being informed by NGO workers.

States	Assam	Delhi	Haryana	MP	Punjab	TN	Total					
Information source for MA drugs [#]	or n=174 n=		n=4*	n=13*	n=2*	n=4*	n=282					
Medical Representative	96.0	81.2	4	12	1	2	90.4					
Wholesaler/Stockist	66.7	52.9	4	12	2	1	63.8					
Medical Officer/Doctor	63.2	42.4	1	2	0	4	54.3					
Internet	19.5	31.8	3	3	0	1	24.1					
Other medical shops/ Chemists	20.1	18.8	0	7	0	1	20.9					
Training/Workshop/ Seminar/Meeting	9.2	28.2	0	0	0	0	14.2					
Brochure/Booklets	5.7	25.9	3	3	0	0	13.5					
NGO workers	2.3	11.8	0	2	0	0	5.7					
Television	0.6	7.1	1	0	0	0	2.8					
n=Chemists who stock MA dro *in number because n is less [#] Total percentages may add to	n=Chemists who stock MA drugs *in number because n is less than 30 #Total percentages may add to more than 100.0 because multiple answers were allowed											

Table 19: Information source for MA Drugs (in %)

3.14. Training of Chemists (N=45)

The proportion of chemists (stocking MA drugs) who reported having undergone training or participating in a meeting/workshop on MA was only 16%. 32% in Delhi and 9% chemists in Assam attended training/workshop/meeting on MA drugs. 32 chemists out of 45 who attended training/ workshop/seminar/meeting shared that it was organised by a pharmaceutical firm/company. While in Delhi, 12 out of 27 chemists mentioned that training/workshop/seminar/meeting was organised by the drug control authority.

3.15. Perception/Attitude on MA (N=1300)

3.15.1. Usefulness of MA for Women

51.5% chemists stated that MA is not useful for women as opposed to 46.2% who considered it to be useful. 72.3% chemists dispensing MA drugs were of the opinion that MA is useful for women as opposed to 38.9% chemists who were not stocking MA drugs at the time of the survey. 88% and 63% chemists stocking MA drugs in Delhi and Assam respectively reported that MA drugs to be useful for women.

3.15.2. Impact on number of Abortions

65% of chemists responded that MA drugs have increased the number of abortions. More chemists hold such a perception in Punjab, Delhi and Tamil Nadu as compared to other states. 80% and 66% chemists not stocking MA drugs in Punjab and Madhya Pradesh respectively had the perception that the availability of MA drugs has increased the total number of abortions in the country.

3.15.3. Usage of MA for Gender-Biased Sex-Selection

84.3% chemists reported that MA cannot be used for gender-biased sex-selection as opposed to 9.8% who stated that it can be used for this purpose. 5.9% across all states did not know the answer. 14% of all chemists stocking MA drugs in Assam reported that MA could be used for sex-selective termination of pregnancy.

	Ass	am	Del	hi	Harya	ana	Madh Prade	iya esh	Pun	jab	Tamil I	ladu	Tot	al
Statement	Not Stocking MA drugs (n=76)	Stocking MA drugs (n=174)	Not Stocking MA drugs (n=165)	Stocking MA drugs (n=85)	Not Stocking MA drugs (n=196)	Stocking MA drugs (n=4*)	Not Stocking MA drugs (n=187)	Stocking MA drugs (n=13*)	Not Stocking MA drugs (n=198)	Stocking MA drugs (n=2*)	Not Stocking MA drugs (n=196)	Stocking MA drugs (n=4*)	Not Stocking MA drugs (n=1018)	Stocking MA drugs (n=282)
MA drugs are useful for women	47.4	63.2	40.6	88.2	26.5	4	46.5	12	29.8	0	48.5	3	38.9	72.3
Availability of MA drugs has increased number of abortions	44.7	54.0	62.4	87.1	52.0	2	65.8	7	79.8	2	73.5	2	64.2	65.2
MA drugs can be used for sex- selective termination of pregnancy	2.6	13.8	2.4	4.7	1.5	0	4.3	1	5.1	0	36.2	0	10.3	9.6
*in number as r	n is less t	han 30		-	-			-	-	-	-	-		-

Table 20: Attitude/Perception of chemists on MA Drugs (in %)

3.16. Perception on Overregulation of MA Drugs (N=1300)

3.16.1. Are MA Drugs Overregulated?

Around 55% of chemists reported that MA drugs are overregulated as compared to other Schedule H drugs. A vast majority of chemists (78%) in Punjab have this viewpoint as opposed to 40% in MP. The proportion of respondents in Tamil Nadu who reported MA is overregulated is also significantly high at 65%. An equal percentage of chemists among those who were stocking MA drugs (55%) and those not stocking (54.8%) stated that MA drugs are overregulated than other Schedule H drugs.

41% chemists who reported that MA drugs are overregulated as compared to other Schedule H drugs, considered maintenance of separate register for these drugs as a reason. 31% explained that they have to keep client's details such as ID, contact details etc. 18% reported requirement of keeping a photocopy of doctor's prescription as a reason as to why they find MA drugs to be overregulated.

3.16.2. Should MA Drugs be Overregulated?

On being asked if MA drugs should be overregulated, 42.1% chemists across the study states said 'yes'. The highest percentage of chemists who reported so were in Tamil Nadu (82%), followed by Assam (55%) and Punjab (52%). Comparatively, the percentage was much lower in MP with only 17.5% chemists in favour of overregulation. 39.4% chemists stocking MA drugs believe these drugs require overregulation, while 42.8% not stocking these drugs hold this view.

States		MA drugs are overregulated as compared to other Schedule H drugs	Overregulation is required for MA drugs	
Assam	Stocking MA drugs (n=174)	65.5	56.3	
ASSAIII	Not Stocking MA drugs (n=76)	42.1	51.3	
Dalhi	Stocking MA drugs (n=85)	40.0	9.4	
Deini	Not Stocking MA drugs (n=165)	48.5	26.7	
Homeono	Stocking MA drugs (n=4)*	0	0	
Παιγαπα	Not Stocking MA drugs (n=196)	44.4	28.6	
MD	Stocking MA drugs (n=13)*	1	0	
IVIF	Not Stocking MA drugs (n=187)	42.2	18.7	
Dunich	Stocking MA drugs (n=2)*	2	1	
Punjab	Not Stocking MA drugs (n=198)	77.8	52.0	
Tamil Nadu	Stocking MA drugs (n=4)*	4	4	
	Not Stocking MA drugs (n=196)	64.3	81.1	
Total	Stocking MA drugs (n=282)	55.0	39.4	
	Not Stocking MA drugs (n=1018)	54.8	42.8	
*in number because n is less than 30				

Table	21:	Regulation	of MA	Druas	(in	%)
Table	~	Regulation		Diuga	,	/0/

3.16.3. Why should MA Drugs be Overregulated? (N=547)

56.1% of chemists felt that overregulation of MA drugs would prevent misuse. 43% cited the need for overregulation so that women don't experience health complications.

	2			•	,	,	
States	Assam	Delhi	Haryana	MP	Punjab	TN	Total
Reasons why MA drugs should be overregulated [#]	n=137	n=52	n=56	n=35	n=104	n=163	n=547
To avoid misuse	23.4	36.5	75.0	34.3	64.4	82.8	56.1
To avoid health complications among the women	60.6	63.5	44.6	60.0	52.9	11.0	43.0
To decrease feticide rate	4.4	3.8	1.8	0.0	0.0	6.1	3.5
Clients do not have sufficient knowledge	6.6	5.8	0.0	11.4	0.0	0.0	2.9
Side effects of MA drugs can lead to death	6.6	0.0	1.8	0.0	0.0	0.0	1.8
To stop sex-selective abortion	0.7	3.8	5.4	0.0	0.0	0.6	1.3
Illegally sold	0.0	0.0	0.0	0.0	0.0	1.8	0.5
[#] Total percentages may add to more than 100.0 because multiple answers were allowed This was an open ended question							

Table 22: Why should MA Drugs be Overregulated? (in %)

Chapter 4 Findings from Mystery Shopping

In four of the six study states - Haryana, Punjab, Madhya Pradesh and Tamil Nadu, 20% of all chemists (n=10 per city) were approached by a mystery client without a doctor's prescription. Findings of mystery shopping are discussed in this chapter.

Mystery shopping approach: Prior to the visits to chemists, in each state, two investigators were trained as mystery shoppers/clients and made familiar with various scenarios that may arise while interacting with the chemist. Written scripts about how to interact with two possible categories of chemists i.e., those who sell MA drugs and those who don't sell MA drugs, were shared with the team members. All possible questions that could be asked in each scenario were explained extensively to the team members as well as how to adapt the discussion with the chemists depending upon their responses. Interaction with chemists was not audio or video recorded but was documented immediately after leaving the chemist shop, at a place, where the investigator could not be seen by the chemist who was visited. Chemists in localities having different socio-economic categories of population were visited within the city. It was ensured that the same chemist is not revisited with the request for administering the chemist survey schedule.

4.1. Stocking of Abortion Drugs

In each state, mystery shoppers/clients approached 50 chemists and asked for MA drugs. Except for MP and to an extent Punjab, results of mystery shopping are consistent with the survey results.

Chemists reported stocking MA drugs:



Table 23: State-wise stocking of MA Drugs by chemists

States	Stock MA drugs	Does not stock MA drugs		
Haryana (n=50)	0 (0.0%)	50 (100.0%)		
Madhya Pradesh (n=50)	28 (56.0%)	22 (44.0%)		
Punjab (n=50)	11 (22.0%)	39 (78.0%)		
Tamil Nadu (n=50)	4 (8.0%)	46 (92.0%)		
Total (n=200)	43 (21.5%)	157 (78.5%)		

4.2. Additional Findings

4.2.1. Reasons for not stocking

Majority of chemists not stocking MA drugs reported legal barriers as the major reason for not stocking; such responses included government ban, frequent checks by the drug inspector and heavy documentation requirements. In Haryana, the majority of chemists reported the influence of 'Beti Bachao, Beti Padhao' as a reason for a government ban. In Madhya Pradesh, among 28 chemists stocking MA drugs, 11 clearly asked the mystery client to come back with a prescription.

4.2.2. Popular brands stocked

Some of the common brands being stocked across states include **Cadila Mifegest Kit, Aristo Mifty Kit** and **Mankind Unwanted Kit**. Other brands available with the chemists included **Khushi MTP Kit, Safe Abort, Insta Kit, Pregnot Kit** and **Termipil Kit**.

4.2.3. Questions asked by Chemists to the Mystery Client

Some of the common questions asked across states included:

✓ Age of pregnant woman ✓ Duration of pregnancy ✓ Last menstrual period ✓ Marital status

4.2.4. Advice given by Chemists

18 out of 32 chemists who did advise the mystery client on the sequence of taking drugs asked the client to take Mifepristone followed by Misoprostol after 24-48 hours. Among 43 chemists stocking MA drugs, 34 chemists advised the client to take the drugs orally. Some of the common side effects according to the chemists included bleeding, nausea/vomiting and diarrhoea. Common responses for complications included heavy bleeding and persistent pain.



Chapter 5 Conclusion and Implications

Chapter 6 Recommendations



Chapter 5 Conclusion and Implications

This study sadly confirms the findings of the previous study that MA drugs are disappearing from the shelves of chemists. In four of the six states, the stocking of MA drugs is negligible and in Delhi, it is a low 34%. Assam is the only state in the study that shows good availability of MA drugs at chemists. Combining findings from the two studies of the ten states studied so far, MA drugs are not being stocked in six states of Haryana, Madhya Pradesh, Rajasthan, Maharashtra, Tamil Nadu and Punjab.

The approval of MA drugs in the country and launch of Combi-pack MA drugs have substantially changed the abortion care landscape for the better in India. Women in large numbers seem to have found MA drugs effective, affordable and convenient in terminating pregnancies since MA allows them some control over the process, ensures confidentiality, respects privacy and chemists may be less or completely non-judgmental compared to staff in a health facility. Given that MA is an overwhelmingly preferred method; it is safe to assume that unsafe abortion's contribution to maternal deaths would have fallen significantly. This study's findings raise many issues some of which are discussed below:

1. Reversal of Gains

The 2015 Guttmacher Institute's Abortion Incidence study, estimated that 81% of all abortions in the country are provided using MA drugs, with 73% MA provided outside of the facility. The study estimated that only 5% of abortions are unsafe⁴. WHO classifies abortions as Safe (when provided by a qualified provider using recommended methods); Less safe (when provided by an unqualified provider by using a recommended method) and Least safe/Unsafe (when provided by an unqualified provider using methods that are not recommended).⁵ The reduction in unsafe abortions in the country can be directly attributed to the availability of MA drugs. If access to MA drugs is compromised, as our study shows, the gains made in reducing unsafe abortions will be lost and women may be forced to resort to unsafe methods. This is likely to adversely impact the gains in maternal mortality and morbidity made over the past couple of decades.

2. Reduced Access and Choice

MA drugs can be provided by a doctor in his/her consulting room with the drugs procured from a nearby chemist. If access to MA drugs is compromised, women would be forced to seek a surgical abortion from a facility, reducing choice. Access to safe abortion will also reduce since there are only 16,296 approved abortion facilities⁶ in the private sector in the country, whereas MA can be provided by all Ob/Gyns and approved MTP providers in their clinics/consulting rooms, which is estimated to be 60,000-70,000⁷. This reduction in access and choice may force many women to seek abortion services from unsafe providers.

3. Increased Cost of Safe Abortion

Availability of MA drugs has resulted in reduction in the cost of early abortion since the method does not require a clinical set-up. It can be prescribed by a provider in his/her consulting room. The cost of the MA drugs and consultation fee is much lower than surgical abortion since the MA Combi-pack drugs prices are fixed by the national pharmaceutical pricing authority. Cost of first-trimester surgical abortion varies from INR 2,000-5000 in tier 2-3 towns and smaller nursing homes/clinics, depending on the gestation. In these towns, cost of MA drugs plus the consultation fee is in the range of INR 700-1000. If MA drugs are not accessible easily, the only choice would be a surgical abortion. Many facilities/providers have started insisting on a COVID-19 test, before providing any clinical services and that would further increase the cost of a safe abortion.

4. Role of Prescription

Generally, it is assumed that many drugs in India are easily available from chemists without a prescription. This assumption is also attributed to MA drugs. The study findings indicate that chemists reported that 77% of their clients came with a prescription. Therefore, the assumption that women easily access MA drugs from chemists without prescription and hence endanger their health seems to be incorrect. Women are making informed choices and consulting their health care providers before seeking a medical abortion.

5. MA Outcomes Positive for Most Women

There is a general perception that medically unsupervised use of MA is resulting in higher level of complications and hence restrictions are required on MA drugs. The findings of this study show this perception is not correct. Chemists report that 77% of their clients came with a prescription; hence they did have medical advice. Chemists also reported that only 12% of clients came back to them for further advice. 28% of those who came back, came for advice on contraception, 8.57% brought their friends/ relatives for MA while 15% returned to provide feedback on the drugs.

58.8% of those who returned (which works out to 7% of all clients) had some issues with the MA drugs. The main issues were related to prolonged bleeding, heavy bleeding or pain. In such cases, the chemists advised their clients to seek assistance from a doctor. Prima facie, it appears that for an overwhelming majority of MA users (as high as 93%) the MA drugs has resulted in a positive outcome. Even those who had returned with issues with the drug did not seem to have any major/life-threatening complications and received the right advice from chemist to see a doctor. The understanding that easy availability of MA drugs is resulting in higher complications, seems to be more of a perception than reality. Also given that most abortions in the country are performed using MA drugs, it would be obvious that the contribution of MA to the number of abortion complications, presented at facilities would be high. A larger and rigorous facility-based study may help clarify this issue further. Anecdotal information from providers indicates that they see very little life-threatening complications and perforations which they used to see in the 1990s and early 2000.

6. MA and Gender-Biased Sex-Selection

One of the main reasons why MA drugs are being overregulated/unnecessary barriers are being imposed on its distribution and sales, is the perception that MA drugs can be used for gender-biased sex-selection. MA Combi-pack is approved for use only up to nine weeks gestation. The most affordable and commonly used method to detect the sex of the fetus is Ultra Sonography (USG) (commonly known as ultrasound). USG is able to identify the fetus only at 13-14 weeks gestation. Therefore, the possibility of MA Combi-pack being used for gender-biased sex-selection is unfounded and needs to be dispelled. Also, estimates indicate that an overwhelming majority of abortions in the country (as high as 97.3%) are for indications permitted in the Medical Termination of Pregnancy Act⁸.

7. Awareness and Knowledge of Abortion Issues

Chemists' awareness of abortions is quite good. 78% are aware that abortion is legal; 98% could differentiate between Emergency Contraceptive Pills and MA drugs; 75.5% know the two drugs and the sequence in which it needs to be taken and 84.3% believe that Combi-pack cannot be used for genderbiased sex-selection. However, their knowledge about routes of administration (sublingual and buccal) is limited. 65% believe the availability of MA drugs has increased abortions and the drugs need to be regulated in the interest of women's health.

Chapter 6 Recommendations

The contribution of unsafe abortions to maternal deaths in India has declined to 8% in 2003⁹ from a high of 13% in 1995¹⁰, due to various proactive steps taken by the Government of India. This decline does not cover the impact of MA, since MA was approved only in 2002 and Combi-pack became available only from 2008 onwards. The latest estimates we have of the contribution of unsafe abortions to maternal deaths precede MA and MA Combi-pack. Given MA is an overwhelmingly preferred method, it is safe to assume that unsafe abortions' contribution to maternal deaths would have fallen significantly.

The study clearly shows that MA drugs have come under greater scrutiny in the past 3-4 years by drug control authorities resulting in their non-availability in chemist shops in four of the six states studied. If proactive measures are not taken, the gains made in improving access to comprehensive abortion care over the past two decades will be lost. Specific recommendations that policymakers particularly, Ministry of Health and Family Welfare could consider are as follows:

1. Address misconception regarding MA and Gender-Biased Sex-Selection

The primary reason for greater scrutiny of MA drugs by drug regulatory authorities is the misconception that MA drugs are being misused for sex-selection. MA Combi-pack is effective and indicated for use up to nine weeks gestation. Ultrasound can detect the sex of the fetus only in early second trimester around 13-14 weeks gestation. Studies have estimated that a vast majority of all abortions in India are in the first trimester¹¹. The following should be considered:

- a. The Drug Controller General of India (DCGI) could send an advisory/guidance to all State Drug Controllers clarifying that MA drugs in Combi-pack are indicated for use up to nine weeks gestation and therefore putting unnecessary barriers in distribution, stocking and sale of MA drugs will in no way address the issue of gender-biased sex-selection. On the contrary, it would force women who need abortions to turn to illegal providers risking their health and lives.
- b. MA drugs fall under Schedule H of the Drugs and Cosmetics Act Rules and they should be held to the same standards/scrutiny that state drug regulatory authorities hold for other Schedule H drugs. MA drugs should not be singled out or held to a higher standard.
- c. DCGI/MoHFW in partnership with civil society organisations should develop guidance, briefs and information materials clarifying the issue and disseminate it to district level drug regulators such as drug inspectors.
- d. State drug regulatory authorities should be updated on provisions of MTP Act, Rules and Regulation that offers confidentiality so that any guidance from drug regulators is not in conflict with the MTP Act.
- e. The Government of India issued important guidelines for monitoring bodies, service providers and government officials to ensure access to safe abortion is not restricted in efforts to address the problem of sex-selection¹². The guidelines give point by point differences on the two acts relevant to each stakeholder group for effective implementation on the ground. The government should ensure proper and targeted dissemination of these guidelines as well as refresher training for implementing authorities.

2. Harmonise Central Drugs Standard Control Organisation approval/ requirements and MTP Act

The MTP Rules amended in 2003 says that MA drugs (Mifepristone and Misoprostol) can be used to terminate a pregnancy up to seven weeks gestation. The DCGI approval for Combi-pack in 2008 is for use up to nine weeks gestation. The MTP Rules need to be amended to eliminate this inconsistency.

The MTP Rules allow an approved provider to prescribe MA drugs at his/her clinic (explanation to section 5 of the MTP Rules 2003). Labelling guidelines issued by the Central Drugs Standards Control Organisation (CDSCO, DTAB-DCC Division) dated 9th August 2019 says "Warning: Product to be used only under the supervision of a service provider and in a medical facility as specified under the MTP Act 2002 and MTP Rules 2003". The MTP Rules 2003 does not state that the product should be used only in a medical facility. The Comprehensive Abortion Care: Training and Service Delivery Guidelines 2018, Ministry of Health and Family Welfare, Government of India¹³ states that Misoprostol can be used by a client at home at the discretion of the provider. This labelling guidance is being interpreted to say that MA drugs cannot be sold in retail. The CDSCO guidance contravenes the MTP Rules, which allows prescription of MA drugs, and hence should be withdrawn immediately.

Since WHO recommends the use of MA drugs combination up to 12 weeks, MoHFW/DCGI should consider increasing the gestational limit for MA drugs use up to 12 weeks. The Drugs and Cosmetics Act and Rules mandate that the chemists have to maintain a prescription register for Schedule H drugs containing details of the prescriber and the patient¹⁴. In practice, this register is not maintained for other Schedule H drugs, however, it is checked by drug inspectors for MA drugs. While maintaining the register is required and should be done by chemists, a selective inspection of one drug over the other impacts its access. Further, this rule also conflicts with the guarantee of privacy as per the MTP Regulations, and therefore, removal of this requirement for MA drugs should be considered.

3. Amend MTP Rules to allow MBBS Doctors to prescribe MA Drugs

As the law stands today, only doctors approved as abortion providers under the MTP Act can prescribe MA drugs. It is estimated that there are only 60,000-70,000 doctors¹⁵ who can prescribe MA drugs while there are over a million qualified allopathic doctors in the country who are allowed to prescribe a variety of allopathic drugs but cannot prescribe MA drugs¹⁶. Amending the MTP Rules to allow all MBBS doctors to undergo a short online/face to face course to prescribe MA drugs should be considered. This will increase the number of doctors who can prescribe MA drugs manifold in a short period and can potentially reduce the sale of MA drugs without prescription. It would also help in improving women's access to medical support and supervision while using MA drugs.

4. Consider classifying MA Combi-pack under Schedule K of the Drugs and Cosmetics Act

Scientific evidence over the past few years suggest that MA Combi-pack drugs if used as indicated, is a safe drug and is unlikely to have any adverse impact on the user. WHO recommends that MA drugs can be administered by non-physician health care workers like qualified nurses, midwives and practitioners of complementary medicine¹⁷. There are a number of countries both developed and developing, which allow non-physician health workers to provide a medical abortion. MA drugs have been included in the core list of WHO Essential Medicines list 2019¹⁸. The list also states that MA drugs can be used without medical supervision. In India, Auxiliary Nurse Midwives (ANMs) are allowed to use Misoprostol (one of the two drugs used for MA) during childbirth and Misoprostol is available at Health Sub-Centres in the public health system. There are a number of hormonal preparations like Oral Contraceptive Pills, Emergency Contraceptive Pills, which are classified under Schedule K. Given the robustness of the MA drugs and the fact that it is likely to be used only once or twice in women's reproductive life (of over three and a half decade), there is a strong case for making Combi-pack MA drugs a Schedule K/ over-the-counter product, to be sold only by chemists.

5. Increased investments in Safe Abortion Communication through IEC and Media Outreach

Given the low awareness of the legality of abortion, there is an immediate need to increase investment in communicating abortion issues through focused communication campaigns. Abortion does not get adequate coverage in state communication/ IEC budget compared to other issues including sex-selection. Media coverage of abortion issues, often in the context of sex-selection, tends to use language and visuals which stigmatise abortion resulting in increased confusion regarding its legality.

6. Providing support to women who access MA Drugs – Setting up toll-free helpline

The data from this study shows that only 33% of the sales of MA drugs are without prescription, which should not be alarming since most Schedule H drugs are easily available without a prescription. Given the poor knowledge about MA drugs, the MA process, gestational limits for MA, confusion about bleeding being a side effect etc., women accessing MA drugs may not be able to access correct information and support during the MA process. To provide support to women, setting up of a toll-free national helpline should be considered. This could be jointly funded by manufacturers/marketers of MA drugs and the MoHFW, Government of India. It should be mandatory for all MA Combi-pack drugs to prominently display the helpline number.

7. Emergency Contraceptive Pills in Tamil Nadu

For some unknown reason, ECPs classified as an over–the-counter drug by DCGI, is not being stocked by chemists in the state of Tamil Nadu, denying access to a safe and simple contraceptive to women and girls in the state. When ASHAs under the national family planning program are allowed to stock and distribute ECPs in the community, it does not make any sense not to allow pharmacies/chemists to stock ECP. 90% of chemists have an incorrect belief that ECP is a banned drug. There is an immediate need for the State Drug Control authorities to clarify the situation and ensure that this important drug is stocked by chemists and is easily available in the state. As a state, Tamil Nadu is highly dependent on sterilisations (94% of all acceptors of contraceptives adopting this method) and limited use of spacing methods¹⁹. In such a situation there is a greater need for ECPs to be easily accessible for women so that they don't end up with an unwanted pregnancy.

The availability of Combi-pack MA drugs has indeed changed the landscape of abortion care in India for the better. The consequence of improper use does not seem to result in an emergency or life-threatening situation and if women do perceive they are having a complication then they are being referred to/seek assistance from doctors or health facility. It is therefore essential that steps are taken immediately to remove unnecessary barriers that have been created in the distribution, stocking and sale of MA drugs to avoid millions of women being denied access to a safe, simple and effective method of terminating an unwanted pregnancy.

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⁷Improving Access to Safe Medical Abortions, Why expanding the Provider Base is essential

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