



Campaign for Gender Equality  
and Safe Abortion.



## **Availability of Medical Abortion Drugs in the Markets of Four Indian States, 2018**

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**A Pratigya Campaign for  
Gender Equality & Safe Abortion study**

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# About Pratigya Campaign for Gender Equality & Safe Abortion

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.

## The Campaign focuses on four thematic areas:

- a) Extending support to the providers to ensure they continue to provide abortion services
- b) Ensuring continued availability of Medical Abortion drugs in the markets and support to women using MA out of facility
- c) Understanding and engaging with the legal landscape, particularly the jurisprudence in abortion related cases
- d) Building strong alliances with organisations and individuals to sharpen the collective voice of the Campaign.

## In-text:

(Chandrashekar, Ananya and Kalpa)

## Bibliography:

Chandrashekar, VS; Vajpeyi, A. and Sharma, K. Availability Of Medical Abortion Drugs In The Markets Of Four Indian States, 2018. 2019, <http://www.pratigyacampaign.org/wp-content/uploads/2019/08/availability-of-medical-abortion-drugs-in-the-markets-of-four-indian-states-2018.pdf>

# Acknowledgements

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Lastly, we are immensely grateful to The David and Lucile Packard Foundation for entrusting us with advocacy efforts to advance women's rights and access to safe abortion in India.

**Sincerely,**

**VS Chandrashekar,**  
Foundation for Reproductive Health Services India

**Ananya Vajpeyi,**  
Foundation for Reproductive Health Services India

**Kalpa Sharma,**  
Centre for Media Studies

# Acronyms

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<b>ANM</b>	Auxiliary Nurse Midwife
<b>B. Pharmacy</b>	Bachelor of Pharmacy
<b>D. Pharmacy</b>	Diploma of Pharmacy
<b>CAC</b>	Comprehensive Abortion Care
<b>CDSCO</b>	Central Drugs Standard Control Organisation
<b>CEDAW</b>	Convention on the Elimination of all forms of Discrimination against women
<b>CMS</b>	Centre for Media Studies
<b>DCGI</b>	Drug Controller General of India
<b>FDA</b>	Food and Drug Administration
<b>ICPD</b>	International Conference on Population and Development
<b>IEC</b>	Information Education Communication
<b>MA</b>	Medical Abortion
<b>MBBS</b>	Bachelor of Medicine and Bachelor of Surgery
<b>MOHFW</b>	Ministry of Health and Family Welfare
<b>M. Pharmacy</b>	Master of Pharmacy
<b>MRP</b>	Maximum Retail Price
<b>MTP</b>	Medical Termination of Pregnancy
<b>Ob/Gyn</b>	Obstetrician/Gynaecologist
<b>PCPNDT</b>	Pre-Conception and Pre-Natal Diagnostics Techniques Act
<b>RMP</b>	Registered Medical Practitioner
<b>WHO</b>	World Health Organisation
<b>UP</b>	Uttar Pradesh

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# Chapter I

## Introduction



## 1.1 Background

Medical abortion (MA) has emerged as the preferred method of abortion care in India with an estimated 81% of the 15.6 million annual abortions being performed using MA drugs.<sup>i</sup> The Drug Controller General of India in 2002 approved the use of Mifepristone in combination with Misoprostol for early abortion. Since then, MA has emerged as a safe, effective and simpler option for women who may have otherwise faced barriers in accessing safe abortion care. In 2002, the Medical Termination of Pregnancy (MTP) Rules were amended to enable the provision of medical abortion up to seven weeks gestation, by a Registered Medical Practitioner (RMP), as defined by the MTP Act, provided s/he has referral access to a MTP approved health facility.<sup>ii</sup> The approval of combination pack (200 mg mifepristone and 800 mcg misoprostol) for medical termination of pregnancy up to nine weeks gestation, by the Central Drugs Standard Control Organisation (CDSCO) in 2008, dramatically changed the landscape for safe abortion in the country with a number of pharmaceutical companies launching MA combipacks.

While a large number of women are accessing MA from retail chemists, available information and literature indicate that chemists' knowledge on MA and its various aspects is quite poor. According to a study conducted in 2015 among chemists in Madhya Pradesh, only 31% of the respondents knew about the legal gestational limit for medical abortion and very few, in practice, advised the clients on the warning signs for complications.<sup>iii</sup> Another study found even lower levels of knowledge among chemists in Bihar and Jharkhand, wherein about 73% of the respondents were unable to identify the side effects associated with the drugs.<sup>iv</sup> The knowledge gap amongst chemists, evident from the available studies indicate that chemists could be passing inaccurate information on MA drugs to women and their partners seeking advice.<sup>v</sup>

Over the past few years, anecdotal evidence, news articles and studies have been pointing towards an increase in regulatory activity impacting the availability of MA drugs in the market. The decline in the child sex ratio from 927 in 2001 to 919 females per 1000 males in 2011 has resulted in stringent enforcement of the Pre Conception and Pre Natal Diagnostics Techniques Act (PCPNDT Act) coupled with focused campaigns to address gender biased sex selection in India. The implementation of the Act has been rigorous in states such as Rajasthan and Maharashtra, where a stark decline in the child sex ratio (909 to 888 and 913 to 894 respectively) has garnered media attention and government action to fight patriarchal mind-sets. The efforts to fight the menace of the declining sex ratio unfortunately have created barriers and roadblocks to women's access to abortion care.<sup>vi</sup> A common misunderstanding that all abortions are sex-selective along with a low level of awareness about the Medical Termination of Pregnancy Act (MTP Act) has resulted in unnecessary raids and crackdowns on provider sites and chemists' shops. Fear and apprehension of increased scrutiny from Food and Drug Administration officials has resulted in non-stocking of MA drugs, as the chemists do not want to face legal hurdles.<sup>vii</sup> There are also ground reports of drug authorities reportedly asking about client details and copy of prescriptions, which is a clear violation of the privacy of women guaranteed under the MTP Act.<sup>viii</sup> Public messaging and Information Education and Communication materials, too, have failed to make a distinction between the two issues, resulting in a misinterpretation of two mutually exclusive laws.<sup>ix</sup>

## 1.2 Study objectives

Pratigya Campaign for Gender Equality and Safe Abortion commissioned a study to understand the availability of MA drugs in the urban markets of four Indian states – Bihar, Maharashtra, Rajasthan and Uttar Pradesh. The study was conducted to 1) Assess the availability of MA drugs in the market and 2) Understand the awareness/knowledge levels and attitudes of the chemists stocking and selling MA drugs.

### Through this study, we aim to:

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

### The areas of enquiry include:

- Current availability of MA drugs
- Reasons for not dispensing MA drugs
- Awareness on abortion and MA drugs
- Information source on MA drugs
- Client experience and their purchasing pattern
- Regulatory issues
- Attitude on abortion and MA

## 1.3 Study methodology

The quantitative cross-sectional survey was conducted by Centre for Media Studies, among a sample of retail chemist outlets located in the markets of five cities in each of the states of Bihar, Maharashtra, Rajasthan and Uttar Pradesh. The study was conducted in five months from September 2018 – January 2019, including field work in the months September – November, 2018.

### 1.3.1 Study area

One-on-one interviews were conducted with retail chemists in their place of business. Table 1 gives the list of the 20 cities where the study was carried out.

**Table 1: States and cities covered under the study**

States	Cities covered
Bihar	Bhagalpur, Darbhanga, Gaya, Muzaffarpur, Patna,
Maharashtra	Aurangabad, Mumbai, Nagpur, Pune, Solapur
Rajasthan	Ajmer, Bikaner, Jaipur, Jodhpur, Kota,
Uttar Pradesh	Agra, Ghaziabad, Kanpur, Lucknow, Varanasi

### 1.3.2 Sample size

Interviews were conducted with retail chemists spread across the municipal corporation area of the city. To capture the variation in responses, representation of retail chemists from low, middle and upper income localities was ensured. In all, 1008 retail chemists were covered in the sample. From each city, 50-52 retail chemists were interviewed. In addition, 42 stockists/wholesalers were also spoken to for their perspective on sale of abortion drugs.

State wise sample distribution is shown in Table 2 below.

Table 2: State wise sample distribution			
State	City	Sample Covered	
		Retail chemists	Total retail chemists
Bihar	Bhagalpur	50	251
	Darbhanga	50	
	Gaya	51	
	Muzaffarpur	50	
	Patna	50	
Maharashtra	Aurangabad	50	252
	Mumbai	51	
	Nagpur	51	
	Pune	50	
	Solapur	50	
Rajasthan	Ajmer	50	252
	Bikaner	51	
	Jaipur	51	
	Jodhpur	50	
	Kota	50	
Uttar Pradesh	Agra	51	253
	Ghaziabad	50	
	Kanpur	52	
	Lucknow	50	
	Varanasi	50	
<b>Total</b>		<b>1008</b>	

# Chapter II

## Key Findings



## Key findings of the study are as follows:



### **Availability of MA drugs (N=1008):**

None of the retail chemists reported stocking MA drugs in Rajasthan and a negligible 1.2% in Maharashtra reported stocking. 66% in Uttar Pradesh and 37.8% in Bihar were stocking and selling MA drugs at the time of the survey.



### **Reasons for not stocking MA drugs (N=743):**

69.4% of all retail chemists who were not selling, cited legal barriers as the main reason and 26.1% reported that 'requirement of collecting prescriptions' was a deterrent. An overwhelming majority 90.4% of chemists in Maharashtra, 76.6% in Rajasthan and 75.6% in Uttar Pradesh reported legal/regulatory issues for not stocking MA drugs. Most retail chemists in Uttar Pradesh reported legal issues (75.6%), followed by side effects associated with the drug (58.1%) as reasons for not stocking. 58.1% of retail chemists, not stocking MA drugs in Uttar Pradesh attributed it to frequent visits by drug inspectors to enquire about these drugs.



### **Awareness on abortion (N=1008):**

43% of the respondents thought abortion is illegal in India, with Rajasthan reporting the highest at 60.7% followed by Bihar at 51.8%. 52% of retail chemists across the four states reported abortion is legal out of which 30% were aware that it is legal only for certain conditions.



### **Awareness on gestational limits for abortion (N=1008):**

Only 26% of chemists were aware that abortion is legal up to 20 weeks gestation in India. 29% of retail chemists reported that abortion can be done only up till 12 weeks gestation. Awareness was lowest at 9.5% in Uttar Pradesh.



### **Awareness on gestational limit for combipack MA (N=1008):**

30% of all retail chemists reported a nine week limit for combipack MA drugs' use, an equal 30% reported a seven week limit.



### **Awareness on MA drugs (N=1008):**

59% of all respondents could name the combination of drugs used for abortion. The knowledge was significantly better amongst those who were stocking at the time of the survey in comparison to retail chemists not stocking. 97% of all retail chemists were able to differentiate between emergency contraceptive pills and MA drugs.



#### **Client purchasing pattern (N=262):**

Retail chemists in Bihar and Uttar Pradesh reported that out of the last 10 clients who visited to purchase the drugs, six were men and four were women. Out of the last 10 clients, 50% in Bihar and 43% in Uttar Pradesh came with a prescription while rest came without a doctor's prescription.

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#### **Interaction between chemists and clients (N=262):**

57% of retail chemists stocking MA drugs in Bihar and Uttar Pradesh reported asking about the duration of pregnancy from clients who came to purchase these drugs. 45.8% of chemists stocking MA drugs reported asking for the doctor's prescription and 36.2% reportedly ask the clients about their last menstrual period. 70.2% chemists reported advising the MA clients on how to take the pills and 56.6% on when to take the drugs.

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#### **Beliefs on abortion (N=1008):**

The retail chemists across the four states had largely conflicting views on abortion. Half of all retail chemists interviewed believed availability of MA has increased the number of abortions in India and 15% of the respondents thought MA can be used for sex selective abortions. Significantly, 42.5% of respondents in Maharashtra reported that MA drugs can be used for sex-selective abortions in India, 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. While 44.6% retail chemists stated MA is not useful for women, a close 42.6% considered MA to be useful for women.

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#### **Specific visits by drug inspectors (N=922):**

Specific visits related to MA were high in Rajasthan at 14.3% and Maharashtra at 17.4% as compared to Bihar reporting at 2% and Uttar Pradesh at 4%. A majority of the retail chemists who reported specific MA related visits mentioned that the drug inspectors check the MA drugs register on such inspections.

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#### **Communication received from drug inspectors (N=930):**

Only 9.1% of retail chemists reported receiving some form of communication on MA from drug authorities. The major form of communication was oral and a majority of these retail chemists (53%) were advised not to sell MA drugs.

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#### **Perception on overregulation of MA drugs (N=1008):**

As high as 56% reported that MA drugs are overregulated as compared to other schedule H drugs. However, more than 40% of the retail chemists also feel that overregulation is required to avoid misuse or health complications from these drugs.



# Chapter III

## Detailed Findings from Retail Chemists' Survey



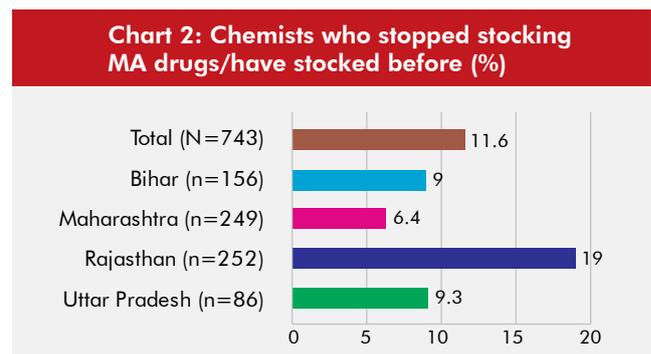
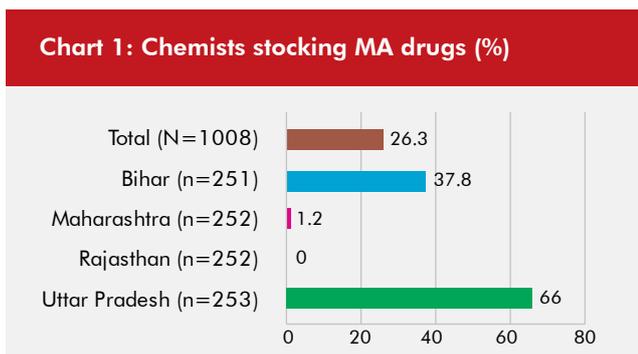
## I. Respondent profile (N=1008)

In total, 1008 retail chemists participated in this survey. All retail chemists interviewed were dealing directly with the clients and on average were working for more than five years at their pharmacies. 68.5% of all retail chemists interviewed were shop owners while 22.4% were working as employees. 9% were members of the shop owner's family. The age of the respondents ranged between 18-85 years while their average age was 40 years. Table 3 shows the education profile of retail chemists across the four study states.

Particulars	Bihar	Rajasthan	Maharashtra	Uttar Pradesh	Total
Highest level of education	N=251	N=252	N=252	N=253	N=1008
M. Pharmacy	0.8	0.0	4.8	1.2	1.7
B. Pharmacy	1.6	15.9	13.9	8.7	10.0
D. Pharmacy	0.8	37.3	56.0	11.9	26.5
Post Graduate	11.6	4.4	1.2	6.3	5.9
Graduate	50.2	23.0	7.5	49.4	32.5
Senior Secondary	20.3	15.5	15.5	17.4	17.2
Others (secondary, non-matric)	14.7	4.0	1.2	5.1	6.3

38.2% of all retail chemists had a professional degree in pharmacy. 74.7% of retail chemists in Maharashtra, 53.2% in Rajasthan and 21.8% in Uttar Pradesh reported holding a qualification in pharmacy (Masters/Bachelors/Diploma), only 3.2% in Bihar were trained in pharmaceutical sciences.

## II. Drug availability (N=1008)

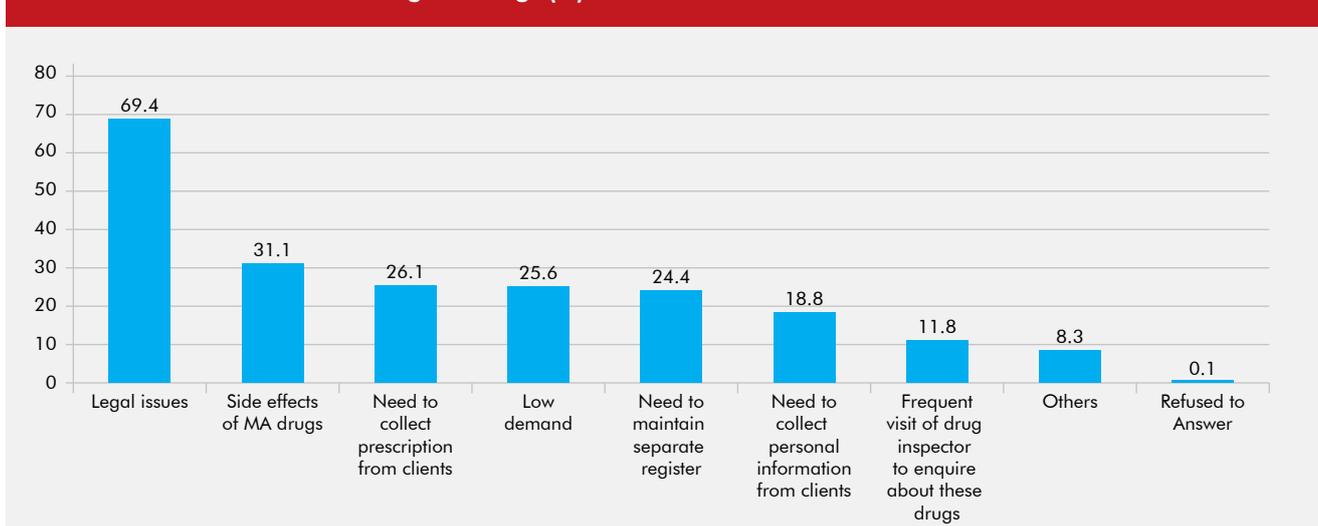


Only 26.3% of all retail chemists reported stocking MA drugs. Notable variation was found among the states. 66% reported stocking in Uttar Pradesh, followed by Bihar at 37.8%. The reported availability of MA drugs was strikingly low in Maharashtra and Rajasthan where the respondents were hesitant to provide information on MA and mostly refused when asked if they were dealing with abortion drugs. In Maharashtra, only three retail chemists said they sell MA drugs while not even a single chemist in Rajasthan admitted to stocking and selling them. Among those who were not selling the drugs, 11.6% revealed that they used to at some point but stopped stocking them eventually.

**Table 4: Reasons for not stocking MA drugs (%)**

Particulars	Bihar	Rajasthan	Maharashtra	Uttar Pradesh
Ever stocked these drugs*	n=156 9.0	n=252 19.0	n=249 6.4	n=86 9.3
Reasons for not stocking drugs at all/anymore	n=156	n=252	n=249	n=86
Legal issues	21.2	76.6	90.4	75.6
Side effects of MA drugs	37.8	39.3	9.2	58.1
Need to collect prescription from clients	7.7	36.1	33.7	8.1
Low demand	56.4	25.8	13.7	3.5
Need to maintain a separate register	0.0	40.5	28.1	10.5
Need to collect personal information from clients	1.3	25.4	24.9	14
Frequent visit of drug inspector to enquire about these drugs	0.0	7.1	8.0	58.1
Others (misuse of drugs, against religion, doctors do not prescribe etc.)	13.5	5.2	10.8	1.2
Refused to Answer	0.0	0.0	0.4	0.0

\* n=Retail chemists who currently do not stock medical abortion drugs  
Total percentage may add to more than 100.0 because multiple reasons were accepted

**Chart 3: Reasons for not stocking MA drugs (%) n=743**

Chemists who reported not stocking (N=743) were asked about their reasons. Legal/Regulatory issues emerged as a common reason for not dispensing the drugs amongst 69.4% of retail chemists across the four states. 31.1% respondents pointed towards the side effects associated with the drugs and 26.1% cited the requirement of collecting prescriptions from clients as a deterrent for stocking MA drugs. The percentage of retail chemists highlighting legal issues was the highest in Maharashtra at 90.4%, followed by Rajasthan at 76.6%, where the drug authorities have been regulating the sales of MA drugs in a bid to address sex selection. In Bihar 56.4% reported not stocking due to low demand. 58.1% chemists in Uttar Pradesh mentioned frequent visits by drug inspectors to enquire about these drugs, as a reason for not stocking.

### III. Price at which MA drugs are sold (N=265)

67.1% of all retail chemists selling MA drugs (N=265) reported offering a discount on the maximum retail price (MRP) to the clients while 20% reported selling the drugs on MRP. 14.3% reported selling some on MRP and some on discount. Most commonly stocked brand as reported by 88.2% chemists in Bihar and Uttar Pradesh was Mankind Unwanted Kit which is priced at INR 390. 28.2% chemists in these states were also stocking Cadila-Mifegest Kit which is priced at INR 408.39.

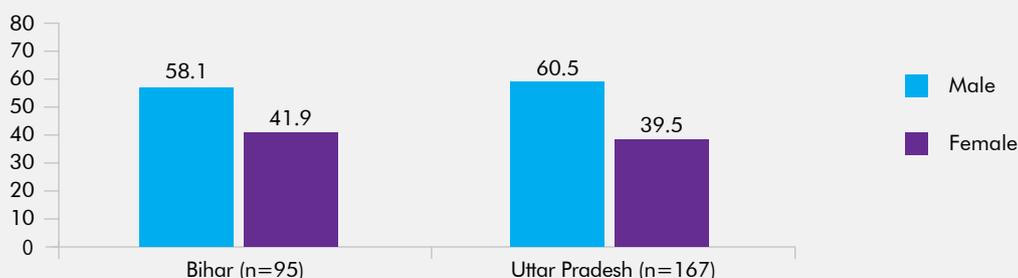
#### IV. Client purchasing pattern (N=262)

Questions on client purchasing pattern which included the role of prescriptions and who was coming to buy MA drugs were asked from chemists who reported stocking and selling MA drugs.

- **Who buys - women or partners:**

In Bihar and Uttar Pradesh, on an average, of the last 10 clients who requested the retail chemists for MA drugs, six were men and four were women.

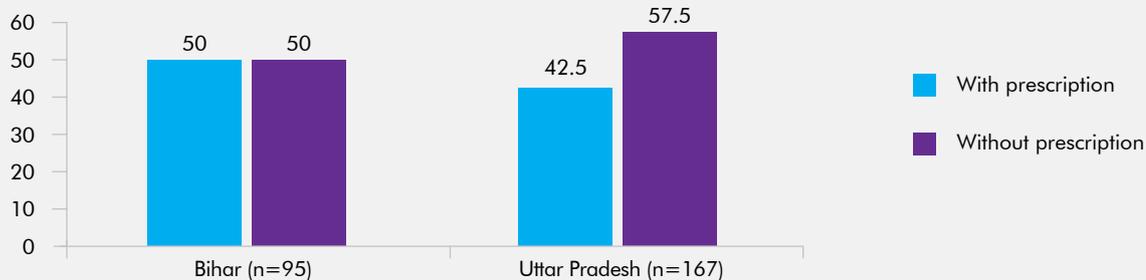
Chart 4: Who visits to buy MA drugs? (%)



- **Role of prescription in MA drug sales:**

Retail chemists were asked the proportion of clients who came with a prescription, out of the last 10 clients who requested for MA. On an average, 50% of the clients in Bihar and 42.5% in Uttar Pradesh came with a prescription to purchase MA drugs. 50% of clients in Bihar and 57.5% in Uttar Pradesh came to buy these drugs without a prescription.

Chart 5: Clients who visit pharmacies with a prescription (%)



#### V. Interaction between the chemist and the client (N=262)

- **Questions asked by retail chemists:**

Respondents selling MA drugs were probed about the kind of questions they ask clients buying abortion drugs. The most commonly sought information was on the duration of pregnancy, last menstrual period and doctor's prescription. 40.1% of the retail chemists in Uttar Pradesh also reported enquiring about the age of the pregnant woman. Other responses included number of living children, place of residence, reasons for undergoing abortion and previous use of MA drugs. 19.8% in Uttar Pradesh stated that they do not ask any questions from the clients before selling the drugs.

**Table 5: Questions asked by the retail chemists while selling MA drugs (%)**

Particulars	Bihar	Uttar Pradesh	Total
	n=95	n=167	n=262
Duration of pregnancy	71.6	49.7	57.0
Doctor's prescription	32.6	53.3	45.8
Last menstrual period	51.6	28.1	36.2
Age of pregnant woman	20.0	40.1	32.5
Marital status	2.1	10.8	7.6
Others	0.0	13.2	8.4
None	4.2	19.8	14.0
Refused to Answer	1.1	0.6	0.8

n=Retail chemists who stock MA drugs

Total percentage may add to more than 100.0 because multiple answers were allowed

- Questions asked by clients to the chemist:**

Effectiveness of MA drugs, ways of administering the drugs and their side effects were some common questions asked by women/partners at the time of purchasing the drugs. A notable number of respondents (25.1%) also reported that the clients ask about the cost of the drugs. 32% of the respondents said that clients do not ask any questions during their visit to purchase abortion drugs.

**Table 6: Questions asked by the clients during purchase of MA drugs (%)**

Particulars	Bihar	Uttar Pradesh	Total
	n=95	n=167	n=262
Effectiveness of MA drugs	44.2	56.3	51.9
How to take MA drug	64.2	32.9	43.8
Side effects	36.8	38.9	38.1
Cost	25.3	25.1	25.1
Name of brands	2.1	0.0	0.8
None	13.7	41.9	31.9
Refused to Answer	1.1	0.6	0.8

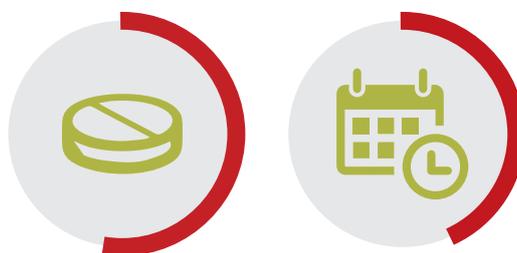
n=Retail chemists who stock MA drugs

Total percentage may add to more than 100.0 because multiple answers were allowed

- Advice given by the retail chemists:**



**70.2%** Retail chemists selling MA drugs reported that they advise the clients about the routes of administration of these drugs.



**56.6% and 45.7%** reported advising about when to take the tablets and the dosage respectively.



**19.2%** Reported informing about the side effects associated with the drugs.

**Table 7: Advice to clients by retail chemists (%)**

Particulars	Bihar	Uttar Pradesh	Total
	n=95	n=167	n=262
Routes of administration	82.1	64.7	70.2
When to take tablets (time)	63.2	53.9	56.6
Dosage	54.7	41.3	45.7
Warning signs that require medical attention	4.2	37.1	24.9
Potential side effects	14.7	21.6	19.2
Where to go in case of any complications	4.2	19.8	14.3
Others	8.5	14.4	12.4
None	2.1	7.2	6.0
Refused to Answer	1.1	0.6	0.8

n=Retail chemists who stock MA drugs

Total percentage may add to more than 100.0 because multiple answers were allowed

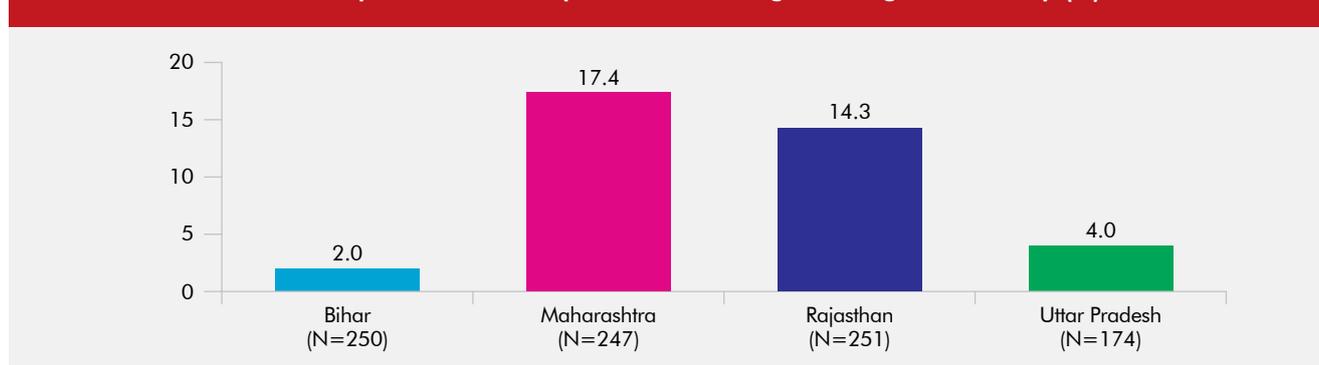
## VI. Client experience (N=262)

Chemists were asked the number of clients, who returned to their pharmacies, out of the last 10 clients who purchased MA drugs. The main reason they came back was to enquire about contraception (reported by 43.8% chemists); treatment of perceived complications (reported by 44.8% chemists) and for treatment of side effects (reported by 29.5% chemists). It is estimated that only 9.6% of all clients returned. 60% chemists stocking MA drugs reported that none of the last 10 clients who bought MA drugs from them, returned. 39.3% chemists reported that clients did return, however the number of those who came back was low. On an average, only two out of the last 10 clients returned to the pharmacies after purchasing MA drugs. The number of clients who came back for each of the reasons was not captured and is a matter of further investigation.

The retail chemists were further asked about their action in case a client makes a return visit to seek treatment for perceived complications, nine out of 10 retail chemists (Bihar: 92.6% and Uttar Pradesh: 91%) responded that they advise the client to consult a doctor.

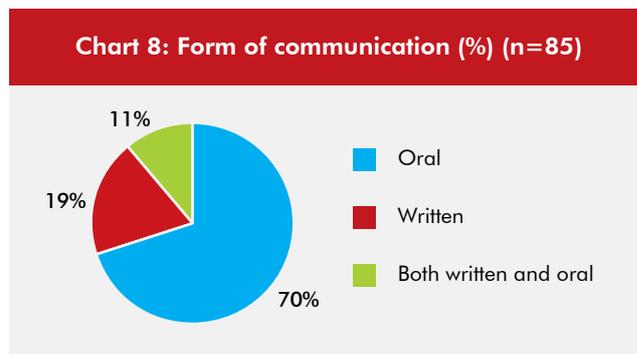
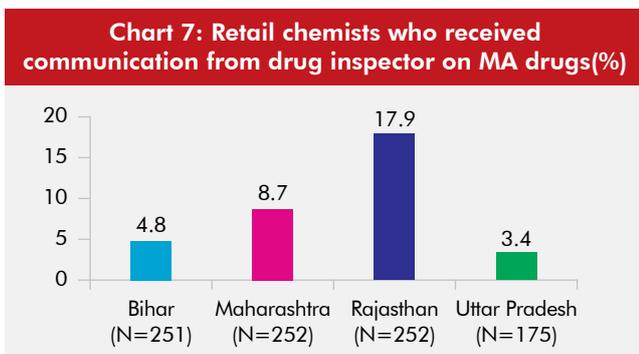
## VII. Regulatory issues (N=1008)

To understand if retail chemists face any regulatory issues, they were asked about visits by drug inspectors to their pharmacies. Almost all respondents in Rajasthan, Bihar and Maharashtra reported that drug inspectors make inspection visits. 37.5% chemists across all four states reported a visit every six months and 27.8% shared that the frequency of these visits is not fixed.

**Chart 6: Specific visit for inspection of MA drugs stocking at retail shop (%)**

Visits by drug inspectors in general and specifically for MA drugs was reported to be high in Rajasthan and Maharashtra with 17.4% chemists in Maharashtra and 14.3% chemists in Rajasthan reporting specific visits related to MA drugs. During these specific visits, six out of 10 retail chemists mentioned that the officials check the MA drugs register, while 27% shared that they inspect how the drugs are being stored. 15% of all retail chemists reported being asked for copies of prescriptions during such inspections.

While overall only 9.1% retail chemists reported receiving any form of communication from the drug authorities on MA and its sale, in Rajasthan it was 17.9%.



A larger number of respondents confirmed getting some form of message in Rajasthan as compared to other states. Majority of these retail chemists received verbal communication; only 19% received a written communication related to the sale of MA drugs. A large number of retail chemists in Rajasthan (73.3%) shared that they were advised not to sell abortion drugs. 31.8% of retail chemists across the four states reported being told to sell the drugs only on prescription.

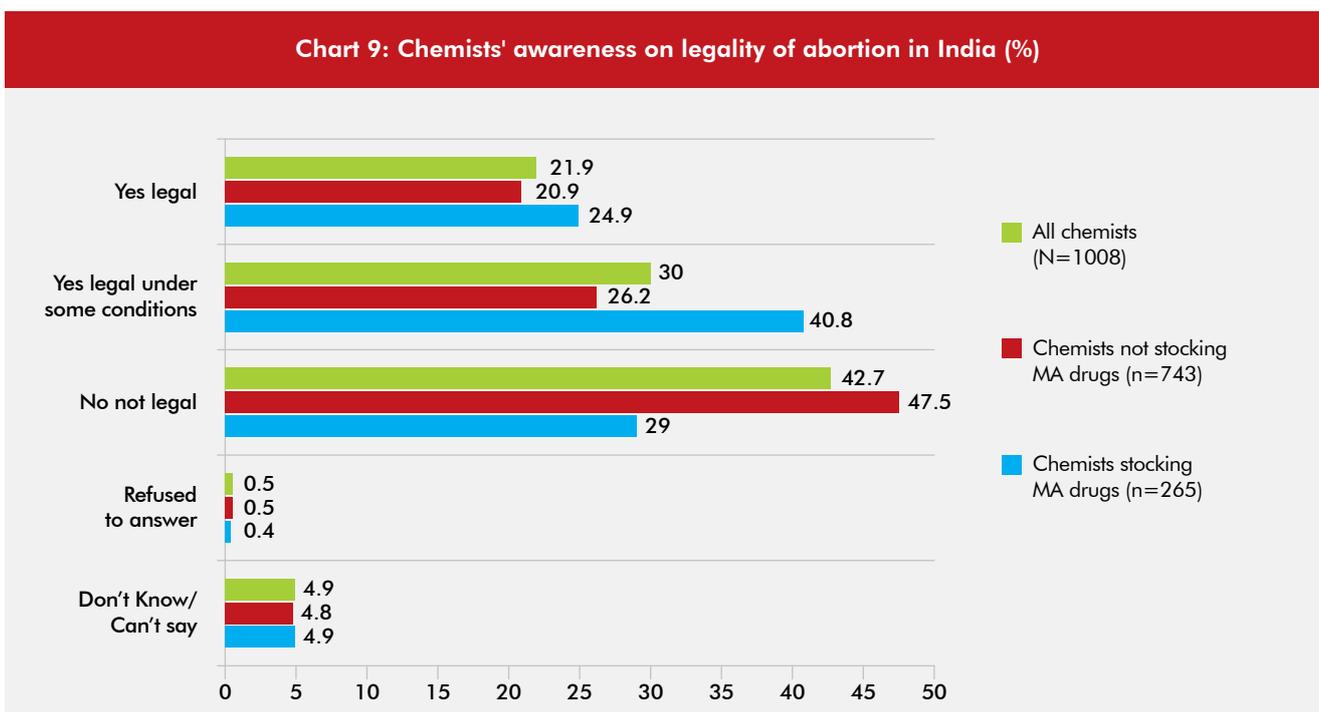
**Table 8: Content of communication received from drug controller/inspector by chemists**

Particulars	Rajasthan	Maharashtra	Total
Major content of communication	n=45	n=22	n=85
Do not keep/sell abortion drugs	33	8	45
MA drugs can be sold only on prescription	5	10	27
Follow all selling rules of MA drugs	4	2	7
Others	4	3	12

n=Retail chemists who received communication from drug inspector  
Multiple responses were accepted

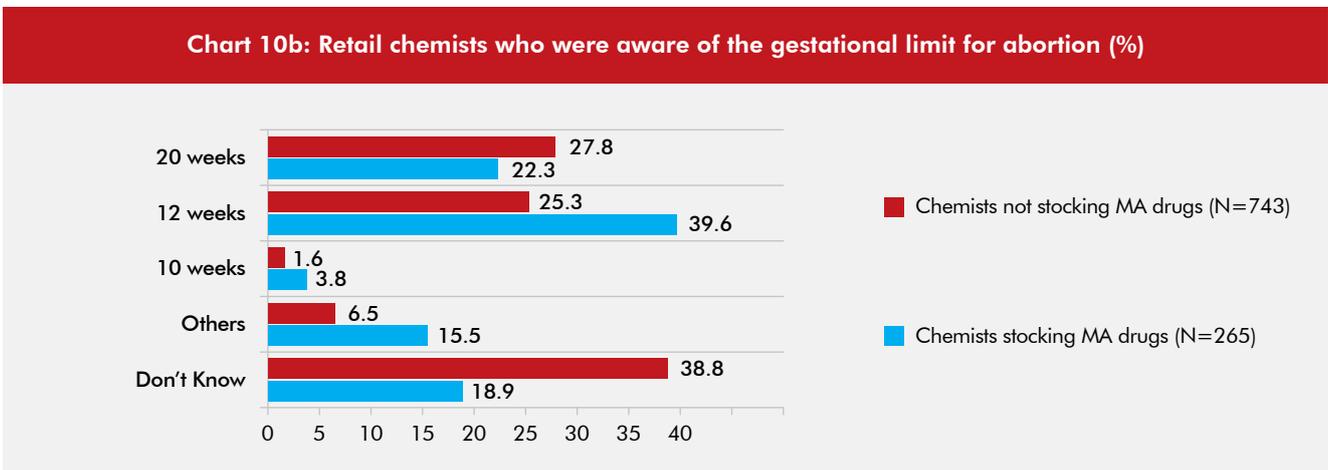
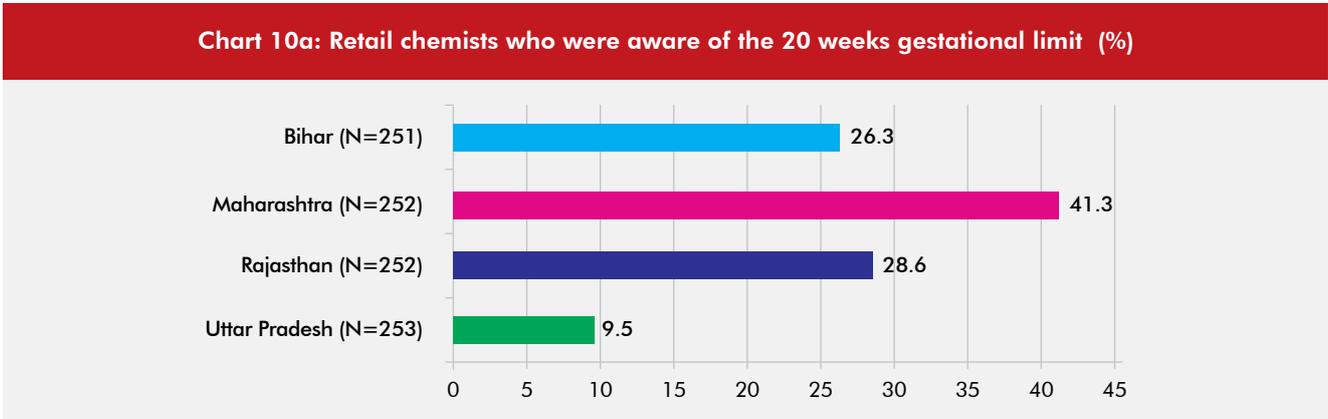
### VIII. Awareness on abortion and MA drugs (N=1008)

52% of retail chemists reported that abortion is legal in India and 30% of those who stated it is legal knew that it is permitted only under certain circumstances/conditions. 42.7% of chemists across all the four states stated that abortion is not legal in the country. 60.7% in Rajasthan and 51.8% in Bihar reported that abortion is illegal. In Maharashtra, 36.5% of chemists stated abortion is permitted for certain conditions, while 26.6% responded that abortion is not allowed at all. The awareness level varied amongst those stocking and those not stocking. Only 26.2% chemists not stocking MA drugs said abortion is legal under certain conditions, while 40.8% of chemists stocking these drugs reported so.



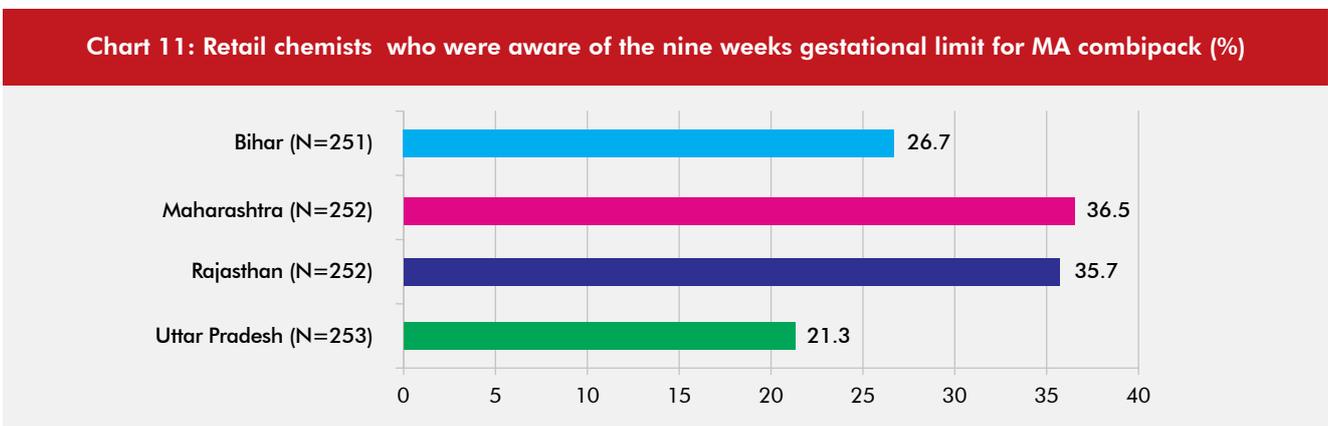
- Gestational limit for abortion:**

All retail chemists were asked about the gestational limit for abortion, of which only 26.4% responded accurately (20 weeks), while about 29% reported that abortion can be done only up till 12 weeks gestation. Among chemists stocking MA drugs (N=265), 22.3% responded 20 weeks, 39.6% reported 12 weeks and 18.9% did not know the gestational limit for abortion. In comparison, 27.8% chemists not stocking the drugs (N=743) accurately responded 20 weeks.



- Gestational limit for MA combipack:**

30% of all respondents answered nine weeks, while an equal number of retail chemists responded seven weeks when enquired about the length of pregnancy up to which abortion can be carried out through MA combipack. Amongst respondents keeping MA drugs, 30.2% responded nine weeks, an equal percentage of chemists not stocking MA drugs gave the same response. 53.6% respondents with MA drugs available and 21.8% chemists not stocking the drugs stated seven weeks.



- **Drugs used for abortion:**

58.7% reported awareness of the combipack drugs (combination of mifepristone and misoprostol) used for abortion, 17.7% responded only mifepristone, and 17.4% responded misoprostol alone. 35% reported that they were not aware or could not recall the name of the drugs used for medical abortion. Among the retail chemists who were stocking the drugs, 95% were able to name the medication in the combipack as opposed to only 45.8% of those not stocking the drugs at the time of survey. 78% of retail chemists who were dispensing before but weren't during the survey period were aware of combipack used for abortion. Almost all retail chemists (97%), however, were able to differentiate between MA drugs and emergency contraceptive pills based on their purpose of use.

**Table 9: Knowledge of retail chemists on MA drugs (in %)**

Particulars	Bihar	Rajasthan	Maharashtra	Uttar Pradesh	Total
Drugs used for abortion	N=251	N=252	N=252	N=253	N=1008
Combi-pack (mifepristone & misoprostol)	64.1	54.8	42.1	73.9	58.7
Mifepristone tablet	1.6	29.0	11.5	28.5	17.7
Misoprostol tablet	3.6	28.6	11.1	26.1	17.4
Ayurvedic Tablets	0.0	0.8	0.0	0.0	0.2
Don't know/Can't recall	33.9	33.7	48.8	23.3	34.9

Total percentage may add to more than 100.0 because multiple answers were allowed

- **Who can prescribe MA drugs:**

More than 95% of the respondents across all states reported that MA drugs can be prescribed by Ob/Gyn, 6.8% mentioned it can be prescribed by MTP certified general physicians. 21.5% in Bihar and 11% in Uttar Pradesh reported that retail chemists/pharmacists can prescribe these drugs. Additionally, according to 35% retail chemists in Uttar Pradesh, ANMs/midwives are also authorised to prescribe drugs for medical abortion.

**Table 10: Who can prescribe MA drugs? ( %)**

Particulars	Bihar		Rajasthan	Maharashtra		Uttar Pradesh	
	Stocking MA (n=95)	Not stocking MA (n=156)	Not Stocking MA (N=252)	Stocking MA (n=3)	Not Stocking MA (n=249)	Stocking MA (n=167)	Not Stocking MA (n=86)
Ob/Gyn	89.4	98.7	97.2	100	97.5	98.8	98.8
ANM/Trained midwife	6.30	3.84	1.2	0	0.4	32.9	38.3
Chemist/Pharmacist	48.4	5.12	2.4	0	0.4	14.9	3.5
General physician	20	14.1	9.1	0	0.4	5.4	11.6
MTP Certified General Physician	1.0	4.48	4.4	0	1.6	14.9	22.0
Others	1.0	0	0.4	0	2	0.59	0
Don't Know /Can't Say	0	0	1.19	0	0	0	1.16

Total percentage may add to more than 100.0 because multiple answers were allowed

- **Sequence of drug use:**

53% of all retail chemists mentioned that they did not know or could not recall the sequence of use of the two drugs. A third of all retail chemists responded accurately (mifepristone on day one followed by misoprostol 24-48 hours later). The highest percentage of retail chemists who responded to the question accurately were from Uttar Pradesh at 52.2%, followed by Bihar at 46.6%. Only 9% in Rajasthan provided accurate information.

**Table 11: Retail chemists' knowledge on sequence of drug use (%)**

Particulars	Bihar		Rajasthan	Maharashtra		Uttar Pradesh		Total	
	Stocking MA (n=95)	Not stocking MA (n=156)	Not Stocking MA (N=252)	Stocking MA (n=3)	Not stocking MA (n=249)	Stocking MA (n=167)	Not stocking MA (n=86)	Stocking MA (n=265)	Not stocking MA (n=743)
Mifepristone on day one followed by misoprostol 24 to 48 hours	88.4	21.2	9.1	33.3	24.4	70.6	16.3	76.6	17.6
First day Mifepristone next day misoprostol	8.4	1.9	31.3	0	2	12.5	3.5	10.9	12.1
Others	1.05	0	1.9	0	2.4	5.38	2.32	3.7	1.7
Don't Know/ Can't Say	2.1	76.9	57.5	66.6	71.0	11.37	77.9	8.6	68.5

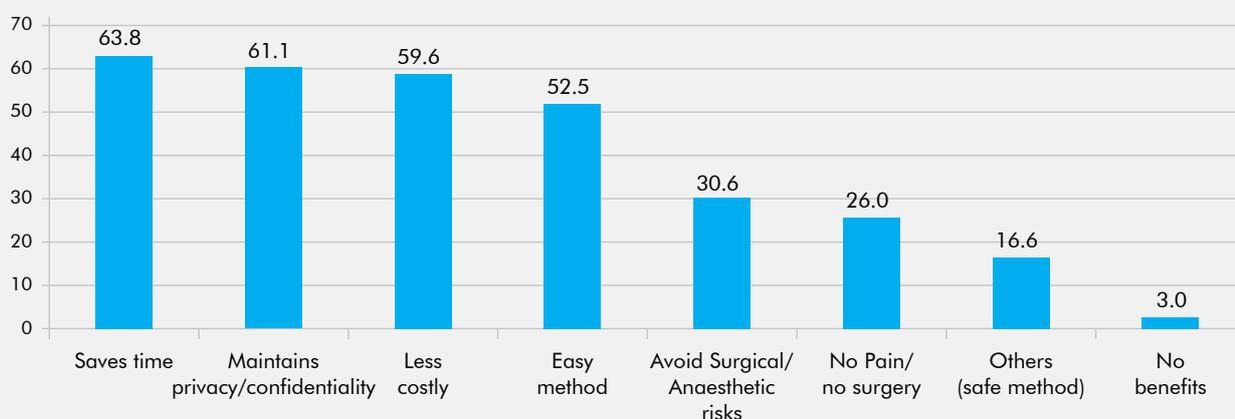
**• Side effects of MA drugs:**

Heavy vaginal bleeding, which is a part of the medical abortion process, was identified as a side effect of MA across all four study states. Nearly 82% of all retail chemists reported bleeding as a side effect. Dizziness/weakness was reported as a side effect by 55% retail chemists, followed by severe abdominal pain (31.2%) and nausea/vomiting (25.5%). In Maharashtra, about one-fourth of the retail chemists did not know about the side effects of these drugs. Amongst chemists stocking MA drugs (N=265), the reported perception of bleeding as a side effect was as high as 91.7%.

**IX. Perceived benefits of MA drugs over surgical method (N=265)**

Retail chemists who were stocking MA drugs, were asked about their perceived benefits of medical abortion over the surgical method, the findings are depicted in Chart 12. 64% of chemists reported that medical abortion saves time, and 61% shared that privacy and confidentiality is maintained through the medical method. Other top benefits of MA as cited by the retail chemists included low cost and ease of use.

**Chart 12: Perceived benefits of MA over surgical method (%) (n=265)**



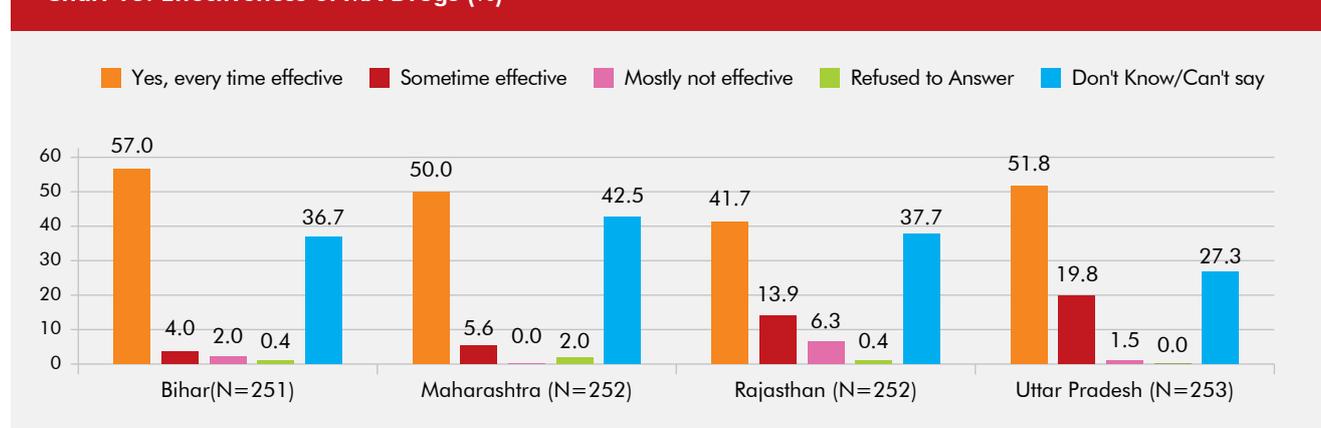
## X. Effectiveness of MA drugs (N=1008)

Half of all retail chemists reported that MA drugs are effective every time, while 11% reported that they are effective sometimes. 36% of respondents across the four study states shared that they did not know about the effectiveness of MA drugs.

**Table 12: Chemists' perception on effectiveness of MA drugs (%)**

	Stocking MA (n=265)	Not Stocking MA (n=743)	Total (N=1008)
Effective every time	80.75	39.16	50.09
Effective sometimes	13.2	9.9	10.81
Mostly not effective	1.13	2.82	2.38
Refused to answer	0.37	0.8	0.69
Don't Know/Can't say	4.5	47.2	36.01

**Chart 13: Effectiveness of MA Drugs (%)**



## XI. Information on MA drugs (N=265)

Most of the retail chemists shared that they get their information on MA drugs from brochures/ booklets and medical representatives. The question was asked only from those who reported dispensing MA therefore the findings are limited to Bihar and Uttar Pradesh. The top responses were largely uniform across both states- however, in Uttar Pradesh more respondents reported brochure over medical representatives, while in Bihar it was the other way round. Information about the source of brochures/booklets was not sought from the respondents. About a third of all retail chemists also reported being informed by the wholesalers/stockists on MA.

**Table 13: Information source on MA drugs**

Particulars	Bihar	Uttar Pradesh	Total
Information source of MA drugs	n=95	n=167	n=265
Brochure/Booklets	42.1	77.8	64.5
Medical Representatives	73.7	54.5	61.9
Wholesaler/Stockists	33.7	33.5	33.2
Other medical shops/chemists	7.4	10.8	9.8
NGO workers	3.2	13.8	9.8
Others	17	12.6	14.1
Refused to Answer	1.1	0.6	0.8

n=Retail chemists who stock MA drugs

Total percentage may add to more than 100.0 because multiple answers were allowed

## XII. Training of retail chemists (N=265)

The number of retail chemists who reported having undergone training or participating in a meeting/workshop on MA was very low with Bihar at 15% and Uttar Pradesh at 9%. 60% of those who attended such trainings/workshops shared that these were organised by pharmaceutical firms/companies, and 37% shared that the training/s were organised by not-for-profit organisations.

## XIII. Perception/Attitude on MA (N=1008)

To understand the attitude of retail chemists on medical abortion, questions were asked on its usefulness; whether it can be used for sex selective abortions and its contribution to the number of abortions taking place.

- **Usefulness of MA for women:**

4.6% retail chemists stated that MA is not useful for women as opposed to 42.6% who considered it to be useful for women. Despite not stocking MA drugs; 43.7% retail chemists in Maharashtra and 21.4% in Rajasthan acknowledged that MA is useful for women. 70.5% chemists dispensing MA drugs were of the opinion that MA is useful for women as opposed to 32.7% chemists who were not stocking MA drugs at the time of the survey.

- **The number of abortions increased by MA:**

More than half of all the chemists responded that MA drugs have increased the number of abortions. More retail chemists hold such a perception in Uttar Pradesh as compared to other states. 71.3% of chemists with MA drugs available stated that the drugs have increased the number of abortions.

- **Usage of MA for sex selective termination of pregnancy:**

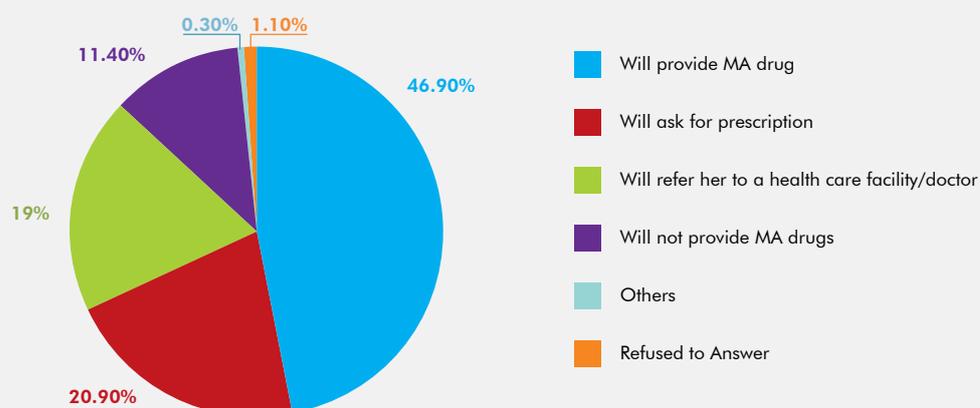
67% chemists reported that MA cannot be used for sex selective termination of pregnancies as opposed to 15% who stated that it can be used for this purpose. The number of retail chemists who hold such a perception is considerably high in Maharashtra at 42.5% as compared to other states. 18% across all states did not know or refused to answer. Among chemists stocking MA drugs, only 3% stated that MA can be used for gender biased sex selection, while 89.4% stated otherwise.

**Table 14: Attitude/Perception of retail chemists on MA Drugs (in %)**

Particulars	Bihar		Rajasthan	Maharashtra		Uttar Pradesh		Total	
	Not stocking MA (n=95)	Stocking MA (n=156)	Not Stocking MA (N=252)	Not Stocking MA (n=249)	Stocking MA (n=3)	Not Stocking MA (n=86)	Stocking MA (n=167)	Not Stocking MA (n=743)	Stocking MA (n=265)
Availability of MA drugs has increased cases of abortions	86.3	76.9	40.4	21.6	66.6	61.6	62.8	44.3	71.3
MA drugs are useful for women	64.2	22.4	21.4	42.9	100	54.6	73.6	32.7	70.5
MA drugs can be used for sex-selective termination of pregnancy	1.0	2.3	10.7	42.5	33.3	5.8	3.59	19.38	3.0

#### XIV. What would you do if a young, unmarried woman asked for MA drugs (N=262)

**Chart 14: What would you do if a young unmarried woman visits your pharmacy for MA drugs? (Bihar, Uttar Pradesh n=262)**



To explore their attitude on MA further, retail chemists who were stocking the drugs were asked what they would do if a young unmarried woman visited them to purchase MA drugs. In Bihar and Uttar Pradesh where reported stocking was significant, 47% said they will provide MA drugs to the woman as opposed to 11.4% who said they will not give the drugs. 19% retail chemists in these states said they would refer the woman to a healthcare facility or a doctor. 21% responded that they would ask the woman for a prescription.

**Table 15: What would you do if a young unmarried woman asks for MA drugs?**

Particulars	Bihar	Uttar Pradesh	Total
<b>Response of retail chemists</b>	<b>n=95</b>	<b>n=167</b>	<b>n=262</b>
Will provide MA drugs	40%	50.8%	46.9%
Will ask for prescription	31.5%	14.9%	20.9%
Will refer her to a health care facility/doctor	13.6%	22.1%	19%
Will not provide MA drugs	13.6%	10.1%	11.4%
Others	1.0%	1.69%	1.4%

All retail chemists other than those who said they would provide MA drugs were asked about their reasons for not dispensing the drugs to 'a young woman' of which 72.6% reasoned that they won't sell to the woman if she comes without a prescription. 39.5% of the respondents said they would refuse to attend to her request if she is below 18 years of age and 9% of retail chemists explained that if the woman was unmarried they would not sell her the drugs.

**Table 16: Chemists' reasons for not providing MA drugs to a young unmarried woman (%)**

Particulars	Bihar	Uttar Pradesh	Total
<b>Reasons for not providing MA drugs</b>	<b>n=57</b>	<b>n=82</b>	<b>n=139</b>
If she does not have a prescription	68.4%	75.6%	72.6%
If she is below 18 years of age	8.7%	60.9%	39.5%
If she does not have a photo Identity (ID)	0%	4.8%	2.8%
If she does not give her contact details	0%	4.8%	2.8%
If she is unmarried	21.0%	1.2%	9.3%
Others	5.2%	0%	2.1%
Refused to Answer	1.7%	2.4%	2.1%

Total percentage may add to more than 100.0 because multiple answers were allowed

## XV. Perception on overregulation of MA (N=1008)

- **MA drugs are overregulated:**

About 56% of retail chemists reported that MA is overregulated as compared to other Schedule H drugs. A vast majority of retail chemists (91.7%) in Maharashtra have this viewpoint as opposed to a 10% in Bihar. The proportion of respondents in Rajasthan who reported MA is overregulated is also significantly high at 68%. 38.11% chemists stocking MA drugs believe these drugs are more overregulated than other schedule H drugs, while 62.1% not stocking these drugs hold this belief.

- **Should MA drugs be overregulated:**

On being asked if MA drugs should be overregulated, around 42% chemists across the study states said 'yes'. The highest percentage of retail chemists who reported so were in Rajasthan, followed by Bihar and Uttar Pradesh. Comparatively, the percentage was much lower in Maharashtra with only 22.6% retail chemists in favour of overregulation. An equal number of chemists who were stocking MA drugs (42.6%) and those not stocking (42.2%), stated that overregulation was required for MA drugs.

**Table 17: Regulation of MA drugs (%)**

Particulars	Bihar		Rajasthan	Maharashtra		Uttar Pradesh		Total	
	Stocking MA drugs (n=95)	Not stocking MA drugs (n=156)	Not stocking MA drugs (N=252)	Stocking MA drugs (n=3)	Not stocking MA drugs (n=249)	Stocking MA drugs (n=167)	Not stocking MA drugs (n=86)	Stocking MA drugs (n=265)	Not stocking MA drugs (n=743)
MA drugs are overregulated as compared to other schedule H drugs	7.3	10.8	67.8	100	91.5	54.4	53.4	38.11	62.1
Overregulation is required for MA drugs	46.3	49.3	50.7	33.3	22.4	40.7	61.6	42.6	42.2

- **Why should MA drugs be overregulated (N=427):**

72% of retail chemists felt that overregulation of MA drugs would prevent misuse. 62% cited the need for overregulation so that women don't experience health complications.

**Table 18: Why should MA drugs be overregulated ? (%)**

Particulars	Bihar	Rajasthan	Maharashtra	Uttar Pradesh	Total
Reasons why MA drugs should be overregulated	n=121	n=128	n=57	n=121	n=427
To avoid misuse	51.2	72.7	84.2	85.1	71.7
To avoid health complications	57.9	75.0	22.8	71.1	62.1
MA drugs can destroy foetus	10.7	1.6	12.3	5.0	6.6
Risk of life	1.7	0.0	0.0	0.8	0.7
People don't have sufficient knowledge on these drugs	0.0	0.0	0.0	0.8	0.2

Total percentage may add to more than 100.0 because multiple answers were allowed

## Key Findings from Wholesellers' Survey

As part of the study, 42 wholesalers/stockists (Bihar: 10, Uttar Pradesh: 10, Rajasthan: 11, Maharashtra: 11) were also interviewed. Findings from the wholesalers/stockists are:

### Availability of MA drugs:

Nearly half of all stockists/wholesalers (20 out of 42) reported distributing MA drugs. Out of these 20, five respondents were company stockists (Mankind, Macleods and Aristo), while the remaining were wholesalers. All respondents in Bihar stocked MA drugs, while in Uttar Pradesh, 80% of the stockists stocked these drugs. In Maharashtra and Rajasthan, only two stockists (one in each state) reported distributing MA drugs. All wholesalers were keeping at least two to three brands of these drugs.

### Reasons for not stocking:

Legal issues was a common reason identified by 68% of the stockists/wholesalers for not selling MA drugs. Specific requirements such as maintaining a separate register for MA drugs (14.2%) and collecting documents from retail chemists (11.9%) were identified as certain procedural challenges in stocking and selling MA drugs. 9.5% of wholesalers/stockists reported low demand as a reason for not stocking the drugs.

### Regulatory Issues:

Nine respondents mentioned that inspectors make specific visits to look at MA drug stocking and check expiry date of abortion drugs or the number of combi-packs stocked. Very few respondents (4) mentioned that inspector asks for other documents such as copy of invoice or purchase register. 16.6% of wholesalers/stockists have received communication on MA from drug inspectors which was mostly verbal in nature. Major content of communication was on the requirement of prescription for selling MA drugs.

## Perception/Attitude on MA Drugs

### Is MA useful for women:

24 out of 42 respondents reported that MA drugs are useful for women.

### Has MA increased the number of abortions:

One in two respondents was of the opinion that introduction of MA drugs in the market has increased the number of abortions. Around half of all wholesalers/stockists also stated that the demand for MA has grown in the last two years.

### Can MA be used for sex selective termination of pregnancy:

Only 7% of all respondents reported that MA can be used for gender biased sex selection.

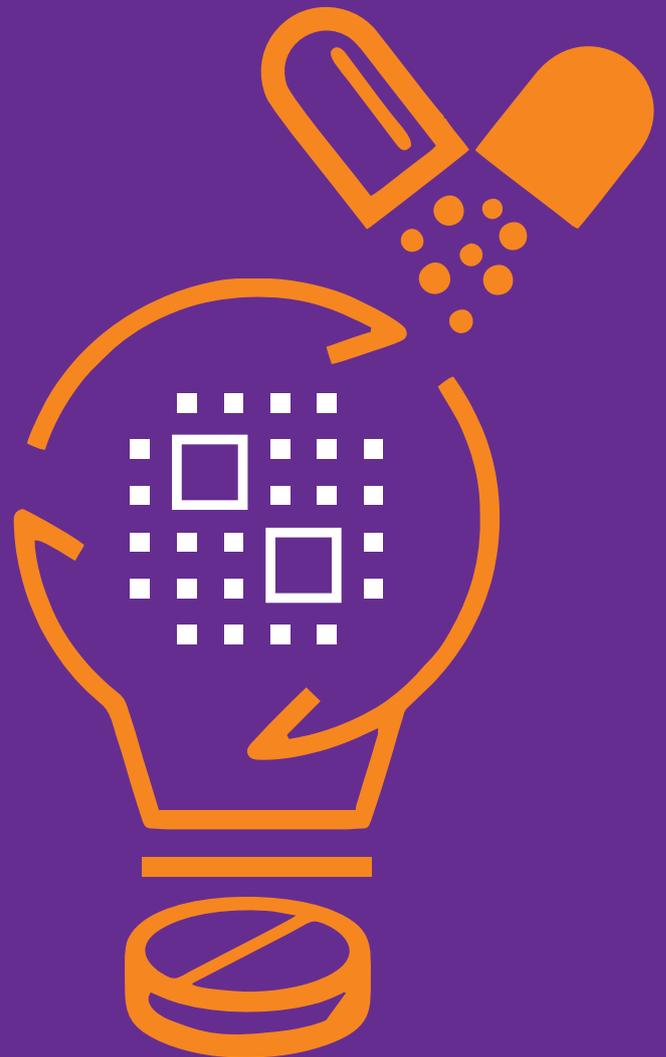
### Overregulation of MA drugs:

20 of the 42 respondents reported that MA drugs are overregulated than other Schedule H drugs and an equal number felt it should be overregulated (20/42) to avoid misuse and possible health complications associated with the drugs.



# Chapter IV

## Conclusion and Implications



Over the past decade, significant progress has been made in improving access to Comprehensive Abortion Care (CAC) in the country. Apart from the approval of MA drugs, the Ministry of Health and Family Welfare (MoHFW) has developed and updated CAC guidelines and training materials, supported training and certification of public sector providers, established model CAC centres in the public sector and included MA drugs in the essential drugs list. These steps clearly show the intent of the government to ensure that women have access to safe abortion care.

Recent estimates on the incidence of induced abortion in India show that a majority of abortion services (73%) are provided by the private sector and 81% of all abortions in the country are MA.<sup>x</sup> The findings of the study against this backdrop are significant since they provide evidence of emerging issues in availability of MA drugs at pharmacies particularly in the states of Rajasthan and Maharashtra. The overregulation and unintended consequences of interventions on addressing gender-biased sex selection is not only impacting availability of MA drugs, but also seem to be adversely impacting knowledge and awareness on legality of abortion. Some key conclusions from this study and their implications are discussed below.

## **1. Non-availability of MA Drugs**

While MA has become the overwhelmingly preferred method of abortion, the non-availability of drugs, particularly in Maharashtra and Rajasthan, is a big cause of worry. None of the retail chemists surveyed reported stocking the drugs in Rajasthan and only 1.2% reported stocking MA drugs in Maharashtra. Non-availability of MA drugs in effect means MA as an option is not available to women. This could result in women being forced to seek services from informal and unsafe providers, risking their lives and health, potentially reversing the gains one has seen in reduced unsafe abortions and its impact on the reduction in maternal mortality and morbidity in the country. Given the number of abortions estimated, this could encourage a black market for MA drugs pushing up prices for women who need MA, further creating economic barriers for women to access their preferred method of abortion.

## **2. Overregulation of MA Drugs**

The non-stocking of MA drugs in Rajasthan and Maharashtra appears to be a consequence of overregulation of MA drugs. A majority of the chemists cited legal barriers and additional documentation requirements as the reason for not stocking MA drugs. There were some chemists (45 out of 85 who received some form of communication on MA from drug authorities) who reported that they have been informally told by drug regulatory authorities not to sell MA drugs. The one easy way to avoid additional scrutiny from drug authorities, which most chemists are adopting, is to not stock MA drugs. Chemists report that they are asked to keep copies of prescriptions, or maintain registers with name of clients to whom they have sold MA drugs. This requirement violates the client confidentiality guaranteed by the MTP Act. Under the MTP Act (Clause 3 of Regulation 5 and Regulation 6 of the MTP Act Regulations, 2003) the name of the client seeking abortion services should not be revealed to anyone unless ordered by the judiciary. Among all respondents, over 91% in Maharashtra and 68% in Rajasthan reported that MA drugs are overregulated, compared to other schedule H drugs.

### 3. Exacerbating the myths/Stigmatising Abortions

The overregulation over the past few years also seems to perpetuate myths among chemists like combipack MA drugs contribute to gender biased sex selection and that abortion is not legal. 43% of chemists believe abortion is illegal; only 26.4% know that abortion is legal up to 20 weeks gestation. 42.5% of chemists in Maharashtra believe MA can be used for gender biased sex selection. More chemists (44.6%) feel MA drugs are not useful for women as compared to those who feel they are useful (42.6%). 21% chemists in Bihar reported that they would not provide MA drugs to a woman if she was unmarried, underlining the impact of stigma in accessing MA.

### 4. Inadequate knowledge among chemists about MA

The study clearly points out that correct knowledge about MA among chemists is poor. 82% consider bleeding as a side effect, when bleeding is actually a part of the MA process. About 53% did not know or could not recall the sequence of taking the combination of drugs. Chemists generally advise women on routes of administration, while we did not capture what routes they are advising (oral, buccal, sub-lingual or vaginal), while we believe they advise it to be used orally, this is an area that needs to be explored. For a large number of clients, the chemist is the first source of contact and hence the poor knowledge on MA would mean, the MA process for women may not be as comfortable and smooth as it should be. Many of the chemists (28.7%) are not aware that MA drugs need to be prescribed only by an Ob/Gyn or a MTP-approved doctor. 8.3% thought this could be prescribed by a general physician and 10.3% thought even ANMs/Nurses could prescribe MA drugs.

### 5. Prescription

On an average, 50% of the clients in Bihar and 42.5% in Uttar Pradesh came with a prescription to purchase MA drugs. This is significant, since there is a general perception that most MA drugs are being sold over the counter without prescription.

### 6. Follow-up

Only 39.3% of chemists stocking and selling MA drugs reported that clients came back to them for follow-up. On an average, two out of the last ten clients returned to the pharmacies after purchasing MA drugs. We estimate that only 9.6% of clients purchasing MA drugs returned to the chemist following purchase/use. The reasons for returning were for seeking contraception; perceived complications or due to side-effects. The small number of clients returning to the chemist post purchase, could indicate that for most women MA drugs seems to be effective or if women do face any problems they prefer to go to a doctor or health facility. When clients come back with questions or complications, chemists normally tend to refer them to a doctor.

Since chemist consider bleeding as a side effect, it is quite likely that many of the so called complications from client may actually be normal MA process and not necessarily a complication. The fact that women who come back to the chemist with perceived problem are referred to a doctor is heartening, since it enables women to seek appropriate support and care if required. No chemist reported any emergency or life threatening complication from clients.

### 7. Affordability

The current maximum retail price of MA combipack is INR 390. The reasonable price of MA combipack has made MA for early abortion significantly affordable, compared to surgical abortion in private facilities where the cost ranges from INR 2,000 to INR 3,400.<sup>xi</sup> Even including the cost of consultation of the doctor, availability of MA seems to have made safe abortion affordable.



# Chapter V

## Recommendations



There is no doubt that the availability of MA drugs, especially combipack has dramatically 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 facility. The contribution of unsafe abortions to maternal deaths in India has declined to 8% in 2003<sup>xii</sup> from a high of 13% in 1995<sup>xiii</sup>, due to various proactive steps taken by the Government of India in the past decade. Combipack became available only from 2008 onwards and since then has shown a significant growth, the latest estimate we have of contribution of unsafe abortions to maternal deaths precede MA Combipack. 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 indicates that MA drugs are under greater scrutiny by drug control authorities and their availability in retail chemist shops is a major cause of concern in two of the four states studied. Anecdotal information suggests that MA drugs are under higher scrutiny in other states like Punjab, Haryana and Madhya Pradesh. In order to ensure that MA drugs are easily accessible, the following recommendations are proposed:

## **1. Address misconception regarding MA and gender biased sex selection among drug regulatory authorities**

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 combipacks are effective and indicated for use up to nine weeks gestation. Ultrasound is able to detect the sex of the foetus only in early second trimester around 13-14 weeks gestation. Studies have estimated that majority of all abortions in India are in the first trimester.<sup>xiv</sup> Hence, greater scrutiny resulting in MA drugs vanishing from shelves of chemists would result in millions of women being denied access to lifesaving drugs and compromise their ability to exercise their sexual and reproductive rights which the Government of India has committed to, under various international conventions like International Conference on Population and Development (ICPD) and Convention on Elimination of all forms of Discrimination against Women (CEDAW). The following could be considered to address this:

- a. The Drug Controller General of India could send an advisory/guidance to all State Drug Controllers clarifying that MA drugs in combipack 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, they should be held to the same standards/scrutiny that state drug regulatory authorities hold for other Schedule H drugs and 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. Update state drug regulatory authorities on provisions of MTP Act, Rules and Regulation that offers confidentiality, so that any guidance from drug regulators are not in conflict with the MTP Act.

## **2. Wider dissemination of Government of India Guidelines on MTP Act and PCPNDT Act**

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 selection.<sup>xv</sup> 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 trainings for implementing authorities.

## **3. Harmonise DCGI approval 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 combipack in 2008 is for use up to nine weeks gestation. The MTP Rules need to be amended to eliminate this inconsistency. Since WHO recommends use of MA drugs combination up to 12 weeks, MoHFW/DCGI should consider increasing the gestational limit for MA drugs up to 12 weeks. The Drugs and Cosmetics Act Rules mandate that the chemists have to maintain a prescription register for Schedule H drugs containing details of the prescriber and the patient.<sup>xvi</sup> 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, selective inspection of one drug over the other impacts its access and is seen in Rajasthan and Maharashtra. Further, this rule also conflicts with the guarantee of privacy by the MTP Regulations, and therefore, removal of this requirement for MA drugs should be considered.

## **4. Improving knowledge of chemist on abortion and MA drugs**

Chemists are the first point of contact for a majority of MA drug users and they do seek information on the drug dosage, side effects etc. Government in partnership with MA drug marketing companies and Chemists and Druggists association could explore the possibility of improving knowledge of retail chemists on abortion in general and MA in particular so that they provide correct information while selling MA drugs.

## **5. 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 estimated that there are only 60-70,000 doctors who can prescribe MA drugs.<sup>xvii</sup> It is estimated that 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 drugs. 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 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.

## **6. Increased investments in safe abortion communication through IEC and media outreach**

Given the low awareness of 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 context of sex selection, tends to use language and visuals which stigmatise abortion resulting in increased confusion regarding its legality.

## 7. Providing support to women who access drugs without prescriptions

The data from this study shows that 50% of the sales of MA drugs in Bihar and 57.5% in Uttar Pradesh are without prescription, which should not be alarming, since most schedule H drugs are easily available without 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. The following could be considered to provide support to women during the MA process:

### a. Liaising with manufacturing companies:

To reach women directly with information and support, easy to understand graphical instructions on routes of administration and dosage can be integrated into the packages. A national helpline number can be disseminated on the packages which women can dial to get more information on MA in multiple languages.

### b. Alternative ways to ensure women get adequate information:

There is a need to explore various alternative interventions for women to get information on use of MA without relying on the chemists. These could be community interventions with involvement of the health workers who are trusted by the women. They could be potential carriers of accurate information and can counsel the women on MA use pertaining to its dosage, routes of administration and what to expect from the process. This would require intensive trainings of the health intermediaries and value clarification so that they are unbiased in supporting women and respect confidentiality. Other possible ways could include introducing helpline services which offer comprehensive information on the medical method of abortion and can be accessed easily and directly by women.

The availability of combipack MA drugs has indeed changed the landscape of abortion care in India for the better. The use of other unsafe methods for abortions has drastically come down and is estimated to be only 5%.<sup>xviii</sup> 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 they are being referred to/seek assistance from doctors or health facility. WHO has recently included MA drugs in the Core List of Essential Medicines (previously it was in the Complementary list). The earlier list had advisory stating “that close medical supervision is required for use of mifepristone-misoprostol for medical abortion”. This advisory is not mentioned in WHO’s latest list of essential medicines, which clearly indicates that MA drugs can be used with minimum level of medical supervision and the risks associated with it are minimal. 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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