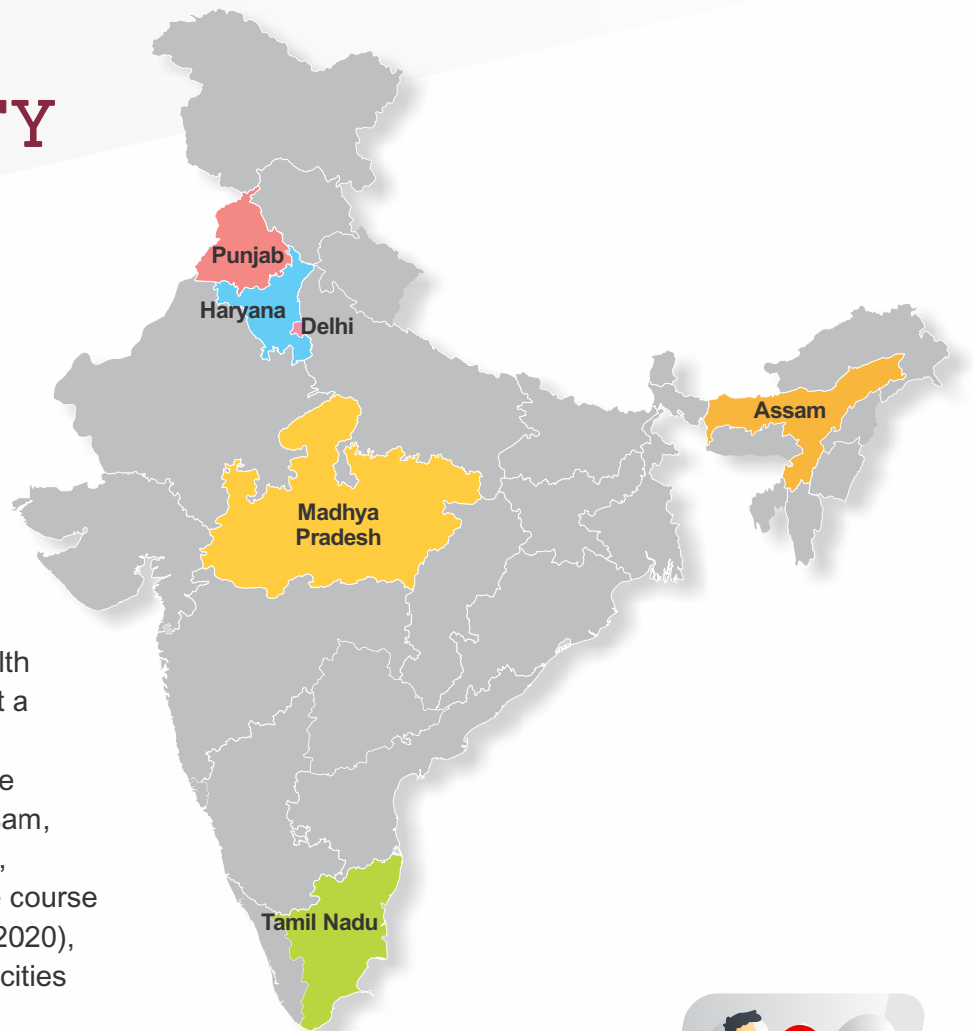


AVAILABILITY OF MEDICAL ABORTION DRUGS

IN THE MARKETS OF
SIX INDIAN STATES, 2020

EXECUTIVE SUMMARY

Foundation for Reproductive Health Services (FRHS) India carried out a study to assess the availability of medical abortion (MA) drugs in the markets of six Indian states – Assam, Delhi, Haryana, Madhya Pradesh, Punjab and Tamil Nadu. Over the course of three months (January-March 2020), we spoke to 1500 chemists in 25 cities and five sub-districts of Delhi to understand the issues impacting the availability of MA drugs. This fact sheet summarises the key findings of the study and presents a few recommendations to address the emerging issues.



Why did we Conduct this Study?

Pratigya Campaign for Gender Equality and Safe Abortion carried out a research in 2019 to assess the availability of MA drugs in four Indian states. The findings revealed an overwhelming shortage of MA drugs in two out of the four states surveyed – Rajasthan and Maharashtra.¹ The main reason for the shortage as pointed out by a majority of chemists was legal barriers around stocking of MA drugs. 56% of all chemists across the four states reported that MA drugs are overregulated as compared to other Schedule H drugs. Given that majority of the abortions (81%) in India are carried out using MA drugs, a shortage in its availability would mean lack of choice for women seeking abortion in India.² To understand the trends and situation in key states, FRHS India, which hosts the Pratigya Campaign secretariat and is a partner organisation, undertook the second phase of the study in six new Indian states.

The Objectives of the Study were



To verify and understand the current status of availability of MA drugs in the market



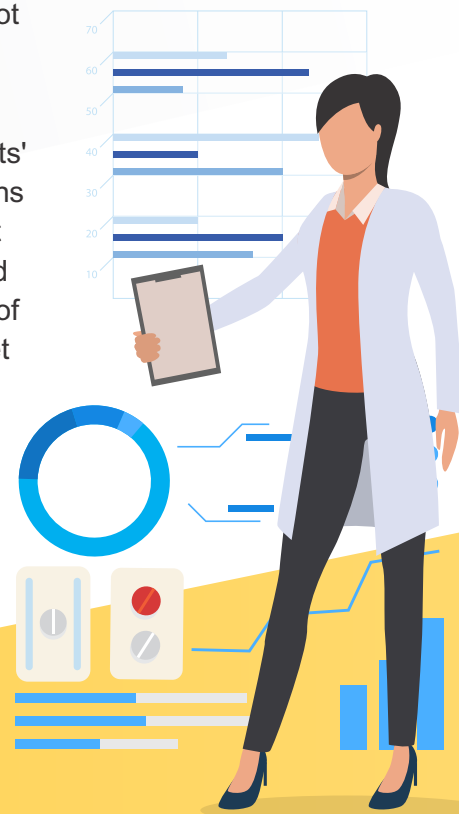
To understand the key reasons for stocking/not stocking of MA drugs



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 MA drugs in their outlet



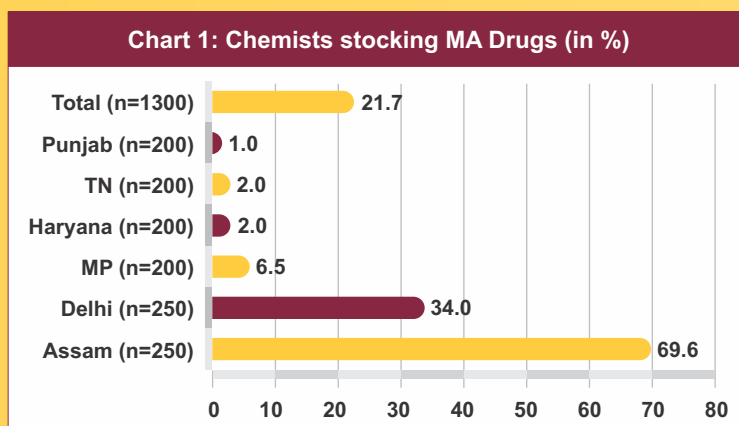
States	Cities/Sub-districts Covered
Assam	Dibrugarh, Guwahati, Jorhat, Nagaon and Silchar
Delhi	Hauz Khas, Najafgarh, Narela, Patel Nagar and Seelampur
Haryana	Ambala, Faridabad, Gurugram, Panipat and Yamuna Nagar
Madhya Pradesh	Bhopal, Gwalior, Indore, Jabalpur and Ujjain
Punjab	Amritsar, Bathinda,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

Key Findings

Is there an Issue with Availability of MA drugs?

Our findings indicate that four out of the six states surveyed are facing an overwhelming shortage of MA drugs. Very few chemists reported stocking MA drugs in Madhya Pradesh (6.5%), Tamil Nadu (2%) and Haryana (2%). The lowest stocking was seen in Punjab at 1%.

Assam reported the highest stocking at 69.6% followed by Delhi at 34%.



Why are chemists not Stocking MA drugs?

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. 79% of all chemists reported legal barriers, excessive documentation and paperwork as reasons for not stocking.

Have the chemists received any form of Communication on MA drugs from Drug Control Authorities?

40% of the chemists stocking MA drugs (n=282) reported receiving some kind of communication from drug control authorities on MA and its sales. 82% received verbal communication while 7% received written communication. Overall, 43.8% chemists who received communication were told to sell MA drugs only on prescription. In Assam, 31% of the chemists who received communication shared that they were told to keep women's details such as name, address and mobile number.

Are chemists aware about the Legality of Abortion in India?

As compared to the first phase of the research, more chemists were aware about the legality of abortion in India. 62% chemists reported that abortion is legal under specific conditions, while only 21% chemists reported that abortion is not legal in the country. Half of all chemists who reported that abortion is legal/legal under specific conditions were aware that abortion is legal up to 20 weeks gestation.

Do Clients Return after Purchasing MA drugs?

Our findings show that on an average, less than two out of every ten clients return to the pharmacy. Out of the last 2820 clients who visited the pharmacies, only 12% of clients came back. Only 7% of the total clients (n=2820) came back because of issues with the drugs.



93%

of clients appear to have had the desired outcome

Are MA drugs being Overregulated Compared to other Schedule H Drugs?

55% of chemists (same among chemists stocking and not stocking) across the six states reported so. 78% chemists in Punjab, 65% in Tamil Nadu, 40% in Madhya Pradesh, 43.5% in Haryana, states which are facing an availability issue, reported that MA drugs are overregulated as compared to other Schedule H drugs. A significant 45.6% in Delhi and 58.4% in Assam also reported overregulation of MA drugs.

Are these Drugs being Purchased Over the Counter?

No, out of the last 2820 clients who visited chemists in Delhi and Assam, 77% reportedly came with a prescription, while only 33% came without one. 84% clients in Delhi and 71% in Assam came with a prescription to purchase MA drugs. This is contrary to the perception that most MA drugs are being sold without prescription.

Do the chemists believe that MA drugs Contribute to Sex-Selective Abortions?

Overall, only 10% have this misunderstanding. A majority of (84.3%) chemists reported that MA drugs cannot be used for this purpose. In Tamil Nadu however, 36% have this misunderstanding.



Findings from Mystery Shopping

The mystery shopping method was carried out among 200 chemists in four states (Haryana, Punjab, Madhya Pradesh and Tamil Nadu) which had the lowest MA stocking percentage. In each of these states, an additional 50 chemists were approached by a mystery client without a doctor's prescription to verify the availability of MA drugs. 78.5% of chemists (n=200) approached via mystery shopping method were not stocking MA drugs. Except for Madhya Pradesh and to an extent in Punjab, results of mystery shopping are consistent with the survey results. In Madhya Pradesh, 56% chemists and in Punjab, 22% reported stocking MA drugs.



Table 2: State-wise stocking of MA Drugs by chemists (Mystery Shopping Approach)

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%)



Inaccessibility of Emergency Contraceptive Pills 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 (ECPs) in Tamil Nadu was also very poor. Only six chemists out of the total sample (n=200) in Tamil Nadu reported stocking ECPs 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.³ 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.



What do the Findings Imply?

● Reversal of Gains:

If access to MA drugs is compromised, women may be forced for unsafe abortion, which is likely to adversely impact gains in Maternal Mortality Ratio (MMR) made over the couple of years.

● Reduced Access and Choice:

If access to MA drugs is compromised, women would be forced to seek a surgical method, reducing choice. Moreover, already there is an acute shortage of approved providers.

● Increase in Cost of Safe Abortion:

The cost of MA drugs and consultation fee is much lower than surgical abortions. Many facilities, these days, have also started insisting on COVID-19 tests before providing any clinical service, thereby increasing the cost of abortions.

● Role of Prescription:

MA drugs being procured without prescription is a misconception. As per the findings, 77% of the clients came with a prescription which also indicates that women are making informed choices and consulting providers.

● MA Outcomes Positive for Most Women:

93% of women who used MA drugs have reported positive outcomes. People have this perception that easy availability of MA drug is resulting in higher complications, while in reality, the providers report very little life-threatening complications and perforations as compared to that of 1990s and early 2000.

● Awareness and Knowledge of Abortion Issues:

78% of chemist knew that abortion is legal; 98% could differentiate between ECPs and MA drugs; 75.5% knew the two drugs and the sequence in which they are to be taken. 83% believe that Combi-pack can't be used for gender-biased sex-selection.

We Recommend

● Address Misconception regarding MA and Gender-Biased Sex-Selection:

The Drug Controller General of India (DCGI) can issue a guidance to state and district drug authorities clarifying that MA Combi-packs cannot be used for sex-selective abortions as they are indicated for use only up to nine weeks, while sex of the fetus, using the most common method, Ultra Sonography can only be determined after 13-14 weeks gestation. MA drugs should be treated like any other Schedule H drug and therefore should be held to the same standards. DCGI/Ministry of Health and Family Welfare (MoHFW) can also partner with civil society organisations to develop Information Education Communication (IEC) material and briefs to clarify the issue and disseminate among drug inspectors.

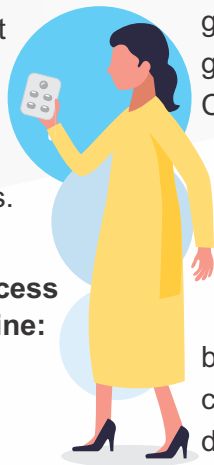
● Amend MTP Rules to allow MBBS Doctors to Prescribe MA drugs:

By allowing MBBS doctors to prescribe, the number of abortion providers will increase from 60,000-70,000 to over a million, enabling women to access drugs with a prescription and receive medical support and care.⁴ Allowing MBBS doctors to undergo a short, preferably online course, on MA must therefore be considered while amending Medical Termination of Pregnancy (MTP) Rules.



● Consider Classifying MA Combi-pack under Schedule K of the Drugs and Cosmetics Act:

There is a strong evidence which suggests that MA drugs are safe for use and are unlikely to have an adverse impact on the user's health. WHO has also listed MA drugs in its core list of Essential Medicines List 2019, stating that it can be used without medical supervision.⁵ Classifying the drug under Schedule K could remove some of the barriers regarding stocking and sale of the drugs faced by chemists.



● Providing Support to Women who access MA drugs – Setting up Toll-free Helpline:

To support women with comprehensive information, a toll-free helpline number should be mandatorily displayed at the back of the MA Combi-packs. This could be jointly funded by manufacturers/marketers of MA drugs and the MoHFW, Government of India.

● Increased Investment in Safe Abortion Communication through IEC and Media Outreach:

Abortion does not get adequate coverage in government IEC and Behaviour Change Communication (BCC) outreach activities. MoHFW should consider investing more on safe abortion communication to clarify the myths and spread awareness on the provisions of the law.

● Harmonise Central Drugs Standard Control Organisation Approval/Requirements and MTP Act:

The MTP Rules amended in 2003 allow the use of MA drugs for termination of pregnancies up to seven weeks gestation, while the DCGI's approval for Combi-pack is up to nine weeks gestation. It also seems that new labelling guidance issued by DCGI in 2019 for MA Combi-pack (“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”) is being misinterpreted to suggest that these drugs cannot be stocked and sold by retail pharmacies. DCGI/MoHFW should consider increasing the gestational limit for MA drugs' use up to 12 weeks in line with WHO recommendation and withdraw the labelling guidance which seems to be creating confusion on the ground.

The Full Report can be Accessed here:

<https://bit.ly/2E5Swjt>



Citation

Chandrashekar, VS; Choudhuri, D and Vajpeyi, A. FRHS India, 2020, Availability of Medical Abortion Drugs in the Markets of Six Indian States, 2020

References

¹Chandrashekar, 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>

²Singh S et al., Abortion and Unintended Pregnancy in Six Indian States: Findings and Implications for Policies and Programs, New York: Guttmacher Institute, 2018, <https://www.guttmacher.org/report/abortion-unintended-pregnancy-six-stat...>

³International Institute for Population Sciences (IIPS) and ICF. 2017. National Family Health Survey (NFHS-4), 2015-16: India. Mumbai: IIPS

⁴Improving Access to Safe Medical Abortions, Why expanding the Provider Base is essential: <https://pratigyacampaign.org/wp-content/uploads/2019/09/improving-access-to-safe-medical-abortions-english.pdf>

⁵World Health Organization.(2019). World Health Organization model list of essential medicines: 21st list 2019. World Health Organization. <https://apps.who.int/iris/handle/10665/325771>. License: CC BY-NC-SA 3.0 IGO