



Availability of Medical Abortion Drugs in the Markets of Six Indian States, 2020

Foundation for Reproductive Health Services (FRHS) India carried out a study to assess the availability of medical abortion (MA) drugs in the markets of Tamil Nadu. Over the course of three months (January-March 2020), we spoke to 250 chemists in five cities of Tamil Nadu 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 including Tamil Nadu.

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



Table 1: States and Cities covered under the Study

States	Cities/Sub-districts Covered
Tamil Nadu	Chennai, Coimbatore, Madurai, Tiruchirappalli and Tiruppur

Key Findings

Only 2% chemists

in Tamil Nadu reported stocking MA drugs

83% of chemists reported



Legal barriers/ issues



Excessive documentation/ paperwork

as reasons for not stocking MA drugs

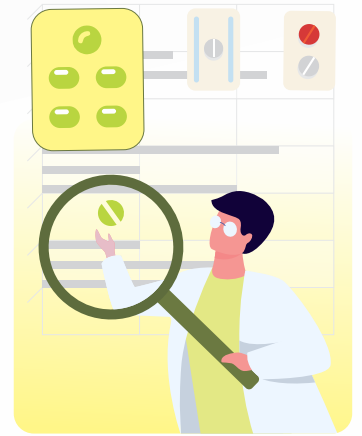
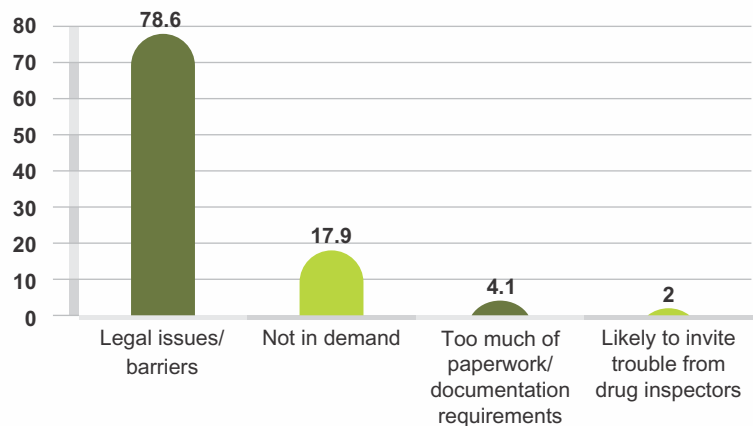


Chart 1: Reasons for not stocking MA Drugs (in %) (N=196)



*Multiple responses were accepted

65% chemists reported that



MA drugs are being overregulated as compared to other Schedule H drugs

53% chemists reported that



MA drugs do not contribute to sex-selective abortions

Are chemists aware about the Legality of Abortion in India?

In Tamil Nadu, 75% chemists reported that abortion is legal in the country. 73% of those who reported so were aware that abortion is legal under certain conditions. 30% of all chemists in Tamil Nadu, other than those who said abortion is illegal, were aware of the 20 week gestational limit. 15% of chemists who reported that abortion is legal, were also able to report the correct gestational limit for MA Combi-pack use (nine weeks).

What are the chemists' Perceptions on MA drugs?

Half of all chemists in Tamil Nadu find MA drugs to be useful for women. 73% chemists have the perception that availability of MA drugs has increased the number of abortions in the country.

What do the Mystery Shopping Findings Indicate?

The mystery shopping method was carried out among 50 chemists in Tamil Nadu as it had a very low MA stocking percentage. In each of the five sample cities, an additional 10 chemists were approached by a mystery client without a doctor's prescription to verify the availability of MA drugs. 92% of chemists (n=50) approached via mystery shopping method were not stocking MA drugs. About 8% chemists were stocking the drugs.

The Curious Case 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?

The findings of this study are in line with the trends observed in the first phase of the study that MA drugs are disappearing from the shelves of retail chemists. There are clear issues in availability of MA drugs in Tamil Nadu. The non-stocking of MA drugs in the state seems to be linked with overregulation. The findings indicate that 85% chemists no longer stock MA drugs to avoid legal issues and excessive documentation work in Tamil Nadu. Evidence shows women in large numbers prefer medical abortion over the surgical method. If MA drugs are not available, it can result in women being forced to seek unsafe methods, which will reverse the gains we have made in reducing maternal mortality.

● 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.

● Issue Clarification on ECPs

There is an immediate need for the Drug Controller General of India (DCGI) and authorities to issue a clarification on ECPs, as there is a prevalent misconception that ECPs are banned in the state. The perceived ban is tremendously affecting the reproductive choices in the state.

We Recommend

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

The 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.

The Full Report can be Accessed here:

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



● 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.

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