FRHS INDIA
Children by choice, not chance

Understanding Marketeer's Perceptions on Medical Abortion Drugs: Not a Viable Business Anymore

Foundation for Reproductive Health Services (FRHS) India conducted a study across the markets of 10 Indian states in 2018 and 2020 to gauge the issue of availability of medical abortion (MA) drugs. In 2018, we surveyed chemists across Bihar, Maharashtra, Rajasthan and Uttar Pradesh, and found negligible stocking in the states of Rajasthan and Maharashtra. A similar study was conducted in 2020 across Assam, Delhi, Haryana, Madhya Pradesh, Punjab and Tamil Nadu and found abysmal stocking in all states except for Assam. Even the national capital of Delhi showed low stocking. In order to further deep dive into the issue on non-availability of MA drugs, a telephonic and online study was conducted across modern retail and online pharmacies. That study too indicated negligible or non-stocking of MA drugs.

In all these studies, **heavy documentation, legal hassles, misconceptions on MA drugs and harassment emerged** as major deterrents against stocking of MA drugs in conventional pharmacies, as well as in modern retail.

The approval of MA combipack drugs by Central Drugs Standard Control Organisation (CDSCO) in 2008 has changed the landscape for access to safe abortions in the country for the better. MA has provided a pregnant person with a safe and effective method of terminating a pregnancy and has emerged as the most preferred method of abortion. When combipack was approved in 2008, three companies had launched their brands. From 2008–2011, as many as 50–60 MA combipack brands were launched. With the increased scrutiny of MA drugs post 2011–12, the number of brands available in the market has reduced drastically to around 30–35. The available brands are Cadila Mifegest Kit, Aristo Mifty Kit, Mankind Unwanted Kit, Khushi MTP Kit, Safe Abort, Insta Kit, Pregnot Kit, Termipil Kit, etc.

MA in India is the preferred method of abortion care with an estimated 81% of the 15.6 million[1] annual abortions being performed using MA drugs. In 2002, the Drug Controller General of India (DCGI) 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. MA, being a non-invasive method, is also proving to be a safe option for pregnant persons, during the pandemic, as mobility is restricted, clients are concerned about visiting health facilities, health facilities are focused on managing the pandemic and many facilities are still not fully functional. In many countries including the United Kingdom, Australia and South Africa, MA is being offered through telemedicine (both doses) to ease pressure on health systems and provide access to pregnant persons, during the pandemic.

Over the past few years, anecdotal evidences, 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 1,000 males in 2011 has resulted in stringent enforcement of the Pre-Conception and Pre-Natal Diagnostics Techniques (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 mindsets. More states have since then joined the fight to address sex-selection. The efforts to fight the menace of the declining sex ratio unfortunately have created barriers and roadblocks to pregnant person's access to abortion care in general and MA in particular[2].

While, in many countries, policies have been changed to make access to MA easier, in India, restrictions seem to be more than before. To understand the gap between markets, users and manufacturers, FRHS India conducted a study on 'marketeer's perspective' on the issue, to learn from them on the gaps.

1 Methodology

To understand the impact and perspective of the marketeers on the MA drugs' distribution and sales over the past few years, due to increased scrutiny, FRHS India connected with 10 companies, private and social enterprises to participate in the study. We were able to interview five respondents from five organisations – two from private and three from social enterprises.

The interviews were conducted virtually upon taking prior appointments. The companies and organisations surveyed are – Accent pharmaceuticals, DKT International India, Population Health Services India, Population Services International India, and Zydus Cadila. The interviews focused on companies' background, involvement in MA business, challenges faced by them in sales and distribution of MA drugs, their perceptions regarding regulation, and the impact of the current regulatory environment on their MA business.

A brief about the companies surveyed

The companies interviewed for the qualitative survey had launched their products between 2008 and 2010, and marketed their brands across the country. Of the five organisations interviewed, four have a pan-India presence and one is a contract manufacturer. Three of the respondents were social enterprises, marketing a range of reproductive health products.

2 Findings

» MA market no longer a viable business

Four of the five respondents mentioned that they have seen increased regulation of MA market and this is impacting sales and distribution of MA drugs in the country. One company indicated that their sales have shown a year-on-year decline by around 30–40%. Respondents indicated that private sector companies no longer find MA business viable for two reasons. One, the profit margins have become thin and two, concerns that the higher regulatory scrutiny may impact their other business. MA drugs come under the price control regimen and the maximum retail price is fixed by the National Pharmaceutical Pricing Authority. While the current MRP is fixed at Rs. 379–420, the marketeers indicated that their invoice price to wholesalers/stockiest is around Rs. 52–65 per combipack. The cost of manufacture/procurement is around Rs. 32–40, leaving them with a thin margin of 15–20% to cover sales, distribution and promotion costs. The cost at which MA combipack is sold to retail chemists/doctors is Rs. 55–80.

The margins for retailers for MA drugs is huge. Social enterprises indicated that this is the prime reason many private sector companies have reduced their focus on MA or have exited the MA business. Social enterprises continue to be in the market, since improving access to quality products at affordable prices is part of their mission. They indicated that the market share of social enterprises has been increasing over the years, since private sector companies are vacating the market. "Many manufacturers/ companies have withdrawn from the market owing to increased scrutiny and reduced margins", reported a respondent. "For large pharmaceutical companies, MA business is a tiny portion of their overall business, often less than 1%, they would not want to risk their other business due to this", said a respondent from the social enterprise company.

» Has there been increased scrutiny on MA drugs?

All respondents indicated that over the past few years, there has been increased scrutiny

on sales and distribution of MA drugs. The level of scrutiny varies from state to state. "There has been a huge push to promote 'Beti Bachao, Beti Padhao' campaign, which is very much required, however, this has resulted in higher scrutiny of MA drugs". The perception that MA drugs can be used for gender-biased sex-selection is the reason why MA drugs invite additional scrutiny. Respondents reported that the level of scrutiny is high in states like Rajasthan, Maharashtra, Punjab and Haryana and expect for one respondent, all others stated that their sales of MA drugs in some of these states have fallen. In recent years, the state of Madhya Pradesh has also seen an increased scrutiny.

Have companies or channel partners faced any regulatory action?

All respondents reported instances of their channel partners/sales persons of channel partners have faced action. Action included cases filed for selling MA drugs, violation of Drugs and Cosmetics Act (sales persons carrying the MA drugs without an order/invoice). A respondent mentioned an instance where the abortion provider mentioned the use of their brand of MA drug and the regulators/law enforcement officials threatened to take action against their sales person and distributor. "We have seen instances of cases being filed under Narcotics Substances Act against chemists/sales persons", a respondent reported. Often the distributors and marketing companies are questioned about to whom they sold the products and details of chemists and doctors to whom the product has been sold. "When our sales persons are hauled up by authorities, they tend to ask for shops and providers to whom MA drug has been sold. This is done with a malicious motive of "raiding registered clinics and create an environment of fear and intimidation". This seems to have created a sort of fear among chemists and doctors which is why they are not keen on stocking MA drugs.

Impact on MA business

Respondent indicated that private companies are no longer interested in MA business, however, social enterprises continue to sell and distribute in spite of the challenges. **"While for private investing in the business is not productive, for social enterprises, despite challenges, responding to the unmet need is a priority."** Respondents also mentioned that to avoid **inviting regulatory scrutiny or trouble, many prefer to purchase.**

In states where regulatory scrutiny is high, the trade is moving to a cash and no records mode, thereby driving the sale of MA drugs below the radar. "In some states, chemists remove the drugs from the box and dispense only the medicine strip, to avoid any potential link of the chemist with the drug. In other words, the client does not have any access to client information materials/leaflets which come along with the pack. This could result in improper use of MA", reported a respondent.

The reporting of such investigations in local press, court cases filed against chemist and sales person are creating a challenging environment for supply chain channel partners and many of them are not so keen on taking on these additional risks. Doctors who used to previously purchase and stock MA drugs to be dispensed to their clients, have also turned cautious and many of them prefer not to stock it anymore.

The contract manufacturer interviewed indicated that orders, they have received from their clients, have more or less remained the same over the past few years, "we were expecting this business to grow substantially, however, we don't see that happening".

What would be an ideal legal environment?

All respondents shared that clarity in law, protection of sales teams, and clear guidelines would be key to creating a safe environment for marketeers and manufacturers to continue in the MA business. "An ideal environment would be where restrictions on MA drugs are eased and clarification is issued by Ministry on usage, stocking, distribution and sale of MA drugs." There are inconsistencies in the guidance provided by the Medical Termination of Pregnancy (MTP) Act and

Rules and the approval by the drug controller. While the drug controller has approved the use of MA combipack up to nine weeks gestation, the MTP Rules allow the use of MA drugs for only up to seven weeks. While the MTP Rules allow MA drugs to be prescribed by a registered medical practitioner, the drug controllers' labelling requirements say that "MA combipack should be prescribed by a medical practitioner and used in a facility which is approved under the MTP Act and Rules". All respondents agreed that the main reason for higher scrutiny of MA drugs relates to gender-biased sex-selection. There seems to be a misconception that MA drugs can be misused for gender-biased sex-selection and the conflation of these two issues is proving to be a barrier. Since the most affordable and commonly used method to detect the sex of the fetus, Ultra Sonography (USG) (commonly known as ultrasound) is able to identify the fetus only at 13–14 weeks gestation, and MA drugs are approved for use only up to nine weeks gestation, the possibility of MA combipack being used for gender-biased sex-selection is unfounded and needs to be dispelled.

Harmonising what the CDSCO guidance/ labelling requirement and MTP Act and Rules say regarding prescription, sale and use of MA drugs along with clarifying the misconception regarding use of MA drugs for gender-biased sex-selection, would go a long way in creating a conducive regulatory environment for MA drugs.

Overall, the marketeers felt that the current situation is sub-optimal and there is a need to address the same.

3 Conclusions

The study findings indicate that manufacturers/ marketeers of MA drugs report that the current regulatory environment for MA is not conducive. All of them report instances of their channel partners – wholesalers, distributors, retail chemists having had to face regulatory action. Marketeers report that profit margins are very thin, and this coupled with a challenging regulatory environment makes marketing MA drugs unviable business proportion. Many private players have already exited the market. Fortunately, the gap created by the exit of private companies seems to have been filled in by the social enterprises. If the existing challenging situation is not addressed, it is likely that even social enterprises may find it difficult to continue making MA drugs available. Since MA is the preferred method of abortion in India, the shortage would have an impact on access to safe abortions in the country and force many pregnant persons to seek unsafe abortion, their health and lives.

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Click here for Availability of MA drugs across Markets of Six Indian States: https://pratigyacampaign.org/wp-content/uploads/2020/08/frhs-india-report-on-availability-of-medical-abortion-drugs-in-the-markets-of-six-indian-states-document.pdf

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[2] Abortion in India: A Literature Review, Guttmacher Institute, 2014, **https://www.guttmacher.org/sites/default/files/report_pdf/abortion-india-lit-review.pdf** p. 28

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