

Abortion Self-Care: A Forward-Looking Solution To Inequitable Access

Following the World Health Organization's (WHO) definition of self-care,* abortion self-care is the ability of pregnant individuals† to manage their unwanted pregnancies with or without the support of health care providers—particularly, in the early weeks of pregnancy (up to 12 weeks' gestation). The advent of medication abortion (MA) has made this possible, as early self-managed MA at home is a safe, acceptable and cost-effective method of pregnancy termination.¹ The drugs currently available for MA are mifepristone and misoprostol, as well as the two packaged together (also known as the combipack), which is more efficacious than misoprostol alone in evacuating the uterus and is considered the first-line medication for MA.² Regardless of the legality of abortion where they live, women worldwide are using these medications to self-manage pregnancy termination inside or outside clinical settings—in conjunction with telemedicine services,³ peer-led support groups,⁴ hotlines⁵ and online information sources⁶—which has contributed significantly to reducing maternal mortality and morbidity from unsafe procedures.⁷

WHO as a normative body has provided technical and policy guidance on safe MA,^{8,9} and has included MA drugs in its Essential Medicines List.¹⁰ By including mifepristone, misoprostol and the combipack in its expression of interest to manufacturers, WHO has created the conditions for greater availability of MA drugs.‡ Furthermore, WHO's recently published *Consolidated Guideline on Self-Care Interventions for Sexual and Reproductive Health and Rights* leverages self-care as key to achieve universal health care coverage.¹¹ WHO recommends managing an early abortion with the combipack without direct medical supervision when pregnant individuals “have a source of accurate information and access to a health-care provider should they need or want it at any stage of the process,” as well as self-assessing eligibility for MA and the completeness of the abortion using low-sensitivity urine pregnancy tests and checklists.

Abortion self-care demonstrates the potential of enabling abortion care, regardless of legal restrictions in any country, the availability of clinicians, or geographical or financial barriers. But despite the technological possibilities and scientific evidence supporting abortion self-care, access to this type of abortion care is not equal for all pregnant people. Since individuals can and will make decisions regarding pregnancy termination with or without the support of trained health workers, an enabling environment is needed to ensure that they do so safely.

This viewpoint focuses on regulatory aspects of MA

that determine women's access to quality and affordable abortifacient drugs, as well as to accurate information on their use. We first describe the manufacturing capacity and regulatory approvals for MA drugs worldwide, and then present case studies of the availability of these drugs and MA practices in Mexico and India, two middle-income countries that have different regulatory frameworks on abortion. We call for a systems approach to enable access to quality MA drugs and information across and within countries where abortion is not completely banned and access to abortion care exists. We call for including MA drugs in countries' and states' lists of essential medicines, ensuring their regulatory approvals, monitoring their quality, improving their affordability and advancing task shifting for the provision of information on MA management by trained health care workers.

Growing Availability and Accessibility of MA

In countries with reliable data, half of all abortions occur via medications,¹² with the proportion greater than 70% in some countries.¹³ With the new momentum around self-care brought about by the COVID-19 pandemic, and coupled with greater availability and accessibility of MA drugs, it will be important to enhance manufacturing capacity to keep up with the potential demand.¹⁴

The role of manufacturers is critical because the drugs that they choose to develop or refine, seek approval for and bring to market determine the options available to women. Worldwide, there are many more manufacturers of misoprostol than of mifepristone or the combipack. For example, 13 misoprostol manufacturers have been either approved by a stringent regulatory authority (SRA)§ or by the WHO prequalification program;¹⁵ however, of the many manufacturers of mifepristone and the combipack, only four and three, respectively, have received SRA approval or WHO prequalification.¹⁶

In tandem, regulatory approvals—especially at the

*WHO defines self-care as “the ability of individuals, families and communities to promote health, prevent disease, maintain health, and to cope with illness and disability with or without the support of a health-care provider.” Source: reference 11.

†Abortion (self-)care is needed for all pregnant individuals. Throughout this viewpoint, however, we sometimes refer to “women” (instead of “pregnant individuals”), as they are the main population requiring abortion and postabortion (self-)care, and research on MA has mainly been conducted on the population identified as “women.”

‡The expression of interest (EOI) is the first step toward seeking WHO prequalification.

§A Stringent Regulatory Authority is usually a national regulatory authority of a European Union country, the United States or Japan.

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national level—are critical because manufacturing capacity without marketing rights do not enhance choice for women. Misoprostol tends to be registered in many more countries than mifepristone,¹⁷ because it has many indications for reproductive health and for treatment of gastric ulcers, it is easy to manufacture and has many manufacturers. On the other hand, mifepristone’s sole indication for pregnancy termination has limited its wider registration, availability and use.

In addition to the existence of MA drugs, their quality** is of concern to policymakers, program managers, health activists and users.¹⁸ Poor quality drugs can lead to ineffective or incomplete abortions, and result in poor health outcomes that are detrimental to users and the health system. Although countries rely on national regulatory authorities for assessing product, approval by an SRA or the WHO prequalification program provides assurance of a good quality product.

The accessibility of quality MA drugs is related to the regulatory approvals given to qualified manufacturers, country regulations for over-the-counter access and drug pricing. In addition, as noted above, the capacity of health care workers to provide clients at their point of access with evidence-based information on abortion self-management and referral contacts is key to ensuring adequate self-care. We will briefly examine these themes in India and Mexico. Compared with India, Mexico has a more restrictive legal framework on abortion; however, the two countries have certain similarities regarding access to safe abortion self-care.

Country Case Studies on Self-Use

• **India.** In 1971, India passed the Medical Termination of Pregnancy Act (MTPA) legalizing induced abortion up to 20 weeks’ gestation under a range of conditions (e.g., pregnancy resulting from rape or incest, or contraceptive failure among married couples).¹⁹ An amendment to MTPA in 2002 allowed the use of mifepristone and misoprostol for MA for pregnancies up to seven weeks and permitted abortion-certified doctors to provide MA even in facilities not registered for abortion provision, as long as a referral linkage with a higher-level facility was in place.²⁰

Since mifepristone was licensed for use in India, the number of MA products and their sales has expanded in the retail market. Between 2002 to 2007, sales of misoprostol-containing drugs increased by 646%.²¹ In 2008, the combipack was approved by the government,²² and sales increased rapidly. MA drugs are included in the Essential Drugs List in India.²³ There are many manufac-

turers and brands of misoprostol in Asia and, hence, misoprostol sold in Asia is among the least expensive in the world.²¹ With increasing popularity of MA drugs, the medicine market is flooded with several brands of misoprostol and the combipack, ranging in price from 300 to 600 rupees (US\$4–8);²⁴ however, the quality of these products is not necessarily assured.

The combipack is registered in India as a “schedule H” drug that cannot be purchased over the counter without a prescription from a qualified doctor. While in some states, the seller is required to keep a copy of the prescription, this is not the case in most. Thus, access to MA drugs in pharmacies without a prescription from a qualified doctor and from informal vendors is widespread in the country.††^{24–26}

Given that adverse sex ratios remain a challenge in India as result of son preference,²⁶ the government has sought to restrict the availability of MA drugs. Instead of questioning the efficacy of policies designed to prevent female feticide, such as the Pre-Conception and Pre-Natal Diagnostic Techniques Act of 1994, several state governments have tightened regulations and monitoring of providers and pharmacists.²⁶ Over-regulation and harassment by government officers are major reasons cited by pharmacists for not stocking MA drugs,²⁷ which limits women’s access to safe and legal MA.²⁸

Of the estimated 15.6 million abortions conducted in India each year, 73% are performed using MA outside of a health facility.¹³ Women know they can obtain allopathic abortifacients in pharmacies,^{26,29} and prefer self-use for reasons of privacy, cost, avoidance of possible surgery or hospital stays, and compatibility with their household duties.^{25,30} Unfortunately, women tend to receive limited or inaccurate information and little or no counselling when purchasing MA drugs from a pharmacy.^{13,24}

Overall, the regulation and efforts regarding access to safe abortion services in India may not be radical, but still represent a progressive approach.

• **Mexico.** Compared with India, Mexico represents a more restrictive setting for abortion. Mexico is a federal republic, and abortion is solely regulated at the state level. There are eight legal indications for abortion (e.g., safeguarding a women’s life or health), and each state’s penal code includes at least two legal grounds; rape is the only indication for abortion in all of Mexico’s 32 states. In Mexico City (as of 2007) and Oaxaca (as of 2019), abortion on request is permitted through 12 weeks’ gestation. Given legal restrictions on abortion, neither reliable data on the volume of MA drugs sold for pregnancy termination nor estimates on how many women self-manage abortion without connecting with a medical service are available. In Mexico City, more than 75% of all legal terminations of pregnancies in clinical settings between 2007 and 2020 were by MA.³¹

Misoprostol has had regulatory approval for treatment of gastric ulcers in Mexico since the 1980s and is available over the counter in pharmacies throughout the country. Mifepristone is registered for obstetric care and has been

**Pharmaceutical product quality is usually defined by identity, purity, strength, potency, uniformity of dosage form, bioavailability and stability. Source: Management Sciences for Health (MSH), *Quality Assurance for Pharmaceuticals*, Medford, MA, USA: MSH, 2012, <https://www.msh.org/sites/msh.org/files/mds3-ch19-qualityassurance-mar2012.pdf>.

††In India, the terms “chemist” and “pharmacist” are used interchangeably. The Pharmacy Council of India (a statutory body of the Government of India) requires each pharmacy to have an attached pharmacist; however, pharmacists are not necessarily available all the time, and noncertified salespersons often dispense medicines to customers.

included in Mexico's List of Essential Medicines (EML) since 2015,³² although every state has its own EML.³³ Mifepristone is solely available in health care facilities. There are five registered manufacturers of misoprostol and two of mifepristone.³⁴ Of those, only two manufacturers—both of misoprostol—are based in Mexico, and the others are based abroad.

Because misoprostol is the MA drug that women in Mexico can more readily access, we focus on it here. Misoprostol is registered as a “fraction IV” drug indicating that a medical prescription is required for its sale, but vendors need not retain it; thus, over-the-counter sale without a prescription is common.^{35,36} Women obtain misoprostol mainly from pharmacy workers, and from friends and physicians;³⁷ however, it can also be obtained through informal vendors online.³⁸ Misoprostol pricing in pharmacies differs per state, but ranges from 440 pesos (US\$20) for generic products to 1,200 pesos (US\$55) for branded products, which is costly considering that, as of 2020, the minimum daily wage in Mexico was 123 pesos (US\$6). Therefore, some pharmacies sell individual pills or blisters to clients, often with little use instruction.^{35,36} Even for those who purchase a complete product, however, the package does not include information on use for MA because misoprostol is not registered for pregnancy termination in Mexico.

The safety of a self-managed abortion in the country is also moderated by the quality of information women and their support networks have at the time of induction, which can be low.³⁷ Pharmacy workers do not hold degrees in pharmaceutical sciences, and they tend to have insufficient knowledge about MA management to advise women on the recommended dosage to induce an abortion.^{35,36}

The Way Forward

As the COVID-19 pandemic has heightened health disparities and inequities,³⁹ policymakers and health care providers should consider the increasing evidence on self-care for pregnancy termination. Evidence worldwide suggests abortion self-care is already widely practiced as women are self-managing abortions regardless of legal restrictions, regulations on over-the-counter sale of MA drugs, and the availability of trained health care workers. In countries where abortion is permitted under at least some legal grounds and access to abortion services exists, actively ensuring the well-being of those who self-manage an abortion is possible. Two minimal conditions are necessary for this: Facilitating the readiness of the market (through a variety of manufacturers, approved country regulations and affordability of drugs), and making step-by-step information on self-use readily available to all individuals and communities.

In India, the legal framework on abortion has been progressive for almost 50 years. Various manufacturers of MA drugs (including the combipack) make them readily available and affordable. However, information provided by pharmacists to buyers on correct use, as well as monitoring

of the quality of MA drugs, is still wanting. In Mexico too, such information and monitoring are needed. In addition, restrictive regulations on abortion create a challenging environment for safe MA self-use. To start with, the combipack is not readily available, and the cost of MA drugs may be prohibitively expensive—especially for underserved and adolescent women.

Health systems play an oversight role to enable an environment in which abortion services and abortion self-care is safe and equitable for all.¹¹ In settings such as India where abortion is broadly legal, self-management of abortion might be a part of an active policy to increase universal health care coverage and reduce inequalities. In more restrictive settings, such as Mexico, the provision of information on self-care for abortion and the availability of quality MA drugs should become a part of a harm-reduction strategy.^{40,41}

To improve the health of individuals seeking an abortion in countries where abortion is not completely banned, governments should enhance the availability and accessibility of MA with the inclusion of MA drugs in policy and service guidance documents, including regulatory guidelines, service delivery guidelines, essential medicines lists and procurement catalogs. To reduce informal sales of low-quality products and increase early MA self-care, countries' competent authorities should further consider the withdrawal of unnecessary regulations of over-the-counter sale of MA drugs. As we have shown in our two country case studies, restrictions do not prevent people from seeking MA and might put them at risk of obtaining poor quality MA drugs with little or no information on correct usage. Increasing access points to MA drugs and information for women is needed to ensure equal access to self-care (e.g., the concentration of pharmacies in urban areas can be a challenge to the availability of MA drugs in rural and interior settings).

National regulators and health authorities must provide oversight of product registration, pricing and quality throughout the distribution chain. Markets too are needed to promote equal access to MA abortion self-care. Governments should work to expand access to generic formulations and promote public-sector availability and competitive pricing in the private marketplace.⁴² Similarly, innovations in retail-market options—such as bundling pregnancy test and MA products—could help bring an economic advantage and improve consumer convenience for safe abortion self-care.⁴³ Governments may subsidize access to these products for poorer and marginalized populations, while allowing out-of-pocket expenses for better-off populations.⁴⁴

Health systems are also responsible for making adequate and understandable information on MA and self-use available to individuals and communities. At a minimum, such information must include MA regimen (protocol, dosage and route of administration), warnings and precautions, possible side effects, signs of complications and clear step-by-step guidance on how to access a trained health

care provider in case one is wanted or needed, as well as for postabortion information that includes contraceptive uptake, if desired.

Policies on task sharing and shifting—in addition to telemedicine protocols and guidelines—are key to promote MA self-care, as well as availability of health care providers should a woman need it or want it at any stage of the process. Medical professionals (especially physicians), who may be reluctant to shift tasks to mid-level providers and health care workers, may benefit from understanding that their contributions to training, supervising and managing difficult cases and possible complications will remain key to women's well-being.^{45,46} Also, government agencies responsible for the safety, efficacy and security of medicines can monitor online information provision on MA, and sanction misleading and inaccurate information that put individuals at risk of complications. Finally, as self-care moves forward, the current discussion among researchers, practitioners and policymakers on what constitutes quality abortion care should consider indicators for abortion self-care beyond clinical settings.⁴⁷

Under an enabling environment, abortion self-care represents a win-win for pregnant people and health systems. Self-managed abortion supports individuals' sexual and reproductive health and rights by giving them the opportunity to control their entire abortion process—from choosing an abortion method to managing confidentiality and costs⁴³—and their postabortion actions. These benefits may also encourage people to terminate their pregnancy at an early gestational age, which helps reduce the risks of complications.⁴⁸ Health systems, too, benefit from task-shifting to lower health cadres and workers and pregnant individuals, as well as by reducing the costs arising from managing abortion complications.⁴⁹

Strengthening self-care constitutes a paradigm shift by equipping the user with the tools and autonomy to manage their own health. Under this paradigm, health care professionals become facilitators of care, while individuals acquire higher responsibility for their own care. As such, pregnant individuals' need to be appropriately equipped with accurate knowledge and available resources to support them before, during and after the process. Today more than ever, unsafe abortion is a preventable pandemic,⁵⁰ and health systems have within reach a safe, effective and comparatively low-cost method to improve pregnant individuals' health outcomes and autonomy over their lives with regard to abortion. MA drugs are widespread in sale and use, but only health systems have the power to steer an enabling environment to ensure equal and safe access to abortion self-care.

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