Critical Analysis of Pharmaceutical Regulation of Early Medical Abortion (EMA) in Great Britain

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Introduction

Legalised abortion was brought into Great Britain by the landmark Abortion Act 1967 (Aiken et al., 2018). Legalised abortion mainly involves the prescription of two medications 'mifepristone and misoprostol' to the pregnant woman. Women in Great Britain are generally assumed to have access to affordable, acceptable and available abortion medications. However, several pharmaceutical regulations on how these medications can be legally prescribed and administered impose impediments to access and service provision. For example, regardless of the procedure type or gestation, two registered practitioners must view and approve all abortion requests (BPAS, 2013). Similarly, both Early Medical Abortion (EMA) medications (mifepristone and misoprostol) cannot be taken at home, but at a registered clinic place, in which case, each medication is administered with a recommended 24-48 hours interval period. If these pharmaceutical regulations are not properly followed, then it will be deemed illegal and offensive crime under the common law in Scotland and under the "Offences Against the Person Act" (OAPA) 1861 in England and Wales.

To uphold the tenets of reproductive justice and ensure reproductive autonomy, women should have equitable and timely access to high-quality abortion (Jayaweera et al., 2020). However, despite these EMA medications are considered safe for pregnant women, they have been strictly regulated, or over-regulated out of proportion to their risks. Serpico (2021) argues "the phenomenon of abortion being treated differently under the law than other comparable health care" (p. 8).

Given these facts, this essay critically analyses pharmaceutical regulation of Early Medical Abortion (EMA) in Great Britain. The essay starts with brief explanations of abortion, early medical abortion (EMA) and the two key medications that are prescribed in EMA. Then the essay critically discusses the pharmaceutical regulatory framework for Early Medical Abortion (EMA) namely: 1) the essential requirement for 'practitioner's prescribed medicines' 2) the essential requirement for the 'place' where prescription and administration of abortion medications can be performed.

Essay Body

In international law, abortion rights have been framed historically with an assumption that the medico-legal paradigm centred on the regulated systems of medical and legal regulations will guarantee safe abortion (Assis & Erdman, 2021). The key legislation in this process involves a set of formal rules signifying who can provide safe abortion, where abortion can be exercised and how this process should be accessed and executed safely. Erdman & Cook (2020) highlight that the right to have abortion is majorly centred on securing grounds for protective measures so that abortion services are only provided under legal and safe grounds. World Health Organisation (WHO) also endorse these regulations in global public health discourse. WHO (1993) defines "unsafe abortion" executed by 'individuals lacking the necessary skills or in an environment that does not conform to minimal medical standards, or both'.

However, these pharmaceutical regulatory policies are also contested at large. For example, the administration of two medications namely, mifepristone and misoprostol is involved in the abortion administered within the first 10 weeks of pregnancy (Early Medical Abortion or EMA) (Parsons, 2020). In Britain, the regulation of EMA complies with "The Medicines Act" 1968, based on which mifepristone and misoprostol are regarded as "prescription-only medicines". This means a professional medical practitioner must prescribe these medicines. Secondly, EMA also needs to comply with the "Abortion Act" 1967 that places a strict set of conditions under which EMA can be prescribed. For example, two registered doctors must sign the prescription and the pregnant women must attend the clinical setting.

Pharmaceutical Regulatory Framework for Early Medical Abortion (EMA)

The essential requirement for practitioner's prescribed medicines

A broad number of healthcare practitioners who have certain qualifications to handle medications can provide prescription-only medicines. Nevertheless, when medicines are used for abortion, additional requirements are placed. For example, the Abortion Act 1967 stipulates that abortions can only be performed by *medical practitioners*. However, it does not force that every aspect of the treatment will necessarily be performed/supervised by them. By contrast, the House of Lords states that the responsibility to terminate the pregnancy for all stages of treatment should be owned by a registered medical practitioner (GBEH, 1981). It necessitates the presence of a doctor *in*

charge who will supervise this whole treatment, in which case, another doctor's second opinion must certify this action of the main doctor *in charge*.

Critical analysis

Why only EMA medications are subject to this restriction?

The Human Medicines Regulations (2012; p. 123) stipulates the following general conditions related to prescription regulation:

a) The prescription must be signed in ink by the prescribing practitioner.
b) The prescription contents must be indelible.
c) The date of signature must be on the prescription or the date when the prescription can be dispensed to the patient. Also, it should contain under 12 patient's age, its name and address along with the working address of the practitioner and his identifying information.

Notably, these regulations allow that other professionals also qualify for prescribing a prescription-only medication such as pharmacist independent prescribers, nurse independent prescribers and doctors (Jackson, 2012). When these prescriptions are provided electronically, these general regulations do not make it compulsory for the practitioner to necessarily examine the patient for making a prescription. By contrast, EMA medicines are surrounded by legal rules in relation to the circumstances of these medications. These legal rules include who specifically can prescribe these medicines, under what circumstances and what is the place where these prescriptions and administration of medications ought to be performed.

When critically analysing these differences, it is noteworthy that by virtue of legal requirements, no other medical procedure is subject to this restriction i.e., signatures of two doctors must be provided before the treatment is performed (Britain House of Commons, 2004; para 89). The same argument is also furthered by Professor Sally Sheldon that signatures of two doctors as an essential requirement of EMA go against the notion of patient autonomy (Sheldon & Wellings, 2019).

Additionally, this pharmaceutical regulation does not cater to the widespread concern of potential delay in patients' access to abortion services. The reason is, the delay in access can be experienced due to the necessary requirement of having two doctors who must be available to sign the prescription, as well as the role of a conscientious objector (if one doctor objects the signature). In light of this potential delay, some guidance can be obtained by the concept of "task-shifting" or "task-sharing" recommended by the World Health Organization (WHO, 2012). This "task-sharing" concept in abortion care services has been utilised in Northern Ireland 2020 regulations,

in which case, the term "medical professionals" has been expanded to include midwives and registered nurses (Sheldon et al., 2020). This means, instead of awaiting signatures of two certified doctors to commence EMA and experience delay in access to abortion services, midwives and registered nurses are also deemed qualified to prescribe abortion medications.

Women's safety or just the legality!

Another question that arises from this conditionality for two essential signatories is whether or not this safety precaution has something to do with the safety of the patient OR it is just a matter of complying with legality? The recent literature regarding the use of EMA medications shows enough evidence that misoprostol home usage has been a safe method of medical abortion (Song et al., 2018; Finch et al., 2019). This is the reason that in many countries where abortion is legal, home use of misoprostol is a common practice. Notably, pharmaceutical regulations in these countries do not force women to compulsory use these medicines beyond clinical supervision. If they prefer, then they can still take these medicines under clinical supervision (Parsons, 2020).

Firstly, the literature suggests that home use of abortion medications has proven safe without the essential requirement of two professional doctors to sign and supervise the abortion procedure. Secondly, there is no evidence when women were prescribed the abortion medication within a clinic, they were admitted for a certain period to check the side effects. Parsons (2020) corroborates that women are generally discharged immediately after prescribing abortion medications under clinical supervision. Interestingly, in Britain, the "Royal College of Obstetricians and Gynaecologists" (RCOG) guidelines suggest that after taking medications, women should leave the clinical setting (Royal College of Obstetricians and Gynaecologists, 2011). Therefore, it can be argued that without the requirement of medical monitoring to check adverse reactions, the essential medical signatures of two doctors for the sake of protecting women's health is factually incorrect. It can be said that this pharmaceutical regulation is generally adopted to follow the legality of the requirement, it has nothing to do with protecting women's health.

On the contrary, evidence suggests that taking these medications (without the necessary condition for practitioner's prescribed regulation) at home promotes health. Hamoda et al. (2005) conducted a questionnaire survey in UK settings to assess the acceptability of home medical abortion to women. A majority of women answered that they can cope with every experience at home that happened during the hospital-based abortion. Women favoured had that choice been available to

them, they would have preferred home abortion compared to abortion in the hospital. Ngo et al. (2011) also conducted a systematic search for prospective cohort studies and randomised controlled trials to compare medical abortions practised in clinics and at home in terms of acceptability, safety and effectiveness. The prospective cohort studies all used misoprostol and mifepristone for abortion. No differences were found in terms of acceptability or effectiveness between clinical-based and home-based medical abortion across countries. The study confirmed the safety of home-based abortion. Studies have corroborated that pain management at home happened to be more easy for women (Fielding et al., 2002; Fiala et al., 2004) contrary to the scary experiences women had after they left the clinic and moved on their way to home (Women's Equality, 2018). These scary experiences include women forcing to check into hotels to manage the symptoms, bleeding on buses, fainting in taxis, etc., which could be managed more safely at home.

Further, imagine the complexity of those cases where women living in rural areas ought to follow the essential requirement for practitioners' prescribed medicines (Heller et al., 2016; Aiken et al., 2018). Distance between the nearest hospital and women's home might be hours away. Women will likely experience heavy bleeding (due to misoprostol) on their way back home. Home abortion is illegal for them and they cannot afford to have multiple visits to the clinic due to difficulties in terms of cost, childcare and work. Therefore, it is highly likely that they will prefer to take both medications (mifepristone and misoprostol) simultaneously even though bypassing a 24-48 hours gap will lower the efficacy and increase complication rates (Lohr et al., 2018).

The essential requirement for practitioners' prescribed medicines has been discussed in the above section. The below section provides an overview of another essential requirement of the 'place' where prescription and administration of abortion medications can be conducted.

The essential requirement for the place where prescription and administration of abortion medications can be performed

One of the key requirements of the Abortion Act (AA) 1967 relate to the restrictions on *where* (specific place) the practitioner can administer Early Medical Abortion (EMA) following prescription. Notably, In Great Britain, these laws have been amended temporarily in 2020 due to the Covid-19 pandemic (Parsons & Romanis, 2021). These changes have not been made permanent as of yet, therefore, they are being enacted as long as the pandemic exists. However, the AA 1967

has given this power of specifying where Early Medical Abortion can be administered to relevant government ministers (Abortion Act, 2022). This power has been further increased by giving authority to the relevant ministers for specifying the use of medicines. This means not only government ministers can specify the place to administer EMA but they also have the power to determine detailed conditions about appropriate medications administration. On the part of both prescribing doctors and pregnant women, not complying with the conditions provided by the relevant minister will equate to committing a criminal offence under the "Offences against the Person Act" (OAPA) 1861.

It can be inferred that these powers given to ministers in Great Britain equate to interfering with the clinical discretion of doctors. The reason is, ministers become the authority for dictating and approving orders of how, when and where the EMA procedure would be performed. If the practitioner ignores the conditions, he will be charged with a potential criminal offence.

Pharmaceutical regulations 'for specifying the place' before the Pandemic

In the context of power for specifying the place where EMA medications can be administered, a British politician, John David Hancock, who served from 2018 to 2021 as Secretary of State for Health and Social Care issued a relevant approval order titled 'Approval of class of place' (Department of Health and Social Care, 2018). Based on this condition, the pregnant woman whose termination of pregnancy is being carried out, her home is approved as a class of place to perform pregnancy termination at the second stage of treatment. This termination of pregnancy will be deemed lawful if,

a) Mifepristone and Misoprostol were prescribed to the woman to terminate her pregnancy after she attended the clinic; and
b) At the clinic settings, Mifepristone was given to the pregnant woman, and then she wanted to execute the second stage of treatment at home provided that Mifepristone was taken not beyond nine weeks and six days of the gestation of the pregnancy.

The conditions specified by the relevant ministerial authority dictate that the pregnant woman can lawfully take misoprostol at her place of residence. However, taking Mifepristone at home will be deemed unlawful. Given these conditions, the practitioner also cannot prescribe both Mifepristone and Misoprostol simultaneously except at the clinic or hospital. Otherwise, the practitioner's prescription will be deemed unlawful. Therefore, the home is designated a place for the termination of pregnancy only if the treatment qualifies for the second stage. So, home is certainly not the

primary place for medications but the EMA can only be lawfully prescribed at the clinic where the written documents are produced, signed by the practitioner and the dispensing instructions for the appropriateness of medications are executed.

Pharmaceutical regulations 'for specifying the place' during the Pandemic

Accessing abortion clinics became more difficult during the Covid-19 pandemic, therefore, home administration of both Mifepristone and Misoprostol was allowed across Great Britain in late March 2020 (Department of Health and Social Care, 2020). These abortion medications were allowed under the following conditions at home:

a) Either the pregnant woman must have an electronic consultation with a registered medical practitioner or with an approved place through electronic means; and
b) For the termination of pregnancy, both drugs must be prescribed; and
c) At the point of administration of medications, the time period does not exceed nine weeks and six days of the gestation of the pregnancy; and
d) The place of medication must be in England where they are staying ordinarily.

Therefore, now the pregnant woman does not need to be at a specific clinical space for taking the prescription, and that her home can be designated as a place where both medications can be administered.

Critical analysis

The Pharmaceutical regulation 'for specifying the place' is arbitrary

While critically analysing these pharmaceutical regulations, one question arises that the administration of abortion medications is to be performed at the home address where the pregnant woman resides. However, what about those women who live in foster care or temporary shelters? This definition of home as a place of medication can result in access issues for homeless women.

Secondly, by examining the pharmaceutical regulation from the perspective of human rights, the Supreme Court of Brazil and many other courts have instructed that criminal law must be used as a last option however that criminal law represents the most punitive, intrusive and onerous power of the state (Machado & Cook, 2018). One justice writes that "the continuation of the pregnancy generates in the woman a serious psychological damage; that is why forbidding the termination of the pregnancy under the threat of criminal law is equal to torture". Furthermore, state power is also restricted under international human rights law in terms of criminalising abortion (European Court of Human Rights, 2004). This is because the power exercised by the state on abortion medication

influences the freedoms and human rights of pregnant women. According to Erdman & Cook (2020), a law is defined as arbitrary from human rights perspective if, without a reason or need, it induces harm, however legitimate it might be.

Given these facts, Pharmaceutical regulations 'for specifying the place' before the Pandemic including the compulsion for the pregnant woman to necessarily attend the clinic is arbitrary. This is because the evidence/data procured during the pandemic clearly demonstrates that (without the compulsion for the pregnant woman to attend the clinic as a place) it is safe. For example, Parsons & Romanis (2021) have demonstrated that in England and Wales, early data on "Telemedical Early Medical Abortion" (TEMA) showed considerable success in terms of safety for pregnant women. Telemedicine abortion care medications have been proven the most acceptable and safest method nowadays (Skuster et al., 2021; Parsons & Romanis, 2021a). In these cases, pregnant women were not obligated to necessarily attend the clinic as a place. Therefore, the pharmaceutical regulation to necessarily attend the clinic and the ministers' power behind this compulsion can be contested as arbitrary. This is because based on the success data on TEMA, it can be said that this compulsion was enacted without a need or reason. On the contrary, it has been discussed (in the previous sections) that attending the clinic as a place induces harm on pregnant women on their way back home. Despite all these facts, pharmaceutical regulations are set to be reverted to the same old conditions (requiring clinical supervision of mifepristone with face-to-face prescription) after the pandemic ends in Great Britain.

Is it necessary to physically examine pregnant women?

One can argue that the pharmaceutical regulation 'for specifying the place' is necessary because the doctor must physically examine the pregnant woman in order to correctly prescribe abortion medications. However, this argument is empty because telemedical abortion medication falls in the remote consultation and prescription method that is appropriated by the General Medical Council (GMC) which is a public body for maintaining the official register of medical doctors in the UK (GMC, 2022). These guidelines state the appropriateness of remote consultation and prescription when:

a) The treatment or clinical need of the patient is straightforward
b) The patients can be given complete information about treatment options that they need or want by video-link, internet or phone
c) Prescription can be performed by a safe system in place
d) Medical records of the patients are accessible

e) Patients' examination is not needed
f) The patient is capacitated enough for deciding about treatment

It is observed that prescribing patients without examination is a routine matter since the guidance provided by GMC in 2013. This means doctors can give consultation and prescription to the patient without requiring in-person examination if they have sufficient knowledge about the health of the patient and they have the satisfaction that patients' needs will be served by medicines. The physical examination might only be required if the doctor does not have access to patient's health records or medium of communication is limited to provide such records.

Notably, there is no legal requirement in the law that necessitates to have a face-to-face consultation to necessarily conduct a physical examination before prescribing the abortion medication. The law is generally silent that in what circumstances physical examination is essential to write the prescription. It can be proposed that the doctor should perform telemedical consultation and then it should be at the doctor's discretion whether he feels satisfied with the patient's condition or he deems necessary to suggest a face-to-face consultation. Otherwise, forcing a face-to-face consultation would equate to overstepping into the domain of clinical discretion.

Conclusion

Regarding the essential requirement for 'practitioner's prescribed medicines', it is injustice that only EMA medications are subject to this restriction. By contrast, general conditions related to prescription regulation do not make it necessary for the practitioner to necessarily examine the patient for making a prescription (Human Medicines Regulations, 2012). Similarly, essential signatures of two practitioners are not legally required for any other medical procedure. This unnecessary pharmaceutical regulation in EMA not only causes a delay in pregnant women's access to abortion services but also has nothing to do with their safety. If this regulation is repealed, it is likely to promote pregnant women's health and safety. Concerning the essential requirement for the place where prescription and administration of abortion medications can be performed, this place-related regulation is arbitrary from a human rights perspective. This is also arbitrary because sufficient evidence-based clinical data during the Covid-19 demonstrates the safety of pregnant women without necessarily attending the clinic as a place. Lastly, the pharmaceutical regulation 'for specifying the place' is also arbitrary because based on the General Medical Council (GMC)

guidelines, under certain conditions, practitioners do not need to physically examine the patient to correctly prescribe medications.

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