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Assessing the Impact of Approval of Mifegymiso on Abortion Access and Care in Canada

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Abstract

Approval of Mifegymiso (mifepristone and misoprostol) by Health Canada in 2015 provided a more effective non-invasive option for medical abortions in Canada and aligned Canada with the 60 other countries that had been safely utilizing the drug combination for decades. Initial approval included a number of stipulations and restrictions that were later lifted, paving the way for the drug to be offered via telemedicine under the supervision of a clinician. The approval was anticipated to increase access to abortion services, especially for those in remote and rural areas who may not have been close by to a facility where an abortion procedure could be offered. Public polling shows approval for medication abortion has remained high, especially in the wake of attacks on reproductive health in the United States. Since Health Canada approval and its marketing, the drug is now universally available across Canada with provincial health systems covering the cost for anyone with a valid health card and prescription. Thirty-two percent of abortions in Canada utilize the drug combination. Celopharma remains the only manufacturer in Canada and there have been delays in commercial release and a handful of shortages due to manufacturing issues.

L'autorisation du Mifegymiso (mifépristone et misoprostol) par Santé Canada en 2015 a permis d'offrir une option non-invasive plus efficace pour les avortements médicamenteux au Canada et a aligné le Canada sur les 60 autres pays qui utilisaient cette combinaison de médicaments en toute sécurité depuis des décennies. L'autorisation comprenait initialement un certain nombre de conditions et de restrictions qui ont ensuite été levées, ouvrant la voie à la prescription du médicament par télé-médecine sous la supervision d'un clinicien. Cette autorisation devrait permettre d'améliorer l'accès aux services d'avortement, en particulier pour les personnes vivant dans des zones reculées et rurales qui n'avaient peut-être pas accès à un établissement proposant des procédures d'avortement. Les sondages d'opinion montrent que le soutien à l'avortement médicamenteux reste élevé, en particulier à la suite des attaques contre la santé reproductive aux États-Unis. Depuis son autorisation par Santé Canada et sa commercialisation, le médicament est désormais disponible partout au Canada et pris en charge par les systèmes de santé provinciaux pour toute personne disposant d'une carte de santé et d'une ordonnance valide. Trente-deux pourcent des avortements au Canada utilisent cette combinaison de médicaments. Celopharma demeure le seul fabricant au Canada et la mise sur le marché a pris du retard et a connu quelques pénuries en raison de problèmes de fabrication.

Key Messages

- Safe and accessible abortion saves lives and is a human right.
- Mifegymiso is the gold standard for medication abortion and had been safely used for 27 years prior to its approval in Canada in 2015.
- Medication abortion (especially via telemedicine) can improve access to abortion in remote and rural areas of Canada.

Messages-clés

- *L'avortement sécuritaire et accessible sauve des vies et constitue un droit humain.*
- *Le Mifegymiso est la référence en matière d'avortement médicamenteux et a été utilisé en toute sécurité pendant 27 ans avant d'être approuvé au Canada en 2015.*
- *L'avortement médicamenteux (en particulier par télé-médecine) peut améliorer l'accès à l'avortement dans les régions éloignées et rurales du Canada.*

1 BRIEF DESCRIPTION OF THE POLICY

Twenty-seven years after a combination of mifepristone and misoprostol (Mifegymiso, the brand name for the combination of mifepristone and misoprostol) was made available as an option for terminating a pregnancy in France, 15 years following its approval in the United States, and 10 years after the World Health Organization (WHO) added the combination to the essential medicines list, was it finally approved for use in Canada in 2015 (Goodyear 2015; World Health Organization n.d.). Before the approval by Health Canada of Mifegymiso in July 2015, abortions could only be accessed in clinics, hospitals or via a combination of off-label prescribed methotrexate and misoprostol (Action Canada for Sexual Health and Rights 2018). This combination had overall similar side effects, success and complication rates to Mifegymiso. However, approval of Mifegymiso was important as abortions induced with Mifegymiso are prescribed on-label in accordance with standard of care, can be offered later in gestation, and complete terminations of pregnancy faster than those induced with Methotrexate. Mifepristone blocks progesterone receptors in early pregnancy leading to endometrial degeneration, synthesis of prostaglandins, uterine contractility, and decline in beta-human chorionic gonadotropin (-hCG) secretion. These events promote the onset of bleeding. Misoprostol is a synthetic prostaglandin E1 that induces cervical ripening and uterine contractions that expel a pregnancy (Soon 2020). Linepharma International Limited applied to Health Canada in December 2012 and was approved after two and a half years of lengthy review, significantly longer than the nine-month approval average. It was regarded by proponents as a way to make abortion in Canada more accessible, especially in remote areas.

At the time of approval, only one in six hospitals in Canada provided abortions and they tended to be concentrated in southern urban areas. The original Health Canada approval allowed for usage up to 49 days after the last menstrual period (LaRoche et al. 2022). It also included the stipulations that clinicians undergo specialized training to prescribe Mifegymiso and that an ultrasound must be done to confirm gestational age prior to the prescription being accessed. Mifegymiso was not available to Canadians until January of 2017 due to production delays. In May 2017, the requirement for specialized training was dropped. Following this, in November 2017, prescribing up to 63 days after the last menstrual period was approved (Health Canada 2017). In October 2019, the requirement for an ultrasound was also dropped (Health Canada 2019). Each of these changes paved the way for wider access to medication abortion and opened the door to telemedicine offerings (Renner et al. 2023). This health reform analysis will examine how approval of Mifegymiso has shaped medication abortion access and care in Canada.

As of 2025, Mifegymiso is on all provincial drug formularies (though in some provinces private plans must be accessed first) as well as the National Defence and Canadian Armed Forces drug formulary, the Correctional Service of Canada formulary, and the Interim Federal Health Program formulary (Action Canada for Sexual Health and Rights 2018). Physicians and nurse practitioners are authorized by provinces and territories, excluding Québec,

to prescribe Mifegymiso in Canada, where midwives can also prescribe it (Public Health Agency of Canada 2024). With a prescription, community pharmacists play an important role in dispensing the medication. Pharmacists are required to verify the appropriate written date of the prescription to ensure the dispensing date falls within 63 days since last menstrual period and to confirm that there are no absolute contraindications which would render the medication unsafe for a given patient. Pharmacists are also a key point of contact for patient counselling around expected side effects, their management and monitoring, as well as missed doses (Rebić 2021). Some clinics can dispense directly to patients without the need to access a pharmacy. British Columbia, Alberta, Saskatchewan, Manitoba, and Ontario also offer telemedicine abortion programs, where patients are screened and get a prescription by telephone or through virtual appointments (Action Canada for Sexual Health and Rights 2024). Given that 18.1% of women live more than 100 km from an abortion clinic, telemedicine plays an important role in furthering abortion access (Action Canada for Sexual Health and Rights 2024).

2 HISTORY AND CONTEXT

2.1 Abortion 1803-1969

For much of Canadian history, providing abortion care or procuring an abortion for oneself were both criminal acts in Canada. Pre-Confederation, the *Malicious Shooting or Stabbing Act 1803* made performing or attempting to perform a post-quickening abortion a death penalty offence in all British colonies. Quickening refers to the first time the movement of the fetus is detectable to the mother, often around 16-20 weeks (Courthouse Libraries British Columbia 2024). The death penalty was removed in 1837 with the *Offences Against the Person Act*. In 1869, two years after Canadian Confederation, the *Offences Against the Person Act* was adopted into Canadian law (Courthouse Libraries British Columbia 2024). Despite this, abortions were performed by some physicians on the black market (Burnett 2019). This carried significant legal risk as the punishment for a provider was life imprisonment (Laurance 2013). Those who could not afford the services of physicians would attempt to self-induce or turn to “back alley” procedures.

Morton Schulman, the Chief Coroner of Ontario in the 1960s, voiced concerns over the number of deaths following unsafe abortions that he encountered during his time as coroner (Burnett 2019). Following the death of Lottie Leanne Clarke, a mother of three who succumbed to sepsis following an illegal abortion, the inquest into her death recommended liberalization of abortion laws. In 1967, the General Council of the Canadian Medical Association publicly called for legalization of abortion under certain conditions. The same year, then Justice Minister Pierre Elliott Trudeau introduced a bill legalizing contraception, homosexuality and some abortions. This amendment to the Criminal Code passed in 1969 and allowed abortions to take place in hospitals as long as a committee of three doctors determined that the pregnancy posed a danger to the health of the pregnant woman (Bur-

nett 2019). Committees were left to define what constituted a threat to maternal health and abortions performed outside of this context continued to carry a potential life sentence if convicted. Hospitals were not obligated to offer abortion services and the process for application and review was time consuming.

2.2 The role of Dr. Henry Morgentaler

After performing his first illegal abortion in 1968, Dr. Henry Morgentaler opened an abortion clinic in Montréal in 1969 in defiance of the law. In May 1970, a convoy of feminist advocates and activists travelled from Vancouver to Ottawa to protest the existing abortion laws by chaining themselves to their seats in the parliamentary gallery (Action Canada for Sexual Health and Rights 2020). Between 1973 and 1975, Dr. Morgentaler was tried three separate times for defying the abortion law only to have the jury acquit him in all three instances. The province of Québec appealed the first charge, and the acquittal was overturned by the Québec Court of Appeals in 1974. Dr. Morgentaler then appealed his conviction to the Supreme Court of Canada, which upheld the conviction, and he was sentenced to 18 months in prison. While in prison, the province brought a second set of charges, which were acquitted by another jury and the Court of Appeal upheld the acquittal. A third trial and acquittal took place in January of 1976 (Canadian Broadcasting Corporation 2009). The Canadian Association for the Repeal of the Abortion Law (CARAL) was established in 1974 in Ottawa with the aim of supporting Dr. Morgentaler's challenge to the 1969 abortion law. Provincial and local chapters were established across Canada to raise funds for the legal challenge.

When the Parti Québécois came to power in 1976, it was clear that no jury would convict for the abortion law and the new Justice Minister dropped the charges against Dr. Morgentaler (Canadian Broadcasting Corporation 2009). He stated publicly that there would be no further trials for abortion clinics in Québec but that abortions performed by unqualified personnel would continue to be prosecuted. In 1975, the federal government appointed Dr. Robin Badgley to chair a committee intended to evaluate whether abortion law at the time was functioning properly. The committee found significant inequities given the distribution of services in only urban centers and the delays and financial hardship that women encountered (Burnett, 2019). Dr. Morgentaler brought a Supreme Court challenge to the abortion law in 1976 but was unsuccessful. That same year, Canada adopted the United Nations International Covenant on Civil and Political Rights, which obligated it to uphold individual right to liberty and security of the person. This principle was incorporated into the 1982 Canadian Charter of Rights and Freedoms. In 1983, Dr. Morgentaler decided to challenge the law in other provinces and opened clinics in Winnipeg and Toronto. By that point, public opinion had shifted considerably with one poll at the time showing that 72% believed the decision to abort should rest solely with a woman and her doctor (Canadian Broadcasting Corporation 2009). Toronto Police brought charges against Dr. Morgentaler who then brought them to the Supreme Court. He argued that

the newly established Charter of Rights and Freedoms guaranteed the right to life, liberty and security of the person and that the abortion law infringed on this right. The Supreme Court agreed and found that the 1969 abortion law was unconstitutional as it violated the Charter of Rights and Freedoms. This ended all criminal restrictions on abortion and its special treatment in the eyes of the law. From then on, it was left to be governed by Canadian laws concerning medical practice such as the Canada Health Act, provincial medical regulations, and insurance restrictions (Arthur 2009).

2.2.1 Public opinion on abortion

Public opinion supporting abortion has remained strong over time, with a 2002 survey showing that 78% of Canadians agreed with the statement that “women should have complete freedom to decide to have an abortion” (Arthur 2009). Recent polling from 2024 mirrors this trend, with 80% of Canadians in favour of a woman’s right to an abortion if she so chooses (Presser 2024). A majority of Canadians (56%) support access to abortion whenever a woman decides she wants one and only 25% would like the issue re-opened in Canada. This has been attributed to the overturning of *Roe v. Wade* in the United States as Canadians have become firmer in their conviction of a woman’s right to choose (Sethi 2022). Public opinion of medication abortions using mifepristone has also been strongly supportive, with one analysis of Canadian media showing an exceptionally high level of support for the approval, introduction, and removal of regulatory barriers to mifepristone for medication abortion (Kendall et al. 2023).

2.2.2 Abortion language and inclusivity

Historically, abortion has been framed as an issue that only impacts women. The reality that non-binary and transgender people may also require abortion care has been overlooked until recently. While the language used throughout this paper reflects the terminology used in polls/court decisions/evidence of the time, it is essential to recognize that reproductive health care, including abortion, is not limited to women alone, and should be inclusive of all gender identities.

3 THE POLICY-MAKING PROCESS

3.1 Interests

Access to Mifegymiso to terminate a pregnancy in Canada was initiated when Linepharma International Limited applied to Health Canada for approval of the drug combination in December 2012. Prior to that, though the drug was available in other countries, it was seen as not cost efficient for a pharmaceutical company to license and manufacture (Kingston 2017). At this time, federal power was held by Prime Minister Stephen Harper as leader of the Conservative Party. He stated that he would not support a re-opening of the abortion

debate, though backbench members of parliament had been permitted to table private members bills aimed at limiting access or redefining fetal personhood (Payton 2015). Approval of Mifegymiso was a decision to be made exclusively by Health Canada, the regulatory body for medication and medical devices. Drug approval decisions are kept at arm's length from the executive branch as they are to be made based on the benefits and harms, rather than an ideological agenda. Pro-life and conservative coalitions were opposed to the approval and felt that Rona Ambrose, then Health Minister, should have intervened to prevent approval (Payton 2015). Minister Ambrose did not publicly comment on the approval. Though the refusal to re-litigate abortion angered some factions of the conservative base, it was considered a strategy that left the party more palatable to a wider swath of the voting public (Canadian Broadcasting Corporation 2011).

Approval of the drug was considered a win for women, especially those living in rural areas for whom travel to an urban centre presented barriers, and the pharmaceutical manufacturer which stood to benefit economically from approval. Pro-choice coalitions such as Action Canada for Sexual Health and Rights, the National Abortion Federation, and the Abortion Rights Coalition of Canada all strongly supported approval, though they argued after approval that costs for the drugs should be borne by governments and not individuals (Action Canada for Sexual Health and Rights 2018). Following approval, the initial list price of \$300 dollars still represented a major barrier to equitable access (Canadian Agency for Drugs and Technologies, 2017).

3.2 Ideas

The body of evidence included in the regulatory submission was robust and demonstrated the safety and efficacy of Mifegymiso. This included rigorous systematic reviews of the supportive literature, as well as a large case-control study published in the *New England Journal of Medicine* that found no increased risk of ectopic pregnancy, miscarriage, preterm birth, or low-birth-weight babies in subsequent pregnancies (Virk et al. 2007). The approval aligned with policy positions held by front-line practitioners such as the Society of Obstetricians and Gynecologists of Canada and the College of Family Physicians of Canada and with public opinion at the time (Society of Obstetricians and Gynecologists of Canada n.d.; College of Family Physicians of Canada n.d.; Kendall et al. 2023).

3.3 Institutions

While provincial and territorial governments in Canada hold primary responsibility for financing, organizing and delivery health services, drug approvals are overseen at the federal level by Health Canada. Following approval of Mifegymiso, all provinces and territories have opted to add the drug to their formularies and chosen to provide universal access as long as the patient holds a valid provincial/territorial health card. In addition to overseeing drug approvals, the federal government cofinances the public health insurance programs overseen

by the provinces and territories (Allin 2020). As such, pharmacists in most jurisdictions can bill provincial plans directly (Canadian Pharmacists Association n.d.).

The federal government also administers direct health care services to key populations including eligible First Nations and Inuit peoples, members of the Canadian Armed Forces, veterans, resettled refugees and some refugee claimants as well as inmates in federal penitentiaries (Allin 2020). Ultimately, provincial and territorial jurisdictions remain the key policy players in shaping equitable access to the drug through universal coverage and an expansion in who can prescribe it and how it can be prescribed.

4 IMPLEMENTATION AND EVALUATION

4.1 Regulatory changes since approval

Since initial approval in 2015, Health Canada has amended its directives around Mifegymiso by increasing the timeline for approved usage up to nine weeks gestational age and removed the stipulations that clinicians undergo specialized training and provide an ultrasound prior to prescribing (LaRoche et al. 2022). Unexpected production delays meant that the medication was not actually available until 2017 (Grant 2017).

4.2 Impact of COVID-19

The arrival of COVID-19 changed the wider landscape of how health care is accessed in Canada, with most provinces and territories establishing and expanding telemedicine billing codes for physicians during the pandemic. This paved the way for Mifegymiso to be prescribed via telemedicine with low-touch/no-touch approaches being found to be safe and effective (Smith et al. 2024). The demand for this service option and its potential to make access more equitable has prompted the Society of Obstetricians and Gynecologists to establish a protocol for members on how to provide virtual abortion care (Costescu et al. n.d.). Given that 18.1% of women live more than 100 km from an abortion clinic, telemedicine access is crucial in furthering abortion access (Action Canada for Sexual Health and Rights 2024). Being able to access care virtually minimizes burden on individuals by allowing them to avoid costly trips to larger centres, saving time off work, childcare expenses, and travel costs. The interprovincial barrier of medical licensing being regulated at the provincial level means that a clinician cannot prescribe to a patient located in a province they are not registered in, though this too has begun to shift. Atlantic provinces have adopted a regional licensing scheme and the president of the Canadian Medical Association has called on adoption of a national licensing scheme in order to make health care more accessible to Canadians (D’Cunha 2025).

4.3 Evaluations of implementation

Québec has been identified as a jurisdiction where Mifegymiso uptake has been slower than the rest of the country. Only 17% of abortions in Québec use the medication compared to 32% in the rest of Canada (Jonas 2024). In response, the provincial government has committed \$7.5 million to support abortion access in the province. An evaluation of Mifegymiso in Canada to examine barriers and facilitators to nurse practitioners prescribing identified the lack of abortion care training during nursing education as a barrier to providers feeling comfortable with prescribing (Carson et al. 2023). Evaluations have also been undertaken to examine pharmacists' experience and that of clinicians since approval (Devane et al. 2019; Zusman et al. 2023). Most evaluations have focused on clinician experiences, and in the wake of COVID, on the safety and efficacy of telemedicine (Smith et al. 2024). A qualitative research study exploring patient perspectives in the Canadian context found that patients particularly appreciate the ability to have an abortion at home, as it eliminates the need for arranging transportation after an appointment, which is often necessary following a procedural abortion. Additionally, the perception of medication as a less invasive and more natural option is seen as another important decision-making factor (LaRoche and Foster 2020).

4.4 Clinical outcomes efficacy and adverse effects

Globally, the combination of mifepristone and misoprostol used for medical abortion of a pregnancy has been found to have a success rate between 92-98% when used for pregnancies that are 49 days or less. This falls to 77-95% for pregnancies 50–65 days (Leichombam and Bawiskar 2023). There is minimal risk of severe adverse events associated with the drug combination when administered in the first 90 days of pregnancy, with an analysis of Canadian abortion data finding fewer than six events per 25,744 medical abortions (Schummers et al. 2022). The drug combination also exhibits a lower incidence of adverse effects, compared to misoprostol alone (Oliveira et al 2025). A recent meta-analysis found a lower occurrence of fever (2.25% with drug combination, 12.12% with misoprostol only) and vomiting (7.65% with drug combination, 14.45% with misoprostol only). Within the Canadian context, the combination of mifepristone and misoprostol has been found to be a safe and effective way to manage early pregnancy loss, with a 93.3% treatment success rate (Farooqi et al. 2024). In the event of an unsuccessful treatment, a dilation and curettage procedure is necessary to remove the gestational sac.

4.5 Medication shortages

Linepharma International Limited being the sole supplier of the drug in Canada leaves the country vulnerable to shortages in the event of manufacturing issues. This was made alarmingly clear after initial approval by Health Canada as well as in 2023 when there were

another two incidents of shortages only months apart. The company attributed the shortages to delivery delays, manufacturing constraints, and shortages of the active ingredients used to make the drug (Stackelberg 2023).

5 CONCLUSION

The objective of Linepharma International Limited seeking Health Canada approval of Mifegymiso was to provide Mifegymiso to the Canadian market. There was an understanding that the timing was right to bring it to market in Canada in terms of regulatory costs versus market capitalization. Despite higher costs than the methotrexate and misoprostol combination that was used historically, the benefits outweighed the costs (Canadian Agency for Drugs and Technologies 2017). Approval of Mifegymiso has expanded access to abortion across Canada, especially after the COVID-19 pandemic when telemedicine options are relatively available. Further evaluation focusing on the user experience would be valuable, as extensive evaluations of clinician experience and health economic costs have already been undertaken. The approval of Mifegymiso by Health Canada represented an important advancement in reproductive rights as it offered a safer, more accessible method of abortion, particularly for those who faced barriers to surgical procedures. It was an important steppingstone towards greater health equity for Canadians.

6 STRENGTHS, WEAKNESSES, OPPORTUNITIES, THREATS

STRENGTHS	WEAKNESSES
<ul style="list-style-type: none"> • Meets gold standard of care offered in other countries. • Provides patients with more autonomy to choose the abortion option that suits them best. • The medication allows individuals the convenience and privacy to manage their abortion at home, reducing the need for travel, time off work, and childcare, thus improving access for people with various life circumstances. 	<ul style="list-style-type: none"> • Initial lack of universal coverage means existing inequities were not addressed. • Mifegymiso is only available with a prescription and must be provided under medical supervision, meaning access may still be restricted by availability of health care providers or pharmacies. • The need for medical supervision (such as in-person visits for confirmation and follow-ups) may limit the accessibility for people in remote areas or those facing barriers to health care.
OPPORTUNITIES	THREATS
<ul style="list-style-type: none"> • Potential for telemedicine expansion to minimize barriers experienced by those living in rural areas. • Opportunity to partner with health care providers to provide education about the safety and effectiveness of medication abortion to reduce misinformation and fear around its use. • Mifegymiso has been found to be acceptable for managing early pregnancy loss (Farooqi 2025). 	<ul style="list-style-type: none"> • While clinicians have the right to conscientiously object to providing Mifegymiso and are ethically required by their respective licensing bodies to refer patients to other clinicians, potential remains for patients to ultimately not access Mifegymiso due to structural barriers to accessing other clinicians such as geographical distance. • Manufacturing issues delayed distribution, can cause shortages. • The approval of Mifegymiso could face opposition from conservative political groups or anti-choice activists who may push to restrict access or limit its availability. • Despite evidence of safety and efficacy, there could be continued misinformation or negative media campaigns against medication abortion, potentially influencing public perception and undermining trust in the option.

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