



Ensuring Access to Medical Abortion in Argentina: Market Assessment Key Findings & Best Practices for Introducing Medical Abortion Drugs in LMIC Markets

Alessandra Tomazzini, Jason Bower & Petra Procter
Concept Foundation

12 October 2021

Agenda

Part 1: Project Overview and Market Assessment Key Findings

- I. Introduction to Concept Foundation and CEDES
- II. Project overview
- III. Market Assessment Key Findings
- IV. Conclusions

Part 2: Meeting with Stakeholders to Build Conditions Conducive to Introduction of New Medicines for Safe Abortion

- I. Objectives of the meeting
- II. Outcomes of the meeting

Project Overview & Market Assessment Key Findings

I. Introduction to Concept Foundation

Concept Foundation (CF) is an international not for profit organization working on improving access to sexual and reproductive health medicines and technologies in low-and middle-income countries (LMIC). Founded in 1989 with support from the UNDP/UNFPA/UNICEF/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction (WHO RHR/HRP) and operates out of offices in Geneva, Switzerland and Bangkok, Thailand.

Mission: Concept Foundation ensures equitable access to essential sexual and reproductive health technologies that are affordable and are of assured quality for all.

I. Introduction to CEDES (Centro de Estudios de Estado y Sociedad)

CEDES (Centro de Estudios de Estado y Sociedad)

CEDES was founded in 1975 as a non-profit, independent and pluralistic civil society organization. It develops research activities in social sciences, training of human resources and technical assistance.

Mission: To strengthen the development of research and train human resources in research guided by quality standards and the commitment to contribute to social debate; to the design, implementation and evaluation of public policies; the formulation of normative frameworks; strengthening accountability; and informed advocacy.

II. Project Background and context

- Timed to coincide with the enactment of **Law 27610** in Argentina and commitment by the Argentinian government to its implementation by the best available standards; a groundbreaking and historic moment which will sustain public policy work to improve the quality of abortion and post-abortion care.
- Drawing on the vast experience of public and community health teams in accompanying and assisting women accessing abortion services.
- Building on evidence of potential negative effects of the use of substandard abortion drugs and services.

II. Project Background and context

- Cost studies showing comparative savings (beyond prevention of morbidity and mortality) from the provision of safe abortion versus care for complications arising from unsafe abortions.
- Timeliness of support granted from the RHSC Innovation Fund and ForoLAC, and the opportunity to compliment ongoing initiatives in Argentina.
- The commitment and experience of Concept Foundation and CEDES as institutions committed to public health and with a history of collaboration with governments and other key actors and stakeholders.

II. Project Overview

Funded by RHSC Innovation Fund, in partnership with Centro de Estudios de Estado y Sociedad (CEDES).

Project Aim: Support the Argentinian Ministry of Health to establish criteria and supportive environment for ensuring access to quality medical abortion supplies and care.

Key objectives:

- I. Conduct market landscape analysis of medicines for medical abortion and medicines regulation
- II. Document findings and key recommendations to enable the rapid and sustainable introduction of quality assured medical abortion products
- III. Convene a stakeholder meeting in 2021 bringing together key government and other stakeholders to facilitate the registration of new medical abortion products in Argentina

II. Project Overview

Market Assessment Methodology:

- Definition of **key elements** required to assess market status of MA medicines
 - Legal framework, policy environment, normative guidelines
 - National strategy
 - Processes and provision of MA medicines and services
 - Current costs of abortion
 - MA products available in the market
 - Abortion market regulation
 - Procurement and distribution of MA products
 - Identification of key enablers and barriers to product introduction
- Conduct of **interviews with key informants** and stakeholders involved in provision of access to MA medicines and services

III. Market Assessment Key Findings

List of key stakeholders to be consulted on the introduction of medical abortion in Argentina:

Government agencies	Professional associations	UN agencies and NGOs
<ul style="list-style-type: none"> • National Director of Sexual and Reproductive Health • ANMAT (National Medicines Regulatory Agency) • President of ANLAP (National Agency of Public Laboratories) • Chief of Staff of the Minister of Health, former Secretary of Medicines • Programa SUMAR • Programa REDES • Superintendencia de Servicios de Salud 	<ul style="list-style-type: none"> • Federación Argentina de Sociedades de Ginecología y Obstetricia (FASGO) • Sociedad de Obstetricia y Ginecología de Buenos Aires (SOGIBA) • Federación Argentina Medicina General (FAMG) • Asociación de Mujeres en Energías Sustentables (AMES) • Asociación Médica Argentina de Anticoncepción (AMADA) • Sociedad Argentina de Ginecología Infanto Juvenil (SAGIJ) • Federation of Midwives of Argentina (FORA) • Red de Profesionales por el Derecho a Decidir • Red de Acceso al Aborto Seguro (REDAAS) • La Fundación para Estudio e Investigación de la Mujer (FEIM) 	<ul style="list-style-type: none"> • UNFPA • UNICEF • PAHO • Latin America Consortium Against Unsafe Abortion (ForoLAC) • ESAR • IPPFWHR

III. Market Assessment Key Findings

Good practices for the introduction of medical abortion drugs

- The combination of mifepristone and misoprostol is the WHO recommended regimen for medical abortion (“Safe abortion: technical and policy guidance for health systems”, 2012; “Medical treatment of abortion”, 2019). This combination is included in the WHO Essential Medicines List.
- The appropriate combination for abortions up to the 13th week of gestational age consists of a regimen of 200mg of mifepristone, administered orally, followed 1-2 days later by 800µg of misoprostol, administered vaginally, sublingually, or buccally.
- The minimum recommended interval between mifepristone and misoprostol is 24 hours.
- Mifepristone and misoprostol may be available separately or packaged together in appropriate doses. The WHO recommendation is a combined container because it is more convenient for both the woman and the person who provides the service.

III. Market Assessment Key Findings

Enablers to Introduction of Medical Abortion drugs:

- Registration of misoprostol product and prior adoption of misoprostol into the national and provincial supply chains
- Law debate increasing availability of information about products, and demand
- Destigmatization of accessing abortion by the general population.
- Comprehensive and evidence-based clinical care guidelines
- Potential improvement of prescriber information leaflets specific to medical abortion indications.
- Increase of information in the public domain on safe abortion care and specifically medical abortion regimens.
- Competitive price of quality assured products.
- Motivated and supportive national health authorities and civil society.

III. Market Assessment Key Findings

Barriers to introduction of medical abortion drugs:

- Product constraints due to monopolies or requirements imposed by pharmaceutical companies
- Conditionality for supply – e.g. need for prescriptions vs. OTC
- High cost of purchase
- Lack of mifepristone products registered
- Few supplier of mifepristone globally
- Lack of clarity about regulatory requirements for registration of medicines which are yet to be introduced to the country, such as mifepristone and the combipack.
- Lack of consistent bioequivalence and clinical data requirements from stringent regulatory agencies
- Difficulties in identifying suitable reference products from countries imposing strict regulations with indications and dosages that meet SRA requirements
- The high cost of quality-assured mifepristone API, and the unwillingness of API manufacturers to supply their API due to competition concerns.

IV. Concluding Remarks

- Law 27610 now mandates the provision of free comprehensive abortion care across Argentina, in line with WHO best practice clinical recommendations.
- Whilst two manufacturers are now making misoprostol products available, the addition of mifepristone will significantly increase the efficacy and safety of the medical abortion regimen.
- Whilst the regulatory requirements of medicines in Argentina are publicly available, specific guidance for misoprostol and mifepristone products would assist in accelerating the product development and registration time.
- Accurate forecasting of medical abortion product requirements is complicated by clinical data limitations and underreporting, and needs will change significantly with the new law and the introduction of mifepristone products.
- Good clinical guidelines are already in place which include mifepristone and are now being updated to reflect the new legal status.

Full report of the market
assessment can be accessed on the
RHSC SAS workstream page and
CF website:

[https://www.rhsupplies.org/uploads/tx_rhscpublications/Market Assessment for Medical Abortion Drugs in Argentina.pdf](https://www.rhsupplies.org/uploads/tx_rhscpublications/Market_Assessment_for_Medical_Abortion_Drugs_in_Argentina.pdf)

<https://www.conceptfoundation.org/concept-foundation/10122/>

Meeting with Stakeholders to Build Conditions Conducive to Introduction of New Medicines for Safe Abortion

Strategic Meeting: Key Points & Outcomes

- Argentina 2021: key time to advance the safe abortion agenda with medications
- Strategic opportunity for Argentina
- Importance of advancing registration of the combipack quickly and with a complete, holistic approach
- The role of the Santa Fe Industrial Pharmaceutical Laboratory (LIF S.E.) in the supply of abortion drugs is integral
- Importance of guaranteeing supply to the private sector
- Recognition of the capacity of the national productive matrix to produce medicines with the best standards, which will allow supply to guarantee safe abortions in the national market and positioning in the regional market
- Need to advance towards a model of access to technology that not only relies on health services but also allows self-management of abortions

Final Thoughts

-
- Strategic value and opportunity of market assessment conducted by an alliance of organizations with a high technical profile
 - Legitimacy given by the technical expertise of Concept Foundation in other contexts and RH medicines contexts
 - Added value of identifying contextual and regulatory conditions that would facilitate or operate as barriers to advance access to medical abortion
 - Strategic contribution of a technical-political meeting with key actors involved in decisions related to the policy of assurance of supplies for abortion