Shadow Report to the Committee on the Convention on the Elimination of All Forms of Discrimination against Women.

46th Session - July 2010

ARGENTINA

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1. Introduction

We are pleased to present our Shadow Report to the Committee on the Convention on the Elimination of All Forms of Discrimination against Women (the Committee, hereinafter the "Committee" and the Convention, as its acronym in English, "CEDAW ") on the occasion of the 46th Session of July 2010.

Lesbians and feminists for the decriminalization of abortion, is a group of lesbians and women belonging to different feminist political spaces, LGBT movement, human rights activists and scholars who came together to implement a telephone hotline on medical abortion, named "Abortion: more information, less risk" (hereinafter "the hotline"), a publicly available telephone hotline where any woman can obtain information about medical abortion. The hotline became operational in July 2009. Since then we have provided scientific and reliable information on medical abortion to 1616 women (between August 2009 and March 2010).

In Argentina, abortion is illegal and punishable by imprisonment, except in case of rape, life or health threatening illness, or if the pregnant woman is mentally ill. Even in these cases, the chance to access legal abortion services, are exceptional. Each year, between 460,000 and 600,000 women experience illegal abortion[1]. Every three days a woman dies as a result of unsafe abortion. Others suffer physical and emotional harm, consequence of the clandestine conditions and the violence they experience.

The prohibition of abortion does not relieve the State from its obligations to prevent unsafe abortion: not to die or get sick from unsafe abortion is a basic human right, universal and non-derogable, shared by all countries, even those where abortion is illegal (according to art. 12 CEDAW, CEDAW Committee, GR 24, Committee on Economic, Social and Cultural Rights, General Comment 14, para. 43 d, e, f, para. 44 a, c, d, among others; Resolution of the Cairo Summit on Population and Development, Millennium Development Goal No. 5).

This report is based primarily on information provided by the 1616 women who called the hotline from all over the country for information on safe abortion with the drug misoprostol. It aims to provide the Committee with specific information on concrete actions and omissions of the Argentine state in realizing the right to health of women, under the terms of Article 12 of the Convention, according to the interpretation of this Committee and other Human Rights Bodies.

[1] National Ministry of Health, *Estimación de la magnitud del aborto inducido en la Argentina*, Pantelides, Edith (Conicet y Cenep-Centro de Estudios de Población) y Mario, Silvia (Instituto Gino Germani), as reported by the Argentine state to this Committee, CEDAW/C/ARG/6, September 8th, 2008. On 3/23/2010, the Argentina delegation of the United Nations Population Fund reported that death from unsafe abortion remains the leading cause of maternal mortality in our country, although 80% of women have access to contraceptives before their first birth. See also Crítica de la Argentina, newspaper, 11/27/2009, "1000 million per year in illegal abortions."

2. Right to health: failures in the prevention of unsafe abortion

In Argentina each woman aborts illegally -on average- two times in her life. But only poor and destitute women, who depend on the public health system, are exposed to the risks of unsafe abortion[2]. We, who have economic resources to access private health services, access safe abortions: surgical (between 2000 and 5000 pesos), with misoprostol (100 to 600 pesos) or a combination of both (between 1500 and 3000 pesos). Poor and destitute women access misoprostol for safe abortions (between 200 and 600 pesos), or they only access unsafe methods: catheters or needles (200 pesos), herbs, or some combination of drugs that may or may not be misoprostol (100 and 500 pesos) [3]. Annually, about 60,000 poor women are hospitalized for unsafe abortion[4].

According to Para 54, GC 14, CESCR, the "*failure of States parties to take all necessary steps to ensure the realization of the right to health…the failure to adopt or implement a national health policy designed to ensure the right to health for everyone; insufficient expenditure or misallocation of public resources which results in the non-enjoyment of the right to health by individuals or groups, particularly the vulnerable or marginalized;... the failure to take measures to reduce the inequitable distribution of health facilities, goods and services; the failure to adopt a gender-sensitive approach to health; and the failure to reduce infant and maternal mortality rates*" violate the obligation of State parties to fulfill the right to health.

The State has an obligation to refrain from obstructing action taken by women in pursuit of their health goals and to take positive measures to respect, protect and fulfill women's rights to be protected from death or sickness from unsafe abortion. These obligations have been recognized on several occasions by the CEDAW Committee, CESCR and the Human Rights Committee, which for decades have been urging States parties to take all kinds of measures to reduce women morbidity and mortality rates for this cause[5].

The international health policy experience is emphatic: lowering morbidity and mortality linked to unsafe abortion requires supplementing efforts to expand access to contraception with policies replacing unsafe abortion with safe abortion methods, and replacing expensive safe abortion methods with safe, cheap and simple to administer abortion methods[6].

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[2] National Ministry of Health, cit.

[3] Prices according to the *First, Second an Third report* on the abortion hotline, www.informacionaborto.blogspot.com

[4] According to the UN, criminalization of abortion is the direct cause of morbidity from unsafe abortion: complications and deaths from this cause are rare in countries where abortion is largely legal, there are concrete experiences of countries that in a year or less reduced or increased in 3/4 the number of deaths from unsafe abortion, swinging from prohibition to legalization (Romania, Nicaragua, Mexico, among others, are well known cases).

[5] Committee on the Elimination of All Forms of Discrimination against Women, General Recommendation No. 24, Women and health - Article 12, 05/02/1999, 20 session, 1999, A/54/38/Rev.1, chap. I. CEDAW Committee, Argentina, Report on the fifty-ninth session, Supplement No. 38 (A/59/38), 2004, Supplement No. 38 (A/52/38/Rev.1), 1997, Brazil, Report on the fifty-eighth session, Supplement No. 38 (A/58/38), 2003, Paraguay, CEDAW/C/PAR/CC/3-5, February 15, 2005., Chile, Report on the fifty-fourth session Session, Supplement No. 38 (A/54/38/Rev.1), 1999, Supplement No. 38 (A/50/38), 1996, Colombia, Report on the fifty-fourth session, Supplement No. 38 (A/54/38/Rev.1), 1999, Mexico, Report on the fifty-seventh session, Supplement No. 38 (A/57/38), 2002, Peru, Report on the fifty-seventh session Supplement No. 38 (A/57/38), 2002 (A/53/38/Rev.1), 1998 (A/50/38), 1996, Dominican Republic, Report on the fifty-ninth session Supplement No. 38 (A/59/38), 2004, Report on the fifty-third session, Supplement No. 38 (A/53/38/Rev.1), 1998, Uruguay, Report on the fifty-seventh session Session, Supplement No. 38 (A/57/38), 2002, Venezuela, Report on the fifty-second session, Supplement No. 38 (A/52/38/Rev.1), 1997. Human Rights Committee, Bolivia, CCPR/C/79/Add.74, May 1, 1997, 22, Colombia, CCPR/C/79/Add.76, May 5, 1997, 24, Guatemala, CCPR / CO / 72/GTM, August 27, 2001, 19, Paraguay, Report on the Fiftieth Session, Supplement No. 40 (A/50/40), February 4, 1996, 208, Peru, CCPR/CO/70 / PER, November 15, 2000, 20, CCPR/C/79/Add.72, November 18, 1996, 22. Chile, CCPR/C/79/Add.104, March 30, 1999, 15, Guatemala CCPR/CO/72/GTM, August 27, 2001, 19, Venezuela, CCPR/CO/71/VEN, April 26 2001, 19. See eg Human Rights Committee: Chile, CCPR/C/79/Add.104, 30/03/1999, 15, Colombia, CCPR/CO/80/COL, 26/05/2004, 13, Costa Rica, CCPR / C/79/Add.107, April 8, 1999, 11, El Salvador, CCPR/CO/78/SLV, 08/22/2003, 13, Guatemala, CCPR/CO/72/GTM, August 27, 2001 , 19, Peru, CCPR/CO/70/PER, November 15, 2000, CCPR/C/79/Add.72, November 18, 1996, 22, Venezuela, CCPR/CO/71/VEN, April 26 2001, 19.

[6] *Preventing Unsafe Abortion and its Consequences, Priorities for Research and Action*, Iqbal Shah, Gutmacher institute, 2006. See also Marge Berer, *Provision of Abortion by Mid-Level Providers: International Policy and Practice.*

Reducing cost of safe abortion services -in order to expand its accessibility and availability, is one of the great challenges of women's health policy, both in countries where abortion is legal or illegal. In this replacement policy, abortion with the drug misoprostol records the highest advances and endorsements[7].

According to WHO, misoprostol is an essential drug for being cheap, effective, widely available in a large number of countries, and for being culturally acceptable to produce safe self-induced abortions until 12th pregnancy week, thus helping to reduce prevalence of avoidable deaths and complications from unsafe abortions worldwide, even in countries where abortion is illegal. Before misoprostol, no method was considered by WHO and other international medical organizations as safe for women to abort by themselves at home, at any stage of pregnancy[8].

This method of safe self-induced abortion was invented by poor Latin American women at least 30 years ago; since then it became popular in Argentina. In Argentina the law allows the production, marketing and selling of misoprostol. Misoprostol form of sale is ruled by provision 3646/98 of ANMAT (National Drug Administration), which imposes the requirement of a filed prescription. While that provision merely recognizes gastric indications of misoprostol, in 2005 the Ministry of Health recognized misoprostol indications for abortions and incomplete abortions. In 2010 ANMAT recognized other obstetric indications of the drug[9]. On the cultural acceptability of the drug, various studies show that safe abortion with misoprostol is well known and widely used by women throughout Argentina[10].

3. Availability and accessibility of misoprostol in Argentina

The normative framework of the right to health makes it clear that essential medicines should be available, accessible, acceptable and of good quality to benefit vulnerable populations worldwide without discrimination.[11] According to CESCR, GC 14, on the right to the highest attainable

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[7] Medical abortion offers many advantages over other abortion methods. From health policy perspective, it is cheaper and less intrusive and complicated than surgical methods. As well, drugs are easy to store and manage, there is no need for high-qualified medical staff to administer the drugs or to inform women on how to use the drugs, there is no need for hospitalization during the process, which can be managed by women at home in many circumstances. Medications have few contraindications and are highly effective and culturally acceptable for most women. Iqbal Shah, Gutmacher institute, 2006, cit.

[8] *Essential medicines List*, WHO, 2010. WHO, IPPF, UNPF, World Bank, among other agencies, included misoprostol in 2006 Essential *Medicines for Reproductive Health: Guiding Principles for Their Inclusion on National Medicines Lists*. In 2003 WHO published information on misoprostol use for early abortion in *Safe Abortion: Technical and Policy guidance for Health Systems*, aimed to achieving MDG 3 and 5. Since 2005 misoprostol (tablets, 200 mcg) is included as oxitocic in the WHO Essentials medicines list, "*Where permitted under national law and where culturally acceptable*". With the same criteria misoprostol is included as an effective abortifacient in the Interagency List of Essential medicines for reproductive health http://www.who.int/reproductivehealth/publications/general/RHR_2006_1/en/index.html , and was included in the mentioned *Guiding Principles for Their Inclusion on National Medicines Lists*. In 2009 WHO added misoprostol indication for management of incomplete abortion (tablets, 200 mcg) to the *Essential Medicines List*. In Argentina, in 2005 the *Guía Técnica para Aborto No Punible*, (clinical practice guidelines) from the Ministry of Health validated the inclusion of misoprostol indication for safe abortion, among other obstetrical uses.

[9] ANMAT Provision 3646/98, Act (Ley) 16.463, Executive Order (Decreto) 9763/64, EO 7123, Act 17.565, Act 19.303, Act 25.649. While the legality of medicines form of sale is regulated and controlled by ANMAT, the legality of the medical indication depends on diagnosis and indication in a concrete case based on principles of Professional Authonomy, Freedom of prescription, and legitimate *off the label* use. Leaflets and ANMAT cannot –and do not- forbid other indications as long as they are based on solid scientific evidence, and on technical and ethical rules of medicine practice, which is exactly the case of misoprostol indication for safe self-induced early abortions.

[10] Among these, see especially *Morbilidad materna severa en la Argentina, Trayectorias de las mujeres internadas por complicaciones de aborto y calidad de la atención recibida*, CEDES, CENEP, 2006.

[11] According to CESCR, GC 14, Para 12, essential drugs, as defined by the WHO Action Programme on Essential Drugs, are part of the interrelated and essential elements that are contained in the right to health. Therefore, right to access essential drugs integrates the right to health as an essential component. Misoprostol is one of such essential drugs integrating the right to health. As such, misoprostol has to be available in quantity and doses required (GC 14, para.12.a), particularly for vulnerable and marginalized people, without discrimination, economically, physically and geographically available. Accessibility "*includes the right to seek, receive and impart information and ideas concerning health issues. However, accessibility of information should not impair the right to have personal health data treated with confidentiality.*" (Para. 12,b,iv).

standard of health (article 12 of the International Covenant on Economic, Social and Cultural Rights), Para 47, stresses that "*a State party cannot, under any circumstances whatsoever, justify its non-compliance with the core obligations set out in paragraph 43 above, which are nonderogable*".

One of these nonderogable obligations is "(t)*o provide essential drugs, as from time to time defined under the WHO Action Programme on Essential Drugs*" (Para 43 d); [12] in agreement with the principle of equity "(t)*o ensure equitable distribution of all health facilities, goods and services*" (Para 43 e); and making sure that "*these services, whether privately or publicly provided, are affordable for all, including socially disadvantaged groups. Equity demands that poorer households should not be disproportionately burdened with health expenses as compared to richer households.*" (Para.12 b iii)[13].

To assess performance of equitable access to essential medicines, WHO appraises 3 indicators periodically in each state party[14]:

- Price, calculated as Median Price Ratio, actual price compared to international reference price
- Availability, calculated as number of facilities having that product at time of survey reported as a percentage
- Affordability assessed for pre-selected course of treatment compared to daily wage of lowest paid government worker

In Argentina, misoprostol is legal, but it is comparatively expensive[15] and is only exceptionally available in public Health care facilities[16]. Since 1998 legal selling of misoprostol requires filed prescription, and although any doctor can lawfully prescribe misoprostol for different uses[17], in

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See also *Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health*, Anand Grover, A/HRC/11/12, 31 March 2009.

[12] Access to essential medicines is a human right; essential drugs are not commodities like any other. A drug that can save lives is a public good. "*If the business of business is business, WHO's Business is global public Health: the organization cannot be neutral with regard to the access of essential medicines to poor populations*". Yves Beigbeder, *International public health: Patient rights vs. The protection of patents*, cited in *El acceso al medicamento como un derecho humano*, Germán Velásquez, WHO, Lima, July 2004.

[13] WHO and the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental Health consider inequality in access to essential medicines as the principal cause of "Diseases of poverty" (i.e. communicable, maternal, perinatal, and nutritional diseases), "*which still constitute 50% of the burden of disease in developing countries, nearly ten times higher than in developed Countries*". WHO, World Health Report, *Primary Health Care Now More than Ever* (Geneva, 2008), Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Anand Grover, A/HRC/11/12, 31 March 2009. According to these reports, "*Over 100 million people annually fall into poverty because they have to pay for health care"* and *"Nearly 2 billion people lack access to essential medicines…The inability of populations to access medicines is partly due to high costs… In developing countries, patients themselves pay for 50-90 per cent of essential medicines… A report from WHO and Health Action International on the results of surveys undertaken in 36 countries reported that in the public sector only one third of essential medicines needed were available and in the private sector only two thirds of such medicines were available",* see in http://daccess-dds-ny.un.org/doc/UNDOC/GEN/G09/127/11/PDF/G0912711.pdf?OpenElement.

[14] WHO, 2008, *Access to essential medicines as part of the fulfilment of the Right to Health*, Richard Laing, With material developed by Hans V. Hogerzeil, MD, PhD, FRCP Edin. Director, Medicines Policy and Standards World Health Organization. *See also Medicine prices, a new approach to measurement*, WHO, 2003 and *Measuring medicine prices, availability, affordability and price components*, 2nd edition, WHO, 2008. Also, *Is access to essential medicines as part of the fulfilment of the right to health enforceable through the courts?*, Hans V Hogerzeil, Melanie Samson, Jaume Vidal Casanovas, Ladan Rahmani-Ocora, Lancet 2006; 368: 305–11

[15] See *Assessing the global availability of misoprostol,* Maria Fernandez, Ph.D., MBA, Senior Market Researcher Ipas, Rodolfo Gomez Ponce de Leon, MD, MSPH, PhD, Senior Health System Adviser Ipas, cit. See also *Ipas Market Research.* For more information contact Maria Fernandez at fernandezm@ipas.org , Types of registered misoprostol drugs sold in 2007, by country.

[16] Currently the drug is not available in the public Health system, 95% of abortions are completed by curettage (CEDES, CENEP, cit), instead of using misoprostol, which offers great comparative advantage. Women cannot access misoprostol for free through REMEDIAR program, which provides free medication in 6000 public primary health care facilities throughout the country (perhaps influenced by the participation of the Conferencia Episcopal Argentina, which took part of the drug selection process as a member of the Committee selecting drugs to be provided for free, in 2002). In Bolivia, Perú and OECD Countries misoprostol has been included in the daily practice of public Health care system and it is increasingly being used in gynecology and obstetrics.

[17] Technically, with misoprostol the woman is the one who initiates the abortion. Article 86 of the Argentinean Criminal Code states that regardless of the illegality of women's actions, medical actions carried out before, during or

practice the vast majority of doctors do not prescribe it, not even doctors providing information on safe abortion in so-called "pre-abortion counseling." [18] According to a survey carried out in 19 provinces during the months of March and April 2010, from 291 Primary Healthcare doctors, 70% receive between one and four consultations on abortion per month. Of them, while 40% provide information on the autonomous use of misoprostol for safe early abortion, only 8% prescribes misoprostol. 60% of them has at least one job in the public health care system[19].

Women who consult for abortion information or services face additional obstacles and barriers to access medical services, such as expulsive behaviors of health professionals and of the health sector members in general. Therefore, most women do not have access to appropriate health care when deciding on abortion (timely, accessible, non-prejudiced, reliable and confidential). According to data gathered by the hotline, of a total of 246 women who called between March and April 2010 for information about abortion with misoprostol, 66% preferred to avoid doctors when deciding on abortion and 90% of women under 20 years old reported not having access to a trustworthy doctor to talk to about their decision to abort[20].

Therefore, although the legal selling price of misoprostol (less than U.S. $ 100) would be accessible to a vast majority of women, including many women under the poverty line, reality is that the vast majority of women (between 60[21] and 90%) only access misoprostol through informal market, paying between 200 and 500% overprice. Buying misoprostol through informal market will cost between 4 and 9 days of work to a woman whose monthly income is $ 3000 (U$ 1000) and between 11 and 24 days if her income is $ 1150 (U$ 400) [22]. Since from the second trimester of pregnancy onwards all abortion methods are considered riskier, acting quickly is key. As a result, women are excluded from the possibility of safe abortion if they cannot afford informal market prices during the 1st trimester of pregnancy.

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after an abortion in accordance to medicine's ethical and technical rules and standards, are never a crime. The above actions of informing, prescribing drugs, and giving medical attention to a woman with an ongoing or incomplete abortion, are legal and part of the medical responsibility for the prevention of unsafe abortion. "*The National Criminal Code requires actions that may lead doctors to criminal responsibility to be of abusive character and nature…abusive in both an objective and subjective manner…an action completely excluded from the normal principles guiding medical ethics and practice (lex artis medica), and that they be executed with knowledge of its abusive character*"(free translation from original Spanish). Sebastián Soler, Derecho Penal Argentino, Tratado, Tomo III, Ed. TEA, Bs. As., 1º edition, 1945, reprinted in 1992, p. 106 -107. "*The State and its officials cannot undermine the protection of the right to health and the right to life which health teams ought to protect by mandate, neither through interpretations of laws or rulings dissuading them from fulfilling their duty, nor by threatening them with the imposition of a criminal sentence, by inducing them to make prohibited distinctions against principles of equality and non discrimination, or by forcing them to deviate from their role to assume other role, as would happen if health team members were obliged to become whistleblowers - or informers - of patients"* Inter American Court on Human Rights, Flores v. Peru, sentence, 2004 (free translation from Spanish original). In Argentina, the last 20 years doctors have been prescribing misoprostol to prevent unsafe abortions, to complete abortions, and to induce labor. In 2005 the National Ministry of Health formally incorporated misoprostol as a safe and effective abortifacient in the Technical Guide for the Legal Abortions (clinical practice guidelines). In this context, if a woman is eligible to using misoprostol for a safe abortion it is unethical, abusive and may be a crime (Art.106 NCC) abandoning or exposing her to an unsafe abortion, for example with catheters or with any method after the first trimester of pregnancy.

[18] This applies, among other, to the pre-abortion teenager counseling carried out by doctors and other health care professionals in the Argerich Public Hospital, in La Boca, a marginalized neighborhood in Buenos Aires City, or in the Alvarez Public Hospital, where a facility for legal abortions has been funded for several years.

[19] Survey carried out by the Metropolitan Association of Generalists and Health Teams (AMEGES) and Lesbians and Feminists for Decriminalization of abortion, see in www.abortoconmisoprostol.blogspot.com During the seminar Abortion with Misoprostol in PHC, held on April 21, 2010 in Buenos Aires City, many doctors expressed their fears about being repressed for prescribing misoprostol, although the National Ministry of Health supports the use of misoprostol as an abortifacient and although none of them was able to identify any real case of a doctor's criminalization for such reason. See in www.abortoconmisoprostol.blogspot.com

[20] According to the cited report, from 1616 hotline calls, 85% of women had received false, incorrect or outdated information, 22% from doctors. 37% of women who called the hotline having 10 weeks of pregnancy or more had received wrong information from doctors.

[21] As reported by the Colegio Público de Farmacéuticos of Buenos Aires Province, 2008, six of every 10 boxes of misoprostol boxes are sold in pharmacies without the required medical prescription. Published in Diario Clarín, March 30, 2008. See also statements by Marcelo Peretta, president of the Argentine Union of Pharmacists and Biochemists, and Rubén Abete, president of the Industrial Chamber of Pharmaceutical companies in Argentina, Clarín, 7/17/09.

[22] The poverty line in Argentina is established based on the price of the "basic food bundle".

According to the 3rd hotline report (April, 2010), of 94 women across the country who bought misoprostol, 89% did so without a prescription, paying between 200 and 500% overprice.

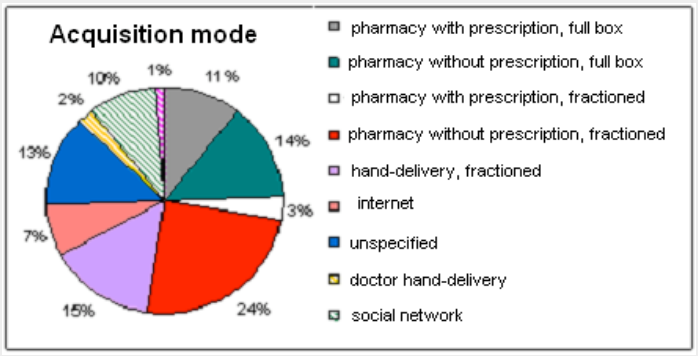

Table: Affordability of misoprostol

Acquisition mode, most relevant	**percentage**	**Average price per tablet**	**Average price per 12 tablets (early abortion)**	**Misoprostol cost compared to daily wage /montly income - (poverty line) $ 1,150 (U$ 400) - $ 3,000 (U$ 1,000)**
Pharmacy without prescription, fractioned	24%	$ 34 (U$ 11)	$ 408 (U$ 136)	11 days 4 days
Hand-delivery, fractioned	15%	$ 78 (U$ 26)	$ 936 (U$ 312)	24 d 9 d
Pharmacy without prescription, full box	14%	$ 44 (U$ 15)	$ 528 (U$ 176)	14 d 5 d
Pharmacy with prescription, full box	11 %	$ 15 (U$ 5)	$ 180 (U$ 60)	5 d 2 d
Social network	10%	$ 0	$ 0	0 0
internet	7%	$ 46 (U$ 15)	$ 552 (U$ 184)	15 d 6 d

4. The restriction of misoprostol

According to CEDAW Committee, GR 24, para, 14, "*The obligation to respect rights requires States parties to refrain from obstructing action taken by women in pursuit of their health goals.*"

CESCR, GC 14, Para 50, states that "*State actions, policies or laws that contravene the standards set out in article 12 of the Covenant and are likely to result in bodily harm, unnecessary morbidity and preventable mortality*", violate the obligation to respect the right to health. "*Examples include the denial of access to health facilities, goods and services to particular individuals or groups as a result of de jure or de facto discrimination; the deliberate withholding or misrepresentation of information vital to health protection or treatment; the suspension of legislation or the adoption of laws or policies that interfere with the enjoyment of any of the components of the right to health…*".

In 1998 the national government, through the ANMAT[23], restricted the sale of misoprostol by imposing the requirement of filed medical prescription. Based on scientific evidence available at that time in 1998, ANMAT evaluated that "*drug needs controlled use and application demanding clear information about the risks ...* (which*) ... makes necessary to adopt appropriate measures for preventing and*

[23] National Administration of Drugs, Food and Medical Technology (ANMAT)

protecting population's health... "(ANMAT, Provision 3646/98). ANMAT considered that the best way to protect people from risky drug use was to establish control over drug prescription, removing the possibility for women to access the medication directly[24].

During the years following the restriction of misoprostol, coinciding with the economic crisis that hit the country in 2001, hospital admissions increased significantly due to unsafe abortions " *in 1995 in Argentina around 53,000 hospital admissions due to unsafe abortions were reported ... in 2000, that number had risen to 79.000, an increase of 50%.*"[25]

These results are similar to those of a study in Brazil, which correlates the increase in hospital admissions due to unsafe abortion with misoprostol ban. Currently it is estimated that hospital admissions for unsafe abortions amounted to 60,000.[26].

Restriction of Misoprostol in Brazil

After its introduction in Brazil in 1986, misoprostol could be bought over the counter, without a prescription. Soon, women acknowledged its effectiveness as an abortifacient and began to use it on their own ... seeking medical care in case of severe vaginal bleeding. By 1990, 70% of women treated for abortion complications reported having used misoprostol. So in 1991 the Ministry of Health restricted the sale. The state of Ceará banned it completely. However, the restriction of the drug did not prevent its use; rather, the drug remained widely available on the informal market, overpriced. Consequently, the number of abortion complications increased after the restriction. In fact, in Campinas abortion deaths tripled after the restriction.

Costa SH. Commercial availability of misoprostol and induced abortion in Brazil. Int J Gynaecol Obstet 1998; 63 (Suppl 1): S131–39.

In Argentina, this restriction immediately affected the production of misoprostol: the only company that produced misoprostol alone (200 mcg tablets), stopped doing so. For 10 years a single private company (Beta) produced misoprostol combined with diclofenac. Since mid-2009, another company has been producing the same combination[27]. Public availability of misoprostol was prevented: because of the stigma associated with the drug after its constraint, misoprostol was not incorporated regularly in public hospitals and public primary health care facilities. Also because of this stigma, some pharmacies stopped selling misoprostol altogether (especially cheap pharmacies, such as Dr. Simi, Dr. Ahorro). In some small cities and rural areas, i.e., Pergamino (Bs. As.) and Ushuaia (Tierra del Fuego), no pharmacy sells misoprostol, regardless of the

[24] The policy of limiting women's access to medicines and technologies essential to sexual and reproductive health by requiring filed prescription is no stranger to women in Argentina. It was used in 1973 by Lopez Rega, who in the government of Isabel Peron prohibited access to contraception by requiring triple filed prescription and closing family planning counseling in public hospitals. Selling misoprostol without prescription is now a crime, and even "progressive" judges are willing to criminalize the provision of misoprostol without prescription, despite knowing the scope of its benefits and that we are dealing here with a life-saving, essential drug. It is the case Judge of Lozada, from Chubut Province, famous for reaffirming in April 2010 the right to legal abortion of a teenager who had been raped by her stepfather. In this case, the Judge followed expert advise and recommended misoprostol as a safe method to perform the abortion on the 20th week of pregnancy (see http://www.sentence.marinaschifrin.com.ar/?p=72). Nevertheless, the same Judge processed two pharmacists in Bariloche in 2009 for selling misoprostol without prescription. (http://www.infomapuchito.com/info/desarro_noti.php?cod=39634 , http://elciudadanobche.com.ar/nuevo/JUNIO_2008/091103/nota.php?id_nota=9575&nota=Avanza%20la%20causa%20por%20la%20venta%20de%20medicamentos%20abortivos%20en%20una%20farmacia)

[25] According to official data, cited in ARGENTINA: Leap in Unsafe Abortions, Economic Crisis Pushes More Women into Back Alleys, Marcela Valente, Inter Press Service, March 12, 2003.

[26] cit.

[27] Currently more than 20 companies produce Viagra (sildenafil), Argentina has one of the cheapest Viagra in the region. It took ANMAT five years to authorize the production of in-hospital use of misoprostol for labor induction (25 mcg tablets) - though generally the process takes less than 1 year, the same agency took less than 1 year to approve the production and marketing of sildenafil (Viagra). See http://www.lanacion.com.ar/nota.asp?nota_id=103955 See also *Viagra's rise above women's health issues: An analysis of the social and political influences on drug approvals in the United States and Japan*, Ilyssa Hollander**,** 22 July 2005.

prescription. Therefore women who live there have to travel hundreds of kilometers to be able to buy misoprostol, hindering timely access[28].

Today, 12 years after the restriction, the number of publications on the use of misoprostol in gynecology and obstetrics increased from 12 in 1980 to 2992 in 2007. Most publications in last years deal with obstetric uses of misoprostol[29].

According to available evidence, benefits of autonomous use of misoprostol for early abortion outweigh possible risks to population health; even if the sale is unlawful, without medical intermediation. WHO and FLASOG establish that medical consultations before and /or after an abortion with misoprostol are not indispensable when the drug is used properly and no complications arise[30]. "*During the last decade several studies have confirmed that even in clandestine conditions: 1) abortions induced with misoprostol are safer than those induced by other methods, 2) There is a temporal association between increased sales of misoprostol and reduction in complications of unsafe abortion.*"[31]

In Argentina for several years various public authorities have recognized that massive autonomous use of misoprostol is significantly contributing to lower deaths and severe complications associated with clandestine abortions[32].

According to Uruguayan doctors misoprostol "*will be in 10 years considered XXI century penicillin*" for lowering severe abortion complications and deaths worldwide. In Uruguay, the law expressly requires medical personnel to inform women on safe autonomous abortion using misoprostol. Paradoxically, in Uruguay abortion is illegal and the law expressly forbids doctors prescribing misoprostol. Despite this prohibition, in Uruguay women access misoprostol informally, and the

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[28] According to the three reports of the hotline (2009-2010). Pergamino is a city of 90,000 habitants; Ushuaia is the capital of Tierra del Fuego, an island near the south pole of 122,000 inhabitants. In 2009 the provincial legislature of Mendoza passed a piece of legislation restricting further the sale of misoprostol and removing it from pharmacies. According to this piece of legislation, misoprostol can only be accessed in-hospital - which in reality makes it inaccessible because, as mentioned, misoprostol is not incorporated into medical practice in public hospitals in Argentina.

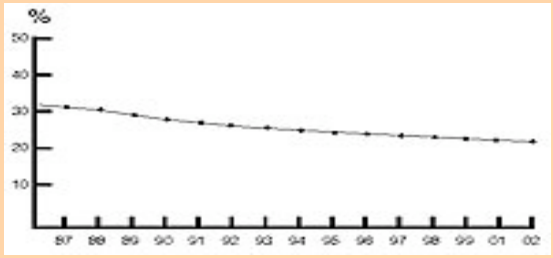
[29] See *Misoprostol, una herramienta de reducción de muertes maternas prevenibles*, 2010, cit, "*The safe use of misoprostol is an important and effective intervention, with the added advantage of great impact to a relatively low cost, and should become a priority to guide decisions maintaining a focus on safe results for pregnant women in each country. [...] Women have the right to enjoy the benefits of Scientific progress and knowledge in maintaining the highest attainable level of health. This context applies perfectly to gynecological and obstetric use of misoprostol, which has attracted the attention of health professionals who are now required to extend this benefit to end users: women*" (Shaw, 2007). Dorothy Shaw, FIGO President.

[30] WHO, www.iwhc.org/storage/iwhc/documents/who_guidance_en_espaol.pdf , FLASOG (Federación Latinoamericana de Sociedades de Obstetricia y Ginecología), www.flasog.org/images/misoprostol.pdf , IPAS, www.ipas.org/Publications/asset_upload_file321_2891.pdf

[31] See *Misoprostol, una herramienta de reducción de muertes maternas prevenibles*, 2010, presentation made for the House of Representatives, National Parliament, Comisión de Legislación penal, Rodolfo Gómez Ponce de León, IPAS – FLASOG, www.abortoconmisoprostol.blogspot.com , based on research from Brazil and the Dominican Republic.

[32] In September 2009, Zulema Palma, MD, a prestigious Feminist Gynecologist member of CLACAI (Consejo Latinoamericano Contra el Aborto Inseguro) and co-founder of Mujeres al Oeste, interviewed by the famous Journalist Jorge Lanata on TV, spoke on demedicalization of women's lives as progress made regarding women's human Rights. Fernando Giayetto, MD, of La Pampa, member of the Provincial Network for Sexual and Reproductive Rights, highlighted in various media that every unwanted pregnancy should be seen as a problem for the health of any individual. "*This would be a sufficient argument for the universal access to safe abortion*" On the same month, Mario Sebastiani, MD, a prominent Gynecologist, Member of the Obstetrics service and of the Committee on Bioethics of the Hospital Italiano, made the following public statement *"[...] Medical knowledge belongs to the people [...] Since no other solution has been offered, [...] the hotline is most welcome (…) whether some like it or not, abortion is disappearing from the medical field to become a private act of women. This is a product of technology and that women have been punished when they needed to approach medicine and its institutions: they found snitches, victimization and prejudice. The answers they found were lousy ... medicine must be on the side of these women".* Interviewed by Josefina Licitra, Diario Crítica, July 2009. In October, Juan Osvaldo Mormandi, MD, Chief of Gynecology, Hospital Eva Perón, San Martín, Buenos Aires province, confirmed in a special news report for one of the most famous TV News Show (Telenoche Investiga) that "*Paradoxically, autonomous use of misoprostol is helping to reduce abortion related deaths"* Likewise, Jorge Tartaglione, MD, Chief of Primary prevention services, Hospital Churruca, in Telefé News, October 2009 (TV News show).

rate of mortality and complications from unsafe abortions dropped to zero in five years. Autonomous use of misoprostol also eradicated covert abortion clinics.[33].



Decreased abortion related mortality associated with autonomous misoprostol use, Tucumán, Pagina 12 Newspaper, 12/11/2004, www.pagina12.com.ar/diario/ suplementos/las12/13-1630-2004-12-11.html

Currently, WHO is systematizing the positive impact of autonomous use of misoprostol both in countries where abortion is legal and where it is illegal[34]. "(M)*isoprostol can improve abortion services where there are not trained providers available, or where other safe abortion methods are not available… Misoprostol is inexpensive, easy to administer and store and is therefore particularly attractive for suppliers in developing countries and for women who seek covert safe abortions … so far the consensus is that abortion with misoprostol is medically safer than other means of self-induced abortion involving the introduction of physical objects or catheters and is able to reduce morbidity and mortality related to unsafe abortion … there is no need to go to the doctor, the confidentiality is assured, and prevents the intrusion of surgery"*[35].

5. Recommendations

In Argentina, unsafe abortion is a risk to which women are exposed almost our whole life. Each of us faces this risk at least two times along her life. 1 of 300 pregnant women dies from complications of abortion or childbirth; in Canada there is 1 death per 7700 women. The risk of death in Argentina is 26 times higher than in Canada, and five times higher than in Cuba (1c/1600) [36]. Morbidity is a much more common result of unsafe abortion than mortality, and is determined by the same risk factors[37].

According to WHO, "*Unsafe abortion is a persistent and preventable pandemic.*" Demedicalisation of misoprostol access (to make it available over the counter without medical supervision and/or

[33] Lionel Briozzo, MD, Responsible of Iniciativas Sanitarias contra el Aborto Provocado en Condiciones de Riesgo, Francisco Cóppola, MD, President of Sociedad Ginecotocológica del Uruguay: www.180.com.uy/articulo/Clinicas-abortivasdesplazadas-por-el-misoprostol . http://www.observa.com.uy/actualidad/nota.aspx?id=92083

[34] In Brazil, demedicalization of access to misoprostol and autonomous use by women lowered the severity of complications related to clandestine abortions and to some extent also reduced the number of hospital admissions for this cause. In Peru, the use of misoprostol has expanded, and while in 1989 it was infrequent, in 1998 the majority of key informants knew the method and reported cases of autonomous use, even in remote rural regions. There is also evidence of autonomous use of misoprostol for safe abortions from Mexico, Colombia and Ecuador, also informing about its cultural acceptability by women. *Unsafe abortion: the preventable pandemic*, David A Grimes, Janie Benson, Susheela Singh, Mariana Romero, Bela Ganatra, Friday E Okonofua, Iqbal H Shah, Sexual and Reproductive health 4, The Lancet Sexual and Reproductive Health Series, October 2006. See also WHO/UNDP/UNPF/WORLD BANK, *Special Programme of Research, Development and Research Training in Human Reproduction Social Science and Operations Research in Sexual and Reproductive Health, Call for proposals /concept papers for research on expanding access to medical abortion in developing countries*, 2010.

[35] *Preventing Unsafe Abortion and its Consequences, Priorities for Research and Action*, Iqbal Shah, Gutmacher institute, cit, p. 5. See also Berer M. *Making abortions safe: a matter of good public health policy and practice*. Bulletin of the World Health Organization 2000, 78 (5): 580-592

[36] *Maternal Mortality in Latin America and the Caribbean*. Schwarcz & Fescina The Lancet 356. December 2000.

[37] "*Maternal deaths in developing countries are often the ultimate tragic outcome of the cumulative denial of women's human rights. Women are not dying because of untreatable diseases. They are dying because societies have yet to make the decision that their lives are worth saving.*" Fathalla MF. Human rights aspects of safe motherhood. Best Pract Res Clin Obstet Gynaecol 2006; 20: 409–19.

intermediation) is part of health policy focused on primary prevention. Replacing unsafe methods with safe, cheap and simple to administer abortion methods and expanding access to modern and safe contraception belong together in primary prevention, as better access to better contraception methods can reduce the need for abortions, but never eliminate it[38]. Similarly, legalized abortion is necessary but not sufficient policy, because law may not result in broad access to safe abortions[39].

Increased access to misoprostol has been associated with improved women's health in developing countries, including Argentina[40]. In Argentina, women are already using misoprostol autonomously to prevent unsafe abortion, incrementally, for at least 30 years. However, making misoprostol accessible to all women along with accurate information for its autonomous safe use in abortions is the current blind spot of sexual and reproductive health and access to essential medicines policy.

Promoting rational use of medicines by prescribers and consumers offers great health benefits and financial savings[41]. However, many countries do not take full advantage of proven policy interventions. In Argentina, access to misoprostol is restricted by a series of regulations and practices that hinder access to this medication, with consequent detriment to women's health.

Demedicalising access to misoprostol in the Argentine context is necessary to end the financial exploitation of women who require safe abortion services (all). According to available data from 2007, the estimated annual value of misoprostol wholesales is U$ 4 million per year. The estimated economic volume of the business of covert abortion in Argentina is about U$ 1 million per day, only accounting for direct costs (payment to service providers)[42].

Changing current misoprostol restricted access policy is necessary because past 40 years technology and scientific knowledge have evolved into simplified, cheaper and safer methods of

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[38] Scope of family planning programs is well documented. In Bulgaria, Kazakhstan, Kyrgyzstan, Switzerland, Tunisia, Turkey, and Uzbekistan, increasing access to quality contraception helped reducing abortion rates, but eliminating abortion proved impossible. In contrast, in Cuba, Denmark, Netherlands, Republic of Korea, Singapore and USA, abortion and contraception increased simultaneously. "*Critics of post-abortion care worldwide complain that the preoccupation with secondary (rather than primary) prevention of unsafe abortion is myopic, tantamount to placing ambulances at the bottom of a cliff instead of erecting a fence at the top.*" *Unsafe abortion: the preventable pandemic*, David A Grimes, Janie Benson, Susheela Singh, Mariana Romero, Bela Ganatra, Friday E Okonofua, Iqbal H Shah, Sexual and Reproductive health 4, The Lancet Sexual and Reproductive Health Series, October 2006.

[39] India legalized abortion in the 70s, but access through the public system is restricted to large cities and in most states, less than 20% of primary care centers provide legal abortion services. Unsafe abortion: the preventable pandemic, cit.

[40] 1997, *When women have no doctor*, Hesperian Foundation, Berkeley, California, USA, Lafaurie MM, Grossman D, Troncoso E, Billings DL, Chavez S. *Women's perspectives on medical abortion in Mexico, Colombia, Ecuador and Peru: a qualitative study*. Reprod Health Matters 2005; 13: 75–83. Brazil Ministerio da Saude. Sistema de informacoes hospitalares do SUS (SIH/SUS). www.dataus.gov.br (July 5, 2006).

[41] "*The definition of rational use of medicines was formulated at the Conference of Experts on the Rational Use of Drugs held in Nairobi in 1985, and endorsed by resolution WHA39.27 on the revised drug strategy and resolution WHA54.11 on the revised medicines strategy. The aim of WHO's medicines strategy for 2004–2007, based on resolution WHA54.11, is that people everywhere have access to the essential medicines they need; that the medicines are safe, effective and of good quality; and that the medicines are prescribed and used rationally. WHO has thus been working to ensure that medicines are used in a therapeutically sound and cost-effective way by health professionals and consumers in order to maximize the potential of medicines in the provision of health care. Thus, the scope of rational or good-quality use of medicines covers the elimination of their overuse and underuse and lack of adherence to treatment.*" See *Progress in the rational use of medicines, Report by the Secretariat*, WHO, 2007, para 2, http://apps.who.int/gb/ebwha/pdf_files/WHA60/A60_24-en.pdf

[42] 1000 million pesos per year (300 million US dollars), according to estimates based on oficial data and information provided by the hotline, see November, 2009, Diario Crítica, 11/27/09, "1000 millones al año en abortos ilegales". "*Argentina has only one commercially available brand—Oxaprost (Beta, Buenos Aires), which combines 200 □g of misoprostol with the NSAID diclofenac. According to the College of Pharmacists of Buenos Aires, women are using this medication for self-induced abortion; approximately 80% of all Oxaprost (misoprostol) prescriptions in Argentina are written by obstetrician-gynecologists. In a recent study, misoprostol retained its effectiveness as an abortifacient when combined with an NSAID*", see *Assessing the global availability of misoprostol*, Maria M. Fernandez, Francine Coeytaux, Rodolfo Gómez Ponce de León, Denise L. Harrison, International Journal of Gynecology and Obstetrics 105 (2009) 180–186. Information on wholesale volume of misoprostol corresponds to 2007. Then only Beta (pharmaceutical company) produced misoprostol; prices have not changed since then. See Rodolfo Gómez Ponce de León, Congreso de la Nación, 2010, cit.

medical abortion. The current health policy should be updated based on scientific information, technology and public policy progress. Ensuring effective prevention of unsafe abortion requires safeguarding broad access to safe, sound and cheap abortion methods. This policy also allows solving the barrier posed by human resources crisis facing Argentina and common to Latin American countries: the lack of trained and willing medical providers willing to take on abortion. "*Measures for de-medicalising primary health services include: adoption of simpler technology and service protocols, authorisation and training of less qualified providers, simplification or elimination of facility requirements, establishment of robust referral links to hospitals, increasing user control and self-medication.*" (Iyengar 2005) [43].

In Argentina, access to misoprostol is mainly conditioned by its price, and price is mainly conditioned by the requirement of medical prescription to legally buy misoprostol in pharmacies. A woman who has access to a doctor's prescription will be able to buy misoprostol in time, and therefore will have access to safe, cheap abortion. Unfortunately, most doctors do not prescribe misoprostol, hindering women's access to this essential drug.

It is imperative that the Argentine government invalidates or derogates the provision of the National Administration of Drugs, Food and Medical Technology (ANMAT) 3646/98 which restricts the sale of misoprostol under filed medical prescription. This provision is discriminatory and has regressive effects on the health of poor and destitute women, blocking their only possibility of preventing the risks of unsafe abortion. It is necessary that the National State includes the drug misoprostol in the list of medications provided for free by the primary public health care system (REMEDIAR program and/or Sexual Health and Responsible Procreation Program, both in the sphere of the National Ministry of Health).

It is also recommended that the State trains health teams and non-professional providers of community health on safe early abortion with misoprostol. As well, it is recommended that the State carries on public campaigns on the safe use of misoprostol for abortions, to ensure respect for the right of women to look after their own health by avoiding risks of unsafe abortions (CEDAW Committee, GR 24, Para 14). According to the hotline, between August 2009 and March 2010, from 1616 women who called seeking for information on safe abortion with misoprostol, 85% had wrong information. Doctors (22%), pharmacists (10%), Internet (25%), and word of mouth (36%) are the main sources of this erroneous information. This misinformation revolves on drug doses lower than those recommended by WHO, errors in routes of administration, poor information on risks, no information on how to distinguish emergencies and how to act[44].

Misoprostol is legal, available and widely known in Argentina. Women have been using misoprostol autonomously and successfully to prevent risks of unsafe abortion. Consequently, morbidity and mortality rates due to unsafe abortion are falling. Given the international Human Rights commitments assumed by Argentina, which are part of the existing domestic legal framework, and given also the progress achieved in the field of women's human rights, we believe that the national government faces a great opportunity to ensure that women, especially poor and young, stop using unsafe abortion methods and stop being exposed to cruelty, sickness, death and economic exploitation.

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[43] Iyengar SD. Introducing medical abortion within the primary health system: comparison with other health interventions and commodities. *Reprod Health Matters* 2005; 13: 13-9 doi: 10.1016/S0968-8080(05)26217-1 pmid: 16291482, cited by Marge Berer, *Provision of Abortion by Mid-Level Providers: International Policy and Practice*, 2007. See also *Misoprostol at grassroots*, Dr. Joachim Osur, 2005.

[44] It is worth mentioning that recently the National Ministry of health implemented a hotline on sexual and reproductive health. While they give information on legal abortion, it does not cover autonomous use of misoprostol, despite the fact of scientific and sanitary policy evidence. Women who call seeking for information on abortion with misoprostol are not given such information, and women who seek legal abortions are referred to a network of hospitals or told to seek for a doctor willing to perform the abortion.