

**MISOPROSTOL AND VIOLATION OF THE RIGHT TO HEALTH AND THE
RIGHT TO INFORMATION ON SEXUAL AND REPRODUCTIVE HEALTH**

Periodic universal review, cycle 2, June 2012

Brazil



CCR, *Comissão de Cidadania e Reprodução*

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UN Human Rights Council

Geneva Switzerland

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Re: Brazil – 13th Universal Periodic Review session

The Commission for Citizenship and Reproduction (CCR, *Comissão de Cidadania e Reprodução*) submits the following concerns and recommendations on **the right to information on sexual and reproductive health** (article 10, CEDAW; DESC Committee general comment No.14; CEDAW Committee general comment No.24; CRC general comment No.4), due to measures taken by the Brazilian state that restrain information on health technology, specifically on the use of misoprostol in the country.

I. CONTEXT

a Restraint to access to information

1 Brazilian state, by means of its Anvisa – National Agency for Sanitary Vigilance (*Agência Nacional de Vigilância Sanitária*) has issued norms that restrain the dissemination of information on sexual and reproductive health, especially concerning the use of misoprostol. This medicine has been increasingly controlled in the country since the 1980s. In 1998, Anvisa issued Regulation 344/1998 (see Appendix) which limited the access to the drug only to hospital facilities, hence preventing access to misoprostol by people in drugstores. At present it attempts to control the flow of information on the drug at internet sites and social networks, by means of Resolutions No. 911/2006 and No.1050/2006, updated by Resolution 1534 of April, 2011 (see Appendix). Besides questioning the Anvisa competence to rule on such matter, we believe that violation of the right to information can not follow the existing restraints to access to the drug itself. Medicine abortion may be legally provided by the Brazilian health national system (SUS) in the cases of rape and serious risk to women's life¹. If women have access to such health technology by diverse means, they must not be prevented from having access to information on how to safely use the drug to perform abortion.

b Use of and access to misoprostol

2 Misoprostol is at present produced and traded in Brazil under the name Prostokos; the drug is used by health professionals for induction to delivery or to legal pregnancy interruption, in accordance with the Ministry of Health norms (on Humane Abortion Care, and on Prevention and Treatment of Damage Resulting from Sexual Violence)².

3 In view of the evidence-based efficacy of misoprostol for various aims in gynecology and obstetrics, the World Health Organization (WHO) has included it in the list of essential medicines; accordingly, the Brazilian Ministry of Health has incorporated misoprostol into its National List of Essential Medicines (Rename/MS)³. Such inclusion followed research that highlighted the importance of using misoprostol in reproductive health care, including for safe abortion; the latter use has proved effective in reducing maternal deaths and changing the morbidity profile by unsafe abortions^{1,4,5,6}.

4 In spite of criminalisation of abortion in Brazil, and of access restraints to the medicine, it is well known that both young and adult women use misoprostol for abortion, by means of irregular access, buying it from the parallel market (hence subject to using fake drugs), and often with scarce or no information on how to use the drug, thus putting at risk their reproductive health^{7,8}.

5 A survey carried out by Instituto Anis and the University of Brasília⁵ showed that 1 in every 7 women up to 40 years old has had an abortion; when considering only women aged 35-39, the rate falls to 1 in every 5. The survey interviewed 2002 women aged 18-to-39 who live in state capitals and in municipalities of over 5000 inhabitants; rural illiterate dwellers were excluded. Data show that resorting to abortion is more frequent among women with lesser education, but doesn't vary following religious affiliation. Among women who had had abortions, 48% had used some medicine; and over half (55%) of them had been taken to hospital due to sequelae. These data highlight that women go on resorting to abortion, while health policies lawfully do not provide it. The last DHNS survey (Demography and Health National Survey 2006)⁹ showed that about 50% of pregnancies – a highly significant proportion – are unwanted by women.

6 As to contraception, in spite of decades-long efforts to spread its use, this is not generalised, differences between regions still prevailing. For instance, in the North region only 13% of married or otherwise conjoint women aged 15-to-44 use the pill, while 39% of South region women do so.

7 Discrimination against women also includes economic, ethnic or racial, and generational, inequality. Studies show that abortion risks affect mostly poor, young women:

8 Mostly poor women, with no access to medical resources for safe abortion, are the ones who run the major risks caused by abortion illegality. According to the Ministry of Health, about 250 thousand women per year are admitted to public hospitals for termination of insecure abortion; the majority of them are young, poor, and black. Abortion is considered a serious public health problem, being the fourth largest cause of death in the country, the first one in the city of Salvador since 1990, and the third in São Paulo. Abortions causes more deaths among black and mixed race women; as a cause of death, its weight is higher for the age groups up-to 15 and 30-through-39 years¹⁰.

9 In order to adequately face this phenomenon, abortion must be understood as an issue of care and of human rights, not as cases of moral infraction by careless women. This political redefinition must rely on studies made at bedside with women that had aborted and resorted to the public health system; the studies show that the majority of them are young, poor, catholic, and have already had other children⁵(p.13-14).

10 On the other hand, women with higher economic level may resort to information and to private health services. Furthermore, their better educational opportunities may favour access to information, including foreign-language information, widely available at the internet. This configures inequality of access to information, another violation to the right of living without discrimination.

11 Scientific evidence of misoprostol effectiveness as an aborting method is one of the factors that lead women to adopt it. There are other reasons, such as the low cost and the privacy it allows for. Misoprostol and other factors that have replaced previous aggressive methods (like resorting to piercing objects) are linked to changes in the maternal deaths profile and in unsafe abortion data in the country. But new vulnerabilities arose, such as the ones pointed out by the review *Abortion and public health in Brazil: 20 years*, published by the Ministry of Health¹¹:

12 On the one hand, access to misoprostol has reduced sequelae and complications due to the risky abortive methods adopted in the 1980s; on the other hand, its illegal context brings new challenges to public health, such as leading women or their partners to purchase it at the illegal drug traffic. And, for many women, after taking the medicine they must immediately seek a hospital in order to end the process. (...)

In fact, as the reality of women who don't resort to healthcare services is unknown, the abortive effectiveness of misoprostol, solely or associated to other methods, can only be established through the cases that reach public or university hospitals.

Studies describe how women start abortion at home with misoprostol (usually at varied or unknown intervals and doses) and end up in hospitals, but it is unknown whether women successfully use the method at home. This gap (...) results in further challenge for public health: in order to seriously address the issues of morbimortality associated to unsafe abortion and of possible sequelae for the foetus due to misoprostol, we must inform women on doses and provide directions for its effective use for home abortion. (p.33-4,39-40)

- 13 The prevention of sequelae and of damage to reproductive health is thus directly associated to correct use of the drug. And dissemination of its correct use must be a main concern of the Brazilian state – not that of hampering such dissemination. It is worth noting that such measures do not demote the importance of seeking guidance and medical attention at the APAs (Post-Abortion Care units), nor do they replace doctors, health care professionals or hospital services or functions.

c The Brazilian state duty toward the right to information

- 14 In Brazil, protection of the right to health is explicit in the 1988 Federal Constitution¹² articles 6 and 196, as a social right of all, and a duty of the state¹. Furthermore, the *Lei Orgânica da Saúde* (Organic Health Law¹³) reinforces that it is the state duty to provide means to the realisation of the right to health, supplying all necessary conditions for the enjoyment of good health, there included preventive actions². The law is also concerned with the importance of the right to information on health, which is of utmost relevance to assure the wide dissemination of information on medicine abortion, due to its content, linked to reproductive health.
- 15 Under the human rights approach, the right to health is a condition to assure the dignity of human beings and is intertwined to the right to life, a principle and a right assured by the Brazilian Constitution¹² (articles 1 and 5). Thus the dissemination of information on health assures the rights to health, to life, and dignity of all – all the more so on the subject of youth's and women's reproductive health, as is the case of medicine abortion. The right to information on sexual and reproductive health is a human right recognised by the Brazilian state, and can not be impaired by restrictive measures.
- 16 The Brazilian state has ratified main international treaties on human rights, which are incorporated into its constitutional law. It must then consider the recommendations issued by the DESC Committee, who monitors the International Pact on Economic, Social, and Cultural Rights, which reaffirm the right to health as connected to other rights; there include the right to information, as it may be interpreted from article 12 of the Pact (DESC Committee general recommendation No.14).
- 17 Human rights conventions corroborate directives established by the International Conference on Population and Development held in Cairo, 1994, whose Programme of Action presents information as a necessary condition for effective sexual and reproductive rights:

7.2 (...) Reproductive health therefore implies that people are able to have a satisfying and safe sex life and that they have the capability to reproduce and the freedom to decide if, when and how often to do so. Implicit in this last condition are **the rights**

1 Federal Constitution article 196 reads: "Health is a right of all and a state duty, assured by means of economic and social policies that aim at reducing risk of diseases and illnesses, and at universal and equal access of all to services and acts for its promotion, protection, and recovery".

2 Article 2 of the Health Law states that "health is a fundamental right of the human being, and the state must provide the necessary conditions for the full exercise of this right". Further on, article 7 establishes that all actions and services provided in the scope of the national health system must follow constitutional directives, and list the principles to be complied with. Among these, we highlight:

Art. 7, V – People being attended to have the right to information on their health;

VI – Information must be disseminated as to health services potential and their use by citizens.

of men and women to be informed on and to have access to safe, effective, affordable and acceptable methods of family planning of their choice...¹⁴

18 The right to information is essential to the fulfilment of other rights (OAS' ICHR Declaration of Principles on Freedom of Expression, Res 1932), there included information for health protection; the greater the amount of information, the better people's ability to make decisions.

19 The ability to make informed decisions is inscribed in the relation between autonomy and information: when the woman gains access to understanding transformations in her own body, she may decide in accordance with her reality. To ban information on abortion-related issues leads to probability of harm to youth's and women's reproductive health – and does not prevent abortion. Withholding information is thus not effective in reducing the number of abortions and, conversely, contributes to worsening conditions wherein decisions to resort to abortion are made.

d UN recommendations on the subject³

20 Restraining norms and their consequences onto women's sexual and reproductive health were an explicit concern of the yearly report by special rapporteur Anand Grover. His report reinforces the importance of information on health and the risks women undergo for lack of information. Among his observations, the High Commission for Human Rights might retain the following:

21 Realisation of the right to health requires the removal of barriers that interfere with individual decision-making on health-related issues and with access to health services, education and information, in particular on health conditions that only affect women and girls. In cases where a barrier is created by a criminal law or other legal restriction, it is the obligation of the state to remove it. The removal of such laws and legal restrictions is not subject to resource constraints and can thus not be seen as requiring only progressive realization. Barriers arising from criminal laws and other laws and policies affecting sexual and reproductive health must therefore be immediately removed in order to ensure full enjoyment of the right to health.

22 In their application, criminal laws and other legal restrictions may prevent access to certain sexual and reproductive health-care goods, such as contraceptive methods, directly outlaw a particular service, such as abortion, or ban the provision of sexual and reproductive information through school-based education programmes or otherwise. In practice, these laws affect a wide range of individuals, including women who attempt to undergo abortions or seek contraception; friends or family members who assist women to access abortions; practitioners providing abortions; teachers providing sexual education; pharmacists supplying contraceptives; employees of institutions that are established to provide family planning services; human rights defenders advocating for sexual and reproductive health rights; and adolescents seeking access to contraception for consensual sexual activity.

23 Criminal laws and other legal restrictions on sexual and reproductive health may have a negative impact on the right to health in many ways, including by interfering with human dignity. Respect for dignity is fundamental to the realization of all human rights. Dignity requires that individuals are free to make personal decisions without interference from the state, especially in an area as important and intimate as sexual and reproductive health. (paragraphs 14-16, A/66/254).

24 At the end of his report, the rapporteur listed recommendations that apply to Brazil. We next present further suggestions, for the second cycle of the periodic universal review.

³ Report prepared by the Special Rapporteur of the Human Rights Council on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Anand Grover, in accordance with Human Rights Council resolutions 15/22 and 6/29. August, 2011 (A/66/254)

II RECOMMENDATIONS FOR THE BRAZILIAN STATE

- 25 To eliminate all hindrances to the free exercise of the right to information, as a measure to foster and assure the right to health, mainly to sexual and reproductive health.
- 26 To disseminate scientific evidence that support the use of misoprostol as well as the correct directions for its use, in the context of publicising sexual and reproductive health acts in the country. This implies the immediate revoking of Anvisa Resolution 1534 (Appendix).
- 27 To approve of the use of misoprostol in all its indications, and expand access to the medicine in all levels of health care.
- 28 To assure that national public policies are free from religious interference, preserving laity of their programmes, resorting to scientific evidence in the attempt to reduce maternal deaths as well as maternal and neonatal morbidity.
- 29 To adopt measures that assure reaching Millennium Goal 5 (improve maternal health), such as those that widen access to information on sexual and reproductive health.
- 30 Foster the provision of information relating to sexual and reproductive health, including evidence-based sexual and reproductive health education.
- 31 Consider, as an interim measure, the formulation of policies and protocols by responsible officials imposing a moratorium on the application of criminal laws concerning abortion, including legal duties on medical professionals to report women to law enforcement authorities.

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APPENDIX

Regulation No.344, of May 12, 1998

Approves of the Technical Regulation on substances and drugs subject to special control.

The Secretary for Sanitary Vigilance of the Ministry of Health (...) resolves:

(...)

CHAPTER III

ON TRADING

Art. 25 (on controlling sales of lists of specific substances and drugs) (...)

Sole Paragraph: Sales of drugs based on the misoprostol substance, included in "C1" list (other substances subject to special control) on the present Regulation, are limited to hospital facilities duly accredited and certified by the competent sanitary office.

(...)

CHAPTER IX

ON PACKAGING AND LABELING

Art. 83 Package labels of drugs containing the substances listed under "C1" (other substances subject to special control), (...) on the present Regulation, or of the respective updates, must bear a horizontal red strip on all sides, at the medium third height and not narrower than one third of the larger face width.

(...)

§ 4th The package front and back faces of drugs containing the misoprostol substance listed at "C1" (other substances subject to special control) on the present Regulation must compulsorily show a symbol of a pregnant woman within a crossed circle and the following expressions on the red strip: "Attention: Use only under medical prescription" – "Can only be used if prescription is retained" – "Warning: Risk for pregnant women" – "Sale and use restricted to hospitals".

§ 5th Directions for use and labels of drugs containing misoprostol must compulsorily show the expressions "Warning: Risk for pregnant women" – "Sale and use restricted to hospitals".

(...)

CHAPTER XI

ON FINAL DISPOSITIONS

Art. 89 Distribution of free samples of the substances or drugs listed on the present Regulation is forbidden.

§ 1st Distribution of free samples of drugs containing substances listed under "C1" (other substances subject to special control) and "C4" (antiretrovirals) on the present Regulation are permitted, in their original packaging, exclusively to medical professionals, who must sign the corresponding distribution certificate supplied by the producer.

§ 2nd In case the professional donates drug free samples to his or her institution, he or she must provide the corresponding signed certificate, which will be kept by the institution, who must also record the quantity of free samples received.

§ 3rd The above mentioned signed certificate must be kept by the producer or the institution that received free samples for a period of two years, being available for controlling by sanitary officials.

§ 4th **In no case may free samples of drugs containing misoprostol be distributed.**

RESOLUTION - RE No. 1534, of April 8, 2011

The deputy president-director of the National Agency for Sanitary Vigilance (Anvisa, Agência Nacional de Vigilância Sanitária), (...) resolves:

Art. 1st To determine the nationwide **suspension** of irregular **publicity of drugs containing misoprostol**, non-registered at Anvisa, or directed to the general public, or on properties and finalities not registered at Anvisa, especially such publicity as disseminated by the internet sites listed on this Resolution Appendix.

Art. 2nd Such publicity suspension constitutes a preventive measure, since that dissemination fosters banalizing use of the drug, which may only occur under medical prescription and guiding; it is also due to the potential risk of using the drug for therapeutic aims not registered at Anvisa.

Art. 3rd Previous specific Resolutions 911 of 03/273/2006, and 1050 of 06/07/2006, are hereby revoked.

(...)

(signed) DIRCEU BRÁS APARECIDO BARBANO