

Mandates of the Working Group on discrimination against women and girls; the Working Group on the issue of human rights and transnational corporations and other business enterprises; and the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health

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Excellency,

We have the honour to address you in our capacities as Working Group on discrimination against women and girls; Working Group on the issue of human rights and transnational corporations and other business enterprises; and Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, pursuant to Human Rights Council resolutions 41/6, 44/15 and 42/16.

In this connection, we would like to bring to the attention of your Excellency's Government information we have received concerning a situation of violation of the rights to sexual and reproductive health of women and girls in Chile, in particular in relation to the distribution of contraceptive pills with defects in their composition. One of the companies involved, Merck Sharp & Dohme (I.A.), is based in your country.

According to the information received:

A serious situation of discrimination against women and girls and violation of their rights to sexual and reproductive health has occurred in Chile over an extended period, due to the existence of defective contraceptive pills. These serious incidents have taken place in a context of systemic violations of sexual and reproductive health, characterised by limitations in access to contraceptives and to voluntary termination of pregnancy.

Since August 2020, 27,689 defective blisters of contraceptive pills have been withdrawn from circulation by the Chilean Institute of Public Health. The batches of pills correspond to four types of pills from three different brands of contraceptives, each with different types of composition problems (Anulette CD from Silesia Laboratory, Contimavelon 20 from Merck Sharp & Dohme (I.A) LLC, and produced by Eurofarma Laboratorios S.A, and Minigest 15 and Minigest 20 from Andrómaco Laboratory).

In public statements issued since August 2020, the Chilean State health authorities stated that the batches of defective pills were isolated cases that have occurred only in some regions of the country. However, according to the information received, the defective pills were obtained in different parts of the country and were distributed in several public health centres and also in pharmacies. The selling and distribution of defective contraceptive pills does not appear to be an isolated issue. According to information gathered by civil society organisations, at least 276,890 blisters have entered the market with composition defects since September 2019.

On 24 August 2020, the Chilean Institute of Public Health published Pharmaceutical Recall Alert No. 26/202041, warning that the product (oral contraceptive method) "Anulette CD Coated Tablets" blister with 28 tablets presented packaging with the wrong arrangement of some tablets or lack of tablets (placebo in location of tablet with active ingredient, tablet with active ingredient in location of placebo or lack of tablets with active ingredient and/or placebo). The concerned company is Laboratorios Silesia S.A. and the contraceptive pills were manufactured at Laboratorio Andrómaco S.A. in Chile (from the Grünenthal group based in Germany). Anulette CD tablets were the first to be withdrawn from the market. These contraceptive pills are the ones distributed in public health services in Chile.

The second brand of pills to be withdrawn from circulation on 5 October 2020, were Minigest 15 and Minigest 20. According to reports by the Institute of Public Health, while it was conducting stability studies, it identified that in these two brands of contraceptives, the amount of active ingredients included in the final doses did not correlate with the registration approved by the institution. Additionally, Laboratorios Andrómaco S.A., which manufacture and distribute the medicines, announced the temporary suspension of Minigest 15 and Minigest 20. The active ingredients in the Minigest tablets are manufactured by the Chinese pharmaceutical company, Sheijiang Xianju Pharmaceutical. Laboratorio Andrómaco S.A. in Chile then finishes compounding the pill.

On 10 October 2020, the recall of Conti-Marvelon 20 tablets was announced, due to an error in the administration scheme. The holder of the Health Registration of these tablets is Merck Sharp & Dohme (I.A.) based in the United States and the manufacturing laboratory is Eurofarma Laboratorios S.A. of Brazil.

On 8 September 2020, the Chilean Institute of Public Health ordered the modification of Resolution 3676, which mandated the suspension from sale of Anulette CD pills, arguing that a visual examination of the pills was enough to determine that they were defective. At this time there were 382,871 women taking Anulette CD, with the suspension of the medicine directly affecting their treatment. The concerned health authorities did not propose safe alternative pills for the affected women and adolescents.

It is essential to highlight that, despite some women acquiring these defective contraceptive pills in pharmacies, the majority of victims affected by these incidents are women in a situation of special vulnerability, i.e. women with lower economic income who receive contraceptive pills in public health centres. This constitutes serious discrimination against women in general terms, but especially against women with fewer economic resources, in violation of several human rights enshrined in international human rights conventions and standards detailed in the Annex.

270 women affected by the batches of defective contraceptive pills approached a non-governmental organisation seeking legal, psychological and social assistance. Among them, 269 became pregnant in an unwanted or unplanned way due to these defective pills. 84 of the victims of unplanned pregnancies

At least three of the victims, [REDACTED], [REDACTED] and [REDACTED] have unsuccessfully requested access to voluntary termination of pregnancy on the grounds of risk for their life. These pregnancies are unwanted pregnancies resulting from the negligence of the State and the laboratories concerned that put the women's physical and mental health at risk and also violate their rights to equality, dignity, and autonomy as well as their economic and social rights.

Due to the denial of access to voluntary termination of pregnancy, an NGO filed an appeal to seek access to abortion for [REDACTED] in view of the risk to her life given her suicidal attempts since the announcement of her pregnancy. To date, the Court of Appeal has not yet issued a decision in favour of the termination of pregnancy to which the victim is entitled under Law 21.030, namely on the grounds of risk to the life of the woman. The victim is only a few weeks away from the full term of her pregnancy. At this late stage, regardless of the decision of the authorities, the victim will no longer be able to access the procedure.

In February 2021, the Chilean Institute of Public Health sanctioned Laboratorios Silesia and Andrómaco S.A. with a fine of 66 million pesos (about 92,000 dollars). This is an extremely low sum, taking into account the harm caused to the women and the fact that this fine is not intended for reparation and redress of the damage to the women who have been affected by this situation. In effect, the affected women have not received any reparation measures or any economic alternative proportional to the damage that has been caused to them, which would support them in the fulfilment of their life projects.

Without prejudging the accuracy of the information received, we would like to express our deep concern regarding the negligence of the United States in preventing human rights abuses by business enterprises domiciled in its territory in contravention of its international human rights obligations, in particular the UN Guiding Principles on Business and Human Rights.

We would like to reiterate the importance of guaranteeing the quality and efficiency of contraceptive pills, through strict quality control and, in addition, through adequate oversight of the pharmaceutical companies in charge of their production.

Women who are victims of unwanted pregnancies due to defective contraceptive pills should be provided with financial assistance for the upbringing of their children, measures for social inclusion, employment and reintegration into the educational system (for those women whose studies were interrupted due to these pregnancies) and access to quality medical services for themselves and their children.

In connection with the above alleged facts and concerns, please refer to the **Annex on Reference to international human rights law** attached to this letter which cites international human rights instruments and standards relevant to these allegations.

As it is our responsibility, under the mandates provided to us by the Human Rights Council, to seek to clarify all cases brought to our attention, we would be grateful for your observations on the following matters:

1. Please provide any additional information and/or comment(s) you may have on the above-mentioned allegations.
2. Please provide details as to the investigation process regarding the contraceptive pills that were being delivered and marketed, and which may have had compositional defects. If no inquiries have taken place, or if they have been inconclusive, please explain why.
3. Please indicate the steps that your Excellency's government has taken, or is considering to take, to protect against human rights abuses by business enterprises domiciled in your territory and/or jurisdiction, such as Merck Sharp & Dohme, and to ensure that business enterprises domiciled in your territory and /or jurisdiction do not produce and sell defective contraceptive pills. This includes conducting effective human rights due diligence to identify, prevent, mitigate and account for how they address their impacts on human rights throughout their operations (including abroad), as set forth by the UN Guiding Principles on Business and Human Rights.
4. Please provide information on the measures taken by your Government to prevent contraceptive pills with compositional defects from being sold and distributed.
5. Please share information on the stability studies carried out for the marketing of contraceptives, including what the process is, identifying the authorities in charge of monitoring it and the standards that must be met to ensure that the quality of the medicines is guaranteed.
6. Please provide information how the quality control procedures of contraceptive pills and their active ingredients released for consumption. Please also provide information on the distribution route of defective contraceptives.
7. Please describe any guidance that your Excellency's Government has provided to US-domiciled business enterprises on respecting human rights throughout their operations in line with the UN Guiding Principles. This includes setting out the Government's expectations as to how human rights due diligence should be conducted, how to consult meaningfully potentially affected stakeholders, and how to remedy any negative human rights impacts
8. Please provide information on any measures that your Excellency's Government has taken, or is considering to take, to ensure that the individual victims of unwanted pregnancies as a result of the defective contraceptive pills, have access to effective remedies, including compensation, in accordance with the UN Guiding Principles.

This communication and any response received from your Excellency's Government will be made public via the communications reporting [website](#) within

60 days. They will also subsequently be made available in the usual report to be presented to the Human Rights Council.

While awaiting a response, we would urge your Excellency's Government to take all necessary measures to protect the sexual and reproductive rights of women and girls, in particular the right to access quality contraception. We would also like to urge your Excellency's Government to take effective measures to prevent the recurrence of such events.

We may publicly express our concerns in the near future as, in our view, the information upon which the press release will be based is sufficiently reliable to indicate a matter warranting immediate attention. We also believe that the wider public should be alerted to the potential implications of the above-mentioned allegations. The press release will indicate that we have been in contact with your Excellency's Government's to clarify the issue/s in question.

Please be informed that a letter on this matter will also be sent to the companies involved in these allegations as well as to the governments of Chile, Germany, Brazil and China where the companies involved are based or have their headquarters.

Please accept, Excellency, the assurances of our highest consideration.

Elizabeth Broderick

Chair-Rapporteur of the Working Group on discrimination against women and girls

Dante Pesce

Chair-Rapporteur of the Working Group on the issue of human rights and transnational corporations and other business enterprises

Tlaleng Mofokeng

Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health

Annex

Reference to international human rights law

In connection with above alleged facts and concerns, we would like to draw your Excellency's attention to the following human rights standards:

We would like to emphasize that the fundamental human rights of women and girls include the right to the enjoyment of the highest attainable standard of physical and mental health, including sexual and reproductive health, which is enshrined in article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR) signed by the United States in 1977. This includes the obligation of all States Parties to guarantee that measures are taken to ensure that health services are accessible to all, especially the most vulnerable and marginalized sections of the population, without discrimination.

The Committee on Economic, Social and Cultural Rights in its General Comment No. 14 stressed that the right to health entails freedoms. These freedoms include the right to control one's health and body, including sexual and reproductive freedom, and the right to be free from any interference (para. 8).

Furthermore, the Committee in its General Comment No. 14 held that the provision for the reduction of stillbirths and infant mortality, and the healthy development of children, as specified in article 12. 2 (a) of the ICESCR, can be understood as requiring measures to improve child and maternal health, sexual and reproductive health services, including access to family planning, pre- and post-natal care, emergency obstetric services and access to information and resources necessary to act on that information. The Committee further highlighted the situation of women and the right to health, noting the need to develop and implement a comprehensive national strategy to promote women's right to health throughout their lives. This strategy should include, inter alia, policies aimed at providing women with access to a full range of affordable, high-quality health care, including sexual and reproductive services. The Committee further affirmed that the realization of women's right to health requires the removal of all barriers to women's access to health services, education and information, particularly in the area of sexual and reproductive health.

As stressed by the Committee on Economic, Social and Cultural Rights in its General Comment No. 22, States parties should aim to ensure universal access without discrimination for all individuals to a full range of quality sexual and reproductive health care, including maternal health care, contraceptive information and services and safe abortion care (para.45). States parties also have a core obligation to repeal or eliminate laws, policies and practices that criminalize, obstruct or undermine an individual's or particular group's access to sexual and reproductive health facilities, services, goods and information and are required to take measures to prevent unsafe abortions and to provide post-abortion care and counselling for those in need (para. 49 a) & e)).

We would also like to refer to article 2 of the Convention on the Elimination of All Forms of Discrimination against Women (CEDAW), signed by the United States in

1980, which condemns all forms of discrimination against women, and article 12 which refers to appropriate measures to eliminate discrimination against women in the field of health, including in relation to family planning, as well as article 16 (1) which refers to the rights of women to decide freely and responsibly on the number and spacing of their children and to have access to the information, education and means to enable them to exercise these rights.

In its General Recommendation 24, the CEDAW Committee affirms that a State party's refusal to provide certain reproductive health services to women under legal conditions is discriminatory (para. 11) and that the obligation to respect rights requires States parties to refrain from imposing constraints on measures taken by women to achieve their health goals (para. 14).

The CEDAW Committee in its General Comment 35 on gender-based violence against women, has recognized that violations of the right to health as well as women's sexual and reproductive rights are forms of gender-based violence that may amount to torture or cruel, inhuman or degrading treatment, inhuman or degrading treatment (paragraph 18), and has identified the social norms underlying the criminalization of abortion, such as those that impose gender roles or punish what is considered unacceptable female behaviour, as one of the causes of gender-based violence (paragraph 19).

As the Working Group emphasized in its position paper on [*Women's autonomy, equality and reproductive health in international human rights: Between recognition, backlash and regressive trends*](#), women's human rights include the rights to equality, dignity, autonomy, information, physical integrity and respect for privacy and the highest attainable standard of health, including sexual and reproductive health, without discrimination; as well as the right to be free from torture and cruel, inhuman and degrading treatment.

The right of a woman or girl to make autonomous decisions about her own body and reproductive functions lies at the very heart of her fundamental right to equality and privacy, with respect to intimate matters of physical and psychological integrity. Equality in reproductive health includes access, without discrimination, to affordable, quality contraceptives, including emergency contraception. Countries where women have the right to terminate pregnancies and are provided with access to information and all contraceptive methods have the lowest rates of termination of pregnancy. Unfortunately, according to WHO, an estimated 225 million women are deprived of access to essential modern contraceptives. The decision to continue or terminate a pregnancy is fundamentally and primarily a woman's decision, as it can determine her entire future personal and family life and has a crucial impact on women's enjoyment of other human rights. Accordingly, and following good practice in many countries, the Working Group on Discrimination against Women and Girls has called for women to be allowed to voluntarily terminate a pregnancy during the first trimester and beyond in cases of rape, child and adolescent pregnancy and risk to the woman's health or life. The Working Group on Discrimination against Women and Girls has called on States to ensure that access to health care, including reproductive health care, is autonomous, affordable and effective (see A/HRC/32/44).

In this context, we would also like to refer to the report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health (A/66/254), which reiterates that the criminalization of sexual and reproductive health services for women creates and perpetuates stigma; restricts their ability to make full use of available sexual and reproductive health commodities, services and information; denies their full participation in society; hampers their access to health services; and affects their access to health care; and it affects women's empowerment. On the other hand, the criminalisation of abortion has a negative impact on women's physical and mental health and may increase the likelihood of women resorting to clandestine abortions.

In this regard, we would like to underline that, as the Special Rapporteur on the right to health has pointed out (A/HRC/32/32), adolescents around the world face discrimination and barriers in accessing the information, services and commodities necessary to protect their sexual and reproductive health, resulting in violations of their right to health. In order to achieve target 3.7 of the Sustainable Development Goals to ensure universal access to sexual and reproductive health services, States should adopt a gender-sensitive and non-discriminatory sexual and reproductive health policy for adolescents and integrate it into national strategies and programmes. More specifically, adolescents must be guaranteed access to sexual and reproductive health information, services and commodities in a confidential and non-discriminatory manner that is responsive to their needs, including family planning, modern methods of contraception, counselling, pre-conception care, maternal care, sexually transmitted infections, diagnosis and treatment, and safe abortion. Adolescent sexual and reproductive health services should be welcoming and open to adolescents, without prejudice, and ensure privacy and confidentiality.

Finally, we would like to highlight the UN Guiding Principles on Business and Human Rights (A/HRC/17/31), which were unanimously endorsed by the Human Rights Council in June 2011, are relevant to the impact of business activities on human rights. These Guiding Principles are grounded in recognition of:

- a. “States’ existing obligations to respect, protect and fulfil human rights and fundamental freedoms;
- b. The role of business enterprises as specialized organs or society performing specialized functions, required to comply with all applicable laws and to respect human rights;
- c. The need for rights and obligations to be matched to appropriate and effective remedies when breached.”

According to the Guiding Principles, States have a duty to protect against human rights abuses within their territory and/or jurisdiction by third parties, including business enterprises.

The obligation to protect, respect, and fulfill human rights, recognized under treaty and customary law entails a duty on the part of the State not only to refrain from violating human rights, but to exercise due diligence to prevent and protect individuals

from abuse committed by non-State actors (see for example Human Rights Committee, General Comment no. 31 para. 8).

It is a recognized principle that States must protect against human rights abuse by business enterprises within their territory. As part of their duty to protect against business-related human rights abuse, States are required to take appropriate steps to “prevent, investigate, punish and redress such abuse through effective policies, legislation, regulations and adjudication” (Guiding Principle 1). This requires States to “state clearly that all companies domiciled within their territory and/or jurisdiction are expected to respect human rights in all their activities” (Guiding Principle 2). In addition, States should “enforce laws that are aimed at, or have the effect of, requiring business enterprises to respect human rights...” (Guiding Principle 3). The Guiding Principles also require States to ensure that victims have access to effective remedy in instances where adverse human rights impacts linked to business activities occur.

Moreover, Principle 26 stipulates that “States should take appropriate steps to ensure the effectiveness of domestic judicial mechanisms when addressing business-related human rights abuses, including considering ways to reduce legal, practical and other relevant barriers that could lead to a denial of access to remedy.”

States may be considered to have breached their international human law obligations where they fail to take appropriate steps to prevent, investigate and redress human rights violations committed by private actors. While States generally have discretion in deciding upon these steps, they should consider the full range of permissible preventative and remedial measures, including policies, legislation, regulations and adjudication.

The UN human rights mechanisms have made clear that this duty to protect human rights does not stop at States’ territorial borders. States are required to “take the steps necessary to prevent human rights violations abroad by corporations domiciled in their territory and/or jurisdiction (whether they were incorporated under their laws, or had their statutory seat, central administration or principal place of business on the national territory), without infringing the sovereignty or diminishing the obligations of the host States” under international human rights law (E/C.12/GC/24, para. 26).