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

REFERENCE:
AL OTH 197/2021

7 June 2021

Dear Mr. Frazier,

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.

We are independent human rights experts appointed and mandated by the United Nations Human Rights Council to report and advise on human rights issues from a thematic or country-specific perspective. We are part of the special procedures system of the United Nations, which has 56 thematic and country mandates on a broad range of human rights issues. We are sending this letter under the communications procedure of the Special Procedures of the United Nations Human Rights Council to seek clarification on information we have received. Special Procedures mechanisms can intervene directly with Governments and other stakeholders (including companies) on allegations of abuses of human rights that come within their mandates by means of letters, which include urgent appeals, allegation letters, and other communications. The intervention may relate to a human rights violation that has already occurred, is ongoing, or which has a high risk of occurring. The process involves sending a letter to the concerned actors identifying facts of the allegation, applicable international human rights norms and standards, the concerns and questions of the mandate-holder(s), and a request for follow-up action. Communications may deal with individual cases, general patterns and trends of human rights violations, cases affecting a particular group or community, or the content of draft or existing legislation, policy or practice considered not to be fully compatible with international human rights standards.

In this connection, we would like to bring to your attention information we have received concerning your company's alleged involvement in 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 errors in their composition.

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, Contimarvelon 20 from Merck Sharp & Dohme (I.A) LLC, Minigest 15 and Minigest 20 from Andrómaco Laboratory, with its active ingredients allegedly produced by Zheijang Xianju Pharmaceutical).

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.

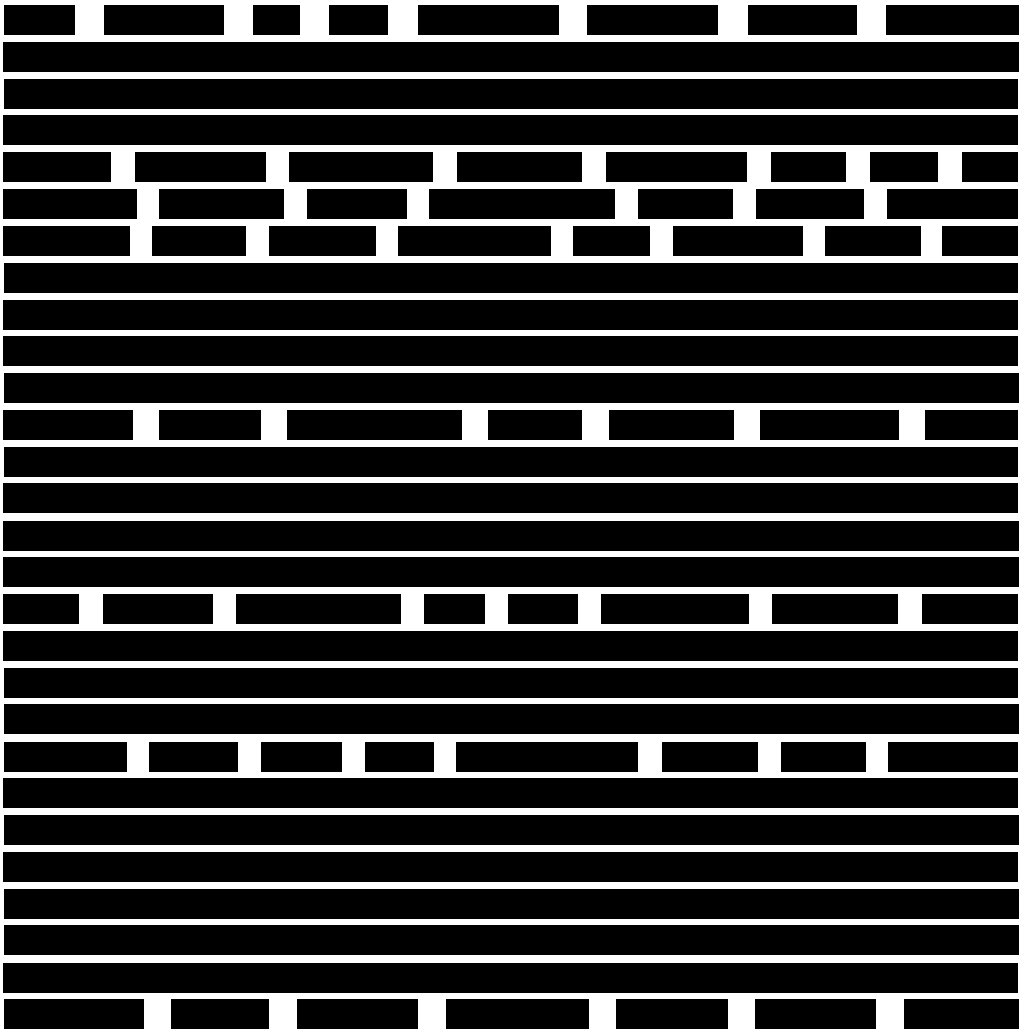
The second brand of pills to be withdrawn from circulation on 5 October 2020, were Minigest 15 and Minigest 20. According to reports by the Institute of Public Health, while it was conducting stability studies, it identified that in these two brands of contraceptives, the amount of active ingredients 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 requested to file a specific complaint. The victims include: [redacted]



[redacted]

These victims were forced to assume an unwanted or unplanned pregnancy, which has resulted in additional forms of discrimination against these women, and violation of other rights including: in some instances being left with no other option but to give up their education; being at risk of losing their jobs; facing distress, depression and physical and mental pain and worsening their socio-economic situation (for many already precarious) with some of the victims having several dependent children or sick relatives who already require care.

The circulation of defective contraceptive pills has put women and adolescents of childbearing age in Chile in a serious situation of violation of their human rights by exposing them to unwanted or unplanned pregnancies. It is very important to note that in Chile, women face considerable barriers to accessing legal abortion, which is permitted under very limited circumstances (risk for the life of the woman, rape or non-viability of the foetus ex-utero).

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 your company's negligence in the process of production and distribution of defective contraceptive pills and insufficient response to

prevent and mitigate the adverse impacts of its activities on women's sexual and reproductive rights, in contravention of relevant international standards, 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 information about the human rights due diligence policies and processes put in place by your company to identify, prevent, mitigate and account for how it addresses adverse human rights impacts of its activities, in line with the UN Guiding Principles on Business and Human Rights.

3. Please provide details on the investigation process regarding the flawed contraceptive pills that were being delivered and marketed in Chile. If no inquiries have taken place, or if they have been inconclusive, please explain why.

4. Please describe the measures that your company has taken, or is planning to take, to prevent recurrence of such situations in the future. In particular please share information on the stability studies carried out before the marketing of contraceptives, including what the process is, the authorities in charge of monitoring it and the standards that must be met to ensure that the quality of the contraceptive products is guaranteed.

5. Please provide information whether your company has provided, or is considering to provide, effective remedy, including adequate compensation, to individual victims of unwanted pregnancy arising as a result of the defective contraceptive pills.

6. Please provide information on whether your company has established or participated in an effective operational-level grievance or complaints mechanism, in line with the UN Guiding Principles, to address adverse human rights impacts caused by your company throughout your operations. Please also provide any information on whether such grievance mechanisms has been used to address any of the concerns or impacts identified by the individual victims of unwanted pregnancy as a result of the defective contraceptive pills, and any outcomes or remedy provided as a result.

This communication and any response received 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.

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 company 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, China and the United States where the companies involved are based or have their headquarters, as well as to other companies involved in the abovementioned allegations.

Please accept, Mr. Frazier, 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 attention to 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. 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.

Furthermore, we would like to note that as set forth in the United Nations Guiding Principles on Business and Human Rights, all business enterprises have a responsibility to respect human rights, which requires them to avoid infringing on the human rights of others to address adverse human rights impacts with which they are involved. The responsibility to respect human rights is a global standard of expected conduct for all business enterprises wherever they operate. It exists independently of States' abilities and/or willingness to fulfil their own human rights obligations, and does not diminish those obligations. Furthermore, it exists over and above compliance with national laws and regulations protecting human rights.

The Principles 11 to 24 and Principles 29 to 31 provide guidance to business enterprises on how to meet their responsibility to respect human rights and to provide for remedies when they have cause or contributed to adverse impacts. Moreover, the commentary of the Principle 11 states that "business enterprises should not undermine States 'abilities to meet their own human rights obligations, including by actions that might weaken the integrity of judicial processes".

The Guiding Principles have identified two main components to the business responsibility to respect human rights, which require that "business enterprises: (a) Avoid causing or contributing to adverse human rights impacts through their own activities, and address such impacts when they occur; [and] (b) Seek to prevent or

mitigate adverse human rights impacts that are directly linked to their operations, products or services by their business relationships, even if they have not contributed to those impacts" (Guiding Principle 13).

Principles 17-21 lays down the four-step human rights due diligence process that all business enterprises should take to identify, prevent, mitigate and account for how they address their adverse human rights impacts. Principle 22 further provides that when "business enterprises identify that they have caused or contributed to adverse impacts, they should provide for or cooperate in their remediation through legitimate processes".

Furthermore, business enterprises should remedy any actual adverse impact that they cause or to which they contribute. Remedies can take a variety of forms and may include apologies, restitution, rehabilitation, financial or non-financial compensation and punitive sanctions (whether criminal or administrative, such as fines), as well as the prevention of harm through, for example, injunctions or guarantees of non-repetition. Procedures for the provision of remedy should be impartial, protected from corruption and free from political or other attempts to influence the outcome (commentary to Guiding Principle 25).