August 6, 2021

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

Ref. AL OTH 197/2021 (dated 7 June 2021)

We have received your Joint Communication dated 7 June 2021, requesting information on contraceptive pills delivered and marketed in Chile ("Joint Communication"). We are responding jointly on behalf of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, NJ USA ("MSD") and on behalf of Organon & Co. ("Organon"). This is because very recently, in June 2021, MSD spun off Organon as a separate company and, as part of that spinoff, Organon now owns MSD's fertility and contraceptive businesses, including the CONTI MARVELON™ 20 (ethinylestradiol and desogestrel tablets) product that is referenced in your Joint Communication.

Both MSD and Organon applaud and strongly support efforts to strengthen the rights to sexual and reproductive health of women and girls worldwide. As you are probably aware, for 130 years, MSD has been inventing for life, bringing forward medicines and vaccines for many of the world's most challenging diseases in pursuit of its mission to save and improve lives. MSD is committed to conducting all of its business activities ethically and consistent with the United Nations Guiding Principles on Business and Human Rights ("UNGPs") and OECD Guidelines for Multinational Enterprises. As a company that seeks to act transparently, MSD is pleased to explain how it has operationalized those commitments through a robust governance and policy framework that extends throughout the organization and supply chain, and to respond to the specific questions in your letter. Organon shares MSD's commitment, and has been launched with the same framework.

As explained in detail below, although there was an error in the artwork on a single lot of blister packages of CONTI MARVELON™ 20, a full medical assessment has determined that the risk of an unwanted pregnancy from following the directions on that packaging was ***extremely remote***. Nor has either MSD or Organon identified any such unwanted pregnancies from this package defect. The companies therefore strongly believe that there have been no adverse impacts, much less any human rights impacts, associated with CONTI MARVELON™ 20. Notwithstanding the extremely remote risk of an unwanted pregnancy, the potentially impacted packages of CONTI MARVELON™ 20 were recalled.

Part I of this letter discusses the dedicated programs that MSD and Organon have taken to address and protect the health of women, as well as the companies' general human rights approach, including product safety and labeling, in particular. Part II then discusses the thorough investigation conducted by MSD into the substance of the issue raised in the Joint Communication. As that investigation revealed, a single lot of CONTI MARVELON™ 20 blister packages containing incorrect artwork was distributed in Chile (and only in Chile) between May 2019 and May 2020. As soon as MSD became aware of the issue,

it engaged its highly experienced medical experts to assess the potential risks resulting from the incorrect artwork. Those experts concluded that the likelihood of an unwanted pregnancy resulting from the artwork error was "extremely remote," and the companies are not aware of any adverse impacts resulting from this error. A swift product recall put in place by MSD, in coordination with the Chilean Institute of Public Health, resulted in less than 3,000 total blister packs being distributed to patients in Chile—representing 1% of the 276,890 total defective blister packs distributed by the various manufacturers discussed in the Joint Communication. Part III discusses concerns the companies share from referencing CONTI MARVELON™ 20 in the Joint Communication. In particular, while the Joint Communication identifies potentially troubling human rights issues connected to the contraceptive products of other companies, MSD and Organon sincerely hope that the inclusion of CONTI MARVELON™ 20 does not create false impressions about the efficacy or safety of MSD's (now Organon's) contraceptive products, which in turn could impair the choice of Chilean women in seeking effective, safe and legitimate contraception in the future.

I. MSD'S AND ORGANON'S COMMITMENT TO HUMAN RIGHTS

MSD's Commitment to Women's Health

MSD has long been a leader in protecting and promoting the health of women and girls around the world. In the past decade alone, the company has invested more than $500 million in its groundbreaking MSD for Mothers program, established to address and confront maternal mortality. The program seeks to reduce and eliminate the deaths of women during or after childbirth through a variety of initiatives and is perhaps the leading maternal mortality program in the world. MSD for Mothers has reached some 11 million women in 48 countries through programs promoting safe, high-quality, respectful care; 15 million people in providing improved access to potentially lifesaving products; 52 million people in providing improved access to quality facilities; and 185,000 providers in providing improved training.

MSD also has launched other innovative programs focusing on the health needs of women and girls. Several years ago, MSD initiated "Rule the Real Talk" to help women spark important conversations about sexual health, including birth control options, with their partners and health care providers. MSD has launched the award-winning Healthy Women, Healthy Economies program, a partnership with the Bill & Melinda Gates Foundation to Family Planning 2020 ("FP2020") to empower women and girls by investing in rights-based family planning and has served as a global leader in access to reproductive health services around the world. MSD has further supported the public health community's goal of ensuring that the reach of voluntary lifesaving family planning information, services and products extends to the world's poorest countries, and has reached 53 million women since 2012 through FP2020. As part of MSD's commitment to health care provider training, the company provided birth control implant training applicators at no cost in FP2020 countries during product launches in those countries, and at a reduced price for cases unrelated to product launch. Over the years, MSD has worked with partners such as the United Nations Population Fund, the United States Agency for International Development, and the Collaborative Supply Planning Group/Reproductive Health Supplies Coalition to avoid stocking imbalances and ensure reproductive health supply chain security.[1]

Consistent with these programs, MSD demonstrated its dedication to making contraceptive products available and accessible to women around the world. In developing countries that have high rates of

[1] *See Women's Health*, available at https://www.msdresponsibility.com/access-to-health/womens-health/.

maternal mortality and low rates of contraceptive prevalence, MSD created a sustainable public-private partnership model, with first-quality products made available at access pricing to promote the availability of contraceptive health programs. Additionally, MSD worked to have certain medicines and vaccines prequalified through the World Health Organization, which can facilitate product procurement by international procurement agencies. MSD's pricing and commercialization for contraceptive products consistently took into consideration a nation's level of economic development and other relevant factors, including the types of family-planning programs implemented by the local government and maternal mortality rates. Finally, MSD routinely offered discounts to organizations that serve women of all income levels, so that the women who rely on their services have routine access to contraceptive options that include non-daily and long-acting reversible methods.

More generally, MSD has pursued impact investing as a core approach to advancing sustainable global health systems, deploying financial resources in ways that may generate not only improved access to health care for underserved populations, but also financial returns and commercial opportunities. MSD's impact investing program was recently recognized by the United Nations Department of Economic and Social Affairs as part of the Sustainable Development Goals Good Practices Initiative at the UN High Level Political Forum, the annual venue for reviewing global progress towards the Sustainable Development Goals.

The Companies' Commitment to Human Rights

Organon itself is a product of MSD's commitment to women's health.[2] In June 2021, MSD created Organon as a separate, independent company to focus intensely on the unique health needs of women.[3] Organon's mission is to deliver impactful medicines and solutions for women, including contraceptives, fertility drugs, and postpartum hemorrhage treatments, to name a few. This mission is carried out through the delivery of over 60 medicines and other products in more than 140 different markets.[4] Organon believes that advancing the health of women directly enhances the health of society, which is inextricably linked to human rights and other Environmental, Social & Governance ("ESG") principles.[5] Many of the MSD programs detailed in the section above will be carried forward and expanded by Organon in the future.

More generally, both companies are committed to respecting human rights, consistent with the UNGPs. MSD has a longstanding and robust approach to responsible business conduct and human rights, as detailed in the company's Corporate Human Rights Policy Statement.[6] Organon is likewise committed to adhering to the same ideals and intends to issue a similar policy statement during its first year of operation as an independent company.

As its Human Rights Policy Statement makes clear, MSD bases its human rights policy commitments on the International Bill of Human Rights and the International Labour Organization's Declaration of Fundamental Principles of Work. The company's commitments are operationalized through a program

[2] *See Organon Code of Conduct*, available at https://www.organon.com/wp-content/uploads/sites/2/2021/05/Organon-Code-of-Conduct-External-English.pdf.
[3] *See Our Focus*, available at https://www.organon.com/our-focus/.
[4] *See Our Story*, available at https://www.organon.com/about-organon/.
[5] *See Environmental, social & governance*, available at https://www.organon.com/about-organon/environmental-social-governance/.
[6] *See Public Policy Statement, Human Rights*, available at https://www.merck.com/wp-content/uploads/sites/5/2020/04/Policy_2019_Human-Rights_MERCK.pdf.

overseen by MSD's Board of Directors that extends throughout MSD's organization, business partners, and suppliers. The Corporate Responsibility unit is responsible for coordinating all human rights due diligence processes and activities. Progress and measures are regularly discussed at Corporate Responsibility Committee meetings, while subject matter experts within the company functions, business sectors, and local units are in charge of initiating the necessary actions.

MSD and Organon expect the same commitment from their business partners, which include individuals or organizations that provide goods and services, as well as their operating subsidiaries, affiliates and divisions.[7] The companies' practices are informed and guided by PSCI's Pharmaceutical Industry Principles for Responsible Supply Chain Management, which set the standard for ethics, labor, health, safety, and the environment for the industry. The Business Partner Code of Conduct and Supplier Performance Expectations expressly apply these standards, along with other corporate policies, to business partners.

These standards are supported by a robust process to meet the companies' commitment to respect human rights throughout their supply chains, including through selection, setting expectations, conducting training, performing due diligence, contractual terms, auditing, managing and monitoring relationships, and responsible sourcing. Before contracting, all new Contract Manufacturer Organizations (including API, Intermediates, Drug Product, Devices and Packaging), direct material suppliers, as well as certain indirect and research suppliers, are required to complete and return a Supplier Self-Assessment Questionnaire ("SAQ") for Ethics & Compliance. The companies' SAQs require suppliers to answer a series of labor and human rights questions covering a range of subjects. Each supplier's response is used to judge whether that supplier has programs and/or procedures in place to address potential risks for labor and human rights related deficiencies.

Product Quality and Safety

Both companies consider human rights and product quality and safety to be ESG issues of the highest priority.[8] Accordingly, each company has a dedicated strategy focused on product quality and safety. These strategies help maintain a reliable, compliant supply of products to customers.

Patient safety is at the forefront of what both companies do. Both companies use and explore new technological advancements such as integrated IT tools and streamlined digital platforms to further enhance how high-quality products are manufactured. MSD and Organon apply and adhere to a strict set of quality standards, and have policies and procedures in place to identify, measure, control and sustain product-quality excellence.

Each company's global quality compliance organization is responsible for establishing the standards that ensure that all products are manufactured, tested, released, and distributed in full compliance with regulatory requirements. Both companies continuously strive to improve these standards in order to enhance procedures and ensure ongoing compliance with current Good Manufacturing Practices ("cGMPs"). MSD and Organon also provide appropriate and ongoing training on cGMPs for their employees, so they are prepared to perform their duties effectively. The companies' systems not only

[7] *See Organon Business Partner Code of Conduct*, available at https://www.organon.com/wp-content/uploads/sites/2/2021/05/Code-Of-Conduct-English.pdf.

[8] *See* https://www.msdresponsibility.com/reporting/corporate-responsibility-materiality/.

ensure that all applicable employees are trained, but also monitor the effectiveness of the training provided.

MSD and Organon products also are widely tested before they are approved for marketing. This testing is governed by a comprehensive regulatory scheme and by research policies. Both companies assess the safety of their products in rigorous nonclinical and clinical trials prior to seeking regulatory approval. Following approval of their products, the companies continue to monitor their safety profiles.

Each company's clinical safety and pharmacovigilance function manages a global system for the collection, review, and reporting of drug adverse event ("AE") reports, defined as unfavorable or unintended changes in the body that occurs when using or following use of a company product, received by the company worldwide, and for the continuous assessment of product safety. The companies' respective chief safety officers hold overall responsibility for the safety of products.

These programs are highly effective. Product recalls are exceedingly rare.

Product Labeling

MSD and Organon also are highly attentive to product packaging and labeling. Labels affixed to product packaging contain information on product usage, possible side effects, and, where appropriate, ways in which to avoid potential health issues. Each of the companies' corporate websites contain contact information for patients, caregivers, and health professionals to report adverse events.

Depending on label changes and their context, MSD or Organon may determine, in consultation with regulatory authorities, that more extensive communications are appropriate. In those situations, the companies work with regulatory authorities to communicate to health care professionals in a timely manner so that they can inform patients through appropriate mechanisms. Communications to health care professionals may include "Dear Health Care Provider" letters and media statements.

The ongoing oversight and monitoring of product labels are a major focus of safety efforts. Label review teams monitor information on company products and work with product risk management and safety teams to develop or update product labeling. The companies regularly communicate relevant information to regulatory authorities worldwide.

Reporting Product Concerns & Grievance Mechanisms

Reporting and responding to patient safety concerns is also a top priority. Both MSD and Organon expect that within one business day of receiving an AE report or a product quality complaint ("PQC") associated with a company drug product, the designated point of contact ("DPOC") will be notified for further review. Both MSD and Organon expect that their third-party contractors, suppliers, and partners pay the same close attention to patient safety concerns.

When a PQC is received at MSD or at Organon, the DPOC collects relevant case information and sends the PQC to a Complaint Handling Unit that reviews the information, ensures completeness, and classifies the complaint category and risk priority. Once classified, the PQC is referred to a Complaint Investigating Unit ("CIU"), which initiates an investigation. If the nature of the complaint is serious, it is then subject to a formal fact-finding process—a team is convened and collects a defined set of information to be presented for discussion and consideration. In the event that the fact-finding committee determines that further action may be required, a quality recommendation memorandum is

presented to the senior vice president of global quality operations recommending that the market action committee should be convened. The senior vice president of global quality operations may elect to convene the market action committee or, in certain circumstances, may elect to directly approve market action.

Both companies also maintain "Speak Up" programs, where any employee, supplier, business partner, or other stakeholder can report concerns, including those related to human rights issues.[9] MSD's Speak Up tool and Organon's Integrity Line each are operated by an independent third-party service, available 24/7 via phone or internet. Anyone who utilizes these tools may choose to remain anonymous (where permitted by law), and all information will be relayed to each company's respective Office of Ethics and Compliance for response or investigation.

Employees can also report concerns to management or to the human resources, compliance, or legal departments. Neither company tolerates retaliation against anyone who raises a concern in good faith, and allegations of misconduct are investigated in accordance with each company's respective investigative process, which promote confidentiality, dignity, respect, objectivity, promptness, and non-retaliation.

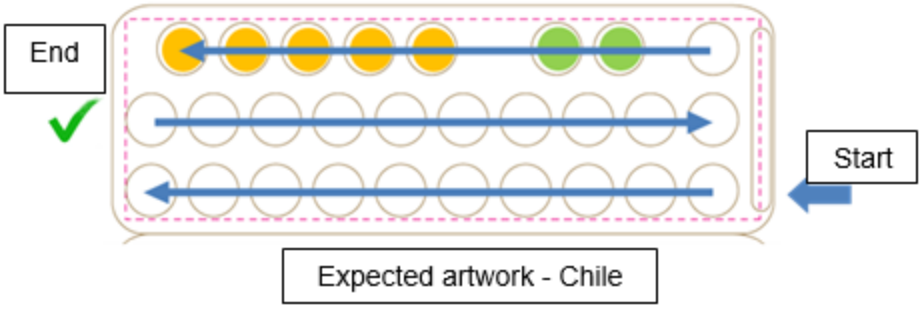
II. MSD'S INVESTIGATION OF THE ISSUE AT HAND

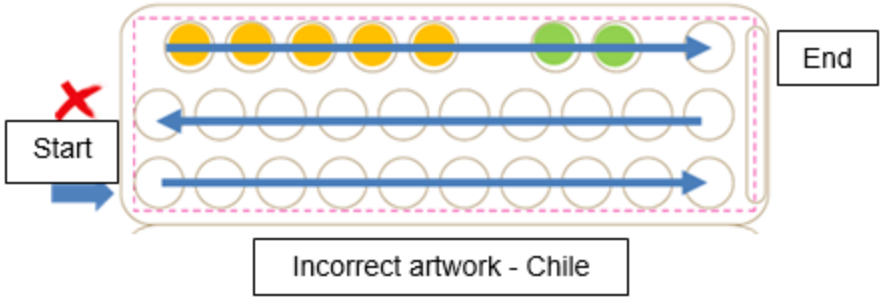
In September 2020, MSD was notified of a potential defect in the CONTI MARVELON™ 20 product in Chile. MSD immediately launched an investigation consistent with its policies and procedures, conducted a medical assessment to assess any potential impact, and swiftly carried out a recall of all potentially impacted products. The medical assessment concluded that there was an extremely remote likelihood of an unwanted pregnancy or other clinically significant adverse medical event occurring as a result of the issue. That conclusion is supported by the fact that no adverse events have been reported in connection with CONTI MARVELON™ 20 in Chile during or since the relevant time period. Nonetheless, the potentially impacted packages of CONTI MARVELON™ 20 were recalled immediately.

Initial Customer Complaint

On September 3, 2020, MSD Chile received a PQC from a consumer stating that the foil on a CONTI MARVELON™ 20 blister pack indicated an incorrect tablet administration sequence. CONTI MARVELON™ 20 is a combined oral contraceptive. The blister pack contains 28 tablets: 21 white tablets with 0.150 mg desogestrel and 0.020 mg ethinylestradiol, two green placebo tablets, and five yellow tablets with 0.010 mg ethinylestradiol. MSD confirmed that the product leaflet included with the CONTI MARVELON™ 20 blister packs correctly instructed the patient to take 21 white tablets, followed by two green tablets, and lastly five yellow tablets. However, after reviewing photographs sent with the complaint, MSD found that the "Start" and "End" references were incorrect on the foil artwork of the blister package, and incorrectly instructed the patient to take 20 white tablets, followed by five yellow tablets, two green placebo tablets, and lastly one white tablet. The blister drawings below exemplify the correct and incorrect sequence of administration:

[9] Available at www.organon.com/integrity; MSDethics.com.





Consistent with MSD's policies and procedures, the PQC was sent to a CIU, which began an investigation and triggered a formal fact-finding process.[10]

Fact/Artwork Investigation

The Quality Director responsible for the packaging site assembled a fact-finding team, which included members from a variety of MSD departments possessing relevant experience and expertise. The internal quality investigation concluded that the blister artwork incorrectly indicated "Start" and "End" information. As the investigation revealed, a new contract manufacturer in Brazil, Eurofarma, had started supplying CONTI MARVELON™ 20 for Chile in May 2019; this change in manufacturer also required a change to the blister format based on the available tooling configurations at the contract manufacturer. The previous artwork, however, was inadvertently used as a reference for the Chilean lot in question, despite the change in configuration of the tablets for the new blister format.

MSD confirmed that Eurofarma manufactured only one lot of blister packs for Chile (Lot #608442), all of which expired in November 2020. Between May 2019 and May 2020, 4,091 blister packs from the lot—a highly limited number, and far less than other companies' products identified in the Joint Communication—were distributed to private wholesalers in the Chilean market. There was no distribution through government programs or public health centers. MSD concluded that only Lot #608442 packaged for Chile received the blister pack with incorrect artwork. No blister packs with defective artwork were distributed outside of Chile.

[10] A second, similar complaint was received by MSD Chile on September 25, 2020, although the investigation was already well underway by then.

Medical Assessment

On September 9, 2020, as part of the fact-finding process, a medical assessment was requested to determine whether risks might exist for a patient taking CONTI MARVELON™ 20 consistent with the sequence on the erroneous artwork on the blister pack (20 white tablets with full potency, 5 yellow tablets with reduced potency, 2 green placebo tablets, and 1 white tablet with full potency), rather than the sequence in the product leaflet (21 white tablets, 2 green tablets, 5 yellow tablets). The assessment was carried out by a highly experienced senior principal scientist and medical doctor in MSD's Clinical Safety and Risk Management for Devices and Product Quality group ("CSRM DPQ").

The assessment included meetings with the quality and engineering teams, engagement with contraceptive and clinical safety experts, review of pertinent medical and scientific literature, analysis of the CONTI MARVELON™ 20 labeling and prescribing information, and searches within MSD's database for AEs. A final report from CSRM DPQ was issued on September 24, 2020, concluding that the risk of an unwanted pregnancy associated with the error in the blister pack artwork was "extremely remote."

The assessment stated that the contraceptive effect of combined oral contraceptives, such as CONTI MARVELON™ 20, is based on the interaction of various factors, the most important of which are the inhibition of ovulation and the changes in the cervical secretion. The assessment examined the likelihood of an unintended pregnancy in every relevant factual scenario—whether the patient followed the leaflet, followed the instructions from the artwork on the foil blister and stopped after one month, or followed the instructions from the artwork on the foil blister and continued to a second month—and concluded that in each scenario, the patient would take a sufficient combination of white (full potency) and yellow (reduced potency) tablets to provide effective levels of estrogen to prevent pregnancy.[11]

That conclusion is consistent with the product label regarding the implications of missed doses, which indicated that for CONTI MARVELON™ 20 to be effective against pregnancy, a patient must not miss more than seven white and yellow tablets combined. In all factual scenarios analyzed, the patient would not breach that threshold of seven missed tablets, which may compromise efficacy. It also is supported by the fact that MSD has not received any reports indicating an unwanted pregnancy from a patient taking CONTI MARVELON™ 20, which would have been expected if one had occurred. Because the blister pack instructions would have provided sufficient levels of estrogen to prevent pregnancy, and no adverse events had been reported, the medical assessment concluded that the risk to patient health in the form of unintended pregnancy was "extremely remote."

Quality Recommendation

On September 29, 2020, consistent with MSD's standard procedures, a fact-finding meeting was held to review and discuss the facts and findings of the investigation, including the medical assessment. Approximately two dozen individuals attended and participated, including individuals from the quality, regulatory affairs, and clinical safety departments of the company. Pursuant to MSD procedure, on October 1, 2020, the findings and recommendations were provided to the senior vice president of global quality operations. These confirmed that the root cause of the artwork at issue was an inadvertent error during the artwork development and approval process, and identified several corrective actions, including: (i) review of the incident with all Latin America teams involved with artwork management; (ii) revision of the global artwork procedures to highlight specific requirements of multi-dose products; (iii) retirement or revision of the existing evaluation of the CONTI MARVELON™ 20 artwork; (iv) evaluation

[11] It is noteworthy that no oral contraceptive has a 100% effectiveness rate against unintended pregnancy.

of potential changes to control approval flow; and (v) review the artwork management system to incorporate applicable corrective action. Each of these corrective actions was thereafter implemented by MSD and have been carried forward at Organon.

Recall

On October 2, 2020, MSD proactively decided to recall Lot #608442. The following week, MSD met with the Chilean Institute of Public Health regarding the facts identified during the investigation and the recall decision. On Friday, October 9, 2020, MSD sent a product recall notification to the Chilean Institute of Public Health, and the next day, it issued a pharmaceutical recall alert, noting an error in the administration instructions contained on the blister packaging. MSD and the Chilean Institute of Public Health agreed that this constituted a Class III recall—the lowest level—as adverse health consequences resulting from the artwork defect were extremely remote.

On October 14, 2020, MSD sent notifications to the three distributors of CONTI MARVELON™ 20 regarding the recall and related information about product quantities under their respective control.[12] The recall took place from October 14, 2020, through January 19, 2021. Of the 4,091 defective blister packs that had been distributed, 1,107 units (27.1%) were received back by MSD, constituting all of the products within the distributors' control. These blister packs were destroyed on January 22, 2021. Because of MSD's swift response, less than 3,000 blister packs bearing the incorrect artwork were ultimately distributed to patients. As was the case during the assessment in September 2020, no AEs associated with the artwork error have been reported to date. Both companies therefore are confident that the error has not caused the negative health impacts described in the Joint Communication.

Nonetheless, MSD and Organon have encouraged any individual or entity with contrary information to alert us immediately. The companies' commitment to responsible business conduct and the UNGPs includes a commitment to engage in good faith when they cause or contribute to adverse impacts and provide or cooperate in their remediation consistent with the UNGPs.

III. POTENTIAL NEGATIVE CONSEQUENCES TO WOMEN IN CHILE OF REFERENCING CONTI MARVELON™ 20 IN THE JOINT COMMUNICATION

In light of the above facts, both companies believe it is important to note several critical distinctions between CONTI MARVELON™ 20 and the other products referenced in the Joint Communication. According to the allegations in the letter, those other products were distributed in vastly larger numbers in Chile and were not limited to one small lot. As mentioned above, the less than 3,000 blister packs that were unable to be recovered following MSD's product recall represent 1% of the 276,890 total defective blister packs distributed by the various manufacturers discussed in the Joint Communication. In addition, the concerns regarding those other products apparently pertain to their efficacy, not an artwork mistake where estrogen levels were not unduly compromised and the risks of an unwanted pregnancy remained extremely remote. Unwanted pregnancies are alleged to have resulted from the use of the other products, while MSD and Organon have received no reports of unintended pregnancies resulting from the relevant lot of CONTI MARVELON™ 20. The other products were distributed through public health centers; CONTI MARVELON™ 20 was not. In short, the companies believe including CONTI MARVELON™ 20 in the Joint Communication in connection with the other identified products is inaccurate.

[12] CONTI MARVELON™ 20 was not distributed in any public health centers.

Further, while both companies are deeply troubled by the potential impacts of defective contraception as identified in the Joint Communication, they are highly concerned that including reference to CONTI MARVELON™ 20 may cause negative health consequences for women in Chile and perhaps elsewhere. Specifically, given current perceptions of contraception and reproductive rights in Chile, both companies worry that including CONTI MARVELON™ 20 in a letter outlining serious concerns about allegedly unsafe products that were distributed on a massive scale may deter women from seeking safe and effective contraception options from Organon in the future, cause women to turn to less effective or even counterfeit products, or otherwise impair the rights or health of women. The companies would be very glad to discuss this issue and these concerns with you in more detail, but very much ask that appropriate discretion be exercised in balancing the need to call attention to the important issue of defective contraception with the risk that improperly referencing effective products and companies like MSD might have unintended effects on the advancement of women's health in Chile.

CONCLUSION

Both companies do hope that the above information sufficiently responds to your inquiries, and that you will take seriously the potential negative consequences to women in Chile associated with the Joint Communication's intimations regarding CONTI MARVELON™ 20. If we can provide further information, please let us know.

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