

**Mandates of the Special Rapporteur on the negative impact of unilateral coercive measures on the enjoyment of human rights; the Working Group on the issue of human rights and transnational corporations and other business enterprises; the Special Rapporteur on the right to development; the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health and the Independent Expert on human rights and international solidarity**

Ref.: AL OTH 95/2022  
(Please use this reference in your reply)

11 October 2022

Dear Mr. Rihter,

We have the honour to address you in our capacities as Special Rapporteur on the negative impact of unilateral coercive measures on the enjoyment of human rights; Working Group on the issue of human rights and transnational corporations and other business enterprises; Special Rapporteur on the right to development; Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health and Independent Expert on human rights and international solidarity, pursuant to Human Rights Council resolutions 49/6, 44/15, 42/23, 42/16 and 44/11.

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 the 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.

We wish to take this opportunity to acknowledge the response to the past joint communication OTH 230/2021, sent on 14 October 2021, and the information provided. We appreciate your company's response to our previous letter, and your company's role in the collective support to ensure the supply of medical dressings, vital for Iranian patients with the skin disease Epidermolysis Bullosa (EB) during this 2022 cycle. We regret to convey, however, our continued concern that although short-term measures have been established, it is evident that the solution is limited and temporary. With this in mind, we wish to reiterate our plea for your assistance in facilitating the procuring of the medical dressings in question.

Mölnlycke Health Care AB

In this connection, we would like to bring to the attention of your company information we have received concerning **financing the procurement by UNICEF of Mepilex dressings for Iranian patients with epidermolysis bullosa (EB) through the Ministry of Health, delivered via a domestic charity.** It is our understanding that this system of supplying the dressings was established because your company **is reluctant to engage directly with the Iranian Government or Iranian associations in view of sanctions imposed by the U.S. Government** against that country. It is also our understanding that UNICEF's purchases are of an *ad hoc* nature related to the arrangements by which they are financed, and that **the lack of a sustainable, reliable supply process negatively impacts the right to health and right to life** of the concerned patients for whom the dressings are destined.

Shipments of medical goods for children, that are exempted from the sanctions, that UNICEF acquires for Iran are subject to serious delays due to operational bottlenecks which are attributed to the lengthy and complicated process of getting necessary approvals and licenses as well as to overcompliance with the U.S. sanctions by parties involved in all aspects of the process, from manufacturers to banks, insurance companies and shipping companies.

According to the information received:

The United States of America imposes a broad and complex network of economic, trade and financial sanctions against Iran. In the last four decades, these have included a comprehensive trade ban, significant measures to isolate Iran from the international commercial and financial system, and secondary sanctions against non-U.S. parties that engage in dealings with Iran. Many of the sanctions were waived or eased in 2015 but were restored in 2018 under Executive Order 13846, "Reimposing Certain Sanctions with Respect to Iran," when the United States withdrew from the Joint Comprehensive Plan of Action.

There is considerable overcompliance with U.S. sanctions against Iran resulting from factors such as their complexity; costs entailed in ensuring compliance; vigorous extraterritorial enforcement, mainly through secondary sanctions; and fears of penalties even for inadvertent breaches.<sup>1</sup> This overcompliance magnifies all effects of the sanctions, including the negative impact on human rights.

After the United States reimposed its sanctions against Iran in 2018, Mölnlycke halted all sales to Iran, including medical products – even though these items were exempt from the sanctions on humanitarian grounds. One such product was Mepilex, a silicone dressing developed by Mölnlycke which eases the suffering of so-called "butterfly children" who have EB, an extremely painful and sometimes-fatal disease.

Mölnlycke's exclusive Iranian importer stopped importing the company's products after the reimposition of U.S. sanctions due to "financial and bank troubles," and it has not been replaced.

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<sup>1</sup> United Nations, "Iran: Unilateral sanctions and overcompliance constitute serious threats to human rights and dignity – UN expert," 19 May 2022, <https://www.ohchr.org/en/press-releases/2022/05/iran-unilateral-sanctions-and-overcompliance-constitute-serious-threat-human>

Since then, Iran's Ministry of Health has sought to obtain Mepilex dressings for Iranian EB patients, who receive them through a domestic charitable foundation, EB Home. As Mölnlycke declines to have direct contact with the Iranian Government, the Ministry requested the involvement of UNICEF, which has a long-term supply agreement with Mölnlycke to purchase the dressings on its behalf.

The Swedish Ministry of Foreign Affairs has engaged with Mölnlycke and UNICEF, as well as with the German Government, to finance the procurement of the dressings through UNICEF. This has led to *ad hoc* arrangements for one-year at a time supplies of the dressings. No solution has been found to obtain supplies in a more durable way.

Shipments of medical goods that UNICEF acquires for Iran are subject to serious delays due to operational bottlenecks due to the lengthy and complicated process of getting licenses as well as overcompliance with the U.S. sanctions by parties involved in all aspects of the process, from manufacturers to banks, insurance companies and shipping companies.

Mepilex dressings can have a shelf life of three years.<sup>2</sup> Taking into account the time lost through implementing the more cumbersome supply process, the limited shelf life further shortens the period in which the dressings may be used once they arrive in Iran.

In the absence of a durable supply solution, procurement must occur repeatedly, each time on *ad hoc* basis without any certainty of success or timeliness. This is naturally a source of anxiety and stress for EB patients who cannot be assured of a steady supply of the Mepilex dressings that in some cases are vital to their survival. Shortages have in fact occurred since the current supply process has been in effect.<sup>3</sup> We have been informed that shortages of these dressings in 2019-2020 resulted in serious complications for EB patients, the deaths of 15 of them, and the serious deterioration of the health status and quality of life of many others.

Without prejudging the accuracy of the information received, we wish to reiterate our serious concerns about the obstacles and difficulties inherent in supplying Mepilex dressings for EB patients in Iran through short-term efforts involving intermediaries, extra steps and logistical delays and the absence of sustainable and durable procurement procedures. We also wish to express our serious concerns that overcompliance with the U.S. sanctions against Iran result in serious shortages of these medical dressings and thus substantially harm the rights to health and to life of EB patients in Iran.

We recall that the International Covenant on Economic, Social and Cultural Rights (ICESCR), to which Sweden is a party, protects "the right of everyone to the

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<sup>2</sup> ProcureNet, a procurement service affiliated with UNICEF and other official agencies, <https://procure-net.com/product/mepilex-transfer-20-x-50-cm-ster-box-4/>

<sup>3</sup> Communication of 14 December 2021 from the Swedish Ministry for Foreign Affairs in response to AL SWE 3/2021, <https://spcommreports.ohchr.org/TmSearch/Mandates?m=263>

enjoyment of the highest attainable standard of physical and mental health,” while the right to life, is embodied in the International Covenant on Civil and Political Rights (ICCPR), also binding on Sweden. These two rights are key pillars of the Universal Declaration of Human Rights (UDHR), which in the case of health attests to the importance of every individual’s health and well-being.

We highlight the reference to “mental health” in the ICESCR because the effects of untreated EB in addition to excruciating suffering, are also mental. Most EB patients suffer from anxiety,<sup>4</sup> due to the fear of future suffering if treatment is interrupted. Anxiety can have an impact on disease outcomes,<sup>5</sup> thus the added stress and anxiety about not being assured of uninterrupted, long-term supplies of Mepilex dressings is relevant here.

The Swedish Government, in its response to our earlier communication dated 14 October 2021,<sup>6</sup> noted that “whether Mölnlycke has decided to halt the export of the medical dressings to Iran due to problems with interpreting the US sanctions regime or whether due to pure business-related considerations, is a matter for Mölnlycke and not for the Government to clarify.” Nonetheless, an awareness of the reason for the decision is warranted to ensure legal compliance with international human rights norms to ensure maximum protection.

As the rights to health and to life are at stake when people suffering from an acutely painful and life-threatening medical condition due to the interruption of supply of a product that can alleviate such suffering and prolong life, when that product has only one source, it would be highly valuable to know if the resumption of U.S. sanctions against Iran in 2018 played any role in Mölnlycke’s decision to not sell products to the country or do business directly with its Government, particularly in view of the humanitarian exemptions that exist precisely to allow products like Mepilex to be sold and shipped to Iran.

As mentioned above, overcompliance with sanctions magnifies their negative impact on human rights, and it may be possible to alleviate this result if specific factors that encourage companies to overcomply are identified and addressed.

Consequently, to the extent that your company’s business procedures allow, we would be most grateful to know what are the real or perceived legal impediment arising from the U.S. sanctions to doing business in Iran or with its Government in the case of these unique products. We would also like to know if there is any other aspect of the U.S. sanctions regime (complexity of the sanctions or the procedure for using its exemptions, compliance costs, extraterritorial enforcement, penalties for inadvertent violations, etc.) which deter Mölnlycke to refrain from doing business that appears to us entirely legal conduct.

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<sup>4</sup> Swaranjali V. Jain and Dedee F. Murrell, “Psychosocial impact of inherited and autoimmune blistering diseases,” *International Journal of Women’s Dermatology* 4 (1), 2018, pp; 49-53, <https://www.sciencedirect.com/science/article/pii/S2352647517300953>

<sup>5</sup> See, e.g., Sally E. Tarbell, “Editorial: Anxiety in Pediatric Chronic Illness: The Elephant in the Exam Room,” *Journal of the American Academy of Child and Adolescent Psychiatry* 59 (5), 2020, pp. 586-587.

<sup>6</sup> Communication of 14 December 2021 from the Swedish Ministry for Foreign Affairs in response to AL SWE 3/2021, <https://spcommreports.ohchr.org/TmSearch/Mandates?m=263>

If the U.S. sanctions played no part in Mölnlycke's decision, and it arose from "pure business-related considerations," this would be equally valuable to know, and no further explanation would be sought.

In a previous communication with Mölnlycke<sup>7</sup>, we referred to the company's human rights responsibilities under the UN Guiding Principles on Business and Human Rights, and Mölnlycke's direct involvement in ensuring the rights to health and to life by virtue of its chosen business. To the extent that the current arrangements for supplying Mepilex dressings to Iran result from your company's decision and have a negative impact on these rights, We reiterate that the Guiding Principles call on Mölnlycke to actively seek to identify and mitigate this harm.

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. Is your company's decision to not do business with Iran or with its Government after the resumption of U.S. sanctions against the country in 2018 a result of the sanctions? If so, we would be most grateful for any explanation as to what specifically prevents or deters your company from supplying these vital products to Iran?
3. If the U.S. sanctions had a role in your company's decision, please identify what possible changes in these sanctions regimes or their enforcement might motivate the company to resume doing business with Iranian counterparts or the Iranian Government.
4. What other conditions, if any, would be necessary for your company to enter into a durable arrangement for supplying Mepilex dressings to Iran for distribution to EB patients? Please explain if such conditions would involve specific actions by Iran's Government or other parties.
5. We would be grateful to know if your company has assessed the human rights impact of its decision, and whether it has taken or plans to take action to mitigate any harmful effects on human rights in accordance with the Guiding Principles or other human rights standards for businesses.
6. Please provide information on steps taken by your company to establish operational-level grievance mechanisms to address any adverse human rights impacts caused by your company in this case.

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<sup>7</sup> [website](#)

We would be grateful for a prompt and thorough response to this letter and respectfully urge your company, in a spirit of due diligence, to review its decision and course of action.

We would also appreciate receiving a response within 60 days. After this period, this communication and any response received from your company will be made public via the communications reporting [website](#). They will also subsequently be made available in the usual report to be presented to the Human Rights Council.

We may consider to publicly express our concerns about this issue in the future as in our view the information thus far available to us is reasonably reliable and a matter of obvious human, human rights and public interest. Any public expression of concern on our part will indicate that we have been in contact with your company to bring these matters to your attention and to seek clarification.

Letters on this subject will be sent to the Governments of the Kingdom of Sweden and of the United States of America. A copy of the letter to the Government of Sweden has also been shared with the Government of the Federal Republic of Germany and with UNICEF.

Please accept, Mr. Rihter, the assurances of our highest consideration.

Alena Douhan  
Special Rapporteur on the negative impact of unilateral coercive measures on the enjoyment of human rights

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

Saad Alfarargi  
Special Rapporteur on the right to development

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

Obiora C. Okafor  
Independent Expert on human rights and international solidarity

## Annex

### Reference to international human rights law

In connection with above alleged facts and concerns, we would like to refer your company to the relevant international norms and standards that are applicable to the issues brought forth by the situation described.

The obligation to protect the right to life requires special measures to protect persons in vulnerable situations whose lives are particularly endangered by specific threats (CCPR, General Comment No. 36, para. 23). We note that the right to life is linked to the positive obligation to ensure access to the basic conditions necessary to sustain life (CCPR General Comment No. 6, para 5; CCPR General Comment No. 36, para 21). Measures, including the obstruction of humanitarian assistance, which restrict access to basic and life-saving goods and services such as food, health, electricity and safe water and sanitation run counter to the right to life (CCPR/C/ISR/CO/4, para. 12; A/73/314, para. 27). We wish to recall that any deaths attributable to such measures amount to an arbitrary deprivation of life (A/73/314, para. 13).

With respect to the right to health, we refer to article 25 of the Universal Declaration of Human Rights (UDHR), in which paragraph 1 states that “Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including (...) medical care (...)” The International Covenant on Economic, Social and Cultural Rights (ICESCR) enshrines “the right of everyone to the enjoyment of the highest attainable standard of physical and mental health” (article 12(1)). The realization of this right entails, *inter alia*, the “treatment and control” of diseases (article 12(2)(c)) and conditions to ensure “all medical service and medical attention in the event of sickness” (article 12(2)(d)).

We call your attention to General Comment No. 14 (2000) of the UN Committee on Economic, Social and Cultural Rights,<sup>8</sup> which states that the agreed interpretation of the right to health includes, *inter alia*, the availability and the physical accessibility of goods necessary to ensure this right (paragraph 12(a, b)), with these goods being “medically appropriate and of good quality” (paragraph 12(d)).

We additionally point out that General Comment No. 14 notes that violations of the right to health can include “the denial of access to health facilities, goods and services to particular individuals or groups” (paragraph 50).

Regarding children, who comprise the majority of patients who suffer from EB, we call your attention to the Convention on the Rights of the Child; besides affirming the above-mentioned right to health generally (article 24), it requires states to ensure effective health care services for children and their parents (article 23(3)), and to take measures to diminish child mortality (article 24(a)).

As for the right to life, enunciated in article 3 of the UDHR and article 6 of the International Covenant on Civil and Political Rights (ICCPR), we wish to refer to the

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<sup>8</sup> CESCR, General Comment No. 14 (2000), 11 August 2000, E/C.12/2000/4, <https://digitallibrary.un.org/record/425041>

UN Human Rights Committee's General Comment No. 36 (2018), which states that this right "should not be interpreted narrowly" and that it "concerns the entitlement of individuals to be free from acts and omissions that are intended or may be expected to cause their unnatural or premature death."

Regarding the withholding of medical treatment or acts that cause treatment to be withheld, such as obstacles causing delays, we refer to the prohibition on inhuman treatment that is contained in the UDHR (article 5), the ICCPR (article 7) and the Convention against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment.

Finally, we draw your attention to the UN Guiding Principles on Business and Human Rights (A/HRC/17/31, Annex), which were unanimously endorsed by the Human Rights Council in June 2011 and are relevant to the impact of business activities on human rights. They outline *inter alia* the responsibilities of business enterprises with respect to 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.

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 caused or contributed to adverse impacts. Moreover, the

commentary to 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 commentary to guiding principle 13 notes that business enterprises may be involved with adverse human rights impacts either through their own activities or as a result of their business relationships with other parties.(...) Business enterprise’s “activities” are understood to include both actions and omissions; and its “business relationships” are understood to include relationships with business partners, entities in its value chain, and any other non-State or State entity directly linked to its business operations, products or services”.

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 lay 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 impacts 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).