

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 SWE 4/2022
(Please use this reference in your reply)

11 October 2022

Excellency,

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 wish to take this opportunity to acknowledge the response and information provided to our past communication, SWE 3/2021 sent on 14 October 2021, as well as the related communication sent to Mölnlycke Health Care AB of OTH 230/2021, and **welcome with appreciation the support provided from the part of your Excellency's Government**, to ensure the supply of medical dressings that are vital for Iranian patients with the skin disease Epidermolysis Bullosa (EB)¹ in 2022, and by bringing to its attention information we have received concerning **difficulties encountered in establishing a durable flow of these and other medical supplies to Iran** in view of U.S. sanctions against the country. 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.

Despite our collective best efforts, **Mölnlycke Health Care AB (Mölnlycke)**, a medical products manufacturer in the Kingdom of Sweden, **is reluctant to engage directly with Iran or Iranian associations despite exemptions** in the sanctions that are meant to allow medical products as humanitarian goods to be sold and shipped to the country; this has **impeded the creation of lasting arrangements** for procuring and shipping the medical dressings in question, forcing a continuation of ad hoc arrangements that add complexity, time and costs to the process and that negatively impact the **right to health and right to life** of patients for whom the dressings are destined.

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

¹ 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>

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 for inadvertent breaches.²

After the United States reimposed its sanctions against Iran in 2018, Mölnlycke halted all sales to Iran, including items that 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, a sometimes-fatal disease involving extremely fragile skin.

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 Mölnlycke has not replaced it.

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 reportedly 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 the United Nations Children’s Fund (UNICEF), to finance the procurement of the dressings by UNICEF. This has led to ad hoc arrangements for one-year supplies of the dressings and follows a similar effort involving Mölnlycke, UNICEF and the German government in 2020. No solution has been found to obtain supplies in a more durable way.

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.

Mepilex dressings can have a shelf life of three years.³ 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.

² 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>

³ 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/>

In the absence of a durable supply solution, procurement must occur repeatedly, each time on an ad hoc basis without any certainty of success or timeliness. This is naturally a source of stress and anxiety 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.⁴ It has been reported that shortages of these dressings in 2019-2020 resulted in serious complications for EB patients which resulted in the deaths of 15 patients 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 difficulties inherent in supplying Mepilex dressings for EB patients in Iran through repeated short-term efforts involving intermediaries, extra steps and logistical delays, and the absence of a sustainable and durable procurement procedures. We also wish to express serious concerns at the reported overcompliance by Mölnlycke with the U.S. sanctions against Iran which has resulted in serious shortages of these medical dressings, and thus substantially harming the rights to health and to life of EB patients in Iran.

We recall for your Excellency's Government that 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," while the right to life, which is closely tied to the right to health, is embodied in the International Covenant on Civil and Political Rights (ICCPR), both of which were ratified by Sweden on 6 December 1971. These two rights are equally present in 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.

In this regard, we highlight the reference to "mental health" in the ICESCR because the effects of EB are more than physical. Most EB patients are reported to have anxiety,⁵ and anxiety can have an impact on disease outcomes,⁶ thus the added stress and anxiety about not being assured of uninterrupted, long-term supplies of Mepilex dressings is relevant here.

In its response to our previous communication, your Excellency's Government stated *inter alia* 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."

In this regard, we call the attention of your Excellency's Government to the UN Guiding Principles on Business and Human Rights,⁷ which underline that States must protect against human rights abuse within their territory and/or jurisdiction by third parties, including business enterprises (Guiding Principle 1), set out the expectation that such business enterprises domiciled in their territory and/or

⁴ 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>

⁵ 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>

⁶ 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.

⁷ Guiding Principles on Business and Human Rights, https://www.ohchr.org/sites/default/files/documents/publications/guidingprinciplesbusinesshr_en.pdf

jurisdiction respect human rights throughout their operations (Guiding Principle 2), provide effective guidance to such business enterprises on how to respect human rights throughout their operations (Guiding Principle 3(c)), and that States should promote respect for human rights by business enterprises with which they engage in commercial interactions (Guiding Principle 6), as your Excellency's Government does indirectly with Mölnlycke by aiding UNICEF's procurement process.

We highlight here that overcompliance with sanctions magnifies the negative impact that the sanctions have on the enjoyment of human rights, and can result from interpreting sanctions overcautiously to avoid various risks. While your Excellency's Government indicates that difficulties in interpreting the U.S. sanctions may be a reason for Mölnlycke's reticence to sell or ship Mepilex dressings to Iran. We express disappointment that the Government does not seem to intend to clarify whether this is indeed the case, and that if it considers such clarification to be the responsibility of Mölnlycke it has not obtained the relevant information from the company.

This reported passive approach falls short of the duties of your Excellency's Government as elaborated in the Guiding Principles, as it indicates a willingness to remain unaware of whether Mölnlycke's decision to avoid all business with Iran derives from excessive caution *vis-à-vis* the sanctions and thus contributes to human rights abuses, or whether it derives solely from "pure business-related considerations." It thus does not know if Mölnlycke complies with the expectations duly expressed by your Excellency's Government that businesses under its jurisdiction should respect human rights,⁸ and it cannot act to remedy any shortfalls in the company's conduct that might be identified in this regard.

We note that the current ad hoc process of supplying Mepilex dressings to Iranian EB patients yields no financial or other material benefit to Mölnlycke or the other parties involved, relative to the supply regime in place before the U.S. sanctions were reimposed. One can thus conclude that the overcompliance with the sanctions that led to the current process involving *inter alia* UNICEF and your Excellency's Government is not the preferred course of action by Mölnlycke or the other parties but instead is perceived by them as essential to their legal, financial or other business interests.

As the complexity and costs of complying with the humanitarian exemptions in the U.S. sanctions against Iran, combined with vigorous enforcement and potentially substantial penalties for accidental breaches, are known to encourage overcompliance, and taking into consideration that Mölnlycke's medical dressings are reportedly the best available treatment for EB patients, an awareness of the reason for Mölnlycke's decision is therefore warranted so that your Excellency's Government may act in accordance with its own human rights obligations.

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.

⁸ Government Offices of Sweden, "Action plan for business and human rights," 2015, p. 13, <https://www.government.se/contentassets/822dc47952124734b60daf1865e39343/action-plan-for-business-and-human-rights.pdf>

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. Has your Excellency's Government sought to determine if Mölnlycke's decision to refrain from doing business with Iran, when such business involves products that are exempt from U.S. sanctions, results from overcompliance with the sanctions and whether it violates or contributes to violating the rights to health and to life of Iranians, including EB patients? Has it requested relevant information from Mölnlycke, and, if so, has Mölnlycke cooperated in providing it?
3. If your Excellency's Government has not sought to determine the reason for Mölnlycke's decision, does it intend to do so in accordance with its own human rights duties, and to take any action that may be necessary to ensure that the company's actions are aligned with the Government's expectations regarding human rights, and with the company's own responsibilities? If it does not so intend, we would be grateful for an explanation of whether your Excellency's Government is aware if its own human rights obligations are being compromised by the company's decision about doing business with Iran.
4. Has your Excellency's Government engaged with the Government of the United States, either alone or through the European Union, regarding overcompliance with U.S. sanctions against Iran as it pertains to Swedish companies that may engage in such overcompliance? Is it willing to engage with the U.S. Government in this regard to clarify the issue with respect to Mölnlycke and its potential to directly sell and ship Mepilex dressings and other medical products to Iran?
5. Has your Excellency's Government engaged with international and Iranian humanitarian actors, as well as UN specialised agencies, with the view to identifying and addressing procurement and delivery challenges that impede their humanitarian work? If yes, please provide information on key observations and outcomes.
6. Please highlight the steps that your Excellency's Government has taken, or is considering to take, to protect against human rights abuse by Swedish business enterprises, ensuring that business enterprises domiciled in its territory and/or jurisdiction conduct effective human rights due diligence to identify, prevent, mitigate and account for how they address their impacts on human rights in this or similar cases.

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 reply, your Excellency's Government is urged to reconsider its restraint in regard to knowing the reason for Mölnlycke's decision to not engage directly with Iran, and to take corrective action if it is found that the reason is not in conformity with the Government's human rights obligations or the company's human rights responsibilities. It is also urged to encourage Mölnlycke's resumption of direct business with Iran for products exempt from the U.S. sanctions regardless of the reason it halted such business, in order that a durable supply system, particularly for Mepilex dressings, can be restored.

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.

Please note a copy of the letter will be sent to the Federal Republic of Germany, as well as the United Nations Children's Fund. Letters on this subject will also be sent to the Government of the United States of America, as well as Mölnlycke Health Care AB.

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

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

Fernanda Hopenhaym
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order

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Annex

Reference to international human rights law

In connection with above alleged facts and concerns, we would like to refer your Excellency's Government 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 States to take 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 recall that any deaths attributable to such measures amount to an arbitrary deprivation of life, which engages the responsibility of the State (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 Excellency's Government's attention to General Comment No. 14 (2000) of the UN Committee on Economic, Social and Cultural Rights,⁹ 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 2(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 Excellency's Government's 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)).

⁹ CESCR, General Comment No. 14 (2000), 11 August 2000, E/C.12/2000/4, <https://digitallibrary.un.org/record/425041>

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 refer to the 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.

We draw your attention to the UN Guiding Principles on Business and Human Rights, which outlines *inter alia* the responsibilities of states with respect to businesses within their jurisdiction. Guiding Principle 1 stipulates that "States must protect against human rights abuse within their (...) jurisdiction by third parties, including business enterprises. This requires taking appropriate steps to prevent, investigate, punish and redress such abuse through effective policies, legislation, regulations and adjudication." Guiding principle 2, which calls on states to "set out clearly the expectation that all business enterprises domiciled in their territory and/or jurisdiction respect human rights throughout their operations," has meaning only if it is known whether companies meet this expectation; it can therefore be assumed that some form of follow-up with companies is integral to the principle.

States are also called upon to take positive action to ensure that companies within their jurisdiction respect human rights by providing "effective guidance to business enterprises on how to respect human rights throughout their operations" (guiding principle 3(c)), and by promoting "respect for human rights by business enterprises with which they conduct commercial transactions" (guiding principle 6).

We further recall that the spirit of solidarity and international cooperation is enshrined in the Declaration on Principles of International Law concerning Friendly Relations and Cooperation among States in accordance with the Charter of the United Nations, which provides that States have a duty to cooperate in the various fields irrespective of differences in their political, economic and social systems. The Declaration stipulates that States are obliged to cooperate, *inter alia*, in the protection and promotion of human rights; in the economic, social and cultural fields as well as the field of science and technology; in the promotion of international cultural and educational progress; and in the promotion of economic growth, especially in developing countries (General Assembly resolution 2625 (XXV), annex, fourth principle).

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.