

**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 USA 19/2022  
(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.

In this connection, we would like to bring to the attention of your Excellency's Government information we have received concerning **difficulties encountered in establishing a durable flow of vital medical supplies to Iran** in the context of U.S. sanctions against the country; and particularly the reluctance of key parties to be involved in the supply **despite the exemptions that are supposed to allow humanitarian goods to be shipped to Iran**. This reluctance, due to **substantial overcompliance with the sanctions**, has impeded the establishment of lasting arrangements for procuring and shipping medical supplies to Iran, forcing a shift toward ad hoc arrangements that add complexity, time, costs and uncertainty to the supply process, which negatively impact the **right to health and right to life** of patients for whom the supplies 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 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.<sup>1</sup>

After the United States reimposed its sanctions against Iran in 2018, Mölnlycke Health Care AB (Mölnlycke), a medical products manufacturer in the Kingdom of Sweden, 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 epidermolysis bullosa (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 Swedish Ministry of Foreign Affairs has engaged with Mölnlycke and UNICEF, to finance the procurement of the dressings. 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.<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 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.<sup>3</sup> It has been reported that shortage of these dressings in 2019-2020 resulted in serious complications for EB patients which resulted in

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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>

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

<sup>3</sup> Communication from Sweden’s Ministry for Foreign Affairs in response to the Special Rapporteur’s communication to the Swedish Government of 14 October 2021 (AL SWE 3/2021), <https://spcommreports.ohchr.org/TmSearch/Mandates?m=263>

the deaths of 15 patients and serious deterioration of health status and quality of life of many others.

Without prejudging the accuracy of the information received, we wish to highlight to your Excellency's Government the difficulties inherent in supplying Mepilex dressings for EB patients in Iran through repeated short-term efforts involving intermediaries, extra steps and logistical delays. We also wish to express our serious concerns about the U.S. unilateral sanctions and overcompliance with these sanctions, resulting in serious shortages of these medical dressings, and thus substantially harming the rights to health and to life of EB patients in Iran.

Regarding the right to health, we wish to point out that your Excellency's Government has repeatedly affirmed this right as it is variously expressed in international agreements and declarations. The International Covenant on Economic, Social and Cultural Rights (ICESCR), which the United States signed on 5 October 1997 and which creates obligations for all states as customary international law, enshrines "the right of everyone to the enjoyment of the highest attainable standard of physical and mental health," while the Universal Declaration of Human Rights (UDHR) 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,<sup>4</sup> and 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.

We equally remind your Excellency's Government of its obligation to ensure the right to life, which is closely tied to the right to health and is enshrined in the International Covenant on Civil and Political Rights (ICCPR), ratified by the United States on 8 June 1992, as well as in the UDHR.

With respect to the right to health, we wish to emphasize that denying or withholding access to health care, which can include obstructing access to a specific medical treatment or causing it to be obstructed, is considered a violation of human rights.<sup>6</sup> 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, operate as such an obstruction by encouraging overcompliance.

Moreover, when an obstruction to health care causes physical suffering, it is viewed as a form of inhuman treatment, prohibited under the Universal Declaration of Human Rights, the International Covenant on Civil and Political Rights (ICCPR) and

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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> UN Economic and Social Council, Commission on Human Rights, Report on the Fifty-Fifth Session (22 March-30 April 1999), p. 43, <https://www.un.org/esa/documents/ecosoc/docs/1999/e1999-23.htm>; OHCHR and WHO, "The Right to Health," Fact Sheet No. 31, 2008, pp. 25-26, <https://www.ohchr.org/documents/publications/factsheet31.pdf>

the Convention against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment. As a former UN Special Rapporteur on torture and other cruel, inhuman or degrading treatment or punishment has pointed out, inhuman treatment, as opposed to torture, may occur unintentionally<sup>7</sup> and “the de facto denial of access to pain relief, if it causes severe pain and suffering, constitutes cruel, inhuman or degrading treatment or punishment.”<sup>8</sup>

We further note that obstructing or contributing to obstructions of shipments of medical products to Iranian patients violates their right to benefit from the scientific progress that led to the development of these products. This right is enshrined in both the ICESCR and the UDHR.

We note that the current process of supplying Mepilex dressings to Iranian EB patients yields no benefit to the parties involved, relative to the supply regime in place before the U.S. sanctions were reimposed. One can thus conclude that the overcompliance resulting in the current supply process through UNICEF is not their preferred course of action but instead is perceived as essential to the parties’ legal, financial or other business interests.

We wish to stress that this overcompliance does not absolve the parties from their duty to comply with their respective human rights obligations and responsibilities, such as those elaborated in the UN Guiding Principles for Business and Human Rights; indeed, this was highlighted to Mölnlycke and to the Swedish Government in communications we sent to them in 2021. Yet it also does not absolve your Excellency’s Government from adhering to its own obligations in this respect, which entail refraining from actions that promote or encourage others to violate human rights, which in this case is occurring through the overcompliance with the U.S. sanctions.

In connection with the matters addressed above, we also must note that the very legality of unilateral sanctions imposed outside or beyond the authorization of the UN Security Council, such as the U.S. sanctions against Iran, is questionable under international law.

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 the issues discussed.

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.

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<sup>7</sup> European Court of Human Rights, *Jalloh v. Germany*, judgment, 11 July 2006, para. 82, <https://www.globalhealthrights.org/jalloh-v-germany/>

<sup>8</sup> UN Human Rights Council, Report of the Special Rapporteur on Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment, Manfred Nowak, 14 January 2009, A/HRC/10/44, para. 72, <https://undocs.org/A/HRC/10/44>

2. It is evident that parties at all levels of the process of supplying medical products to Iran, including Mepilex dressings, are deterred from using the humanitarian exemptions established in the U.S. sanctions against Iran, resulting in overcompliance. Has your Excellency's Government identified, or has it sought to identify, the specific deterrent(s)? If so, has it sought to alleviate the deterrent(s) in any way, in view of the negative impact of the overcompliance on human rights?
3. If your Excellency's Government has not sought to determine why the humanitarian exemptions are being ignored by parties involved in supplying medical products to Iran, we would be grateful to know if it is willing to make the appropriate inquiries, and to remove any deterrents to the use of the humanitarian exemptions that are identified?
4. Please explain if your Excellency's Government has addressed, or plans to address, the practice of overcompliance with U.S. sanctions against Iran and with other U.S. sanctions, in view of the human rights impact.
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. Is your Excellency's Government willing to establish a clear, readily understood procedure that provide for an unimpeded flow of humanitarian goods? We would appreciate knowing if it is possible for it to identify and publicize, including by brand name, the list of medical products that may be shipped to Iran the need to get licences and without fear to be penalized, so that all interlocutors including banks, transportation and insurance companies may engage in such humanitarian trade to the benefit of the recipients' right to health and to life.

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 review its sanctions against Iran in light of its human rights and environmental obligations, as well as its other obligations under international law, and to take any action necessary to ensure that its conduct is aligned with international legal norms.

We may consider to publicly express our concerns about this painful 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 letters on this subject will also be sent to the Kingdom of Sweden, as well as Mölnlycke Health Care AB.

Please accept, Excellency, 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 order

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 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,<sup>9</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 wish to 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)).

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<sup>9</sup> UN C 14 (2000), 11 August 2000, document E/C.12/2000/4.

As for the right to life, enunciated in 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 call your Excellency's Government's attention to the ICESCR's recognition of "the right of everyone (...) (t)o enjoy the benefits of scientific progress and its applications" (article 15(1)(b)). This right is also embodied in the UDHR, which states that "Everyone has the right freely to (...) share in scientific advancement and its benefits" (article 27(1)).

Finally, we 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.