Mandates of the Special Rapporteur on the negative impact of unilateral coercive measures on the enjoyment of human rights; the Special Rapporteur on extrajudicial, summary or arbitrary executions; the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health; the Independent Expert on the promotion of a democratic and equitable international order; the Independent Expert on human rights and international solidarity and the Special Rapporteur on torture and other cruel, inhuman or degrading treatment or punishment

REFERENCE:
AL OTH 230/2021

14 October 2021

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; Special Rapporteur on extrajudicial, summary or arbitrary executions; Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health; Independent Expert on the promotion of a democratic and equitable international order; Independent Expert on human rights and international solidarity and Special Rapporteur on torture and other cruel, inhuman or degrading treatment or punishment, pursuant to Human Rights Council resolutions 45/5, 44/5, 42/16, 36/4, 44/11 and 43/20.

We are independent human rights experts appointed and mandated by the United Nations Human Rights Council to report and advise on human rights issues from a thematic or country-specific perspective. We are part of the special procedures system of the United Nations, which has 56 thematic and country mandates on a broad range of human rights issues. We are sending this letter under the communications procedure of the Special Procedures of the United Nations Human Rights Council to seek clarification on information we have received. Special Procedures mechanisms can intervene directly with Governments and other stakeholders (including companies) on allegations of abuses of human rights that come within their mandates by means of letters, which include urgent appeals, allegation letters, and other communications. The intervention may relate to a human rights violation that has already occurred, is ongoing, or which has a high risk of occurring. The process involves sending a letter to the concerned actors identifying 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. In this connection, we would like to bring to your attention information we have received concerning the fact that Mölnlycke Health Care AB (Mölnlycke), which develops and produces medical products, has stopped selling to Iran after the United States reimposed sanctions against the country in 2018, although the sanctions permit the continued sale to Iran of products of a humanitarian nature; and that Iranians

Mölnlycke Health Care AB
with a skin ailment who relied on a type of dressing produced only by Mölnlycke experienced increased pain and suffering when they could no longer obtain dressings of this type. It was reported, moreover, that the deaths of some Iranian patients may have been associated with the lack of access to the dressings.

According to the information received:

Epidermolysis bullosa (EB) comprises a group of rare genetic skin conditions in which patients lack the anchor that connects the skin’s outer and inner layers, causing each to move separately. EB patients have extremely fragile skin and recurrent blisters and sores resulting from routine friction between the layers or trauma. Some types of EB can lead to early death. Many EB patients are children.

Dressings applied to wounds on the skin of EB patients must be changed very frequently, which can result in further damage, bleeding and pain. Silicone-based dressings minimize these effects while protecting the surrounding skin and facilitating healing.

Mölnlycke, based in Sweden, produces an absorbent silicone dressing called Mepilex that uses a proprietary adhesive technology to adhere to the skin while not sticking to wounds.

Daya Teb Company (Daya Teb) has been the only Iranian importer of Mölnlycke products under an exclusivity arrangement. An Iranian foundation that provides support for EB patients, EB Home, had been acquiring Mepilex dressings from Daya Teb and distributing them free of charge to EB patients in the country.

The use of Mepilex dressings reduced the harm and suffering of Iran’s EB patients, who number approximately 1,000. No other products performed as well as Mepilex, the lack of which is reportedly negatively impacting the right to health and poses risks to the life of patients affected by Epidermolysis bullosa in Iran.

After the United States re-imposed unilateral sanctions against Iran in 2018 (under Executive Order 13846, issued in connection with the U.S. withdrawal from the Joint Comprehensive Plan of Action), Daya Teb was unable to continue importing Mölnlycke products “due to financial and bank troubles,” and Mölnlycke decided “not to conduct any business in relation to Iran for the time being” while “constantly monitoring the situation” in the hope of resuming “in the near future.”

Mölnlycke’s decision to halt doing business with Iran “also applies to business conducted under any form of exemption to the US economic sanctions.”

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3 Ibid.
Without prejudging the accuracy of the information received, it should be mentioned that states have the main duty under international human rights law to guarantee that activity under their jurisdiction or control does not result in human rights violations, and that companies have the responsibility to protect human rights independently of the states’ ability or willingness to fulfil their duty in this regard. This corporate responsibility is set out in Pillar II of the UN Guiding Principles on Business and Human Rights4 (Guiding Principles). It calls on all businesses to avoid infringing on the human rights of others and to address adverse human rights impacts in which they are involved (Guiding Principle 11). In connection with this, all companies should have in place “policies and processes appropriate to their size and circumstances,” including a “human rights due diligence policy to identify, prevent, mitigate and account for how they address their impacts on human rights” (Guiding Principle 15). Business enterprises also have the responsibility to “(a)void causing or contributing to adverse human rights impacts through their own activities, and address such impacts when they occur” (Guiding Principle 13a), and to “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 13b). Moreover, companies are expected to use their leverage to “effect change in the wrongful practices of an entity that causes a harm” (Commentary to Guiding Principle 19).

The Swedish Government has also stated its “clear expectation” that Swedish companies “should not cause, contribute or be linked to human rights abuses” domestically or abroad and “should address adverse human rights impacts with which they are involved.”5 A state agency has recommended studying the potential for a statute “that provides the possibility to investigate and take legal proceedings against company-related violations of human rights by Swedish companies that occur outside of Sweden.”6

We are aware that Mölnlycke does have a policy regarding human rights as part of a broader code of conduct. The policy notes, inter alia, that “(a) as an international company, we have a particular duty to respect, promote, and comply with the principles of ethical and social responsibility associated with human rights”7 and also that “(w)e must not be directly or indirectly involved in situations that entail violations of human rights.”8 As publicly elaborated, the policy relates to Mölnlycke’s employees as well as individuals working for companies throughout its supply chain, and focuses on labor-related rights pertaining to employment and the workplace environment, and on freedom from slavery, forced labor, child labor and human trafficking. Its scope is summarized in the statement: “We have zero tolerance for human rights abuses, whether in our factories or anywhere in our supply chain.”9 Nonetheless, the policy

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9 Ibid.
appears to omit various other human rights and other stakeholders, notably consumers
of the company’s products.

Specifically, Mölnlycke’s business activity directly implicates it in protecting and fulfilling the right to health, and by extension the right to life and other human rights, of individuals in countries where its medical products are used. The right to health is enshrined in the Universal Declaration of Human Rights, one of the documents cited by your company as a basis for its human rights policy, and in other documents such as the International Covenant on Economic, Social and Cultural Rights.

We understand that your company sells its products in almost 100 countries, or approximately half of the world’s countries. Decisions on which national markets it serves have consequences for the right to health by enhancing the enjoyment of this right by individuals in the countries where these products are available. While no deterioration occurs in markets where Mölnlycke has never sold its products, a decision by your company to stop making a product available in a country where it was previously sold, when no equivalent product can replace it, has negative consequences for the right to health of individuals who were being aided by it. For EB patients in Iran, their improved ability to enjoy the right to health that was attributable to Mepilex dressings was reversed by the company’s decision to stop selling its products in the country.

We assume that the underlying attitude toward human rights elaborated in your company’s policy – that Mölnlycke must not be directly or indirectly involved in situations that entail violations, and that it has zero tolerance for abuses – is not selective and extends to human rights in general. It therefore must be emphasized that denying access to health care, which can include withholding a specific medical treatment or causing it to be withheld, is considered a violation of human rights. Moreover, when this 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 and the Convention against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment. As a former UN Special Rapporteur on torture, inhuman or degrading treatment or punishment has pointed out, inhuman treatment, as opposed to torture, may occur unintentionally, 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.”

It appears that your company is involved in a situation that entails violations of human rights through its decision to suspend doing business with Iran, even if the decision may have been a rational business response to the inability of its designated importer to purchase its products, and even if the halt was envisioned as temporary and brief. While the information received does not include details about Daya Teb’s

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10 Ibid.
11 https://www.molnlycke.com/about-us/
troubles, it suggests that the company is unable to comply with financial or other obligations to Mölnlycke that are necessary for business to be conducted. As Daya Teb’s troubles appear linked to the U.S. sanctions, it is logical to infer that they may relate to its financial situation or to procedural difficulties in concluding international payment transactions, or both, as a result of the sanctions.

It is understood that Mölnlycke began developing and producing dressings a century before the drafting of the Universal Declaration of Human Rights and subsequent documents, including the Guiding Principles, that comprise modern human rights obligations and responsibilities.\footnote{https://www.molnlycke.com/about-us/our-history/} This gives your company a historic role in satisfying the right to health, which is wholeheartedly recognized and commended. Yet Mölnlycke’s activity also confers on it a special responsibility for due diligence in today’s human rights context, as its withdrawal from any market it serves for any reason can negatively impact the enjoyment of this right if its products have enhanced it and cannot be replaced.

A decision by your company to stop serving a national market may not always generate such concerns; a brief suspension, for example, might cause no discernible disruption in the availability of Mölnlycke products. In the case discussed here, however, the decision was linked to a course of action – monitoring the situation in the hope of being able to resume business quickly – that appears unduly passive when viewed against the Guiding Principles and the Swedish Government’s expectations, particularly as a rapid resumption did not occur. It is a matter of grave concern that more than two years have elapsed since your company stopped supplying Mepilex dressings to Iran, prolonging the reported harm to Iranian EB patients’ right to health.

In this regard, it bears reiterating that the Guiding Principles call on Mölnlycke to actively attempt to mitigate this harm, using the options it has available for the types of action to be taken.

Moreover, by deciding to stop doing business with Iran rather than with Daya Teb, your company has discarded the possibility of engaging with an alternative importer in the country, even temporarily, that may not share its reported problems, thereby shutting off a potential channel for implementing Guiding Principle 13b.

Your company’s code of conduct states that it complies with sanctions laws, and that “(d)ue to sanctions, Mölnlycke may be prohibited from doing business in certain markets or with certain third parties.”\footnote{Code of Conduct, p. 19, https://www.molnlycke.com/SysSiteAssets/corporate/documents/code-of-conduct-2021.pdf} However, a decision to refrain from doing business that is not prohibited under U.S. sanctions against Iran exceeds simple compliance with the sanctions; the intent and breadth of this over-compliance is clear from the fact that the decision covers business that might be done under “any form of exemption.”\footnote{Letter from Mölnlycke to EB Home (see footnote 2).}

It is acknowledged that Swedish law creates an obligation for Mölnlycke’s board of directors to ensure that the company’s affairs are managed in the best interests

\footnote{https://www.molnlycke.com/about-us/our-history/}
\footnote{Letter from Mölnlycke to EB Home (see footnote 2).}
of its shareholders.\textsuperscript{18} However, the shareholders’ interests are not restricted to achieving financial gains from their investments; they are also addressed by fulfilling the Swedish Government’s expectation, mentioned above, that companies should not be linked to human rights abuses and should address adverse impacts when they occur. Indeed, the recognition by Swedish companies that human rights constitute legitimate shareholder interests was affirmed by a study\textsuperscript{19} in which Mölnlycke’s ultimate parent entity, Investor AB (Investor), participated.\textsuperscript{20}

Furthermore, the interests of a company’s shareholders can extend to their personal values, which is particularly relevant to the situation discussed here because foundations formed and governed by the Wallenberg family are simultaneously the largest shareholders of Investor, and thus of Mölnlycke,\textsuperscript{21} and major financial donors to activities that promote respect for human rights. It is especially noteworthy that the Marianne and Marcus Wallenberg Foundation, a principal shareholder of Investor, is also a top private source of funding for the Raoul Wallenberg Institute of Human Rights and Humanitarian Law,\textsuperscript{22} which has produced a book about implementing the Guiding Principles.\textsuperscript{23}

In connection with the above alleged facts and concerns, please refer to the \textbf{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 explain the nature, extent and form of any human rights due diligence that your company conducted (a) prior to its decision to stop exporting Mepilex dressings, and more generally products that are exempt from U.S. sanctions, to Iran; and (b) since the decision was implemented, to guarantee that human rights are not affected.

2. What factors contributed to the decision to stop exporting Mepilex dressings, and more generally products that are exempt from U.S. sanctions, to Iran? Please identify whether the following played a role in the decision, and provide details: compliance costs, transaction costs, third-party cooperation (banks, transportation providers, etc.), financial risks, legal risks, sanctions enforcement risks, delays.

\textsuperscript{20} \textit{Ibid.}, p. 10.
3. Please explain to the best of your company’s knowledge if the technology or materials used in Mepilex dressings might cause them to be considered “dual use” items. Are there any other reasons to believe that Mepilex dressings might not be approved for exemptions from the U.S. sanctions?

4. We would be grateful to know if your company has reviewed its decision to halt exports of Mepilex dressings, and more generally products that are exempt from U.S. sanctions, based on its constant monitoring of the situation. If so, how often has this been done, what have been the outcomes, and how are they justified?

5. Please specify what conditions (financial, political, legal, etc.) your company deems necessary for it to resume sales or donations of Mepilex dressings to Iran, either through a commercial importer, a humanitarian agency or any other entity that operates in the country.

6. Has your company taken any action to assist Daya Teb with its reported financial and banking troubles? If so, please describe the action taken. Please also specify if your company has been in contact with the source(s) of Daya Teb’s troubles and any leverage that your company may have applied to them.

7. Please explain if your company faces contractual or other obstacles to engaging an alternative entity (company, humanitarian agency, etc.) to import Mepilex, and more generally products that are exempt from U.S. sanctions, into Iran.

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

We would appreciate receiving a response within 60 days. Passed this delay, this communication and any response received from you 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 publicly express our concerns about this issue in the future as it is matter involving the suffering of many, including children and that should warrant careful attention. We also deem that the wider public should be informed about the potential human rights implications of these allegations. Any public expression of concern on our part on this issue will indicate that we have been in contact with your company to bring it to your attention and seek clarification.

A letter on this subject will be sent to the Government of the Kingdom of Sweden.

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
Morris Tidball-Binz
Special Rapporteur on extrajudicial, summary or arbitrary executions

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

Livingstone Sewanyana
Independent Expert on the promotion of a democratic and equitable international order

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

Nils Melzer
Special Rapporteur on torture and other cruel, inhuman or degrading treatment or punishment
Annex
Reference to international human rights law

In connection with the above 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.

With respect to the right to health, we refer to Article 25 of the Universal Declaration of Human Rights, 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 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, 24 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 occur through entities other than states that are insufficiently regulated by States (paragraph 48), and that violations can include “the denial of access to health facilities, goods and services to particular individuals or groups” (paragraph 50).

Regarding children with 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)).

With respect to the right to life enunciated in Article 6 of the International Covenant on Civil and Political Rights, I refer to the UN Human Rights Committee’s General Comment No. 36 (2018), in which it 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, we refer to the prohibition on inhuman treatment that is contained in the Universal Declaration of Human Rights (Article 5), the International Covenant on Civil and Political Rights (Article 7) and the Convention against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment.

We additionally call your attention to the UN Guiding Principles on Business and Human Rights, which apply to all states and companies and recognizes “(t)he role of business enterprises as specialized organs of society performing specialized functions, required to comply with all applicable laws and to respect human rights.”

Guiding Principle 11 calls on companies to “avoid infringing on the human rights of others and (...) address adverse human rights impacts with which they are involved.” It also says companies “should not undermine States' abilities to meet their own human rights obligations,” which include ensuring the right to health.

We refer to Guiding Principle 13, which states that “the responsibility to respect human rights requires that business enterprises: (a) Avoid causing or contributing to adverse human rights impacts through their own activities, and address such impacts when they occur; (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.”

In its commentary to Guiding Principle 13, the UN Office of the High Commissioner of Human Rights notes that a company’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.”

We call your attention to Guiding Principle 15, which calls on each company to have in place a policy and a process to meet its responsibility to respect human rights. It should also have a human rights due diligence process to identify, prevent, mitigate and account for how it addresses the impact its activities have on human rights, and a remediation process to correct any adverse human rights impact it causes or to which it contributes. Guiding Principle 22 states that a company which has, through its due diligence process, identified a human rights problem that it has caused or contributed to, should provide for or cooperate in the problem’s remediation.

We further refer to Guiding Principle 17, which details how human rights due diligence should be carried out: “The process should include assessing actual and potential human rights impacts, integrating and acting upon the findings, tracking responses, and communicating how impacts are addressed,” and “should cover adverse human rights impacts that the business enterprise may cause or contribute to through its own activities, or which may be directly linked to its operations, products or services by its business relationships.”

The commentary to this principle states that “(h)uman rights due diligence should be initiated as early as possible” when a company engages in an action. It also notes that “(q)uestions of complicity may arise when a business enterprise contributes to, or is seen as contributing to, adverse human rights impacts caused by other parties.”

We point out that Guiding Principle 18 calls on each company to “identify and assess any actual or potential adverse human rights impacts with which they may be involved either through their own activities or as a result of their business relationships. This process should: (a) Draw on internal and/or independent external human rights expertise; (b) Involve meaningful consultation with potentially affected groups and
other relevant stakeholders, as appropriate to the size of the business enterprise and the nature and context of the operation.”

The commentary to Guiding Principle 18 states that “(t)he purpose is to understand the specific impacts on specific people, given a specific context of operations. Typically, this includes assessing the human rights context prior to a proposed business activity, where possible; identifying who may be affected; cataloguing the relevant human rights standards and issues; and projecting how the proposed activity and associated business relationships could have adverse human rights impacts on those identified.” It further states that “(i)n this process, business enterprises should pay special attention to any particular human rights impacts on individuals from groups or populations that may be at heightened risk of vulnerability (…).”

We also refer to Guiding Principle 19, which calls on companies to take appropriate action to prevent and mitigate adverse human rights impacts. The commentary to this principle states that if a company finds it “contributes or may contribute to an adverse human rights impact, it should take the necessary steps to cease or prevent its contribution and use its leverage to mitigate any remaining impact to the greatest extent possible. Leverage is considered to exist where the enterprise has the ability to effect change in the wrongful practices of an entity that causes a harm.”

The commentary to Guiding Principle 19 further states that “(i)f the business enterprise has leverage to prevent or mitigate the adverse impact, it should exercise it. And if it lacks leverage there may be ways for the enterprise to increase it. Leverage may be increased by, for example, offering capacity-building or other incentives to the related entity, or collaborating with other actors.” It also notes that if the company lacks the leverage to prevent or mitigate adverse impacts and cannot increase its leverage, it should consider ending the relationship with the entity involved, although if the company retains the relationship as essential to its business, “it should be able to demonstrate its own ongoing efforts to mitigate the impact (of any harm to human rights) and be prepared to accept any consequences – reputational, financial or legal – of the continuing connection.”