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 SWE 3/2021

14 October 2021

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; 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.

In this connection, we would like to bring to the attention of your Excellency’s Government information we have received concerning the fact that Mölnlycke Health Care AB (Mölnlycke), a company based in the Kingdom of Sweden which develops and produces medical products, stopped selling them to Iran after the United States reimposed sanctions against that country in 2018, although the sanctions permit the continued sale to Iran of products of a humanitarian nature; and that Iranians 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 and the higher risk of fatal infections this can lead to.

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 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, suffering and risk of infections, including fatal outcomes, 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,”¹ 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.”²

Mölnlycke’s decision to halt doing business with Iran “also applies to business conducted under any form of exemption to the US economic sanctions.”³

Without prejudging the accuracy of the information received, it should be mentioned that states have an obligation under international human rights law to guarantee that activity under their jurisdiction or control does not result in human rights abuses. This obligation, affirmed by your Excellency’s Government through its ratification of numerous international human rights conventions, applies, inter alia, to the activity of companies based on Swedish territory. Their responsibility to protect human rights, in turn, is set out in the UN Guiding Principles on Business and Human Rights⁴ (Guiding Principles), which apply to their activity without any geographic restriction.

The role of states in implementing the Guiding Principles is one of due diligence that entails “taking appropriate steps to prevent, investigate, punish and redress” human rights abuses by companies (Guiding Principle 1) through actions such as laws, policies, guidance and encouragement that have the intent of protecting human rights (Guiding Principle 3). While international law does not oblige states to ensure that companies based on their territory comply with human rights in their foreign business activities, it is incumbent upon states to make clear that they expect companies to respect human rights “throughout their operations” (Guiding Principle 2). Moreover, states are called upon to help businesses mitigate the human rights-related risks of their activities and business relationships in conflict zones because of the increased risk of human rights abuses in such areas (Guiding Principle 7(a)). As countries subject to sanctions are equally recognized as zones with an increased risk of human

³ Ibid.
rights abuses, states can be deemed to have the same duty when companies based on their territory have activities and business relationships in sanctioned countries. This duty involves taking appropriate action “to ensure that businesses are not involved with human rights abuse” in connection with their engagements in the areas in question (commentary to Guiding Principle 7).

It is recognized that your Excellency’s Government has 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.” The Government has also stated that it expects Swedish companies to establish human rights policies and to perform due diligence by adhering to a procedure that includes, inter alia, the following steps: “Identify and monitor the risks throughout the value chain (employees, business partners, suppliers, distribution and customer channels) and assess where responsibility for risks lies and how the company can have a positive impact;” and “Establish an integrated and ongoing process in the company to identify, prevent and manage human rights risks and opportunities.”

Möllycke indeed has a policy regarding human rights in which it acknowledges its duty “to respect, promote, and comply with the principles of ethical and social responsibility associated with human rights” and states that the company “must not be directly or indirectly involved in situations that entail violations of human rights.” The policy relates to Möllycke’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.

Nonetheless, it appears to omit various other human rights and other stakeholders, notably consumers of the company’s products. Indeed, the due diligence procedure that your Excellency’s Government has elaborated for companies also does not cover situations in which the human rights of individuals who use their products are harmed directly or indirectly by the actions of the companies or their business relationships. These individuals are outside of the “value chain” cited above.

In Möllycke’s case, its 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 and in other documents such as the International Covenant on Economic, Social and Cultural Rights.

As Möllycke sells its products in almost 100 countries, it should be noted that its 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 its products are available. While no deterioration occurs in markets where the

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10 https://www.molnycke.com/about-us/
company has never sold its products, a decision 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 Mölnlycke’s decision to stop selling its products in the country.

It 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 and other cruel, 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 thus appears that although Mölnlycke’s actions seem aligned with the due diligence procedures that your Excellency’s Government has set out for respecting and protecting human rights, the 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 due to circumstances arising from the U.S. sanctions, and even if the halt was envisioned as temporary and brief.

It is further noted that Mölnlycke’s 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 expectations of your Excellency’s Government, particularly as a rapid resumption did not occur. It is a matter of grave concern that more than two years have elapsed since Mölnlycke stopped supplying Mepilex dressings to Iran, prolonging the reported harm to Iranian EB patients’ right to health.

The fact that this situation arose, and the separate fact that it became prolonged, indicate that, firstly, the due diligence procedures set out for Swedish companies by your Excellency’s Government to ensure that they respect and protect human rights is inadequate to cover (1) the entire range of individuals whose rights may be negatively affected by the companies’ activities and business relationships, (2) the entire range of rights that may be negatively affected, and (3) any harm to human rights that arises outside of the existing parameters for the process; and, secondly, that the Government’s own due diligence mechanisms are insufficient to ensure that Swedish companies do not breach, or are not linked to breaches, of the full range of human rights that the Government is obliged to protect.

Indeed, in this case, Iran cannot ensure the full enjoyment of the right to health for its own EB patients as it has no power or legal authority to oblige a foreign company to make its products available there. With regard to both levels of due diligence – by Swedish companies and by your Excellency’s Government – it is noted that neither the Government’s 2015 Action Plan for business and human rights nor the 2018 follow-up to that plan14 seemed to anticipate the type of situation described in this letter; nor did it appear to be considered in the submission that your Excellency’s Government made in 2020 to the UN Working Group on Business and Human Rights for its report on “Business and human rights: towards a decade of global implementation,” in which the goals and targets for the next decade were outlined.15

It bears mentioning that in 2018, the Swedish Agency for Public Management, Statskontoret, 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.”16 It is not known whether this recommendation was acted upon, but the fact that it was made serves as recognition within your Excellency’s Government that its due diligence mechanisms for ensuring that Swedish businesses respect and protect human rights can be improved.

As for the Kingdom of Sweden’s responsibility to protect the human rights of foreign as well as domestic individuals, your Excellency’s Government incorporates this into its foreign policy, in which “promoting and increasing respect for human rights is a priority issue” and “the overriding aim (…) is to help enable people in other countries to enjoy the rights that have been established within the UN framework and other international contexts.”17

It is noted that Mölnlycke’s decision to stop doing business with Iran rather than with its exclusive importer, Daya Teb, precludes the possibility of an alternative arrangement for importing Mepilex into Iran. This runs counter to its responsibility under Guiding Principle 13b, which calls on it 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.” The company’s intent to not seek an alternative arrangement is clear from its over-compliance with the U.S. sanctions, as its decision to halt business with Iran also covers business that might be done under “any form of exemption.”18

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 of its shareholders,19 but it must be stressed that these interests are more than

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18 Letter from Mölnlycke to EB Home (see footnote 2).
financial in nature, and that human rights are recognized by Swedish companies as being among them.\textsuperscript{20} It is further acknowledged that Swedish companies have a legal obligation to report on their policies regarding human rights and their implementation of these policies.\textsuperscript{21}

However, it is also observed that while your Excellency’s Government has expressed support for developing an EU-wide human rights due diligence requirement for companies,\textsuperscript{22} there is no current obligation under domestic law for Swedish companies to perform due diligence in the course of carrying out their human rights policies, nor are there any regulatory standards for assessing and detailing the implementation of these policies in their obligatory reports.\textsuperscript{23} This can result in inconsistencies in their reports, which can hinder your Excellency’s Government in performing its own due diligence with respect to the companies’ human rights conduct, and thus in complying with its international 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 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 Excellency’s Government conducted with respect to Möllylycke (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. Please specify any action that your Excellency’s Government has taken to ensure that Möllylycke is not involved directly or indirectly with human rights abuse arising from its decision to stop shipping Mepilex dressings, and more generally products that are exempt from U.S. sanctions, to Iran; and to help it mitigate any such abuse that might occur. In this regard, please also indicate whether it sought to encourage Möllylycke to take advantage of the INSTEX trading system in which the Kingdom of Sweden is a shareholder, as well as the form of any such encouragement, and the company’s response.

3. We would be grateful to know if your Excellency’s Government sought to help Möllylycke with any specific problems related to its ability to


comply with the humanitarian exemptions in the U.S. sanctions against Iran.

4. Please indicate any action your Excellency’s Government has taken with respect to the study recommended by Statskontoret on the potential for a law pertaining to violations of human rights by Swedish companies that occur outside of Sweden. Please also indicate any other action it has taken, or plans to take, to improve the mechanism by which it conducts human rights due diligence as it pertains to the actions of Swedish companies and their business partners, including those abroad.

5. Please explain if your Excellency’s Government plans to make human rights due diligence a legal obligation for domestic companies, regardless of any action toward this end which may be taken at the level of the European Union. If no such plans exist, please explain how it intends to achieve a situation in which Swedish companies comply with the Government’s expectations that they will respect and protect human rights in all of their activities.

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, we urge that all necessary interim measures be taken to halt the alleged violations and prevent their re-occurrence and in the event that the investigations support or suggest the allegations to be correct, to ensure the accountability of any person(s) responsible for the alleged violations.

We may publicly express our concerns in the near future as, in our view, the information upon which the press release will be based is sufficiently reliable to indicate a matter warranting immediate attention. We also believe that the wider public should be alerted to the potential implications of the above-mentioned allegations. The press release will indicate that we have been in contact with your Excellency’s Government’s to clarify the issue/s in question.

Please be informed that a letter on this subject matter will be sent to Mölnlycke.

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

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 Excellency’s Government 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, 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, we 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 recognizes their existing obligations.
to respect, protect and fulfil human rights.

Guiding Principle 1 outlines the duty of states to “protect against human rights abuse within their territory and/or 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.”

In conjunction with this, we refer to Guiding Principle 3, which elaborates how this is to be done through legislation and policies. Paragraph (a) calls on states to “(e)nforce laws that are aimed at, or have the effect of, requiring business enterprises to respect human rights, and periodically to assess the adequacy of such laws and address any gaps;” while Paragraph (b) reminds states to ensure that other laws pertaining to businesses, such as corporate law, “do not constrain but enable business respect for human rights.” Paragraph (c) calls on states to “(p)rove effective guidance to business enterprises on how to respect human rights throughout their operations,” which in the case of transnational enterprises entail their foreign as well as domestic activities.

We refer also to Guiding Principle 2, in which states are obliged to “set out clearly the expectation that all business enterprises domiciled in their territory and/or jurisdiction respect human rights throughout their operations.”

We call your attention to Guiding Principle 7, which calls on states to ensure that business enterprises operating in conflict zones are not involved in human rights abuses because in such areas “the risk of gross human rights abuses is heightened,” a situation that equally exists in countries that are subject to sanctions. In connection with this heightened risk, Paragraph (a) refers to the duty of states to engage with business enterprises “to help them identify, prevent and mitigate the human rights-related risks of their activities and business relationships.” The commentary to Guiding Principle 7 notes that this duty involves taking appropriate action “to ensure that businesses are not involved with human rights abuse” in such areas in light of the heightened risk.

We further draw your attention to the duties of companies that are outlined in the Guiding Principles and that states are called upon to ensure. Guiding Principle 11 specifies that business enterprises should “avoid infringing on the human rights of others and (...) address adverse human rights impacts with which they are involved.” We refer to Guiding Principle 13, which elaborates the duties of companies to “(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.”

We additionally refer 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, as well as a due diligence process to identify, prevent, mitigate and account for the impact its activities may have on human rights. 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. These duties are reinforced in Guiding Principle 19, which
calls on companies to take appropriate action to prevent and mitigate adverse human rights impacts.