



مرکز حقوق کیفری بین المللی ایران
Iranian Center for
International Criminal Law

**Complaint to the Swedish National Contact Point
under the Specific Instance Procedure of
the OECD Guidelines for Multinational Enterprises**

Company Concerned:

Mölnlycke Health Care
SE-402 52 Gothenburg, Sweden
Telephone: +46 31 722 30 00

Plaintiff:

Iranian Center for International Criminal Law
Fluwelen Burgwal 58, 2511 CJ Den Haag
Telephone: +31 616 5040 73

Recipient:

Swedish National Contact Point for the OECD Guidelines for Multinational Enterprises
Swedish Ministry of Foreign Affairs, 103 39 Stockholm, Sweden
Ms. Ulrika Lyckman.



Parties

1. The Complainant, Iranian Center for International Criminal Law (ICICL), is a non-governmental organization, registered under Dutch Law in 2013, which aims to promote accountability for violations of fundamental human rights. It has longstanding experience in the representation of victims of international crimes and serious violations of human rights in the Middle East. ICICL has a local office in Tehran, Iran, that represents of a number of Epidermolysis Bullosa (EB) patients whose rights are adversely affected by the US unilateral economic sanctions against Iran.
2. Mölnlycke Health Care is a Swedish medical device company headquartered in Gothenburg, Sweden, and active internationally. It is a world-leading company founded in 1849. The company has different divisions, including wound care division that produces medical device wound healing solutions such as dressing, compression products and skin care products that are to be used by Iranian EB patients.

Jurisdiction of Swedish NCP

3. This complaint is being made to the Swedish NCP given that Mölnlycke has its headquarters in Sweden, thus allowing the Swedish NCP authority, as the host country, to consider the case.
4. With this complaint ICICL requests the Swedish NCP to investigate whether or not Mölnlycke complies with the OECD's Guidelines for Multinational Enterprises in their actions in case concerning the Iranian EB patients, in particular children, who are in need of the company's products.

Basic Facts of the Case

a. Nature of the Disorder

5. Epidermolysis Bullosa (EB) is a group of rare genetic skin conditions, which is characterized by extremely fragile skin and recurrent blister formation, resulting from minor mechanical friction or trauma.¹ Skin has two layers; the outer layer is called the epidermis and the inner layer the dermis. Normally, there are ‘anchors’ between the two layers that prevent them from moving independently from one another. In people with EB, the two skin layers lack the anchors that hold them together, and any action that creates friction between the layers (like rubbing or pressure) will create blisters and painful sores. Sufferers of EB have compared the sores to third-degree burns. In many countries, Butterfly Children is a term often used to describe younger patients because their skin is as fragile as a butterfly’s wings². Sometimes, children with the condition are also described as Cotton Wool Babies. While many who live with milder forms of EB can lead long and productive lives, the list of manifestations and secondary complications in the more severe forms is lengthy and requires multiple interventions from a range of medical specialists. Those forms of EB result in disfigurement, disability, and in some cases early death³. EB can also be an autoimmune disease in which the body produces antibodies to the structural components of the skin. Other manifestations of EB include: anemia, cardiomyopathy, syndactyly (fusion of the fingers and toes), renal insufficiency, dysphagia (difficulty swallowing), malnourishment, cancer, constipation, osteoporosis, muscular dystrophy, and pyloric atresia. There are nearly 1000 identified EB patients in Iran.⁴

¹ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4920676/>.

² <https://www.apr.ch/apr-pharma-products/therapeutic-pharma/rare-dermatological-diseases/>.

³ <http://www.studentsinwarsaw.com/butterfly-as-a-synonym-of-suffering-the-worst-thing-you-never-heard-of/>.

⁴ <https://ebhome.ngo/en/eb-in-iran/>.

6. Care for EB patients focuses on managing the condition as EB has no cure yet.⁵ The lives of patients are overshadowed by pain and discomfort – and stress is a constant as they seek to avoid the physical contact that will damage their skin. Wound dressings are an essential tool to protect the skin of EBs. Because the skin of this group of patients is so fragile and dressing changes so frequent that atraumatic dressings are recommended to prevent further damage, pain or bleeding. Silicone-based dressings are easier to apply and remove than traditional dressings. They also protect the wound and peri-wound skin and create a favourable environment for wound healing.
7. Mölnlycke produces a product that is called Mepilex absorbent foam dressing that is trusted around the world to treat a wide range of chronic and acute wounds.⁶ The product is easily conformable and highly absorbent, to effectively manage wound exudate. Every Mepilex wound dressing includes Safetac – the original less-pain contact layer with silicone adhesion. Dressings with Safetac are clinically demonstrated to minimise damage to the wound and skin at removal. Iranian EBs used to be treated by Mepilex purchased from Mölnlycke for years, which was so effective in harm and suffering reduction. Nonetheless, the new wave of the US sanctions in 2018 stopped the supply of Mepilex by the company.

c. Pulling Out of Iran Due to the Sanctions

8. Following withdrawal from the Joint Comprehensive Plan of Action (JCPOA), the US re-imposed stringent and comprehensive sanctions against Iran. Sanctions have been designed to put Iran under a “maximum pressure campaign”, “placing unprecedented stress on Iran’s economy, [and] forcing Tehran to make increasingly difficult choices”. Despite US government

⁵ <https://www.molnlycke.us/our-knowledge/epidermolysis-bullosa/>

⁶ <https://www.molnlycke.co.uk/products-solutions/mepilex/>



claims that it has kept a ‘humanitarian window’ open in its sanction’s regime, according to Human Rights Watch, “the consequences of US sanctions have posed a serious threat to Iranian’s right to health and access to essential medicines”.⁷

9. After the reimposition of the US unilateral sanctions, Mölnlycke stopped selling to Iran the Meplix product. In March 2019, the company wrote to the director of EB Home, an Iranian NGO, that due to the US economic sanctions, it had “decided not to conduct any business with relation to Iran for the time being. This also applies to business conducted under any form of exceptions to the US economic sanctions”.⁸ The decision is still in place and Iran is unable to supply Meplix through the company concerned.

D. No Alternative

10. According to the EB Home, there are some domestic alternatives for the dressing. Nonetheless, they are not as effective as Meplix because other products get attached to the blister causing additional excruciating pain for patients. Moreover, after some efforts to purchase similar medications from another pharmaceutical company, not only the pain of EBs did not decrease but also it was greatly intensified causing severe bleeding and neurological reactions. Following complaints from the families of the patients, doctors launched extensive researches into the issue and found out that since the patients’ body systems had been used to specific medications for a long

⁷ https://www.hrw.org/sites/default/files/report_pdf/iran1019sanctions_web.pdf

⁸ <https://www.atlanticcouncil.org/blogs/iransource/irans-butterfly-children-impacted-by-sanctions-and-corruption/>



period, it reacted negatively to other similar medications. The Iranian government is among the 48 countries that purchases medications and has so far failed act seriously in their regard due the high cost of launching a production line for this medication. Also, some Iranian physicians and experts have tried to work in order to launch this production line but for many reasons such as financial interest there was no cooperation and proper exchange of information from laboratories and pharmaceutical companies.⁹

b. Impacts on the Children

11. Lack of access to Meplix, that is a product without an effective alternative, has caused great suffering and serious injury and pain for the EB children in Iran. Non-existence of this necessary solution results in the wound extension and infection.
12. So far, nearly 30 Iranian EB patients, mostly children, have lost their lives, including Mesana Mouradi (2018-2019); Massoumeh InanlouDoghouz (2009-2018); Sina GhareGhanloue (2015-2018); Zeinab Adboulmaleki (1989-2018); Khadijeh Rahmani (1988-2019); Armin Allahyari (2008-2019); Ava Ariyafar (2017-2019); Mehdi HassanPour (1990-2019); Sahar Shamsi (2008-2019).
13. In addition, due to the lack of medicine, the pain of survivors have increased by 70 percent.¹⁰ There is no end to the suffering and injury inflicted on EBs.

⁹ <http://ebchildren.org/we-fight-for/>

¹⁰ Ibid.

Breach the OECD Guidelines

14. Mölnlycke has breached OECD Guidelines by failing to undertake appropriate human rights due diligence, adversely affecting the human rights of EB patients in Iran, and failing to remedy its impacts.

a. Failure of Due Diligence

15. According to the General Policies section of the OECD Guidelines, enterprises including Mölnlycke have two obligations, namely to “avoid causing or contributing to adverse impacts on matters covered by the Guidelines, through their own activities, and address such impacts when they occur” (paragraph 11). Adverse impacts are “either caused or contributed to by the enterprise or are directly linked to their operations” (paragraph 14). In this regard, an enterprise shall “carry out risk-based due diligence, for example, by incorporating it into their enterprise risk management systems to identify, prevent and mitigate actual and potential adverse impacts” (paragraph 10). The Guidelines explicitly stipulate that potential impacts are to be addressed through prevention or mitigation, while actual impacts are to be addressed through remediation”. (paragraph 14). In particular, enterprises shall “carry out human rights due diligence as appropriate to their size, the nature and context of operations the severity of the risks of adverse human rights impacts” (paragraph 5, Human Rights section).

16. The Guidelines require multinational companies to conduct due diligence for all their actions, including disengagement for any reason. On the subject of disengagement specifically, the OECD Guidelines, General Policies, Paragraph 22 sets out that “The enterprise should also take into account potential social and economic adverse impacts related to the decision to disengage”. This is further clarified by language in the OECD Due Diligence Guidance for Responsible Business Conduct: "A decision to disengage should take into account potential social and economic adverse impacts. These plans should detail the actions the enterprise will take, as

well as its expectations of its suppliers, buyers and other business relationships”. Moreover, Paragraph 23 of the OECD Guidelines, General Policies stipulates that companies may engage with suppliers and other entities in the supply chain to improve their performance. Supply chain implies "business relationships" generally too. The gist of Paragraph 23 is that a company can and should engage with business partners, including governments, to encourage them to take part in addressing risk management. Although these paragraphs follow discussion of disengagement resulting from irresponsible actions of a partner, the main purpose of these provisions is to ensure and promote the broader principle of responsible disengagement. All disengagement decisions, like all business decisions, are subject to the OECD Guidelines’ general due diligence requirement to follow all the relevant steps of the due diligence process, including to prevent and avoid impacts wherever possible and mitigate, including through leverage, any impacts that are not fully avoidable.

17. OECD Watch's guide to Responsible Divestment in the Time of Corona distills from the OECD Guidelines themselves a basic step-by-step process companies should engage in before they divest. The first step is working with the government at issue and businesses in the same industry to try to anticipate and mitigate likely impacts. The third step is for companies to avoid disengagement altogether if possible. And, finally, the fourth step is for them to disengage, but in a responsible manner..
18. In the situation of Iranian EB patients, Mölnlycke has evidently failed to observe due diligence as required by the Guidelines. Mölnlycke decided to stop its relationship with Iran without taking into account the risk of its decision and without offering an effective alternative to prevent adverse impacts on the human rights of the EB patients. The company concerned has been aware that in the ordinary course of events stopping selling its products to Iran will cause or at least contribute to the adverse impacts on the human rights of those child patients who used to benefit from its products. The adverse impacts on the EB children were widely publicized.



For instance, in December 2019, Iran’s Ambassador to the UN spoke about one of the Iranian EB victims, a two-year old girl called Ava who had already died. After the meeting, according to the Media, US Ambassador to the UN Kelly Craft expressed her condolences to the Iranian Ambassador.¹¹ In addition, Mölnlycke was specifically informed by the Iranian EB Home about the situation of EB patients in Iran. Therefore, the company had both actual and constructive knowledge of the adverse impacts on EB children exerted by its decision not to sell the dressing to Iran due to the US sanction.

19. Mölnlycke considered disengagement from Iranian suppliers because of the US unilateral sanctions, a reason that is not explicitly predicted by paragraph 22. The fact that Mölnlycke considered disengagement for an external reason does not in any way change its responsibility under the Guidelines to undertake due diligence to prevent and mitigate impacts resulting from its act of disengagement.
20. If Mölnlycke had fulfilled its obligations under the OECD Guidelines, first and foremost, it should not have sought to prevent impacts by not disengaging at all. Instead of putting an end to its business relationship with its Iranian partners, it should have claimed a right under the humanitarian exception to continue providing the medical device. At the very least, Mölnlycke should have shown evidence that it explored this option. The fact that it did not investigate the possibility of continuing sale under a humanitarian exception, and in fact proceed under a humanitarian exemption, represents a failure of due diligence, in particular when the US had claimed it had established a humanitarian window and an exception and exemption mechanism in its sanctions regime against Iran.
21. Second, and in the alternative, even if Mölnlycke had to disengage, because for instance it did not qualify for a humanitarian exception, it could and should have taken all necessary measures to prevent or mitigate the

¹¹ <https://www.reuters.com/article/us-iran-usa-un-idUSKBN1YO074>.



anticipated adverse impacts of its own disengagement by trying to engage with business partners to find ways to mitigate the impact of Mölnlycke 's disengagement. Mölnlycke knew the grave impacts its disengagement would have on sick children in Iran. Mölnlycke should have tried to negotiate a variety of arrangement with the Iranian and Swedish governments and/or local medical device providers to enable the children and other EB patients to still receive better devices and care. For example, Mölnlycke could have perhaps:

- Shared technical knowledge with the local medical device makers to enable them to provide better devices;
- Reached an agreement for the Swedish government to serve as an intermediary in providing the device;
- Reached an agreement for children to receive care and the device in a neighboring country outside of Iran,
- Sold its products to a third and intermediary party who was able to provide Iranians with the product.

22. Mölnlycke's failure to take any actions to prevent or mitigate the adverse impacts of its action to disengage represents a breach of its due diligence responsibilities under the OECD Guidelines.

23. Mölnlycke also breached the OECD Guidelines' due diligence provisions by failing to adequately communicate and engage with stakeholders throughout its decision to disengage. As annexed to this complained, Mölnlycke alerted a key Iranian NGO that it would disengage, *only* upon the initiative and inquiry made by the NGO, and otherwise it did not engage in any consultation with impacted stakeholders to discuss and develop plans to prevent or mitigate impacts. This conduct also represented a complete failure of the stakeholder consultation and communication elements of due diligence.

24. Given the above-mentioned provisions and facts, it is evident that Mölnlycke terminated its business relationship with Iranian partners without conducting an effective due diligence. Mölnlycke's conduct is a clear example of irresponsible disengagement.

b. Breach of Human Rights Provisions

25. Mölnlycke due diligence failure led the company to breach OECD Guideline's provisions on human rights, in particular failing to respect the children's right to life and health and to provide remedy for impacts it caused or contributed to.

26. According to Chapter IV, enterprises should "have a policy commitment to respect human rights" and "avoid causing or contributing to adverse human rights impacts and address such impacts when they occur". Mölnlycke's action caused, or at a minimum contributed to, serious human rights impacts for Iranian children with EB. The policy adopted by Mölnlycke, namely cutting trade with Iran, has adversely impacted the right to life and the right to health of EB patients in particular the children. These fundamental human rights have been enshrined in all international and regional human rights instruments. For instance, according to Article 3 of the Universal Declaration of Human Rights "Everyone has the right to life". Article 25 of the Declaration stipulates that "everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care". The Mölnlycke's policy and operation has evidently violated the right to life of those EB patients who have died due to the lack of the dressing, and has put other children' lives in danger. In addition, its decision not to sell the dressing to Iran has seriously violated the right to health of Iranian EB patients. In addition, Mölnlycke has breached the responsibility to provide or cooperate in providing remedy for impacts it has caused or contributed to. According to the OECD Guidelines, due diligence requires that potential impacts are



to be addressed by companies through prevention or mitigation, while actual impacts are to be addressed through remediation. Remediation is the process of providing a remedy for a harm. Thus if an enterprise has contributed to or caused an adverse impact in its supply chain, it should take appropriate action to ensure remedy. Mölnlycke, however, failed to take any steps either to itself provide, or to cooperate in other methods to provide, remedy to the impacted children.

Requested Actions

A) Asks of the NCP

27. Iranian Center for International Criminal Law respectfully asks the Swedish NCP to accept this complaint and support dialogue between the complainant and the company concerned through mediation.
28. Iranian Center for International Criminal Law also asks the NCP to use this complaint as an opportunity to provide clarity for companies like Mölnlycke on the full extent and nature of the due diligence and human rights responsibilities MNEs maintain during disengagement, even when disengagement results from government imposition of sanctions on a country in the companies' value chains.

B) Demands of the company

The Complainant calls upon Mölnlycke, under the supervision and mediation of the Swedish NCP, to:

Continue ensuring the product to Iranian EB patients

29. Ensure it either
 - a. finds an effective way to continue selling its products directly in Iran, for instance, by obtaining a permission and exemption from the sanctions imposer, or



- b. arranges a suitable alternative so that the children can keep getting the life-saving health product they need.

Reparation

30. Provide both
 - a. the children who have been adversely impacted by its decision to terminate sale of products, and
 - b. the families of EB patients who have lost their lives due to the lack of access to the Mölnlycke's products,

with adequate, effective and prompt reparation (financial or otherwise, to be discussed in mediation with the Swedish NCP) for the mental, moral, physical and emotional harm they have experienced that Mölnlycke has caused or contributed to.

Acknowledgement

31. Apologize publicly and officially for the suffering imposed on the EB victims by its failure to observe human rights due diligence.

Policy improvement

32. Publish a policy statement confirming Mölnlycke's commitment to human rights, including in relation to the human rights of customers living in countries that may be covered by economic sanctions.



Annexes

Date: 2019/2/25
Number: 97/12/1001
Attachment: None....

Non-Profitable Organization for supporting EB patients
Non-governmental
Non-profitable
Non-political
Voluntary

خانه ای بی
Reg.No. 4205

Dear Mr. Richard Twomey
Chief Executive Officer of Molnlyke Company

As you are aware, Epidermolysis bullosa (EB) as a deadly genetic disease affects a great deal of families. The disease, by causing complications on skin and engaging in the development of the internal organs, causes physical, mental and psychological problems for the patients and unfortunately, some patients will be deceased. EB Home is the only registered Non-Governmental Organization (NGO), which activates for support of the patients since 2015. Nowadays, more than 800 patients are members of The Home. The main activities of EB Home are providing health care services to EB patients, supply medical items for them, apprise the public of the disease and prevention and intensive care of it. Our most significant duty is Sending Mepilex dressing via the premium Post service for all EB patients free. All posted dressings have tracking code, which is the evidence that the patients receive these worth and critical dressing. However, since re-imposition of The Economic Sanctions by The United States of America, this duty is interrupted. As you know, Dayateb Company import Molnlyke products to Iran exclusively and the only source of supply of Mepilex Dressing for EB Home. According to the Company, it is impossible to import Molnlyke products due to financial and bank troubles. Thus, EB patients are not able to Mepilex Dressings any more. Humanitarian products, in particular health care exemption on US New Economic sanctions. Undoubtedly, it will be possible to adopt reasonable measures to resume imports of Mepilex to Iran. Fulfilment of this depends on cooperation between EB home and Molnlyke Company. Whereas the patients need Mepilex urgently and they lack of them for months, it is graceful and honorable that your company acts appropriately to solve this problem.

Respectfully Yours
Seyed Hamid Reza Hashemi Golpaygani
Founder and CEO of EB Home

خانه ای بی
شماره ثبت 4205

No. 164, Brazil St., Sheik Bahai St., Tehran., Iran
Tel: +98 21 88 61 39 77
Fax: +98 21 8861 4750
info@jobhome.ir



EB Home
Seyed Hamid Reza Hashemi Golpaygani
No. 164, Brazil St. Sheik Bahai St,
Tehran, Iran

Dear Mr. Seyed Hamid Reza Hashemi Golpaygani,

I am referring to the letter sent from you, as founder and CEO of EB home, to Mr. Richard Twomey, CEO of Mölnlycke Healthcare.

First of all we would like to recognize the work you do for the patients diagnosed with Epidermolysis bullosa (EB), and express our appreciation for you choosing to work with Mepilex dressings as part of your treatment program. EB is indeed a terrible disease and we do express our greatest sympathy for the patients suffering from it.

Unfortunately, due to the US Economic sanctions in force Mölnlycke Healthcare have decided not to conduct any business in relation to Iran for the time being. This also applies to business conducted under any form of exemption to the US Economic sanctions. We are constantly monitoring the situation and hope to be able to support your need in the near future.

We sincerely regret the situation.

Sincerely yours,

Kristin Hedibad
Executive Vice President, Legal
General counsel