

1. Iranian Center for International Criminal Law and Mölnlycke Health Care

Date (15/11/2021)

The objective of the initial assessment process under the Procedural Guidance is to determine whether the issues raised in the specific instance merit further examination. If so, the NCP will offer or facilitate access to consensual and non-adversarial procedures, such as dialogue, mediation or conciliation (e.g. 'good offices') to the relevant parties. As specific instances are not legal cases and NCPs are not judicial bodies, NCPs cannot impose sanctions, directly provide compensation nor compel parties to participate in a conciliation or mediation process.

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1.2 Overview of the NCP and its role

The OECD Guidelines for Multinational Enterprises are recommendations by governments to their companies, regardless of where they operate. These recommendations focus on several areas such as disclosure, human rights, employment and industrial relations, the environment, the fight against corruption, consumer interests, science and technology, competition and taxation. In addition, the concepts of responsible supply chains and due diligence have been introduced. The various National Contact Points (NCP) are responsible for monitoring the implementation of these Guidelines. The NCP:s have a dual role in raising awareness and promoting observance of the Guidelines as well as contributing to the resolution of issues that arise relating to the implementation of the OECD Guidelines. The NCP:s can contribute to the resolution of issues raised by different means such as offering good offices, and where applicable, issuing determinations, recommendations, and carrying out follow up. In Sweden, the National Contact Point is chaired by a representative from the Ministry for Foreign Affairs. It has a tripartite structure composed of social partners, implying that unions and employer organisations are also represented.

Executive Summary

The submission of a specific instance by the Iranian Center for International Criminal Law (ICICL) against the company Mölnlycke Health Care was received on 15 May 2021 by the Swedish National Contact Point. The specific instance concerned the following chapters of the OECD Guidelines on Multinational Enterprises: Chapter II (failure of due diligence and of communicating with stakeholders) and Chapter IV (breach of human rights provisions, in particular failing to respect the childrens' right to

life). The reception was acknowledged on 17 May and notified to OECD on 18 May. Mölnlycke Health Care was notified of the submission on 25 May. Mölnlycke Health Care submitted their response to the specific instance on 16 June. The NCP validated the submission's partial admissibility on 18 June. The NCP and Mölnlycke Health Care had a meeting on 19 August. The same day the NCP had an internal meeting. The NCP and ICICL had a meeting on 17 September, and the NCP also convened internally the same day.

A draft initial assessment has been shared with the parties. The Swedish NCP decided on 15 November 2021 that the issue did not merit further examination, but that the NCP could give recommendations concerning the due diligence of the company. The initial assessment is shared on the website of the Swedish Government (www.regeringen.se).

1.3 Substance of the submission and the enterprise's response

Iranian Center for International Criminal Law targets Mölnlycke Health Care with respect to its decision to stop selling its wound healing products in Iran. According to the complaint Mölnlycke Health Care does not respect the recommendations in the OECD Guidelines regarding general principles and human rights.

ICICL states that the company's decision to stop selling its wound dressing Mepilex has had severe implications for patients suffering from Epidermolysis Bullosa (EB), a disease which is characterized by extremely fragile skin and recurrent blister formation. Following the US sanctions on Iran in 2018 the company stopped the supply of Mepilex as well as other business conducted under any form of exceptions to the sanctions.

ICICL refers to EB Home (an Iranian NGO) which has informed that there are domestic alternatives for the wound dressing but they are not as effective as Mepilex, and that research has shown that patients' body systems used to specific medications for a long time reacted negatively to other similar medications.

ICICL alleges that the company has breached to undertake appropriate due diligence as required by the guidelines and that the company decided to stop its relationship with Iran without taking into account the risk of its decision for EB patients, and without offering an effective alternative to prevent adverse impacts on the human rights of these patients. Furthermore, ICICL states that the company could prevent or mitigate the impacts through e.g. cooperating with other entities.

According to ICICL the company did also breach the OECD guidelines by failing to adequately communicate and engage with stakeholders throughout its decision to disengage.

In addition to this ICICL claims that the due diligence failure led to the breach of the OECD Guidelines on human rights, in particular failing to respect the childrens' right to life and health and to provide remedy for impacts it caused or contributed to.

ICICL asks that the Swedish NCP accepts the complaint and supports dialogue between the complainant and the company through mediation.

ICICL further asks the Swedish NCP to use the complaint as an opportunity to provide clarity for companies like Mölnlycke Health Care on the full extent and nature of the due diligence and human rights responsibilities that multinational enterprises maintain during disengagement, even when it results from government imposition of sanctions on a country in the companies' value chains.

ICICL calls on Mölnlycke Health Care to:

- Continue selling the product to Iranian EB patients through permission and exemption from the sanctions imposer or through the arrangement of a suitable alternative.
- to provide children who have been adversely impacted by the decision to terminate sale of products and the families of EB patients who have lost their lives, with adequate, effective and prompt reparation (financial or otherwise) for the harm they have experienced that Mölnlycke has caused or contributed to.
- Apologize publicly and officially for the suffering imposed on the EB victims by its failure to observe human rights due diligence.
- Publish a policy statement confirming Mölnlyckes commitment to human rights, including in relation to the human rights of costumers living in countries that may be covered by economic sanctions.

Recommendations of the 2011 Guidelines targeted by the referral:

Chapter II on General Policies

10. 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 as described in paragraphs 11 and 12, and account for how these impacts are addressed. The nature and extent of due diligence depend on the circumstances of a particular situation.

11. Avoid causing or contributing to adverse impacts on matters covered by the Guidelines, through their own activities, and address such impacts when they occur.

Commentary on General Policies

14. ... Potential impacts are to be addressed through prevention or mitigation, while actual impacts are to be addressed through remediation. The Guidelines concern those adverse impacts that are either caused or contributed to by the enterprise,...

22. ... The enterprise should also take into account potential social and economic adverse impacts related to the decision to disengage.

23. Enterprises may also engage with suppliers and other entities in the supply chain to improve their performance...

Chapter IV on Human Rights

2. ... avoid causing or contributing to adverse human rights impacts and address such impacts when they occur.
4. Have a policy commitment to respect human rights.
5. Carry out human rights due diligence as appropriate to their size, the nature and context of operations and the severity of the risks of adverse human rights impacts.

Mölnlycke Health Care responded on 16 June. Below is a summary of that response:

- Mölnlycke sincerely regrets the suffering that EB patients are going through as a consequence of the disease.
- Mölnlycke refutes any claims or allegations made by ICICL concerning the company's alleged breaches of the OECD Guidelines for Multinational Companies or concerning any human rights violations.
- Mölnlycke does live up to the requirements of the OECD Guidelines and has the requisite policies and procedures in place to manage the potential impact the Mölnlycke business has on patients, customers and other stakeholders as well as on human rights. Furthermore, the company rejects the allegation that it has failed to undertake appropriate human rights due diligence. The company also states that it has a solid corporate governance structure and a Code of Conduct in place as well as policies regarding the respect for human rights.
- The unfortunate situation for the EB patients in Iran does not constitute a breach of the Guidelines from Mölnlycke's side. Mölnlycke points out that it is at every company's own discretion to decide where and with whom they conduct business. Not being present in a certain market cannot constitute noncompliance with the Guidelines since there is no mandatory obligation to contract.
- In connection with the decision to not continue to conduct business, Mölnlycke made a number of considerations on how the decision would affect its business, its customers and the patients using its products.
- The board of directors of Mölnlycke, appointed by the owner of the company, has decided not to conduct any business, directly or indirectly, in relation to Iran as long as the US and United Nations sanctions are in force. The decision applies also to business conducted under any form of exception to the sanctions. The latter part is due to the fact that there are secondary sanctions which de facto makes it impossible to find a bank or financial institution that is willing to support in monetary transaction involving sales of any kind to Iran.
- When it comes to conducting due diligence, including due diligence before deciding to disengage its business with Iran, it is also the responsibility of Mölnlycke to evaluate possible

risks should Mölnlycke decide to conduct business with Iran despite the sanctions and secondary sanctions.

- As for the product in question, Mölnlycke points out that it does not cure the disease that causes the wound. Furthermore, there is no adequate causality between the lack of dressings and the regrettable suffering or loss of lives of EB patients. Moreover, the products of Mölnlycke are not the only available to relieve the symptoms of the disease.

- Mölnlycke disagrees to the allegation that it has not engaged with other parties to mitigate the impact of its disengagement. On the contrary, in 2019 Mölnlycke engaged in collaboration with UNICEF which in 2020 led to a shipment of Mepilex products bound for Iran, via UNICEF. The value of the transaction was 1.000.000 Euro. Mölnlycke has reached out to UNICEF offering engagement in the same set up again.

- In general Mölnlycke is in favour of mediation as a way of solving a dispute between parties. However, in this particular case Mölnlycke does not see mediation as a possible way to solve the root cause of the problem, namely the sanctions and secondary sanctions.

- The company has acted in a responsible way when deciding not to conduct business with Iran and has taken appropriate actions when the possibility to collaborate with UNICEF occurred. Therefore Mölnlycke, and the complaint against the company should in no way be used as an example in any negative way

- It is the responsibility of the government of Iran to cater for its inhabitants, including patients with chronic, incurable diseases such as EB. Therefore Mölnlycke rejects to pay any kind of damage.

1.4 The proceedings of the NCP to date

Since receipt of the submission, the NCP has carried out the following actions:

The submission of a specific instance by the Iranian Center for International Criminal Law (ICICL) against the company Mölnlycke Health Care was received on 15 May 2021 by the Swedish National Contact Point. The specific instance concerned the following chapters of the OECD Guidelines on Multinational Enterprises: Chapter II (failure of due diligence and of communicating with stakeholders) and Chapter IV (breach of human rights provisions, in particular failing to respect the childrens' right to life). The reception was acknowledged on 17 May and notified to OECD on 18 May. Mölnlycke Health Care was notified of the submission on 25 May. Mölnlycke Health Care submitted their response to the specific instance on 16 June. The NCP validated the submission's partial admissibility on 18 June. The NCP and Mölnlycke Health Care had a meeting on 19 August. The same day the NCP had an internal meeting. The NCP and ICICL had a meeting on 17 September, and the NCP also convened internally the same day.

A draft initial assessment has been shared with the parties. The Swedish NCP decided on 15 November 2021 that the issue did not merit further examination, but that the NCP could give recommendations concerning the due diligence of the company. The initial assessment is shared on the website of the Swedish Government (www.regeringen.se) on 17 December 2021.

1.5 Initial assessment by the NCP

The NCP has decided that the submission is partly admissible, i.e. as far as it concerns the due diligence. This decision has been taken following an assessment by the NCP as to whether that issue is i) “bona fide”, i.e. real or authentic and ii) relevant to the implementation of the Guidelines, i.e. within the scope of the Guidelines. To achieve this, the NCP took into account the following criteria:

1.5.1 What is the identity of the party concerned (e.g. submitter(s)) and its interest in the matter?

Mölnlycke Health Care is a global company with headquarters in Gothenburg, Sweden, which designs and supplies medical solutions in almost 100 countries. The company had sales of appr. 1,793 million Euros in 2020 and employs around 7.900 people.

The 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. ICICL has a local office in Teheran which represents a number of EB patients.

1.5.2 Are the issues raised material and substantiated?

The submission is partly material as it relates to alleged non-observance of provisions in the OECD guidelines concerning due diligence, specifically in Chapter II (General policies), paragraph 10. As for the call on the company to continue to sell the product or to provide reparation for not providing the product, these parts are considered to be outside the scope of the Guidelines.

1.5.3 Is there a link between the activities of the enterprise(s) and the issues raised?

The issues raised against Mölnlycke Health Care partly concern their responsibility to conduct risk-based due diligence in accordance with paragraph 10, Chapter II (General Policies) in the Guidelines.

1.5.4 How have similar issues been, or are being, treated in other domestic or international proceedings?

As far as the members of the Swedish NCP are aware, similar but not comparable cases have been submitted but not accepted by other NCP:s.

1.6 Conclusion

First of all the NCP would like to express its sympathy with all the patients suffering from the Epidermolysis Bullosa and with the families who have lost their loved ones due to this disease.

The Swedish NCP decided on 15 November 2021 that the issue did not merit further examination, but that the NCP could give recommendations concerning the due diligence process of the company. The NCP does not see that it can contribute to the resolution of the issues in addition to this.

As regards the call on the company to continue to sell its product, or to provide reparation, the NCP considers these parts to be outside the scope of the Guidelines. This conclusion is based on discussions within the NCP. The NCP notes and welcomes that the company has expressed a willingness to enter a new arrangement with UNICEF.

Concerning the matter of risk-based due diligence, the NCP would recommend the company to be more clear and transparent about this process. The company has informed the NCP about the process and measures taken when deciding not to continue to be present on the Iranian market, and the NCP believes that it would be helpful if this information could have been more detailed. The NCP would also encourage the company to be as transparent as possible about the due diligence to external stakeholders when such a process is taking place.