Mandates of the Special Rapporteur on the negative impact of unilateral coercive measures on the enjoyment of human rights and the Independent Expert on human rights and international solidarity

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8 February 2023

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 and Independent Expert on human rights and international solidarity, pursuant to Human Rights Council resolutions 49/6 and 44/11.

In this connection, we would like to bring to the attention of your Excellency's Government information we have received concerning the negative impact on the right to health and other human rights resulting from responses by pharmaceutical companies to U.S. sanctions against Iran. Specifically, we have received information that a subsidiary of the Swiss company Novartis AG (Novartis) has stopped providing at least some vital medications for Iranians suffering from thalassemia, and the French company Roquette Frères (Roquette) has stopped providing to Iran the ingredients it produces for making medicines used in treating thalassemia, following the re-imposition and expansion of U.S. sanctions against Iran since 2018, even though the sanctions permit the continued sale to Iran of products of a humanitarian nature.

According to the information received:

Thalassemia is a congenital blood disease that is associated with splenomegaly and bone changes. It is a genetic disease that affects your body's ability to produce hemoglobin and healthy red blood cells.

Iran has a particularly high prevalence of thalassemia relative to most other countries and is described as "one of the major centers" for the disease.[1] Roughly 23,000 Iranians have thalassemia.

The most important treatment protocol for thalassemia involves life-long use/injections of compatible blood units at regular intervals and the use of iron-depleting medicine to control the amount of iron deposited in the patient's body by the blood transfusions. If iron-depleting medicine is not used, patients can develop secondary diseases such as diabetes, osteoporosis, kidney failure, heart and liver problems, etc.

Novartis is a pharmaceutical company based in Switzerland that develops and produces medical products. These include medicines with deferoxamine and deferasirox, which reduce iron overload in the blood and are used in treating thalassemia. Novartis is the overwhelmingly dominant supplier of these medicines globally.

[1] Parisa Saiyarsarai, Elahe Khorasani, Hasti Photogeraphy, Mohsen Ghaffari Darab and Meysam Seyedifar, "Cost-utility of new film-coated tablet formulation of deferasirox vs deferoxamine among major beta-thalassemia patients in Iran," *Medicine* 99 (28), 2020, p. 2, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7360196/

One Novartis medicine, Desferal, consists of deferoxamine and is administered by injection. Another, Exjade, uses deferasirox and is produced as tablets and also as granules to sprinkle onto food. A second deferasirox medicine, Jadenu, is also produced as tablets and granules and can be taken more simply and under more conditions than Exjade,[2] removing constraints to its use by patients.

Modava (Modava Pharmaceutical Co.) is an Iranian company that is part of the Shafayad Group, a larger Iranian pharmaceutical enterprise. Under an agreement concluded between Novartis and Modava in 2010, Modava manufactures and imports Novartis products for the Iranian market.

Roquette is a company based in France. It produces pharmaceutical ingredients that are used in producing medicines for the treatment of thalassemia and has in the past supplied these ingredients to Iran.

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 (JPCOA), and has subsequently expanded its sanctions against the country.

The full impact of the U.S. sanctions in Iran is magnified by considerable overcompliance on a global scale resulting from complex, time-consuming and/or costly compliance procedures; extraterritorial enforcement and fears of penalties for inadvertent breaches; and sanctions-related obstacles to financial transactions for goods and services, including humanitarian goods such as medicines, that the sanctions do not prohibit.[3]

Since the re-imposition of U.S. Sanctions, Iran has experienced a lack of access to medicines for treating thalassemia, and disruptions in patients' treatment. This has led to an increase of secondary diseases and mortality among Iranian thalassemia patients; the traditional mortality rate of around 25-30 per year increased to 120-150 per year in 2018-2021.

In 2019, Novartis confirmed its intent to ensure that Iranian thalassemia patients have access to its medications and to accelerate plans for Modava to manufacture Jadenu. Nonetheless, in 2021, Iran was still reliant on imports and was able to obtain only 1.5 million injection doses for thalassemia patients, out of the 10 million needed, while it was not possible to import the oral medication (Jadenu) for these patients.

Novartis currently declines to provide some thalassemia medicines to Iran. In mid-2022, its Novartis Pharma Services AG subsidiary informed Modava that an order placed in 2021 for Jadenu granules could not be fulfilled in the foreseeable future because of an internal decision. Novartis nonetheless said it was willing to supply Jadenu to Modava in bulk form.

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[2] Novartis, "Novartis announces FDA approval for JadenuTM to simplify treatment administration for patients with chronic iron overload," press release, 30 March 2015, https://www.novartis.com/news/media-releases/novartis-announces-fda-approval-jadenutm-simplify-treatment-administration-patients-chronic-iron-overload

[3] United Nations, "Iran: Unilateral sanctions and overcompliance constitute serious threats to human rights and dignity – UN expert," 19 May 2022, https://www.ohchr.org/en/press-releases/2022/05/iran-unilateral-sanctions-and-overcompliance-constitute-serious-threat-human

In the context of the re-imposed U.S. sanctions, Roquette advised an Iranian company with which it did business that it was discontinuing cooperation with Iran.

Without prejudging the accuracy of the information received, we wish to express our serious concerns about the U.S. sanctions and overcompliance with them in view of their role in harming the rights to health and to life of thalassemia patients in Iran.

We wish to point out that your Excellency's Government has repeatedly affirmed the right to health as it is variously expressed in international agreements and declarations. The International Covenant on Economic, Social and Cultural Rights (ICESCR), which the United States signed on 5 October 1997 and which creates obligations for all states as customary international law, enshrines "the right of everyone to the enjoyment of the highest attainable standard of physical and mental health," while the Universal Declaration of Human Rights (UDHR) attests to the importance of every individual's health and well-being. The right to life, closely tied to the right to health, is enshrined in the International Covenant on Civil and Political Rights (ICCPR), ratified by the United States on 8 June 1992, as well as in the UDHR.

We wish to emphasize that denying or withholding access to health care, which can include obstructing access to a specific medical treatment or causing it to be obstructed, is considered a violation of the right to health.[4] The complexity and costs of complying with the humanitarian exemptions in the U.S. sanctions against Iran, combined with vigorous enforcement and potentially substantial penalties for accidental breaches, operate as such an obstruction by encouraging overcompliance.

This type of health care impediment is also viewed as a form of inhuman treatment that is prohibited under the UDHR, the ICCPR and the Convention against Torture and Other Cruel, Inhuman or Degrading Treatment of Punishment, which the United States ratified on 21 October 1994. As a former UN Special Rapporteur on torture and other cruel, inhuman or degrading treatment or punishment has pointed out, inhuman treatment can include the de facto denial of medication when patients suffer as a result.[5]

In this context, it should be mentioned that states are obliged to guarantee that activities under their jurisdiction or control, including by third parties, do not result in human rights abuses. As the third parties may be business enterprises that are required by your Excellency's Government to comply with U.S. sanctions, the obligation to prevent human rights abuses applies to the design and enforcement of the sanctions as this influence how companies respond to them – including companies outside of the United States, in view of the jurisdictional reach asserted by your Excellency's Government in enforcing the sanctions extraterritorially. The UN Guiding Principles

[4] UN Economic and Social Council, Commission on Human Rights, Report on the Fifty-Fifth Session (22 March-30 April 1999), p. 43, https://www.un.org/esa/documents/ecosoc/docs/1999/e1999-23.htm; OHCHR and WHO, "The Right to Health," Fact Sheet No. 31, 2008, pp. 25-26, https://www.ohchr.org/documents/publications/factsheet31.pdf
UN Human Rights Council, Report of the Special Rapporteur on Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment, Manfred Nowak, 14 January 2009, A/HRC/10/44, para. 72, https://undocs.org/A/HRC/10/44

on Business and Human Rights[6] (guiding principles) reminds states of their obligations in this regard (guiding principles 1 and 2) while also detailing the companies' responsibility to protect human rights.

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). 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 rights abuses,[7] 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 these countries (commentary to guiding principle 7).

We are aware of reports that medical companies have been prosecuted by the U.S. Treasury Department "for selling small amounts of medical supplies to Iran"[8] despite the sanctions' exemptions for humanitarian goods. We are also aware that banks and other essential supply chain participants have been reticent to play their roles in the provision of medicines to Iran because of the complexity of sanctions and aggressive U.S. enforcement.

We are further aware that a Novartis business unit, Alcon, agreed in 2016 to pay nearly 17 million USD to the U.S. Government to settle "potential civil liability" for "apparent violations" of U.S. sanctions relating to the sale of pharmaceutical and medical products to Iran between 2008 and 2011, even though the U.S. Treasury's Office of Foreign Assets Control "determined that (…) the apparent violations were not egregious;" and that the "apparent violations" in question had exposed Alcon to a potential maximum penalty of nearly 139 million USD had the settlement not been reached.[9]

The reticence of companies to provide medicines and their ingredients to Iran, even if authorized, is thus understandable in view of the legal and financial risks that the companies perceive to exist as the result of the U.S. sanctions and their enforcement. It is in this context that we express our deep concern about the inability of Iranian thalassemia patients to obtain the medications they need.

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 these allegations.

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6 https://www.ohchr.org/sites/default/files/documents/publications/guidingprinciplesbusinesshr_en.pdf

7 OHCHR, "The Corporate Responsibility to Respect Human Rights: An Interpretive Guide," UN publication HR/PUB/12/02, 2012, p. 80, https://www.ohchr.org/documents/publications/hr.pub.12.2_en.pdf

8 Sina Azodi, "How US sanctions hinder Iranians' access to medicine," Atlantic Council, 31 May 2019, https://www.atlanticcouncil.org/blogs/iransource/how-us-sanctions-hinder-iranians-access-to-medicine/
U.S. Department of the Treasury, "Enforcement Information for July 5, 2016," https://home.treasury.gov/system/files/126/20160705_alcon.pdf

As it is our responsibility, under the mandates provided to us by the Human Rights Council, to seek to clarify all cases brought to our attention, we would be grateful for your observations on the following matters:

1. Please provide any additional information and/or comment(s) you may have on the above-mentioned allegations.

2. As Iran's high prevalence of thalassemia makes it an obvious market for relevant medications and their ingredients, the inability of Iranian patients to access such medicine since the re-imposition of U.S. sanctions can reasonably be attributed to deterrents that are created for the non-U.S. companies involved, or others in their supply chains, to using the sanctions' humanitarian exemptions. Has your Excellency's Government identified, or has it sought to identify, the specific deterrent(s)? If so, has it sought to alleviate it/them in any way, in view of the negative impact of the resulting overcompliance on human rights?

3. If your Excellency's Government has not sought to determine why the humanitarian exemptions are being ignored by parties involved in supplying thalassemia medicines and their ingredients to Iran, we would be grateful to know if it is willing to make the appropriate inquiries, and to remove any deterrents to the use of the humanitarian exemptions that are identified

4. Please explain if your Excellency's Government has addressed, or plans to address, the practice of overcompliance with U.S. sanctions against Iran and with other U.S. sanctions, in view of the human rights impact.

5. Has your Excellency's Government engaged with international and Iranian humanitarian actors, as well as UN specialized agencies, with the view to identifying and addressing procurement and delivery challenges that impede their humanitarian work? If yes, please provide information on key observations and outcomes.

6. Is your Excellency's Government willing to establish a clear, readily understood procedure that provides for an unimpeded flow of humanitarian goods? We would appreciate knowing if it is possible to identify and publicize, including by brand name, the list of medical products, including those for treating thalassemia, that may be shipped to Iran without the need to get licenses and without fear to be penalized, so that all interlocutors including banks, transportation and insurance companies may engage in such humanitarian trade to the benefit of the recipients' rights to health and to life.

This communication and any response received from your Excellency's Government will be made public via the communications reporting website within 60 days. They will also subsequently be made available in the usual report to be presented to the Human Rights Council.

While awaiting a reply, 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 about this situation in the near future as it is an issue involving the health, lives and suffering of many people, including children and people living in very vulnerable conditions - a situation which we believe deserves special attention. We also believe that this is a matter of public interest, and that the public in Iran, in the US and elsewhere should be made aware of it should this situation is perpetuated without corrective action. Any public expression of our concerns in this regard will indicate that we have been in contact with Your Excellency's Government to clarify the case.

Please be informed that letters on this matter will be also sent to the Swiss and French Governments, as well as to Novartis and Roquette. A copy of this letter will be sent to the Government of Iran.

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

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

Annex

Reference to international human rights law

In connection with above alleged facts and concerns, we would like to refer your Excellency's Government to the relevant international norms and standards that are applicable to the issues brought forth by the situation described.

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,[10] 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).

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 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

[10] https://digitallibrary.un.org/record/425041, document E/C.12/2000/4.

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)rovide 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.