

Ethics, Risk, Compliance

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FOR ELECTRONIC DELIVERY

Professor Alena Douhan

Special Rapporteur on the negative impact of unilateral coercive measures on the enjoyment of human rights

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

CC: Ms. Beatriz Balbin Chamorro
Chief Special Procedures Branch
Office of the United Nations High Commissioner for Human Rights (OHCHR)
Palais des Nations, 1211 - Geneva 10, Switzerland
Email: ohchr-registry@un.org

Ref: AL OTH 134/2022

Dear Professors Douhan and Okafor:

Thank you for your letter dated 8 February 2023 regarding our supply of Desferal and Jadenu to thalassemia patients in Iran, and for the opportunity to respond.

Your letter claims that "Novartis is currently refusing to supply certain thalassemia drugs to Iran" and thereby "violating patients' rights to health and life." This statement is factually not correct and therefore misleading.

Novartis is committed to ensuring that its medicines are accessible to patients in accordance with registered specifications and local and international regulatory guidelines.

As an example of this commitment, following a decision by the United States in 2018 to increase sanctions against Iran, Novartis worked tirelessly with the governments of Switzerland, Iran, and the United States to establish a payment channel for humanitarian goods. These efforts culminated on 27 January 2020 with the first pilot transaction of the Swiss Humanitarian Trade Arrangement ("SHTA"). This first pilot shipment included three lifesaving drugs: Sandostatin LAR (used to treat certain types of cancer), Myfortic and Neoral (both immunosuppressants used to prevent organ rejection after transplant). The SHTA was then formally launched on 27 February 2020.³

² Letter pg. 5.

Press release, United States Department of the Treasury, "United States and Switzerland Finalize the Swiss Humanitarian Trade Arrangement" | U.S. Department of the Treasury (27 February 2020).

¹ Letter pg. 3.

³ Press release, Switzerland, State Secretariat for International Financial Matters, "Payment mechanism for humanitarian supplies to Iran in effect" (admin.ch) (27 February 2020).

However, for our medicines to reach thalassemia patients in Iran, Novartis relies on the action and collaboration of the Iran Ministry of Health and Food and Drug Authority in allocating sufficient foreign currency resources to import these medicines through regular commercial channels.

With respect to thalassemia medicines, Novartis has supplied these medicines continuously since 2019. We have been, and remain, ready to satisfy orders for these medicines. We continue to work closely with our distributor partner and manufacturing partner in Iran. These are the only contractually authorized parties to supply imported Novartis medicines in Iran. Novartis intends, to the best of its abilities, and barring any production and supply chain limitations, to continue supplying these medicines through 2023 per contractual arrangements with these partners in Iran.

We note that, in 2022, Novartis even decided to supply these thalassemia medicines for patients in Iran *before* receiving the related payments. Novartis made this exceptional deviation from our standard operating procedures in order to increase Iranian patient access to these medicines. Consequently, shortfalls in availability of these medicines during the past four years are likely due to lack of orders and/or insufficient foreign currency allocated by the Iranian authorities for imports of these medicines.

Your letter also enquires about the status of Modava Pharmaceutical Company, our local manufacturing partner in Iran. As part of operating a business in approximately 140 countries globally, we routinely pursue or reject opportunities to produce certain medicines locally in countries around the world. We made internal business decisions in 2022 to reduce, or not pursue, localized production in many countries, including Iran. We make similar decisions in many countries around the world; this is not specific to Iran or these thalassemia medicines.

Finally, we wish to draw your attention to certain statements in a press release published by the UN Office of the High Commissioner for Human Rights (OHCHR) on 14 February 2023, following your letter to us on 8 February 2023. The press release states that "[UN] experts said the supply of [thalassemia] medications from the Swiss pharmaceutical group Novartis – the leading supplier ... was denied to Iran." This assertion is incorrect, for the factual reasons described above.

More concerning is that Novartis was not contacted for comment prior to the publication of the press release, and the statements were not made as "allegations" against Novartis. Instead, they were described as facts that the UN experts had identified. We were disappointed to see these allegations made publicly just six days after sending Novartis your official communication on 8 February 2023, and well before the expiry of the 60-day deadline during which Novartis was invited to comment.

On 15 February 2023, we notified the OHCHR Chief of Special Procedures Branch of these procedural discrepancies. We held a productive video conversation with them on 3 March 2023 to discuss our concerns. We would appreciate that any further communication regarding this matter from your office refer to the facts above, and that you contact Novartis for review and comment *prior* to any future publication regarding this matter, or any other OHCHR or Special Procedures publication related to our company.

We hope that our formal response hereby clarifies inaccuracies of your 8 February 2023 letter and the 14 February 2023 press release.

Sincerely,

Klaus Moosmayer Chief Ethics, Risk, and Compliance Officer, Novartis

Peter Nestor

Global Head of Human Rights, Novartis