

May 11, 2022

Business & Human Rights Resource Centre
London, UK

Dear BHRRC,

Please find below the response from Novartis to the Business & Human Rights Resource Center's survey, **"Russian invasion of Ukraine: What companies have to say about their human rights due diligence."**

Novartis condemns the war in Ukraine. The continued acts of unprovoked violence are harming innocent people, and this defies our mission to improve human health globally. We remain committed to providing access to medicines to patients in every country where we operate. Our immediate priority is to protect the safety and security of our people and provide medicines to patients.

Please refer our website for ongoing updates and statements on Ukraine at www.novartis.com.

Regards,

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Business & Human Rights Resource Centre Survey Questions

For companies operating or investing in Ukraine

Nature of involvement

1. How long has your company or subsidiary been operating or investing in Ukraine? In summary, can you briefly describe the nature, sector, scale, and geographic area of these operations or investments?

Novartis operates the following divisions in Ukraine

- The Novartis Innovative Medicines division provides patented treatments in multiple disease areas, including oncology and rare diseases.
- The Sandoz Division provides high-quality, affordable generics and biosimilars.

Assessing risks

2. How is your company enhancing its due diligence to identify, prevent, and mitigate heightened human rights risks and comply with international humanitarian law? What measures is your company taking to ensure it relies and acts upon robust monitoring of the situation, including through consultation with your workers, affected communities, human rights groups, and/or humanitarian organizations?

The global Novartis Emergency Management (NEM) team is engaged closely with the Ukraine Country NEM team and Novartis employees on a continuous basis to monitor and assess the situation on-ground and provide employees with security guidance and support services including:

- Hotline staffed by professional counselors offering psychological support.
- Receiving country support including temporary assignments where possible for employees and their families who have had to leave Ukraine.
- An accommodation platform hosted on the company intranet providing employees an opportunity to welcome a displaced Ukraine employee and their family into their home.

Our humanitarian efforts have extended to:

- Donating more than one million packs of our medicines amounting to over 25 million USD in medical aid to Ukraine and in the border areas.
- Donating 3 million USD to non-profits supporting refugees and displaced people in Ukraine and bordering countries.

Our global Engagement & Volunteering team is providing employees with voluntary donation opportunities and volunteering opportunities with our strategic partners which include Save the Children, Tent Partnership for Refugees, the International Rescue Committee, the International Committee of the Red Cross and the Swiss Red Cross among others.

The Novartis Global Drug Discovery Disruption SWAT team are minimizing impact to clinical trials in Ukraine through a centralized risk assessment and mitigation approach.

Mitigating risks and tracking effectiveness

3. What measures is your company or subsidiary taking to ensure that your business relationships, products, services, operations, or other actions do not contribute to Russian military activities or occupation in Ukraine (including Crimea and occupied parts of Donetsk and Luhansk Oblasts)?

Novartis entities in Ukraine and Russia do not have business relationships with the Russian military and are not contributing in any way to the military activities and occupation in Ukraine. The collaboration with the Ukrainian authorities and local organizations have made it possible for Novartis to donate medicines from within and outside of the country. We have always been committed to providing access to medicines to people who need them, no matter where they are.

4. Is your company or subsidiary planning to scale-down or suspend your operations in Ukraine? If so, what are the immediate and longer-term steps that your company has taken or is prepared to take to mitigate the negative impacts of this decision on affected communities and your workers?

Novartis and Sandoz remain committed to providing access to medicines to patients in Ukraine, to the best of our ability under the circumstances. We – as an industry – have a humanitarian obligation to ensure that our medicines remain available to patients, regardless of where they are in the world. As the conflict in Ukraine is unprecedented and has made much of the country a combat area, all Novartis clinical trials in Ukraine have been stopped.

5. What steps is your company or subsidiary taking to ensure that your risk prevention and/or mitigation measures do not negatively impact Ukrainian civilians?

Please see above, responses to Questions 2 & 3.

Exercising leverage

6. Is your company or subsidiary taking any other actions to promote respect for humanitarian law, human rights, democracy, and peace in Ukraine?

Please see above, responses to Questions 2 & 3.

For companies operating or investing in Russia

Nature of involvement

1. How long has your company or subsidiary been operating or investing in Russia? In summary, can you briefly describe the nature, sector, scale, and geographic area of these operations or investments?

Novartis operates the following divisions in Russia

- Innovative products including Novartis Pharmaceuticals and Novartis Oncology.
- The Sandoz division for generic pharmaceuticals and biosimilars.
- Novartis Neva, our pharmaceutical manufacturing facility in St. Petersburg.

Assessing risks

2. How is your company enhancing its due diligence to identify, prevent, and mitigate heightened human rights risks and comply with international humanitarian law? a. What measures is your company taking to ensure it relies and acts upon robust monitoring of the situation, including through consultation with your workers, affected communities, human rights groups, and/or humanitarian organizations?

Consistent with our approach in Ukraine, a NEM team has been established in Russia to ensure continuous communication with employees and ensuring that we continue to deliver medicines to patients in need in Russia. The safety of our employees and the ongoing patient access to medicines remain our top priorities. The NEM team is carefully monitoring compliance with all new international sanctions imposed on Russia.

Mitigating risks and tracking effectiveness

3. As the situation in Ukraine unfolds, is your company or subsidiary planning to cease operations in or divest from Russia? If so: a. What have been the key considerations informing this decision and did you consult with your workers and/or other affected stakeholders as part of your decision-making process? b. What are the immediate and longer-term steps that your company has taken or is prepared to take to mitigate any negative impacts of your exit on affected communities and your workers, including addressing any loss of income?

As a pharmaceutical company, we view access to medicine as a human right and remain committed to providing access to medicines to patients in every country where we operate. At the same time, we are careful to comply with the new international sanctions imposed upon Russia. We have suspended capital investments, media advertising, and other promotional activities in Russia. Additionally, while we remain committed to provide access to our medicine in Russia, we have responsibly paused the initiation of new clinical trials and the enrollment of new study participants in existing trials, while remaining committed to the Declaration of Helsinki - Ethical Principles for Medical Research involving Human Subjects. These measures will be kept under review.

4. If your company or subsidiary chooses to continue operating in Russia, what human rights due diligence has been undertaken and how are you planning to mitigate harm in Ukraine?

While we remain committed to provide access to medicines in every country we operate, including Russia, we are implementing temporary mitigations to maintain patient safety. Following the guidance provided by the Association of Clinical Trials Organizations (ACTO) we have responsibly paused new clinical trials in Russia and the enrollment of new study participants in existing trials, these measures will be kept under review. The Sandoz small molecules local clinical trials in Russia will continue as planned to ensure patient safety. If there are ongoing participants, all activities are focused on conducting the trial for these participants aligned with the Declaration of Helsinki- Ethical Principles for Medical Research involving Human Subjects. We are also identifying alternate routes and methods for the shipping and delivery of materials, supporting off-site study visits, and shipping study drugs directly to patients' homes.

5. What kind of due diligence measures does your company use to ensure that it does not have any business relationships with sanctioned Russian individuals and entities? Beyond sanctions compliance, how does your company ensure that it does not have any business relationships with individuals or entities with a track record of rights violating conduct?

We are carefully monitoring compliance with all new international sanctions imposed on Russia. All employees have been provided with the contact details of relevant internal functions such as Customs & Trade Compliance, Trade Sanctions, Legal, Ethics Risk and Compliance and Business Continuity Management to raise alerts on being exposed to sanctioned vendors, customers and banks.

Exercising leverage

6. How does your company intend to use your leverage to protect the rights of your workers and communities affected by your operations in Russia, including freedoms of association and expression?

Freedom of association and expression within Novartis is an important element in our [Code of Ethics](#) and other internal policies and guidelines. At Novartis we have strong commitments to ethical standards across our business.

7. Is your company providing any support to Russian activists who are taking action against the war and in support of democracy and peace in Ukraine?

We are not providing such support.