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Patients, Politics, Pressure :: Pharma Stays Steady [Mostly] In Russia Sanctions Context

Observations at 30 March 2022

David R Curry

As announcements of Russia sanctions continue at "day 35", they are impacting individuals as well as goods and services -- ranging from chocolate bars and luxury yachts at one end of the spectrum to limits on access to the global SWIFT network supporting global financial transactions at the other.

One critical area not referenced in the kaleidoscope of sanctions issued so far is the supply of medicines *to* Russia or the conduct of research/clinical trials *in* Russia.

We continue to examine the nuanced intersection of international trade law, IHL [international humanitarian law], the Geneva Conventions and other instruments/frameworks in the context of Russia's belligerence in Ukraine. How pharma *should* proceed in Russia in this unhappy situation is not as clear as some pundits and ethicists portray. We will write further in this shortly.

In the meantime, we aggregated online statements and media releases by 16 major biopharma companies with sales, operations or research in Russia on how they *are* proceeding. The attached compilation is current as of 29 March 2022.

We used this compilation to assess two questions:

- [1] what actions have pharma companies announced regarding continuing supply of their medicines to Russia?
- [2] what actions have pharma companies announced regarding clinical trials they have underway or planned in Russia?

[1] Medicines to Russia: Pharma Stands on Principle, Stays Steady

To begin, IFPMA - the global pharma trade organization - is oblique at best in its short statement "...We are united in our mission of providing treatments and vaccines to all those affected by the war, wherever they are..." Russia is not mentioned in the statement [p.25 of the attached compilation].

The 16 companies whose statements we captured are remarkably consistent in confirming that they will continue to supply their medicines/pharmaceutical products to Russia and to Russian patients -- referencing mission, principles, ethical obligation and similar rationales.

There are a few that have suspended export of "non-essential" medicines [Lilly, "suspended exportation of non-essential medicines" (not defined)] or selected product lines [J&J - "personal care products"].

Otherwise, the statements exhibit some interesting variation in the "vigor" of the commitment to continue medicines supply, ranging from Astra Zeneca ["taking all required measures to ensure an uninterrupted supply"] to AbbieVie ["doing everything possible to minimize disruption"] to GSK ["make them (medicines) available while we can"] to Roche ["within the scope of available possibilities"].

The chart below intends to summarize the positions taken, but the full statements in the attached compilations should be referenced for further analysis.

AbbieVie	CONTINUE ALL MEDS*	"doing everything possible to minimize disruption"
Astra Zeneca	CONTINUE ALL MEDS*	"taking all required measures to ensure an uninterrupted supply"
Bayer	CONTINUE ALL MEDS*	"ethical obligation[against] withholding essential health products
Boehringer-Ingelheim	CONTINUE ALL MEDS*	
Gideon Richter	CONTINUE ALL MEDS*	"too early to responsibly judge potential effect of restrictions"
GSK	CONTINUE ALL MEDS*	"make them available while we can"
Johnson & Johnson		"suspend supply of our personal care products"
Lilly		"suspendedexportation of non-essential medicines"
Merck	CONTINUE ALL MEDS*	"continue supplying essential medicines and vaccines "
Novartis	CONTINUE ALL MEDS*	"accessin every country where we operate"
Pfizer	CONTINUE ALL MEDS*	
Roche	CONTINUE ALL MEDS*	"within the scope of the available possibilities"
Sanofi	CONTINUE ALL MEDS*	"essential and life-changing medicines and vaccines"
Servier	CONTINUE ALL MEDS*	
Takeda	CONTINUE ALL MEDS*	

^{*} Most company statements offer slightly varying language confirming that current meds shipments are continuing. Some selected phrasing is including here. See full statements in summary attached.

[2] Clinical Trials in Russia: Varying Confirmations and Interruptions

To gain some perspective on clinical trials activity in Russia we did a simple search in clinicaltrials.gov. Using pull-down menu filters, we captured capture trials occurring in the Russian Federation that were either Recruiting, Not yet recruiting, Active not recruiting, or Enrolling by invitation. The result: 1,673 studies which met the criteria.

We still need to distinguish how many of these trials are sponsored by the companies whose statements we surveyed, but are satisfied that the scale overall warrants the analysis below.

In our research, we encountered a position taken by the *Association of Clinical Trials Organizations (ACTO)* - *Russia*, an non-profit industry group whose members include many of the companies whose statements are analyzed here. ACTO's statement of March 5, 2022 [p.24 in the attached compilation] leads with the recommendation that trial sponsors "postpone launching new projects, opening new sites, enrolling patients in trials which are already underway until the situation has been clarified, if the risks for trial subjects and the organization of the trial processes are high, and also if it is yet impossible to realistically assess the risks..."

Well, that certainly provides generous cover for a range of actions and rationales.

ACTO is not referenced in any of the company statements, but there is significantly more variation in how pharma company are addressing clinical trial activity in Russia compared to the supply of medicines issue discussed above.

We found it interesting that most, but not all, companies were reasonably clear that active trials underway would continue, even though recruiting/enrollment for these trials would be suspended. We did not find any specific driver for this recruiting suspension [e.g. logistics, risk, safety, staffing] in the statements we examined.

Pfizer was an outlier here in stating that it "will work with FDA and other regulators to transition all ongoing clinical trials to alternative sites outside Russia" and that "consistent with our commitment to putting patients first, we will continue providing needed medicines to the patients already enrolled in clinical trials."

Most companies, but not all, specifically state they are pausing new trials activity. Again, the specific rationale for the pauses, or the anticipated implications for patients who might otherwise enroll, are not articulated.

The chart below intends to summarize the positions taken, but the full statements in the attached compilation should be referenced for further analysis.

AbbieVie	CONTINUE TRIALS*	PAUSE NEW TRIALS	STOP RECRUITING CURRENT
Astra Zeneca	CONTINUE TRIALS*	PAUSE NEW TRIALS	STOP RECRUITING CURRENT
Bayer NO TRIALS MENTION			
Boehringer-Ingelheim	CONTINUE TRIALS*		
Gideon Richter NO TRIALS	MENTION		
GSK	CONTINUE TRIALS*	PAUSE NEW TRIALS	STOP RECRUITING CURRENT
Johnson & Johnson			STOP RECRUITING CURRENT
Lilly		PAUSE NEW TRIALS	
Merck	CONTINUE TRIALS*	PAUSE NEW TRIALS	STOP RECRUITING CURRENT
Novartis		PAUSE NEW TRIALS	STOP RECRUITING CURRENT
Pfizer	CONTINUE TRIALS*	PAUSE NEW TRIALS	STOP RECRUITING CURRENT
Roche NO TRIALS MENTION	1		
Sanofi	CONTINUE TRIALS*		STOP RECRUITING CURRENT
Servier	CONTINUE TRIALS*	PAUSE NEW TRIALS	STOP RECRUITING CURRENT
Takeda	CONTINUE TRIALS*	PAUSE NEW TRIALS	STOP RECRUITING CURRENT

^{*} Most company statements offer slightly varying language confirming that current trials are Continuing. See full statements in summary attached.

This modest analysis should be strengthened and we welcome observations, corrections of fact, and challenges to our thinking. We also recognize that this is an extremely dynamic situation: we have already seen several "updates" to earlier company statements issued over the last two weeks. Presumably, the politics and pressure on multinational firms to align with the spirit of sanctions will continue. The spotlight will no doubt turn to the pharma sector, and more than once.

We will continue to monitor statements from these companies and report further on their actions and evidence around the resulting impacts.

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Pharma in Russia-Belarus-Ukraine Selected Statements :: 29 March 2022

This compilation was originally developed 19-20 March 2022 and updated on 29 March 2022.

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Pharma Company List Sources

<u>List of Pharmaceutical Companies in Russia/Top Pharmaceutical Companies in Russia</u>, Good Clinical Practice Network, [accessed 20 Mar 2022]

EFPIA - Pharmaceutical industry response to the war in Ukraine

10.03.22

List of member companies with links to respective statements..

Top-10 Largest Pharma Companies in Russia by Sales, Global Medical, [accessed 20 Mar 2022]

The largest sales

As statistics in 2019 shows, Russian people consumed the drugs of over 900 manufacturers all over the world. At that, vast majority of the drugs are supplied by 10 companies only:

- **1. Bayer.** The undisputed leader of the Russian pharmaceutical market. Moreover, the company from Germany is in top 20 largest international pharmaceutical companies. Russian consumers know the company by Aspirin, Alka-Seltzer, Rennie and others.
- **2. Novartis.** Russian top-2 and world's top-3 drug manufacturers. The Swiss company is primarily engaged in innovative drugs manufacture. Exoderil, Linex and other drugs are most demanded by the Russian consumers.
- **3. Sanofi.** Despite a slight decrease, the French company is still in the lead and is well known to the consumer thanks to Magne B6, Lazolvan, Festal and some others.
- **4. Servier** One more French big name and high sales company. Yet through it all, nearly 90% of the company's drugs have full-cycle production in Russia.
- **5. Teva.** The headquarters of this trans-world company is located in Israel, and the company is actively developing the Russian pharmaceutical market and expanding its activities every year. Recently, the company presented its first Russia-produced drug for migraine.
- **6. OTC-Pharm**. The role of this company in the Russian pharmacy market leaders' rating is constantly growing. Today it is the largest manufacturer of OTC-drugs like Genferon, Rino Stop, Arbidol, Pentalgin and others.
- **7. Takeda.** The Company is Japanese world leader in the production of oncology, neurology and other rare diseases drugs. It is in Russia only that the company takes the top-10. Latest data show the Company takes the top 15 of global pharmaceutical companies.
- **8. KRKA.** The world generics leader. The company's products are sold in over 70 countries. At that, the Company has its own dealer centers in each country, which significantly reduces the manufacturing costs.
- **9. Gedeon Richter.** Hungarian 115 year-old company represented mainly on the European market. The company has 9 own research centers and produces both generics and original drugs.
- **10. GlaxoSmithKline.** The British company is primarily engaged in the production of drugs for respiratory diseases, HIV, and vaccines (including pediatric ones).

GE2P2 Global Note:

The website for OTC-Pharm and KRKA did not evidence any announcements on Ukraine, Russia or Belarus.

AbbVie's response to the Ukraine crisis [undated]

[Accessed 29 March 2022]

Our thoughts are with the people of Ukraine and those affected across the region. As a global biopharmaceutical company, we have a responsibility to patients who depend on our medicines. We are committed to ensuring our patients in Ukraine, Russia, and throughout the region continue to have access to our essential and life-saving medicines.

AbbVie's presence in Ukraine and throughout the region

Our priority is to ensure the safety of our colleagues and help patients get the medicines they need.

As the tragic events continue to unfold in Ukraine, AbbVie has temporarily suspended operations for all our aesthetics products in Russia.

We do not have any manufacturing plants in the region. Importantly, we will continue to monitor the safety of our employees in Ukraine and the surrounding region.

Status of clinical trials

AbbVie is doing everything possible to minimize disruption to the treatment and care of our patients and clinical trial participants. We have paused the start of new clinical studies and the screening and enrollment of clinical trial participants in ongoing studies in Ukraine and Russia. We are committed to ensuring our clinical trial participants have access to the investigational medicines they need...

humanitarian / Philanthropic response

Our philanthropic focus is on humanitarian, employee, and donation support.

AbbVie is:

- Donating a total of \$1 million to nonprofit partners for medical care and supplies for Ukraine and Ukrainian refugees.
- Donating essential medicines to the Ukrainian government and our disaster relief partners.
- Providing relief and additional financial support as needed to Ukrainian employees and their immediate families.
- Doubling the AbbVie Foundation's employee donation match for select disaster relief partners with active humanitarian relief efforts in Ukraine and surrounding countries.

As this situation evolves, we will continue working with our nonprofit partners and employees to support relief efforts as we hope for a peaceful resolution.

Our actions in response to the Russia-Ukraine war AstraZeneca

[Accessed 29 March 2022]

UPDATED 25 March 2022 PUBLISHED 11 March 2022

In line with our purpose as a healthcare company, we are doing everything possible to ensure patients can continue to access medicines and that stocks are in place and can be maintained.

Protecting the safety and wellbeing of our employees

We have 200 people in our Ukraine team and are providing all practical support possible to ensure their wellbeing, physical and financial security. This includes:

- Providing additional financial support.
- Setting up advice and emotional support services for employees and their families.
- Rolling out virtual online sessions for employees' children to maintain educational activities.
- Helping those now in neighbouring countries, such as providing temporary accommodation for our team members and their families.

Supply of medicines

Patients rely on our life saving medicines, and it is more urgent than ever that medical supply chains continue to operate, enabling health systems and workers to deliver essential care. To this end, we are:

- Continuing to work in Ukraine and Russia, and are taking all required measures to ensure an uninterrupted supply of our essential and life-saving medicines.
- Supporting ongoing treatment at settlement sites and working with the governments to address the influx
 of patients in surrounding countries. This includes working with the EU on the continued provision of care
 for any Ukrainian refugees now residing in member states.
- Working together with the wider healthcare community, to ensure sanctions do not impact the supply of medicines to patients in need.

As far as clinical trials in Russia are concerned, we are not starting any new trials at this time and have paused enrolment of new patients into existing studies.

We are not planning any new investments in Russia.

Contributing to humanitarian relief efforts

We continue to provide urgent humanitarian support in Ukraine and neighbouring countries. To date, we have donated:

- Twenty-four pallets of medicines, worth \$3 million, to our humanitarian relief partner Direct Relief, which is working directly with the Ukrainian Ministry of Health.
- \$1 million to support relief agencies working in Ukraine, Poland and surrounding areas with a focus on providing healthcare and humanitarian assistance to those affected by the conflict. Funding is being provided to Project HOPE, working with and through the World Health Organization, and International Medical Corps.
- Medicines via The Red Cross affiliates in neighbouring countries to respond to the unfolding refugee crisis.
- \$1 million to UNICEF and The Red Cross, including \$500k of employee donations, which AstraZeneca is matching.

Bayer Statement on Ukraine

"Last Updated: Wednesday, March 16, 2022"

[Accessed 29 March 2022]

More than two weeks have passed since Russia's invasion of Ukraine. From the outset, we have utterly condemned this brutal aggression against a sovereign country. Our hearts ache as we see the devastation and death affecting innocent civilians, including children. Thousands have been killed or wounded, millions are fleeing the country, and the humanitarian situation of those who stay is deteriorating by the hour. We stand by the people of Ukraine who can fully count on our solidarity and support.

Attacks like these demand a very clear stance. And we have been very clear about ours. Here is what we are doing:

Assisting our colleagues and supporting the people of Ukraine

We continue to prioritize the safety of our 700 colleagues in Ukraine and will continue to provide them and their families with financial aid, shelter, and evacuation assistance. In response to the humanitarian crisis, Bayer has established a 3 Million Euro Disaster Relief Fund and provided both monetary assistance and donations of health products like antibiotics to help up to 27,000 Ukrainian patients.

Our employees continue to respond generously - donating more than 1 Million EUR so far through a Red Cross relief campaign, which the company will be matching.

Furthermore, Bayer colleagues have set up a platform where employees can offer housing to colleagues from Ukraine and their families who may need temporary shelter while country organizations and employee-led initiatives are organizing local volunteering campaigns.

Our seeds and agricultural inputs stand ready for the planting season for farmers in Ukraine and we hope that the Ukrainian farmers will be able to secure the 2022 harvest. We are prepared to support them as the window for planting is closing in only a few weeks.

Stopping all non-essential business in Russia and Belarus, while ensuring continued access to health and agriculture products

As a response to Russia's invasion of Ukraine, **Bayer stopped all spending in Russia and Belarus that is not related to supplying essential products in health** and agriculture. This includes

- Suspending all advertising and other promotional activities.
- Halting capital investment projects indefinitely.
- Not pursuing any new business opportunities.

We have also heard voices calling for a complete stop of delivery of all our products to Russia and Belarus. We understand these concerns as the war raises moral and ethical issues for every company.

Our position is that this senseless war has already taken many lives. As a Life Science company, we have an ethical obligation – in every country we operate in. Withholding essential health and agriculture products from the civilian populations – like cancer or cardiovascular treatments, health products for pregnant women and children as well as seeds to grow food – would only multiply the war's ongoing toll on human life.

In a recent statement on the invasion of Ukraine, the G7 agricultural ministers made clear that any increase in food price levels and volatility in international markets could threaten food security and nutrition at a global scale and would especially affecting the most vulnerable. By supplying farmers around the globe, we want to

support protecting food supply chains from further disruption and help to prevent what could be an unprecedented food crisis.

For the 2022 growing season, we have already provided essential agricultural inputs to farmers in Russia to alleviate additional pressure on the global food system. Nevertheless, we will closely monitor the political situation and decide about supplies for 2023 and beyond at a later stage, depending on Russia stopping its unprovoked attacks on Ukraine and returning to a path of international diplomacy and peace.

These are difficult times that put us to the test, both, emotionally and ethically. At Bayer, we will do everything in our power to live up to our responsibility to reduce the suffering caused by this terrible war. This is what our vision "Health for all, Hunger for none" calls for.

The situation remains volatile, and we will continue to monitor developments and evolve or adjust our response as necessary. As we do so, we stand with all those calling for an immediate end to this war, and we hope and pray for peace to return to Ukraine – and our world.

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Solidarity with Ukraine Boehringer-Ingelheim

Our company condemns the military aggression against Ukraine and is committed to helping those in need in the longer term with monetary and in kind donations [Accessed 29 March 2022]

Update March 18, 2022

The ongoing war in Ukraine touches all of us at Boehringer Ingelheim deeply. Our thoughts are with our colleagues, their families and all Ukrainians. We are committed to helping those in need and to assisting those who help. From the start of the war our priority has been to support our nearly 100 colleagues and their families in Ukraine.

We continue to see many support initiatives across our company, from donating to accommodating refugees. We facilitate these efforts by giving colleagues in Europe up to 10 volunteering days to help. We have made an initial EUR 2.5 million financial donation to emergency relief organizations in the early days of the war and started an ongoing process of medicines donations for Ukraine.

We realize that the war will have a long-term impact. We want to be there for Ukrainians not only now, but also when they can start rebuilding their country. We will therefore donate 12 monthly payments of each EUR 1 million to the Polish and German Red Cross organizations, from this month.

Providing people with the – often life-saving – medicines they need has always been our absolute priority. We do everything to keep supplying people in Ukraine, which is not easy now. We have also provided medicines to people in Russia for the past 30 years. We believe we cannot leave them without their medication now. This includes patients participating in current clinical trials Our operations in Russia will be limited to the supply of medicines and in full compliance with the sanctions imposed on the country.

The situation in the region will remain volatile in the coming period and we are closely following developments. We all hope that the aggression against Ukraine and the horrible suffering of Ukrainians will soon come to an end.

February 28, 2022, including update March 9, 2022

"On behalf of the Board of Managing Directors, I would like to express our feelings of sorrow and consternation over the start of a war in the middle of Europe. This affects people across the region, where families have members on both sides of the border, and where sons and daughters are called to duty in a war that only brings suffering and pain", says Hubertus von Baumbach, Chairman of the Board of Managing Directors. "War can never be accepted as the means of resolving conflicts."

It was in February 1992 that we established our presence in Ukraine and Russia, which has grown to a total of nearly 800 employees today. "During these 30 years, we have achieved many milestones together in the interest of health, for the benefit of patients, and in the interest of life. Our Ukrainian as well as Russian colleagues have become integral members of the Boehringer Ingelheim family," Hubertus von Baumbach continued. "Our thoughts are with them, as well as the many people who simply want to live in peace. On behalf of my colleagues, my deepest sympathies are with them all."

Richter provides humanitarian aid to Ukrainians affected by the war

[Accessed 29 March 2022]

01/03/2022

Gedeon Richter's leadership is shocked and greatly saddened as it follows the developments of the war in Ukraine. Richter's marketing activities in Ukraine have been suspended until circumstances once again allow for normal operation.

Gedeon Richter has played an important role in the pharmaceutical supply of Ukraine for decades, presently we employ 200 people in the country. Our affiliate is based in Kyiv. To the best of our knowledge our colleagues in Ukraine are safe and well as far as circumstances allow, and their lives are not under direct threat.

Nevertheless, we are deeply concerned about their safety. We feel it is our responsibility as an employer as well as personal duty to help them in this situation as much as we can. Communication is vital in crisis situations, therefore Istvan Jakubovics, Country Manager of our Ukrainian affiliate, is in constant phone contact with our local colleagues. We assured them in a message that we continue to count on their work once normal operations resume. In addition, we transferred their wages ahead of schedule which has proved to be especially helpful with the increasingly limited money supply. We continue to work on finding other ways to support them financially.

As a socially responsible company with local presence in Ukraine, Gedeon Richter Plc. provides the following humanitarian aid to Ukraine's population:

- Donate HUF 10 million to the Charity Service of the Order of Malta, and an additional HUF 10 million to "Jónak lenni jó" (It's good to be good), the donation initiative of the Hungarian public television.
- Provide humanitarian pharmaceutical aid from our supplies in our customs warehouse in Ukraine if it is logistically possible.
- Offer pharmaceutical donations of essential medicines to UNICEF and the Hungarian Interchurch Aid.
- Organize a donation initiative on corporate group level to help our Ukrainian colleagues and their families.

Our company has played an important role in the essential pharmaceutical supply of Russia for more than 70 years, therefore we feel responsible for supplying the Russian patients, too. A significant number of them with chronic illnesses have been taking Richter's medicines for years. According to our information operations are uninterrupted in the country, and it is too early to responsibly judge the potential effect of the restrictions against Russia on our Company and the pharmaceutical supply we provide.

We remain hopeful that the situation will be resolved soon, peace talks can begin, and the conditions for the long term development of the region can be restored.

Our response to the situation in Ukraine - GSK

[Accessed 29 March 2022]

[undated]

Alongside the global community, we share deep concern about the tragic events happening in Ukraine. We are taking actions guided by our purpose, and as a company dedicated to health and care for people and patients.

Our first priority is the safety, security and wellbeing of GSK people, wherever they are located. After this, our focus is to make sure our products reach the people who need them, including supporting humanitarian efforts in Ukraine and surrounding countries.

We condemn the fighting and the harm and suffering it's causing to people in Ukraine and beyond. The actions taking place are in violent contradiction to our purpose, and unshakeable belief that all people should be treated with dignity, respect and humanity.

GSK in Ukraine

We employ 400 GSK people in Ukraine and we're doing everything we can to help them stay safe in very difficult conditions.

We have stopped our business operations and are focused on advising and supporting our people who are staying in their homes and those who wish to relocate, where possible, to safer areas. We're helping people with practical support where needed – providing access to mobile phone networks and healthcare in other countries, as well as supporting with temporary accommodation and food for them and their families.

Our teams in neighbouring countries are doing everything they can to support our people coming across the border and the broader humanitarian response

Humanitarian support

We are providing targeted humanitarian support through long-term NGO partners who have teams on the ground in Ukraine and neighbouring countries. We'll continue to respond as the situation evolves, guided by our humanitarian principles.

- We have donated £3.25million to the Red Cross and Save the Children who are providing food, water, first aid, medicines, warm clothes and shelter for people in Ukraine and refugees at the border.
- We have donated £250,000 to Crown Agents (an NGO that has worked with the Ukrainian Ministry of Health (MoH) for the past 20 years) to fund 2,500 medical trauma kits; and are in discussions with them on how to enable continued supply of essential medicines into Ukraine.
- Through ViiV Healthcare, we are making available significant donations of anti-retroviral medicines to the WHO, national AIDS programmes and NGO partners to support children and adults living with HIV who have been impacted by the conflict. ViiV has also made an initial £200,000 in emergency funds available to existing partners through our Positive Action programme.
- In addition to our company donation, our employees around the world have donated over £280,000 to Save the Children and the Red Cross, which GSK will match.
- We have responded to urgent product requests from the Ukrainian MoH with donations of 100k units of medicine and consumer products from our warehouse located near Kyiv, including antibiotics, asthma medicine, treatments for epilepsy patients and pain relief products.
- We are in discussions with UNICEF around supply of essential childhood vaccines to Poland, to protect the rapidly growing refugee population

GSK in Russia

The situation in Russia is complex and rapidly changing. Our priorities are to support GSK people and support access to essential products.

We support global sanctions and will comply with them and take a precautionary approach to stop, to the fullest extent possible, any direct involvement and support to the Russian government and military.

In line with our purpose to support people's health, regardless of race, sex, nationality, ethnicity, language or religion, we believe everyone has the right to access healthcare and, as an innovator and supplier of needed medicines, vaccines and everyday health products, we have a responsibility to do all we can to make them available while we can.

Latest update

We continue to review our approach and adjust our business – across Pharmaceuticals, Vaccines and Consumer Healthcare.

- We have already stopped advertising our products and will now move to stop promotion-related activities in Russia.
- We will move to prioritising supply of products that are essential for people's health while we can (and in compliance with sanctions).
- We are not starting any new clinical trials and will not enrol new patients into existing clinical trials.
- Any profits we make from our operations in Russia in the interim will be used in support of humanitarian relief efforts.

We will continue to keep our approach under active review, given circumstances continue to change rapidly.

Johnson & Johnson Statement on War in Ukraine

[Accessed 29 March 2022]

NEW BRUNSWICK, N.J., March 29, 2022 – The war in Ukraine has resulted in a devastating humanitarian crisis. As a global healthcare company, we believe access to healthcare is fundamental. From the outset, Johnson & Johnson joined the world in support of the innocent people impacted. We took immediate action to care for our employees and uphold our responsibility to patients in the region by:

- Donating \$5 million to support the work of the International Rescue Committee (IRC) and International Federation of Red Cross (IFRC) and Red Crescent to provide humanitarian support for refugees in the border countries.
- Providing product donations including hygiene kits, health packets and medical supplies.
- Launching an unlimited matching program for our global employees with Global Giving Ukraine Crisis Relief
 Fund.
- Continuing to work with our longstanding partners in global health International Health Partners (IHP, UK),
 Americares (US), Direct Relief (US), IFRC, Save the Children and UNICEF to support those in the region by providing them access to our supply chain network to strengthen their reach and capabilities.
- In early March, we suspended all advertising, enrollment in clinical trials, and any additional investment in Russia.

Now, due to the increasing scale of the humanitarian crisis, we are taking these additional actions:

- Doubling our donation to support the humanitarian assistance work from \$5 million to \$10 million.
- Reaffirming our commitment to supply our medicines and medical devices in the region.
- We have decided to suspend supply of our personal care products in Russia.

We remain steadfast in our support – inclusive of job security, transport, lodging and financial assistance – for our employees and their families in Ukraine. Above all, we continue to hope for rapid resolution, and we will continue to monitor the need for additional humanitarian relief.

Lilly Shifts Business Focus in Russia

[Accessed 29 March 2022]

March 15, 2022

For nearly 150 years, Lilly has worked to ensure patients have access to the medicines they need, no matter where they may live. We have an ethical and moral obligation to help alleviate human suffering and to protect the lives of patients. Lilly is deeply concerned with the tragic loss of innocent lives in Ukraine – and recognizes the challenges people are facing with access to essential medications like insulin.

We have taken several actions in response to the crisis in Ukraine. In addition to our donations of lifesaving medicine and the Lilly Foundation's philanthropic commitment announced on March 3, Lilly has been focused on the safety of our employees in Ukraine.

We also have suspended all investments, promotional activities, and new clinical trials in Russia, as well as the exportation of non-essential medicines to that country. Our Russian operations are now only focused on ensuring people suffering from diseases like cancer and diabetes continue to get the Lilly medicines they need. Should we generate any profits from our sales in Russia, we will donate them to organizations dedicated to humanitarian relief.

We hope for an immediate end to the hostilities and a resolution to this crisis as soon as possible.

Merck to continue supplying essential medicines and vaccines in Russia and will donate any profit from Russia to humanitarian causes

[Accessed 29 March 2022]

Updated: March 28, 2022

We are saddened by the invasion of Ukraine and we continue to stand united with the Ukrainian people. We hope for an urgent and peaceful resolution, and our paramount concerns are the safety and well-being of our employees and ensuring our patients and customers have continued access to medicines and vaccines needed for patient and public health.

For humanitarian reasons, Merck has a responsibility to in Russia. Merck has saved and improved lives around the world for more than 130 years, and we remain committed to doing so. Any profits resulting from these sales will be donated to humanitarian causes. We will maintain scientific exchange of information with stakeholders in critical therapeutic areas. However, the company will not make further investments in Russia. This includes stopping all promotional activities, capital investments and business development initiatives. Additionally, screening and enrollment in ongoing clinical trials, and planning for new studies in Russia have been suspended. We are continuing to treat patients already enrolled in existing clinical trials and collect data from these studies underway, and we are working hard to ensure no patient is left behind. Merck does not have research or manufacturing facilities in Russia and is operating in compliance with all international sanctions while working to ensure continued access to essential medicines and vaccines.

During this tragic time, Merck's commitment to helping the people affected is unwavering. We are using our resources to help alleviate the human suffering in Ukraine. Merck and MSD are taking various actions to address the humanitarian crisis, which include the:

- Delivery of molnupiravir to Ukraine through a supply and purchase agreement we have with the government.
- Donation of molnupiravir to Direct Relief for distribution to refugees. We are preparing to donate additional courses specifically for people affected by the invasion of Ukraine.
- Donation of product, including PROVENTIL, an inhaler used in patients with asthma, TIENAM IV (marketed as PRIMAXIN in the U.S.), an antibiotic used to treat infections in hospitalized patients, and KEYTRUDA for existing patients in need. We are actively assessing needs for additional products.
- Commitment of \$1 million USD directed to humanitarian partners, American Red Cross, Direct Relief,
 International Medical Corps and Project HOPE, delivering urgent assistance to those affected in the region.
- Utilization of our donation program for U.S. and Puerto Rico employees to donate to Ukraine relief efforts.
 Contributions will be matched 100% by the company. Employees outside of the U.S. can receive a company match toward their donation to the Red Cross and Direct Relief, and the contribution will be matched 100% by the company.
- Donation of vaccines from Merck Animal Health to farmers in Ukraine to support the continued raising of livestock and food production.

As of March 28, our total cash and product donations amount to more than \$65 million USD.

Merck will continue to monitor this tragedy and update its response as this crisis unfolds. The focus now remains on supporting the well-being of our employees, doing what we can to ensure access to our medicines and vaccines, and further using our resources to alleviate the unimaginable human suffering in Ukraine.

Novartis condemns the war in Ukraine and commits to supporting humanitarian efforts

[Accessed 29 March 2022]

Mar 22, 2022

Novartis condemns the war in Ukraine. This unprovoked act of violence harms innocent people and defies our mission to improve human health globally.

As a medicines company, in the last few days, we have delivered more than 600 thousand packs of antibiotics, painkillers, cardio-vascular, and oncology treatments to maintain supply to those who rely on these drugs in Ukraine and in the border areas where people are seeking refuge.

Novartis has also made an initial USD 3 million donation to charities supporting refugees and displaced people in Ukraine and bordering countries. We are continuing to support our employees and their families in Ukraine, and those who have left the country. Our thoughts are with the citizens of Ukraine, Novartis will continue to contribute to the humanitarian efforts in and for the people of the country.

We 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 international sanctions imposed upon Russia.

We have implemented a package of measures that include suspending capital investments, media advertising, and other promotional activities in Russia. In addition to that, while we remain committed to provide access to our medicine in Russia, we responsibly pause the initiation of new clinical trials and the enrollment of new study participants in existing trials. These measures will be kept under review.

We are hopeful that the war in Ukraine will soon reach a peaceful resolution.

Pfizer Updates Company Position in Russia

Pfizer will maintain humanitarian supply of medicines to Russians and donate all proceeds to providing direct humanitarian support to the people of Ukraine [Accessed 29 March 2022]

NEW YORK, March 14, 2022 — Pfizer Inc. (NYSE: PFE) Pfizer stands with the unified global community across the public, private and civil society sectors in opposition to the Russian war in Ukraine and the brutal situation it has created.

The international community has implemented unprecedented sanctions to Russia. As with all previous instances, for humanitarian reasons, medicines were excluded from these sanctions. Pfizer concluded that a voluntary pause in the flow of our medicines to Russia would be in direct violation of our foundational principle of putting patients first. Ending delivery of medicines, including cancer or cardiovascular therapies, would cause significant patient suffering and potential loss of life, particularly among children and elderly people.

However, maintaining the supply of medicines to Russia does not mean we will continue doing business as usual in Russia. Today we are announcing that effective immediately Pfizer will donate all profits of our Russian subsidiary to causes that provide direct humanitarian support to the people of Ukraine. This will be in addition to all other recently announced donations from Pfizer to Ukraine.

...Additionally, we will no longer initiate new clinical trials in Russia, and we will stop recruiting new patients in our ongoing clinical trials in the country. Pfizer will work with FDA and other regulators to transition all ongoing clinical trials to alternative sites outside Russia. Consistent with our commitment to putting patients first, we will continue providing needed medicines to the patients already enrolled in clinical trials.

Finally, while Pfizer doesn't own or operate any manufacturing sites in Russia, we will cease all planned investments with local suppliers intended to build manufacturing capacity in the country.

These decisions align with our patient-first values and ensure that every dollar of profit derived from Russia will strengthen Ukraine and its people as they continue to valiantly defend their nation and freedom from this unprovoked and unjustified attack.

Roche donates additional medicines and diagnostics for Ukraine

[Accessed 29 March 2022]

Basel, 23 March 2022 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced the donation of additional medicines and diagnostics to Ukraine.

Beyond the already communicated 150,000 packs of an antibiotic medicine the new donation includes another 4,600 packs of specialized medicines for the treatment of influenza, rheumatoid arthritis, SMA and various cancers. We are also donating reagents and consumables for automatic testing of up to 120,000 blood donations and 31,000 units for diabetes management.

This latest donation demonstrates our commitment to meeting the need for Roche medicines and diagnostics in Ukraine whenever possible. Roche is in contact with multiple global and local partners as well as charities to understand how to best continue to support the people of Ukraine with medical supplies.

Roche vehemently condemns the violent invasion of Ukraine. We are doing everything necessary to safeguard and support our employees and their families whilst also ensuring global supplies of our products. Roche remains hopeful the war will reach a peaceful resolution as soon as possible

Roche announces donation of essential medicines to Ukraine

Basel, 02 March 2022 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced an initial donation of essential medicines to Ukraine. Roche vehemently condemns the violent invasion of the country.

Roche is working diligently to support the country and people of Ukraine with medical products in accordance with Roche's overall mission and announced today that we are donating 150,000 packages of Rocephin, a critical antibiotic used to treat the symptoms of many kinds of bacterial infections and listed on the World Health Organization's list of essential medicines.

These donations will be delivered to Ukraine as soon as possible to address the urgent need in the country. Roche is working with external partners to facilitate transport into the country despite the current lack of humanitarian corridors into Ukraine.

Roche remains in contact with multiple global and local partners as well as charities to understand how it can best continue to support the people of Ukraine with additional medical supplies. The situation is evolving quickly and further details will be shared when available

About Roche's response to the situation in Ukraine

Roche's primary focus is doing everything necessary to support our employees and their families in Ukraine. At the same time we are ensuring that our critical medicines and diagnostics reach the people who need them both in Ukraine and other countries impacted by the crisis. We are making every effort to ensure continued supply to Ukraine, Russia and Belarus within the scope of the available possibilities. This includes working through local distributors, using remote support systems for laboratories and working with partners in neighboring countries to set-up blood donation programmes. We are also actively working on solutions to ensure continued access to treatment for Ukrainian patients in ongoing clinical trials, including for those who have left Ukraine and moved to other countries.

Our response to the situation in Ukraine - Sanofi

[Accessed 29 March 2022]

Update as of March 23

We continue to be shocked and saddened by the terrible brutality of the Russian aggression against Ukraine and the resulting suffering of the Ukrainian people. This is an enormous tragedy, and we continue to consider how we can best help the people of Ukraine.

We want to share an update on our company's response to date.

As a purpose-driven organization working in the field of healthcare, we continue securing access to essential medicines and vaccines for patients.

We stand in opposition to the Russian war in Ukraine and in full support of the position of the international community, we have decided to stop immediately any new spending not related to the supply of our essential and life-changing medicines and vaccines in Russia, as well as in Belarus.

This includes all advertising and promotional spending and a halt to any new recruitment of patients for ongoing clinical trials, though we will continue to treat patients already enrolled.

A complete cessation of our activities would deprive people of the essential and life-changing medicines and vaccines they need and add to suffering. This would contradict our purpose. We will stay focused on patients, as we always have.

We are doing everything we can to support Ukraine and the Ukrainian people, starting with our own colleagues. A set of exceptional measures were taken last week to help our employees in Ukraine face this critical situation. We are also providing specific support through our teams in neighboring countries to colleagues and their families who have made the difficult decision to leave Ukraine.

In addition to our company's financial donations to the Red Cross, our Sanofi Foundation is coordinating and accelerating the donations of essential medicines and vaccines to support Ukrainian patients and Ukrainian refugees. As of today, 10.5 million daily treatments (e.g., insulins, anti-epileptics and medicines used in emergency situations) have been donated, potentially benefitting 360,000 patients.

We continue to hope that a resolution to this crisis will be found as soon as possible. We will continue to play our part in supporting our own colleagues in Ukraine, as well as the Ukrainian people and patients, for as long as it will be needed.

Servier's response to the war in Ukraine (as of 28/03/22)

[Accessed 29 March 2022]

28/03/2022

Servier is deeply saddened by the loss of life and destruction caused by the war in Ukraine. Servier condemns this war and calls for a prompt return to peace. All our thoughts go out to those affected by this brutal and tragic situation, starting with our Ukrainian colleagues and their families.

As a company dedicated to saving and improving lives, **Servier has a unique humanitarian responsibility to ensure that essential medicines remain available to patients wherever they are.**

With regard to the quickly-evolving situation and in accordance with international sanctions imposed on Russia, we have made the following decisions:

- We suspend any spending not related to our medicines necessary to meet patients' essential needs in Russia and Belarus.
- We suspend the start of new clinical trials in Russia and Belarus, as well as the recruitment of new patients for ongoing trials. We nevertheless commit to continuing to provide the necessary therapeutic units to patients previously enrolled in clinical trials.
- We suspend any new investments in Russia and Belarus.
- We will use our profits from our Russian subsidiary this year to support the people of Ukraine.

In addition, in line with the Servier Group's mission and values:

- We are offering support to our employees in Ukraine and to those who have made the difficult decision to leave the country. Many of our colleagues are working to ensure the safety and well-being of our Ukrainian employees and their families in any way possible, including offering solutions for housing.
- We are doing everything we can to contribute to humanitarian aid and support Ukrainian people. The Servier Group has already made donations of medicines and emergency kits. In addition, we have offered financial support to organizations operating in the field, for a total amount that exceeds €1.5 million to date. We have also created a fund for our employees around the world so that they may contribute to relieving suffering in Ukraine via voluntary charitable donations.

It is our hope that the war in Ukraine and the suffering of Ukrainians will soon come to an end.

Takeda Provides Update on Operations in Russia

[Accessed 29 March 2022]

March 21, 2022

As the conflict and humanitarian crisis in Ukraine continues, we are announcing an update to our company position in Russia.

Takeda has taken further action to discontinue activities in Russia that are not essential to maintaining supply of medicines to patients and providing ongoing support to our employees. This includes suspending all new investments, suspending advertising and promotion, not initiating new clinical trials and stopping enrollment of new patients in ongoing clinical trials.

Our focus only on essential activities is consistent with our values and ethical responsibility to our patients in Ukraine, Russia and the region who depend on our treatments. Notwithstanding, we are adhering to all international sanctions imposed on Russia.

We will be increasing our humanitarian relief efforts, including monetary and medicine donations to benefit people affected by the conflict in Ukraine, and we will continue to assess new ways to provide support as we look to meet the needs of patients across the region.

Takeda will continue to monitor the situation closely and take appropriate actions grounded in our values.

Takeda Pledges Donation to Support Humanitarian Efforts in Ukraine

March 10, 2022 [Accessed 20 March 2022]

We are heartbroken by the ongoing humanitarian crisis in Ukraine and the impact on people living within the country and those who have had to flee their homes.

Our commitment to patients, regardless of where they live, and to our people is unwavering and is even more important in times of crisis. We are making every effort to protect our colleagues in Ukraine and to continue to supply patients in Ukraine and in the region with much needed treatments.

We are supporting the global humanitarian efforts by contributing JPY 300 million (approx. \$2.6 million USD) to The International Federation of Red Cross and Red Crescent Societies, which is actively providing urgent local humanitarian support to people displaced and impacted by the conflict. We are also donating medicines to hospitals working to provide care around the clock to patients in need, and will continue to evaluate ways to provide additional support services for patients and the treatment community. Our colleagues around the world are helping those in need in Ukraine by contributing with their personal donations to several local and global non-governmental organizations.

<u>Teva Announces Donations of Essential Medicines in Support of Ukrainian Refugees</u> [Accessed 29 March 2022]

March 14, 2022

- Teva is donating medicines valued at over \$11M, for acute therapies in support of Ukrainian refugees
- The donations include approximately 27 million doses of medicines in over 1 million packages of antibiotics and other essential medicines as well as hygienic products for Ukrainian infants and children

TEL AVIV, ISRAEL— 14 March, 2022—Teva Pharmaceutical Industries Ltd. (NYSE and TASE: TEVA) today announced a donation of essential medical products valued at over \$11M, for acute therapies in humanitarian support of Ukrainian refugees.

The donations made by Teva include approximately 27 million doses of medicines in over 1.3 million packs of medicines, valued at over \$10.8 million (wholesale acquisition cost), most of which have been made in partnership with Teva's trusted long-term partner 'Direct Relief'. Many of the Teva medicines donated are listed on the World Health Organization's list of essential medicines, and include antibiotics, treatment for respiratory conditions, and other treatments.

Teva has also donated over 25,000 packs of antibiotics valued at approximately \$180,000 to 'United Hatzalah', a leading Israeli non-profit emergency and relief organization, as aid in refugee camps and field hospitals on the border of Ukraine. The medicines arrived at the border of Ukraine last week and are helping to treat thousands of refugees who have fled the war.

Moreover, Teva is cooperating with 'People in Need', a European NGO, to provide around 82,000 packs of medicines valued at approximately \$180,000 for Ukrainian infants and children that are struggling with poor hygienic conditions as a result of the humanitarian crisis.

As a leading pharmaceutical company we are upholding our responsibility and commitment to provide critical and essential medicine to all patients, wherever they are in the world. In accordance with Teva's mission to provide access to quality medicines and improving the lives of patients across the world we are currently assessing additional donations programs throughout Europe, and are maintaining dialogue with our network of trusted partners and other international humanitarian aid organizations to understand the emerging needs, and make a contribution through our expertise and supply chain, while doing everything possible to also continue to supply our vast portfolio of essential medicines to other patients.

[GE2P2 Global Note: No statement or announcement specifically referencing Russia or Russia operations identified at 29 March 2022]

ACTO's Position on Conducting Clinical Trials in Russia

[Accessed 29 March 2022]

March 05, 2022

Taking into account the significant risks and the high degree of uncertainty in relation to conducting clinical trials in the territory of Russia, ACTO calls to focus on the principles of the Helsinki Declaration and the ICH GCP standards, and therefore, first of all, take care of the health, welfare and observance of the rights of patients.

In particular, ACTO recommends the following:

- postpone launching new projects, opening new sites, enrolling patients in trials which are already underway
 until the situation has been clarified, if the risks for trial subjects and the organization of the trial processes
 are high, and also if it is yet impossible to realistically assess the risks;
- consider it acceptable to approve amendments to the protocol concerning patient safety already after taking specific measures to ensure patient safety;
- continue recording all deviations from the protocol, thoroughly and in accordance with the procedure;
- if possible, try switching to working with available laboratories (local or based in countries where biological materials can be delivered), and also, whenever feasible, postpone the collection of biological materials until the logistical issues have been clarified;
- if possible, try to arrange new routes for shipping medicinal products, laboratory kits, other supplies and equipment for trials, during the use of which the transportation requirements can be ensured;
- consider delivery of the investigational product to the patient by a distributor engaged by the sponsor, whenever feasible, and if there are detailed instructions prepared by the sponsor and provided to the patient;
- premeditate alternative communication channels between the trial organizers, the research team and patients in case of problems in the operation of the existing channels.

<u>Association of Clinical Trials Organizations (ACTO) - Russia</u>

ACTO was duly established at the end of November 2007 as non-commercial organization of the companies/ legal entities and clinical research community engaged in clinical trials in Russia. The situation involving the export of biological samples, which occurred in May 2007, was the stimulus that led companies to create the Association. At that time there was a lack of uniting power, to appeal on behalf of business.

The primary objectives of the Association are to further develop Russia as clinical research country/market, to ensure a proper and effective balance between the interests of parties involved in clinical trials including the patients, the medical community, and the governmental agencies, to harmonize local legislative basis for the clinical trials with the respective worldwide standards, and to promote an ethical business model.

To date, ACTO's members are 24 pharmaceutical companies, contract research organizations and a company providing supply chain solutions for clinical trials: Almedis, Boehringer Ingelheim, Bristol-Myers Squibb, COREX Logistics, Dokumeds, <a href="Eli Lilly Vostok S. A., ICON, IQVIA, Janssen Pharmaceutica, KCR, Labcorp, MB Quest, Medpace, Novartis, Novo Nordisk, Parexel, PPD, PRA Health Sciences, PSI, Servier, Syneos Health RUS, Worldwide Clinical Trials (WCT).

Pharma in Russia in Sanctions Context
Initial Observations; Selected Company Statements at 29 March 2022
GE2P2 Global david.r.curry@ge2p2global.org

Joint Industry Statement on the War in Ukraine - IFPMA

21 March 2022 – The global research-based pharmaceutical industry stands in solidarity with the people of Ukraine and condemns the invasion of their country and the suffering it continues to cause. Overcoming the challenges that this unprecedented humanitarian crisis poses for patients is our main concern.

We are united in our mission of providing treatments and vaccines to all those affected by the war, wherever they are. Safe passage of medical products remains a top priority.

The industry is working in a variety of ways to support those affected by the unfolding humanitarian crisis. This includes providing free essential medicines and giving financial support to NGOs on the ground. We are monitoring for supply chain disruptions and building supply capacity where it's needed as well as working with the wider health community to address issues as they arise.

To learn more about individual company efforts, please visit the website set up by the European Federation of Pharmaceutical Industries and Associations' (EFPIA), found here.

GE2P2 Global Position on Pharma Activity – UKR/RUS/BLR Context

28 March 2022

The Foundation holds that:

- [1] continuing the supply of licensed medicines to Russia and Belarus generally,
- [2] continuing clinical trials that are active [enrolling/underway], and
- [3] continuing the supply of unlicensed medicines [such as under expanded access/compassionate use],

should continue as the ethically-resilient posture for biopharma in the Russia/Belarus context until it becomes impossible to continue these activities in a medically-responsible and operationally-sound manner.

Further, we hold that organizations assessing changes around the above must treat these three activity areas as interdependent, recognizing that interruptions in access to medicines are more likely than not to result in harm to patients, however unintended.