

Pharma Industry & COVID-19

This alert is intended to provide our clients with a brief overview of the impact of COVID-19 on pharma industry and the steps being taken to combat the price hike during this time of pandemic.

INTRODUCTION

Covid-19 has belabored the world meticulously in the past few months, with certain countries devastated the most by its adverse effects. The extensive level of interconnectedness between countries and people across the globe, has allowed it to spread quickly globally after it originated in China.

Therefore, it is important to highlight how trade policy in relation to the pharmaceutical industry can help to fight the current pandemic. Trade measures could support the many national efforts that are currently ongoing to slow the spread of Covid-19 and to treat patients.

With concerns rising about medicine availability during the global COVID-19 coronavirus pandemic, European Pharmaceutical Review explores how the pharmaceutical supply chain is faring. The pharmaceutical supply chain is gravely affected by the restrictions posed by the sanctions and lockdowns enforced by governments on the free movement of goods and people.

CHAPTER I: UNITED STATES

United States Riposte to Coronavirus

- In regard to the Food and Drug Administration, Trump commented that he would “**cut through red tape**” to reduce regulatory barriers.

- The regulatory body also announced an update to its policy on diagnostic testing for COVID-19.

Some Members of US Congress have called for broader tariff relief or at least new exclusions for existing tariffs and a moratorium on any new tariffs. Other Members and U.S. domestic producers argue that such liberalization could open the U.S. market to a flood of imports during an economic downturn. The Office of the United States Trade Representative (USTR) announced on March 6, 2020, that it would lift tariffs imposed under Section 301 of US Trade Act of 1974, authorities on 19 specific products and 8 10-digit subheadings of medical supply and equipment items from China.

The Trump Administration’s relatively late formal invocation and activation of the Data Protection Act, which could effectively serve as an export constraint on U.S produced medical supplies, arguably left discretion to U.S. companies to decide whether to fill export or domestic orders first. By contrast, governments in Taiwan, Thailand, France, and Germany boosted production but restricted exports, further curtailing U.S. supply options.

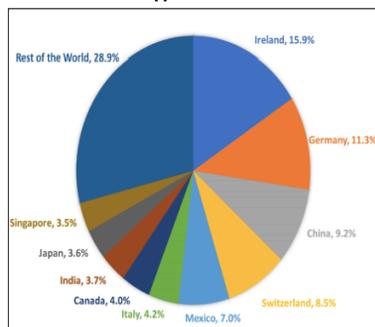
In 2019, U.S. exports of N95 masks and other products covered by the ban amounted to about \$1 billion. Imports were worth about \$6 billion. There were also reports that the U.S. crackdown on exports had gone beyond N95 masks and other protective equipment.

In Barbados, Health Minister Jeffrey Bostic stated that an order of 20 ventilators donated to the Caribbean island nation by an unnamed philanthropist had been blocked from leaving the U.S., though five others were due to land next week.

After Trump Threat, India Lifts Export Ban on COVID-19 Treatment Drug:

India has partially lifted a ban on the exports of a malaria drug after U.S. President Donald Trump sought supplies for the United States, according to government officials with knowledge of the matter.

U.S. Imports of Pharmaceuticals and Medical Equipment, Products, and Supplies in 2019



Profiteering on Drug/ Patients Registration

GENEVA/ NEW YORK — Médecins Sans Frontières (MSF) has called for no patents or profiteering on drugs, tests, or vaccines used for the COVID-19 pandemic, and for governments to prepare to suspend and override patents and take other measures, such as price controls, to ensure availability, reduce prices and save more lives.

US diagnostic test maker Cepheid provides another example of pandemic profiteering. The corporation just received US FDA Emergency Use Authorization for a rapid COVID-19 test that delivers results in just 45 minutes, using existing testing machines that have been routinely used for tuberculosis (TB), HIV and other diseases.

President Donald Trump eased restrictions on exports of masks and other protective equipment needed to fight the Covid-19 pandemic just days

after their introduction as he confronted a backlash from allies around the world.

Faced with domestic criticism of his administration’s handling of the Covid-19 crisis and cries of shortages from hospitals on the front lines, Trump has imposed a ban on export of N95 masks, surgical gloves and other protective equipment.

Cepheid said it will be allowed to continue exporting some masks to Canada and Latin America from the U.S. The fate of exports to other parts of the world remained unclear.

Treatment Cost for COVID-19

- A covid-19 patient got treated in BOSTON and the total cost for her treatment was USD 34,927.43.
- A new analysis from the Kaiser Family Foundation estimates that the average cost of COVID-19 treatment for **someone with employer insurance and without complications would be about \$9,763.**
- **Someone whose treatment has complications may see bills about double that: \$20,292.**

CHAPTER II: CHINA

The Ramification of COVID-19 on China’s Pharmaceuticals Industry

China Nationalizes Medical Production and Supply

In early February 2020, the Chinese government nationalized control of the production and dissemination of medical supplies in China. Concerned about shortages and its ability to contain the COVID-19, the Chinese government transferred authority over the production and distribution of medical supplies from the Ministry of Information, Industry and Technology (MIIT) to the NDRC, China’s powerful central economic planning ministry.

NDRC commandeered medical manufacturing and logistics down to the factory level and has been directing the production and distribution of all medical-related production, including U.S. companies' production lines in China, for domestic use.

In response to government directives, foreign firms with significant production capacity in China, including 3M, Foxconn, and General Motors, shifted significant elements of their operations to manufacturing medical PPE. By late February 2020, China had ramped up face mask production—both basic surgical masks and N95 masks—from a baseline of 20 million a day to over 100 million a day.

China has banned the export of coronavirus test kits and other medical supplies that do not meet the country's own standards. China's Ministry of Commerce, General Administration of Customs, and National Medical Products Administration (NMPA) announced that Chinese customs will only allow the export of medical supplies which are certified by the NMPA. Customs previously allowed the export of medical supplies that had been certified by medical regulators in other countries, but not by the NMPA.

China has placed an export prohibition on test kits and medical supplies, taking into account the circumstances. The prohibition dated 01 April 2020. Thus, the Chinese government has decided to ban specific medical product supplies, emanating from non-licensed firms. This ban is towards all the countries for a period unknown and dependent on the current situation.

In addition to the manufacturing and production related decisions and developments, the Chinese companies are also seeking to lead the way in developing the vaccine and cure for COVID 19. While this significantly increases the chances of finding the cure or developing the vaccine, it does not necessarily mean that there will possibly be any new developments adding to the already pharmaceuticals. On the treatment side for example, Chinese companies are seeking a patent in Wuhan for an already existing treatment for Ebola

developed by Gilead, Remdesivir which has shown positive results in treating COVID 19 patients. This raises several issues since the patent apparently filed by the company seeks to cover only the 'use' of the compound which was not covered by the original patent filed by Gilead since the compound, when developed was only an experimentation drug for Ebola and the Marburg virus. This situation presents a classic example of the issues with patent regime being regional i.e. where an individual or company seeking to get a patent in a country has to file it in the patent office of that country which assesses it according to their own applicable patent laws. For example, Pakistan and numerous other countries do not permit the patenting of a new use of a known or existing product, in this case the compound to treat Ebola whereas certain countries permit such patenting. Now if the Chinese patent law permits patents over new uses of existing products, the Chinese company may be able to exploit the Gilead patent in a limited way undermining the value of the drug since Gilead will potentially only be able to exploit it the purpose it was originally filed for. This holds true also because the Wuhan patent for new use was filed before the Gilead patent for new use thereby winning the priority race.

This makes it pertinent for pharmaceutical companies to assess and determine the timing and the applicable laws in a country regarding patents and their filing.

China Sends Tonnes of Medical Equipment to Aid Pakistan

Islamabad receives 15,000 protective suits for doctors to eradicate coronavirus outbreak. "At least 2 tonnes of masks, test kits, ventilators, medical protective clothes worth Rs67 million were handed over [to Pakistani officials] at Khunjerab Pass", the highest paved international border between Pakistan and China.

"This is the friendship higher than mountains" the embassy tweeted.

Further, a plane carrying 50,000 coronavirus testing kits also arrived in Karachi on March 27 2020. This was the second bulk consignment sent by China's Alibaba and Jack Ma Foundation within days. On March 25, the foundation sent 500,000 surgical masks and 50,000 N95 respirators to Pakistan. Sindh Chief Minister Murad Ali Shah, Consul General of China Li Bijian and other officials received the supplies at Karachi airport.

Pakistan will receive around 20 tonnes of medical goods and 20 ventilators on an urgent basis from China this week, said Chairman National Disaster Management Authority (NDMA), Lt. Gen. Mohammed Afzal, during March 27 2020 media talk. Additionally, two more planes would bring 100 tonnes of urgently needed medical equipment from Beijing and Chengdu next week.

CHAPTER III: EUROPEAN UNION

Change in Policy from European Union to Tackle COVID-19

In order to combat the effects of the COVID-19 outbreak, requests were made by Italy on 19 March 2020, France on 21 March 2020, Germany and Spain on 23 March 2020, Austria, Cyprus, Czechia, Estonia, Greece, Croatia, Lithuania, the Netherlands, Poland, Portugal and Slovenia on 24 March 2020, Belgium, Bulgaria, Denmark, Finland, Hungary, Ireland, Luxembourg, Latvia, Romania, Slovakia and the United Kingdom on 25 March 2020 and Sweden and Malta on 26 March 2020 for relief from import duties and exemption from value added tax ('VAT') on imported goods.

In lieu of the same Commission Decision (EU) 2020/491 of was passed on 3 April 2020 to provide relief from import duties and VAT exemption on importation granted for goods needed to combat the effects of the COVID-19 outbreak during 2020.

Also, Article 22(2) UCC and Article 11 UCC Delegated Regulation (EU) 2015/2446 further oblige the customs authorities to accept such applications for a decision that meets all the requirements. Therefore, customs authorities are not legally

entitled to refuse applications for customs decisions that meet the legal requirements.

For ease in business Article 112(1) and (3) UCC provides that customs authorities may refrain from requiring a guarantee or charging credit interest if it is established on the basis of a documented assessment that this would create serious economic or social difficulties.

The European Commission, which imposed its own restrictions on exports on March 15 2020, did not address the restrictions placed by US on. Its own limits on exports, which require the granting of special permits for any protective equipment or ventilators leaving the bloc, are due to expire in six weeks.

In a phone interview with Bloomberg, the head of the World Trade Organization, Roberto Azevedo, said he was worried that the introduction of restrictions on trade could lead to others. **"If one is in place, others copy,"** he said.

WTO RULES contain a key exception that permits its members to impose discriminatory trade restrictions as long as they are necessary to protect human health. But Azevedo said G20 nations needed to stick to a commitment made last month to keep any such measures **"targeted, proportionate, transparent and temporary."**

In Brazil, Health Minister Luiz Henrique Mandetta last week said that the country's efforts to source its own medical supplies from China have "fallen through" after the U.S. made large orders for the same supplies.

France has placed an Export prohibition on hydroxychloroquine Medicaments, banning the exports. This prohibition is extended towards all the countries irrespectively and was brought into force on 26 March 2020. The prohibition period will be stretched as long as is necessary, until the pandemic is controlled.

Germany has lifted the export bans on medical equipment which were issued earlier this month dated 19 March 2020. This measure was taken to

avoid shortages of masks, goggles and gloves, according to the Ministry of Economy.

Russia has placed an export prohibition and ban the export of masks and personal protective suits to all countries. This measure was taken on 04 April 2020, extending to a period unknown, exclusively dependent upon the situation.

Two top French doctors said on live TV that corona vaccines should be tested on poor Africans, leaving viewers horrified. The comments triggered outrage on social media. A resilient reaction to this comment came by Moroccan lawyers' collective said it was going to sue Mira for racial defamation.

“Africa isn't a testing lab,” retired Ivory Coast soccer star, Didier Drogba, wrote on Twitter. “I would like to vividly denounce those demeaning, false and most of all deeply racist words.”

In a statement on Friday, Mira's employer, the Paris network of hospitals, quoted Mira as saying: “I want to present all my apologies to those who were hurt, shocked and felt insulted by the remarks that I clumsily expressed on LCI this week.

CHAPTER IV: PAKISTAN

Pakistan's Endeavors to Fight COVID-19

Pakistan lifts ban on import of life-saving drugs from India. The Pakistani government permitted the import of life-saving drugs from India, despite the escalation of tensions with the country and closure of all trade and diplomatic channels since August 5, 2019. Pakistani pharmaceutical companies import more than 50 per cent of their raw material from India and China to produce medicines.

The Ministry of Commerce issued the Statutory Regulatory Order (SRO) in this regard to amend the Export Import Order, 2016. The Ministry has released the SRO after approval of the Federal Government.

Pakistan has banned the export of masks to all countries. This restriction was brought to force to

meet the national demands, dated 27 February 2020, after COVID-19 fraught its hold further deep into the country. The expiry date of the ban is yet to be finalized, depending on the situation.

Responding to Afghanistan Government's special request, and based on humanitarian considerations, it has been decided to facilitate movement of cargo trucks and containers to cross-over into Afghanistan through Torkham and Chaman border crossing points thrice a week.

Drug Regulatory Authority of Pakistan

The Drug Regulatory Authority of Pakistan is governed by the Drug Regulatory Authority of Pakistan Act, 2012 (The 2012 Act). The 2012 Act provides the Authority with the power and function to issue guidelines and monitor the enforcement of regulation for pricing and mechanism for fixation of prices of various therapeutic goods.

DRAP also has the power to develop, issue, adopt and enforce the standards and guidelines to ensure safety, efficacy and quality of therapeutic goods with rational use at reasonable price.

The Drugs Act 1976, gives Federal Government the power to fix maximum prices of drugs by notification in the official Gazette. Under The Drug Act, the Federal Government can also delegate any of its functions, including fixation of maximum prices, to any Body or Authority by notification in the Official Gazette.

DRAP sent a letter dated 10 April, 2020 to grant permission to specific manufacturers for the production of Hand Sanitizers.

A technical committee has been constituted by PEC to prepare Fast Track Acceptance Test Procedure for Locally Developed Mechanical Ventilators for COVID-19 Pandemic.

The Drug Regulatory Authority of Pakistan (DRAP) has Started a

Crackdown on Medical Stores Selling Medicines at Exorbitant Rates

According to a statement issued by the Ministry of National Health Services, the Ministry got a complaint that a medicine for blood pressure was being sold for Rs1,200 instead of Rs170.

A joint team of Rawalpindi Drug Control Authority and Anti-Corruption Establishment imposed a fine of Rs10,000 on a medical store for selling substandard hand sanitisers and face masks on artificially inflated prices.

District drug inspectors Naveed Anwar and Jawad Ahsan raided a chemist shop on College Road along with area magistrate and found substandard sanitisers. The samples have been sent to the Drug Control Authority for testing.

After the laboratory report, the magistrate imposed a fine of Rs10,000 on the owner of the medical store and destroyed all the sanitisers. Also, 70,000 face masks have been seized due to quality control issues.

Minister for National Health Services (NHS) Aamer Mehmood Kiani has said that 226 medicines worth tens of millions of rupees, manufactured by 59 companies, have been confiscated by the government over the last few days.

“These companies were selling medicines at prices higher than the maximum retail prices due to which the Drug Regulatory Authority of Pakistan was directed to act against these firms. We will not tolerate price hike as it directly affects poor people,” the minister said while speaking to journalists at the Press Information Department.

Special Assistant to PM on Health, Dr Zafar Mirza said that the prices of essential medicines had been reduced by 15 percent on the special directives of the Prime Minister and vide online complaints, circa 50,000 actions were taken against illegally escalating the prices in markets.

The Drug Regulatory Authority of Pakistan has continued raiding on various medicine supplying companies in different cities and continues to seize their stock for selling drugs at exorbitant rates.

Meanwhile, DRAP has also issued a notification, banning the sale of chloroquine medicines without a prescription. It has also directed that such medicines be sold only by licenced pharmacies and drug stores. The drug stores have been instructed to keep records of all prescriptions as well. DRAP further stated that it has been observed that some people are hoarding the stocks of anti-malarial drug.

The Competition Commission Pakistan (CCP) Warns Pharmaceutical Sector of Anti-Competitive Practices

CCP is mandated under The Competition Act 2010 (The Competition Act 2010) to ensure free competition in all spheres of commercial and economic activity, to enhance efficiency and to protect consumers from anti-competitive practices including prohibited agreements.

CCP while setting aside its Show Cause Notice issued to Pharma Bureau for prima facie cartelization, has warned that the pharmaceutical sector is under its watch and any collusive or anti-competitive activity shall be strictly dealt with. In yet another instance of impartial and unbiased enforcement, the CCP's Bench has set aside the findings of its enquiry in the matter of alleged violation of Section 4 of the Competition Act, by the Pharma Bureau.

Pharma Bureau is an association and representative body of more than 20 multinational pharmaceutical companies. In 2016, CCP issued suo motu notice and conducted an inquiry into allegations published in national dailies that a number of multinational pharmaceutical companies have inflated prices of a range of medicines up to 300% at the behest of the Pharma Bureau.

A Bench of the CCP set aside the findings of its inquiry in the matter of alleged violation of Section 4 of the Competition Act by the pharmaceutical

bureau. This was done as during the hearings the CCP team could not substantiate the allegations.

The Competition Act, acting in capacity if a regulator prohibits the use of certain actions and or omission to manipulate the market which would in turn lead to creating an unfair market for consumers. Such practices include the abuse of dominant position, prohibited agreements, deceptive marketing practices and approvals of mergers/ acquisitions. The point of contention is what practices might tantamount to breach of competition laws and how market leaders in the pharmaceutical sector will head caution before artificially accelerating prices.

National Action Plan for COVID-19 (Pakistan)

- The National action plan has been brought into force specifically to **cater the needs that will come into existence solely due to the pandemic.**
- It will **serve as a policy document for ensuring that all guiding principles for outbreak preparedness, containment and mitigation are followed.**

Price Control and Prevention of Profiteering and Hoarding Act, 1977

This Act has specially been passed to govern the pricing of products. In times like these the Act can prove to be of utmost importance as many companies are still charging exorbitant rates for sub-standardized medicines. Within the scope of the Act is regulation of prices, production, movement, transport, supply, distribution, disposal and sale of the essential commodity and the price to be charged or paid for such products at any stage of transaction.

In case of breach the penalties consist of imprisonment up to three years and monetary compensation of one hundred thousand rupees.

Pakistani Students Invented A Low-Cost Ventilator

- **A team of students has won first prize for inventing a low-cost ventilator which they are hoping to introduce in Pakistan.**
- Their device, **The Umbulizer**, will cost around **\$2,000 (Rs 280,000)** compared to a regular ventilator that usually costs about \$15,000 (Rs 2million). These machines, which help people breathe, are so expensive that countries like Pakistan cannot afford them.

COVID-19: Pakistan Supreme Court Orders the Arrest of Prisoners Released Earlier Due to Coronavirus Spread

- The Supreme Court of Pakistan has ordered the arrest of all the undertrial prisoners who were released last month on the orders of lower courts as part of precautionary measures to combat the spread of COVID-19.
- The apex court overturned the judgement of the lower courts and declared the verdict on their release to be null and void. The decision was announced by a five-member larger bench under Chief Justice of Pakistan, Justice Gulzar Ahmed.

CHAPTER V: IRAN

US sanctions on Iran caused hindrance in Iran's attempt to battle COVID-19 crisis. On March 6 2020, the US Treasury Department's Office of Foreign Assets Control (OFAC) issued guidance that transactions involving Iran's foreign exchange assets held abroad, when used to buy humanitarian items, would not face US sanctions. However, because waivers are no longer available for purchasing Iranian oil and sanctions against Iran's Central Bank, Iran's access to currency to purchase needed medical supplies on the international market has become further restricted.

However, by definition of drugs under US export regulations, some of the equipment which is crucial for fighting the virus, such as decontaminant equipment and full-masks respirators, require special license. The Washington Post reported that the rate of special licenses OFAC issued for export of specific medicine and medical devices to Iran has drastically declined under the Trump administration.

Turkey has delivered medical supplies and medicines to Iran amid the global coronavirus outbreak. Iran has also formed a collaboration with Russia to jointly fight the coronavirus outbreak. The two countries will exchange experiences and conduct consulting to eradicate the disease.

The World Health Organization (WHO) has also delivered a new shipment of emergency medical supplies to the Iran as part of COVID-19 response measures.

CHAPTER VI: INDIA

Exertions From The Indian Pharma Industry

Covid-19: Pharma Companies Ask Govt. to Lift API's Export Restrictions

- Pharmaceutical lobby groups have urged the Indian government to lift restrictions on export of Active Pharmaceutical Ingredients (APIs) and formulations, saying that they have enough stock and there will be no shortage of these formulations in India amid the coronavirus outbreak.

Shipment of hydroxychloroquine to US likely to start next week: IPA

"The shipments of hydroxychloroquine to the US are likely to start next week. Indian pharma companies are committed to meet both, domestic and export commitments".

NEW DELHI: Shipment of anti-malarial drug hydroxychloroquine to the US is likely to start next week, post a threat made by Trump to take

adversarial measure if India continues to hog an essential medicine. Leading pharma industry body has said. Hydroxychloroquine is being touted as a game changer in fight against COVID-19 pandemic.

UK to receive first batch of 3 million paracetamol packets from India by Sunday.

LONDON: The UK will receive a first batch of 3 million paracetamol packets from India by Sunday as it expressed a gratitude to the Indian government for approving this "important shipment" after New Delhi lifted its export ban amid the coronavirus pandemic.

CONCLUSION

In the prevailing times especially for a country like Pakistan, which is still progressing towards self-sufficiency, the pandemic proves to be an opportunity for the people of Pakistan to allow rehabilitation for the economy and civil obedience to prevail. The most contentious industry in Pakistan is the pharmaceutical industry as their actions will either save lives or lead to devastation. In such times of hardship and pain it is important to ensure that companies and the manufacturers do not attempt to take unfair advantage of the pandemic by creating substandard medicines and charge exorbitant rates for the same. Pakistan is a regulated state, having laws for all sectors, with the existence DRAP having express mandate to regulate the price and quality of drugs. Further Pakistan's limitation laws place a very wide limit as to the timings to bring legal action against such accused who have manipulated their system for their own advantage.

Pharmaceutical products can be taken up for testing at any time from any place the authorities deem fit, if the standards do not meet statutory requirements action will be taken against them in according to law.

Furthermore, leniencies are being provided by the State Bank of Pakistan and the Federal Government to ease import and export restrictions so companies may be able to diversify their operations and still turn a reasonable profit in such times. However, all such transactions are governed

and controlled by the Federal Government and if by chance any transaction goes unchecked the government will always maintain the record of such transaction for regulatory oversight.

The most apposite step to take presently is to ensure that the medicines, masks, sanitizers PPEs and all the equipment needed to tackle the pandemic are made available to public at large at regulated rates.

Another germane aspect of the pandemic is to understand how the pandemic will play out in the

future and how governments will create different fish nets to ensure that public interest will eventually prevail and therefore companies must adapt to the system of governance in place and strategically place themselves in a safe and business savvy position. Continuous litigation and or caesuras being made by the government in relation to standard

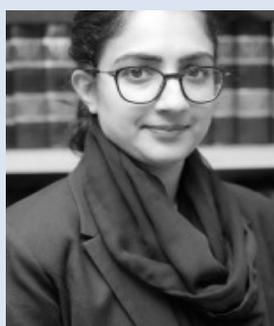
- products will in the long run financially drain the organizations and therefore prudence must prevail in encapsulating regulatory oversight and common business sense

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Please do not hesitate to reach out to us or any of our team members for further clarity.

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Ahmer Bilal Soofi & Co. is a partnership concern registered in Pakistan under the Partnership Act 1932 having its registered office at 9-Fane Road, Lahore, Pakistan.

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