

TIME TO ADAPT

COVID-19

Supply Chain & Procurement disruptions in the Life Sciences sector



IMPACT ASSESSMENT IN PHARMACEUTICAL INDUSTRY

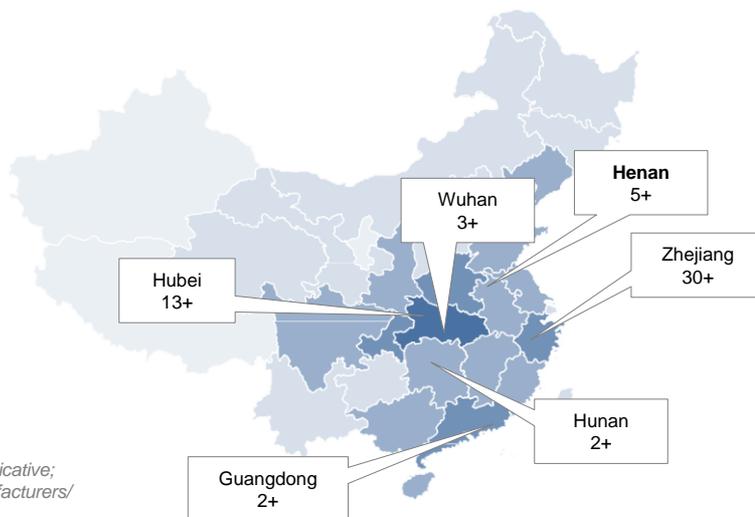
Context

China is the backbone of global pharmaceutical industry and has been adversely impacted due to Coronavirus outbreak

Concentration of Pharma Companies in Affected Regions¹

Confirmed Cases

- Very High
- High
- Medium
- Low



¹ The number of suppliers is indicative; It represents key pharma manufacturers/suppliers in the affected regions

Impact Across Pharmaceutical Space

	Impact of Coronavirus	
	Global	APAC
Home to world's 15% and US' 13% approved sites providing ingredients and services for drug manufacturing		
Accounts for ~97% of US' antibiotics import		
Comprises ~31% of global medical devices market		

LEVEL OF IMPACT Low High

Pharmaceutical companies across the globe are hit by supply chain disruptions

1 Drug, APIs and Supplements

- Chinese companies in major cities - including Beijing, Guangdong and Shanghai – halted operations until 9th February, raising concerns around global supply of APIs, amino acids, vitamins and finished drug products
 - Ibuprofen, Paracetamol, Chloramphenicol, Azithromycin, Vitamin C and Vitamin E are amongst the key impacted APIs and vitamins
 - China accounts for ~40% of global API production; hence, any disruption in supply from China will have a global impact
- Some companies have resumed operations amid heavy scrutiny by the health department; however, they are not operating at full capacity
 - Firms in Shanghai, Shenzhen, Suzhou or Nanjing must provide employees' travel history and continuously track health status of every employee on regular intervals
- Key pharmaceutical activities such as site inspections/certifications and post holiday seasonal maintenance have also been halted
- Further, driven by increasing internal demand, China may divert some of its drug manufacturing capacity towards internal consumption, worsening the overall demand–supply balance of drug/drug ingredients globally
- On 3 March, India restricted the export of 26 APIs and formulations including antibiotics, vitamins and hormones, to ensure the availability of drugs in the domestic market. In addition, on 25 March, India restricted the export of Hydroxychloroquine API and formulation
- In average, API prices have increased 10-15% and up by more than 50% in some cases (ex.: Paracetamol, Montelukast sodium)

These key changes underline a strong risk on stock in Europe whether for finished products or raw material.

2 Pharma packaging

- China accounts for ~10% of the global pharmaceutical packaging market and hence, pharmaceutical companies procuring drug packaging raw materials/products from China will likely be impacted
- Indeed many packaging facilities in Hubei, Zhejiang or Hunan remained closed after the extended lunar new year holiday



3 Specialty Chemicals and Feedstock

- Extension of Chinese Lunar New Year holidays (in light of the disease outbreak) and rising number of affected population (>45 million) has hit manufacturing activity in the country, thereby impacting supply of various raw materials/ commodities used by pharmaceutical industry.
- Manufacturers producing chemicals such as isopropanol (feedstock) announced shutdown for an extended period
- Further, due to an increase in demand of hand sanitizers and other hygiene products, pharmaceutical feedstock such as ethanol are witnessing a surge in demand; this will likely impact the prices of these feedstock in medium term



Supply of raw materials – APIs, amino acids (taurine) and certain vitamins – will be throughout S1 2020

Key Pharmaceutical Products Manufactured in Coronavirus-affected Regions*

- | | | | |
|--------------------------|---------------------------|--------------------------|---|
| • Acarbose | • Coenzyme Q10 | • Lincomycin hcl | • Sodium benzoate |
| • Ambroxol hcl | • Colistin sulfate | • L-Leucine | • Sodium tripolyphosphate |
| • Aminoacids | • Dexamethasone | • L-Tryptophan | • Sorbitan oleate |
| • Amoxicillin trihydrate | • D-Glucosamine sulfate | • L-Tyrosine | • Sulfanilamide |
| • Amprolium hcl | • Dimethyl sulfoxide | • Lutein | • Taurine |
| • Azithromycin | • Dimetridazole | • Marbofloxacin | • Testosterone propionate |
| • Beta-carotene | • DL-Methionine | • Methylparaben sodium | • Thiamphenicol |
| • Beta-methasone | • Enrofloxacin | • Metronidazole | • Vitamin A, AD3, B12, B2, B9, C, D3, E (various forms) |
| • Biotin | • Ethyl vanillin | • N-Acetyl-D-glucosamine | |
| • Calcium butyrate | • Florfenicol | • Norfloxacin | |
| • Calcium pantothenate | • Fosfomycin calcium | • Ofloxacin | |
| • Candestartan cilexetil | • Ibuprofen | • Paracetamol | |
| • Chitosan | • Ketoprofen | • Phosphoric acid | |
| • Chloramphenicol | • L-Arginine | • Polysorbate 80 | |
| • Ciprofloxacin hcl | • L-Citrulline DL-Mallate | • Potassium carbonate | |

*The list is indicative and not exhaustive

Governments remain worried on drug supply and are issuing advisories to domestic pharmaceutical companies

As drug exports are likely to suffer in H1 2020, governments across countries (including the US, the UK, Belgium and Czech Republic) are keenly tracking the Coronavirus data and have issued advisories asking pharmaceutical companies to maintain stocks as supply constraint/high prices may persist for several months

US

The US FDA is expecting a disruption in generic drugs supply, with a possibility of moderate-to-severe drug shortage if the current scenario extends for another 2 months

- On 27 February 2020, US FDA issued a statement that 1 drug (undisclosed) is in short supply due to Coronavirus impact
- On 31 March 2020, New drug shortages were reported including Chloroquine Phosphate Tablets, Hydroxychloroquine Sulfate Tablets, Nizatidine Capsules, Rifapentine Tablets. The shortage has occurred a week after FDA approved the use of Anti-Malarial drugs Chloroquine and Hydroxychloroquine for emergency Coronavirus treatment
- The country is expected to face shortage of antibiotics, such as amoxicillin, doxycycline and penicillin, and other key drugs, as 90% of the core components are sourced from China

However, gene therapies and blood derivatives remain least-impacted categories

UK

The UK government added two long-established medicines to the MHRA's list of products that are prohibited from parallel export until further notice. The export of the AbbVie's Kaletra / Aluvia, a fixed combination of lopinavir and ritonavir, as well as the generic drug chloroquine phosphate and the generic drug hydroxychloroquine are being restricted.

As the Chinese government has directed mask manufacturers to prioritize domestic market, it is expected to cause a drop in supply for the rest of the world including the EU, the UK and the US

EU

The European Union is facing delays in supplies of medicines and medical supplies (such as face masks), due to Coronavirus trade disruptions

Germany, Czech Republic, France and Belgium have also raised concerns over the drug supply

"We are keenly aware of the negative impact on medical products supply chain, including potential disruptions to supply or shortages of critical medical products in the US. It's worth noting that there are no vaccines, gene therapies, or blood derivatives licensed by the FDA that are manufactured in China."

– **Stephen Hahn, FDA Commissioner**

"We have seen that there might be a possibility of drug supply shortage due to the Coronavirus. We know that many active ingredients are made in China, particularly in Hubei province, and are looking into solutions."

– **Jens Spahn, German Health Minister**

Global pharmaceutical companies are turning to alternative routes for procurement over supply chain concerns

RISK MITIGATION STRATEGIES

Critical Inventory Management

Pharmaceutical companies are collecting data to assess their exposure to the Chinese market and are carrying out inventory assessment to ride-out the disruption

Efficient utilization of Existing Resources

Companies are leveraging in-place contingency plans such as utilizing existing distribution centers in low-risk areas for critical products

Driven by the ongoing US–China trade war, pharmaceutical companies must already be partially prepared with contingency plans to minimize any disruptions stemming from the Chinese economy

Capacity Identification Outside China

Companies are also assessing alternative manufacturing sites that can be utilized to cover for lost production

Because any change of API sourcing is subject to regulatory approval (variation in the API dossier) most Health Authorities will be likely to cooperate and accelerate the procedure

Alternative Sourcing Destinations

Pharmaceutical companies are looking to partner with suppliers in alternative destinations, or increase procurement volume from existing suppliers in alternative locations

However, pharmaceutical may face challenges related to supplier availability in new geographies, expected lead times, knowledge transfer, productivity and logistics concerns

Further, it is proving tough to switch to alternative suppliers quickly, as these suppliers must be approved by regulators (such as FDA and EMA)

INDUSTRIES SPEAK

American
pharmaceutical
company

“ We consistently and diligently monitor the supply chain for our medicines; we operate 40 sites and works with over 200 suppliers globally. This provides us with capacity and redundancy as needed and majority of our finished products and APIs come from countries other than China.”

American
pharmaceutical
company

“ We have robust business continuity plans in place to prepare for unforeseen events, which includes “critical inventory” at major distribution centres outside high-risk areas, as well as working with external suppliers.”

British
pharmaceutical
company

“ We are fine in the short term, as we were prepared for these kind of issues but we are alert on the possible long-term concerns.”

Swiss
pharmaceutical
company

“ We have API coming from China, but with existing stock reserves, we have opportunity to source from another location. We have robust plans for dealing with the impact of potential health crisis.”

For US-based companies, the impact of Coronavirus could be cushioned by the existing contingency plans that they may have developed to deal with ongoing trade war issues

While vaccine development phases are accelerating, alternatives like HIV drugs are tested for treatment

- Pharmaceutical companies with potential drugs in Phase 2 will benefit the most, as they are likely to receive fast track regulatory approvals in light of the current scenario, thus reducing the time-to-market; many companies are likely to divert their R&D investments in this direction
- Doctors/researchers are currently relying on HIV and flu antivirals, blood plasma infusions (and IgG IV extracted from patients recovering from infection) and traditional Chinese medicines for treatments; Currently, the World Health Organization has listed ~700 studies, conducted to treat COVID-19
- Pharmaceutical companies are actively researching potential drugs to inhibit Coronavirus, especially in their already commercialized portfolio to accelerate the time-to-market
- Cobra Biologics, is working as part of a consortium led by the Jenner Institute, Oxford University to rapidly develop, scale-up and produce the potential adenoviral vaccine candidate, ChAdOx1 nCov-19 (ChAdOx1), for fast-tracked clinical trials for COVID-19
- A drug discovery platform powered by artificial intelligence (AI) technology has identified 18 potential treatments for COVID-19.
- April 14, 2020 - Sanofi and GSK announce that they have signed a letter of intent to develop an adjuvant vaccine for COVID-19, using innovative technology from both companies, to help address the ongoing pandemic.

DRUGS

PRECLINICAL

Regeneron: Monoclonal antibody research in partnership with HHS

Takeda: Polyclonal antibody therapy

Lilly: Antibody drug

VIR: Monoclonal antibody research being conducted

Hisun: Clinical trial being conducted on Favilavir – first Coronavirus approved drug in China

PHASE I

Ascletic: combination of two antivirals

PHASE II

Gilead: Remdesivir

Abbvie: HIV drugs, Lopinavir and Ritonavir Kaletra already in market

Jonhson&Johnson: HIV protease inhibitor, Prozcobix (darunavir) showing favorable response against Coronavirus

Cipla: generic HIV drug, Lopimune (lopinavir/ritonavir) ready to be deployed

VACCINES

PRECLINICAL

Sanofi: Plaquenil (hydroxychloroquine)

Pfizer: Collaboration with BioNTech to develop mRNA-based vaccines

Jonhson&Johnson: Potential vaccine candidates being developed

Hoth Therapeutics: Self assembling vaccine (VAS)

Arcturus Therapeutics: Covid-19 vaccine

GSK: Adjuvant technology made available to CEPI*

Inovio: Vaccine developed in partnership with Beijing Advaccine

GeoVax: Vaccine being developed in collaboration with BravoVax

Novavax: Vaccine for MERS and SARS virus being developed

Vaxart: Oral vaccine candidate being developed

PHASE I

Moderna: mRNA vaccine funded by CEPI* being developed

CanSinoBIO: Covi-19 vaccine

PHASE II

Vaccitech: ChAdOx1 MERS vaccine used against Covid-19

Coronavirus outbreak: Purchasing Operations are also impacted

In March 2020, the International Federation of Pharmaceutical Manufacturers & Association (IFPMA) and other Biopharmaceutical leaders have made several commitments to fight the Coronavirus outbreak. They identified three main challenges:

- Support and help Governments and health organizations fighting the Coronavirus
- Increase the research and development of diagnosis tests and vaccines
- Secure continuity of supply for essential medicines and for other life-threatening diseases

How does this crisis question the current procurement organizations and strategies in the Pharmaceutical industry?

1 **Securing essential medicines supplies while accelerating research and development for COVID vaccines and tests**

Securing the supply for essential medicines

In reaction to the Coronavirus outbreak, the demand for some essential medicines and medical devices has considerably increased: face masks, hand sanitizers, rubber gloves, basic medicines (such as Paracetamol), etc.

The Pharmaceutical companies must adapt to meet these needs by increasing purchases and production.

- For example, the French pharmaceutical company Sanofi (producer of Doliprane®), has increased its production by 50%.
- Likewise, the Swiss company Novartis has also adapted its production line (Sandoz subsidiary for generics) to be able to better meet the increasing demand.

In addition to the increasing demand, some existing drugs are proposed as potential alternative treatments, and therefore require more production. For now, Hydroxychloroquine, HIV drug Kaletra (produced by AbbVie) and HIV protease inhibitor Prozacobix (produced by J&J) have shown encouraging results against Coronavirus.

Meanwhile, Pharmaceutical companies must ensure supplies for other life-threatening diseases and take measures to keep the production going for the most critical products. Some production sites are kept opened (e.g. for the two French Novartis sites mainly producing biotechnology and gene therapy products) and more resources are put on the whole value chain (antibiotics, corticosteroids, long term treatment medicines...highlighted by Sanofi)

But to support and enable the increase in production, the Pharmaceutical procurement departments must above all secure the raw materials supply, especially for the 'active substances' (molecule having the therapeutic effect). This is easier for the Pharmaceutical companies having internal production strategies (e.g. for Sanofi only buying ~10% of its 'active substances' in Asia). But for the others, new strategies and solutions must be urgently found to secure the raw materials supply. Notably, Pharmaceutical companies closely work with Governments and public organizations to go through customs first.

Accelerating R&D in the fight against Coronavirus

Over the past few weeks, Pharmaceutical companies have made important direction changes in their R&D strategies. R&D spends have switched towards COVID-19's vaccines, treatments and diagnostics' developments have been made as well as new collaborations and partnerships with other industries and academic organizations. Among many collaborations, the British actor GlaxoSmithKline (GSK) works with The University of Queensland (Australia) and the US leader Pfizer has recently partnered with BioNTech (German company) to develop a vaccine candidate against COVID-19 infection.

Pharmaceutical companies and their procurement teams have adapted their processes with the authorities to be more flexible and to set up fast-track regulatory approvals. For example, the FDA (US Food and Drug Administration) approved the Coronavirus test from the Swiss Pharmaceutical company Roche in only 24 hours, instead of several months usually.

2 Work closely with strategic and critical suppliers

Implement actions plans with strategic and critical suppliers

To secure the supply, close and strong relationships with suppliers are more than ever crucial for Pharmaceutical procurement functions in this time. It is essential to identify the most strategic, but also the most critical suppliers, to establish new collaborative strategies and to avoid any risk of supply shortage.

For essential medicines, medical devices and supplies for other life-threatening diseases, procurement departments must adapt their strategies and focus on products' components 'at risks' to make sure every action is considered to maintain the production. Depending on the situation, appropriate decisions must be taken by buyers such as:

- Multi-sourcing
- Cash payment and shorter payment terms to support suppliers' increased activities
- Suppliers' involvement in inventory planning
- Suppliers' involvement in demand forecasting to help buyers order the correct quantity, avoiding supply shortage and high storage costs.

Prepare the post-crisis phase by evaluating suppliers' recovery capabilities

Despite emergency needs and the current challenges the Coronavirus outbreak brings to the procurement departments, buyers also need to think beyond and anticipate the post crisis phase and the impacts on their suppliers.

Buyers will specifically have to:

- Identify the most important criteria to evaluate the suppliers' capacity to recover (size, core business, financial health, production disruption ...)
- Share auto evaluation grids with the suppliers to assess their situation depending on their criticality level
- Identify the different levers (optimization, resources, structure...) to help suppliers recover
- Set up strategies to manage various suppliers' situations (depending on the geographical zone, suppliers' size...)

3 Review China and USA dependency rate and sourcing strategies

Think about China and USA dependency rate

Like every crisis, some lessons will be learned by the companies. The sudden activity and production's stops in China has more than ever proved how dependent some Pharmaceutical companies can be from this area. In the Pharmaceutical sector, almost 80% of the 'active substances' are produced in the USA and in China and China accounts for almost 80% share of the PPE (Personal Protective Equipment) market supply.

Facing this, buyers need to think about new ways to be less dependent and consider self-oriented strategies to be more resilient in the event of another crisis (sanitary, financial...)

In this perspective and to reduce its dependency rate from Asian suppliers, Sanofi has recently announced the gathering of a commercial division and six European plants (including two in France) into an independent entity for the production of pharmaceutical ingredients.

Review sourcing strategies towards more local suppliers

Over the past few years, the sourcing tendency has mainly preached internationalization and diversification of the suppliers portfolio, especially in low cost countries.

However, this tendency might be highly questioned and procurement functions will certainly review their sourcing strategies towards more local and closer suppliers.

Would "*deglobalize*" be the main procurement strategy output of the Covid-19 outbreak ?

This would certainly help Pharmaceutical companies to better manage and control their supply risks with exotic suppliers, to reduce their environmental impact and to boost the European industrialization. Some Pharmaceutical procurement departments have already initiated this reorganization but the creation of a local vendor base takes time. The hardest task for buyers will be to adapt their sourcing strategies while maintaining competitive costs.

Are companies prepared to weather the storm?

Key questions to consider

- Do you have risk management strategies/contingency plan for business continuity?
Are you aware of the key categories in your supply chain/procurement which can get impacted?
- Are your suppliers/manufacturing units outside China capable of scaling up to compensate for the affected suppliers?
- Do you have critical inventory for key products in low-risk areas?
- Do you have supply chain visibility to ensure timely solutions for any disruptions
- As commodity prices (including oil) trend lower, are you prepared to leverage this opportunity for cost savings?
- China may witness a labor pool shortage in the short-term, is there a plan B?
- Are you keeping track of the relevant developments proactively?
- Have you discussed possible concerns and mitigation strategies with your suppliers?
- Which alternative sourcing destinations and potential suppliers can be considered to diversify the supplier base (outside China)?

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