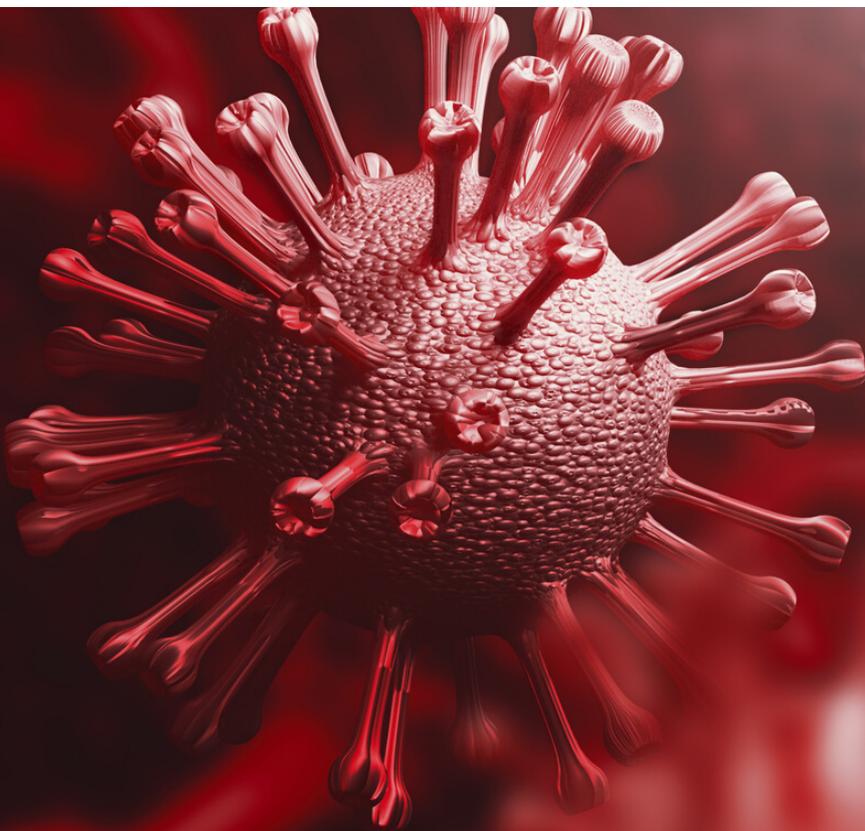


April, 2020

**Pandemic Legal intelligence**  
IMPACT OF COVID-19 ON PHARMA SECTOR

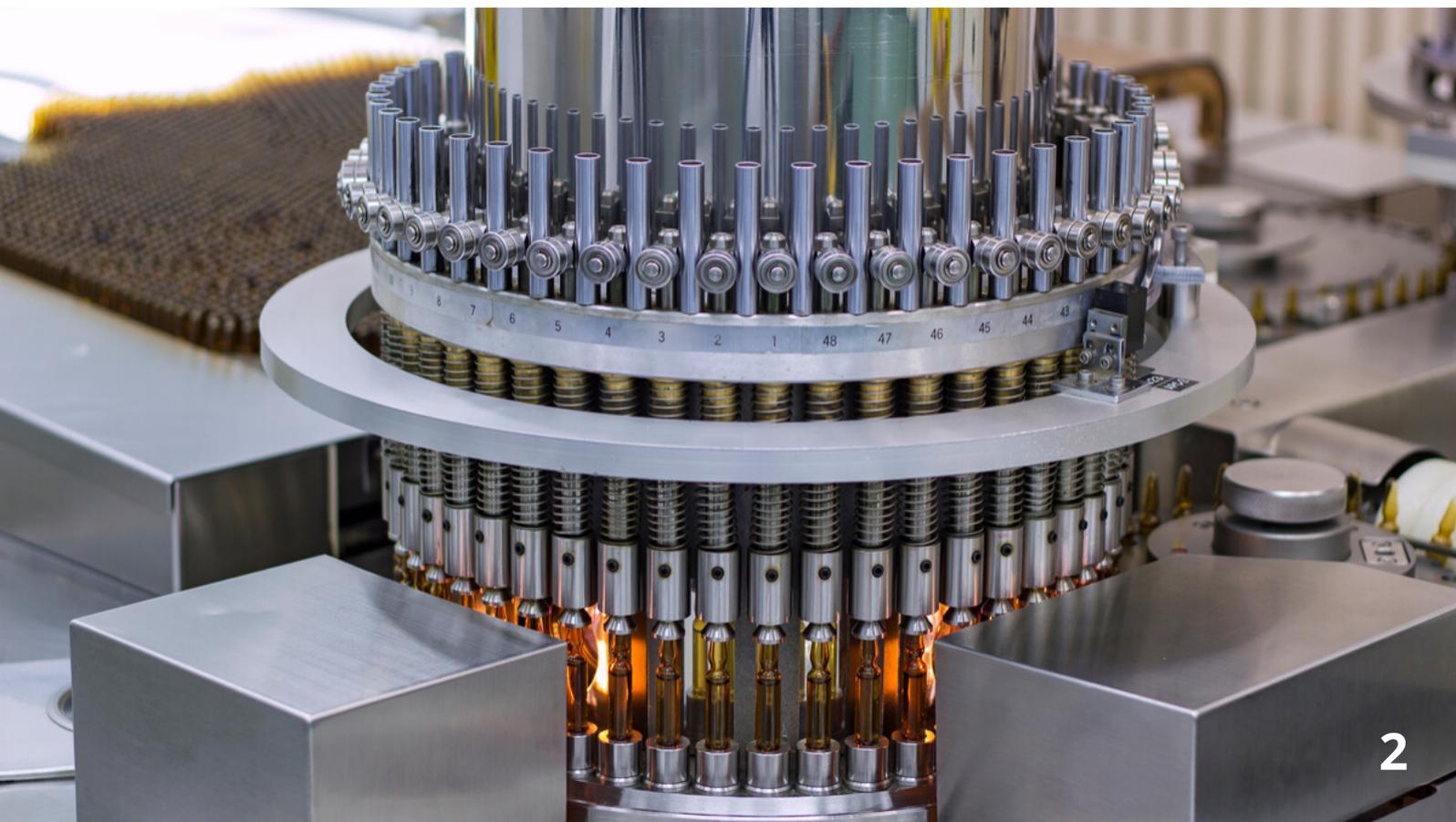


**Legal intelligence Series - COVID | VIII**

AHMEDABAD | BENGALURU | NEW DELHI | KOLKATA | MUMBAI

Pharmaceuticals have always been a huge component of India's ever-growing trade expansion strategy, especially since the country has already stated its goal of diversification of exports both in terms of the products that are being exported and the countries to which they are exported.

India is a leading exporter of generic drugs across the world and as demand expands across the globe, Indian pharmaceutical industry aspires to become the world's largest supplier of drugs by 2030.



India aims to increase its Pharmaceutical industry revenue to \$120 billion-\$130 billion by 2030 from the current revenue of \$38 billion at a compound annual growth rate (CAGR) of 11-12%.

The current pandemic has not only created a havoc in the country as a whole, it has also put the entire Pharmaceutical industry in a dilemma and right now, it is difficult to decide whether it is boon or bane for the industry.

However, such an unprecedented situation also brings certain genuine queries in the minds of the companies which we have tried to answer below:



## Supply of Pharma Products

### 1. How will the current pandemic situation affect the continuity of supply of medicines from Pharmaceutical in Industry?

Answer: COVID-19 is a very dynamic situation. We believe there would be indirect effects on the continuity of supply of medicines due to lockouts, manpower supply, raw materials supply issue, stoppage of transportation, etc.

The Government, however, has done its best in ensuring that pharmaceutical manufacturers do not face any shortage of supply of raw material or labour or any other directly or indirectly related service. This is to ensure that all types of medicines are always available in the market.

The Letter bearing No. F. No. 21(2856)/Div. IV/2020/NPPA dated 26.03.2020 issued by the National Pharmaceutical Pricing Authority (NPPA), a wing of the Government of India under the Department of Pharmaceuticals has also given instructions for unobstructed movement of pharmaceutical goods in light of the Ministry of Home Affairs order of even no. 40-3/2020-DM-I(A) dated 24.03.2020 and 25.03.2020.



## 2. Whether the Pharmaceutical Industry has to revisit their Supply Chain Model?

Answer: Different areas around the country are facing different issues and subject to the terms & conditions of the transactions with the suppliers and the purchasers as well as the internal policies of the company, there can always be a possibility of legal consequences in the future.

Issues can crop up due to various hindrances and invite a wrath under Insolvency & Bankruptcy Code 2016, Indian Contract Act 1872, Specific Relief Act 1963, etc. where one party may create legal issues due to disruption of the supply chain and ultimate loss faced. These implications could lead to claims worth multi-million rupees both domestically as well as internationally.

Therefore, it is better to take an expert's opinion to understand the legal implications that can arise.



## Masks and Sanitizers

### 3. Under which notification masks and sanitizers have been included in the Essential Commodities Act, 1955?

Answer: The Ministry of Consumer Affairs, Food and Public Distribution vide notification no. F. No. 26(1)/2020-ECR&E, dated 13.03.2020 has included masks and sanitizers under the Essential Commodities Act, 1955 at Sr. no. 8 in the Schedule.

### 4. Whether there would be any new tax implications on pharmaceutical industries owing to the inclusion of Masks and Sanitizers as essential commodities under the Essential Commodities Act, 1955?

Answer: As of now there are no specific notifications from the Central Board of Indirect Taxes and Customs (CBIC) regarding the change in rates of tax or any other exemption or levy of tax on masks and sanitizers. It seems there would be no new tax implications but still it is advisable to take expert opinion to avoid unnecessary tax related litigations.



## **Import of Active Pharmaceutical Ingredients (APIs)**

**5. Whether there would be any impact on Indian Pharmaceutical Companies as far as the import of drugs and medicines is concerned since China is the world's largest exporter of Active Pharmaceutical Ingredients (APIs) and intermediates and approximately 70 per cent of India's total API requirement is met by imports from China?**

**Answer:** In case the supply disruption continues over the next three to nine months, the pressures on credit buffers could intensify and rating transitions would be imminent, especially in case of the entities rated 'INDIA' and below, India Ratings and Research (Ind-Ra).

Till date there is no direct notification or circular which has been issued by the government regarding the import of APIs from China.



## Export of Active Pharmaceutical Ingredients (APIs) and Drugs

**6. Whether there are any notifications concerning restrictions on export of Active Pharmaceutical Ingredients (APIs) and formulations by Government of India?**

**Answer:** The Directorate General of Foreign Trade (DGFT) vide notification no. 02/2015-2020 dated **06.04.2020**, has amended notification no. 50/2015-2020 dated 03.03.2020 and has made "free for export" certain API's like antibiotics, hormones and vitamins, amongst others medicines.

### **Exception:**

As per Policy Circular no. 33/2015-20 dated 20.03.2020, an exception has been created for the export of APIs and formulation made by these APIs to be allowed from SEZ Units.

Similarly vide Policy Circular no. 34/2015-20 dated 20.03.2020, exports of all formulations as mentioned in Notification no. 50/2015-20 dated 03.03.2020 shall be allowed under Advance Licenses issued on or before 03.03.2020. However, no enhancement of quantity is permitted for import or export in these Advance Licenses.



## List of APIs allowed to be exported

<b>Sr. no.</b>	<b>ITC HS Code</b>	<b>Description</b>
146B	29332910	Tinidazole
146C	29332920	Metronidazole
146D	29335990	Acyclovir
146E	29362210	Vitamin B1
146F	29362500	Vitamin B6
146G	29362610	Vitamin B12
146H	29372300	Progesterone
146I	29414000	Chloramphenicol
146J	29415000	Erythromycin Salts
146K	29419050	Neomycin
146L	29419090	Clindamycin Salts
146M	29420090	Ornidazole
156A	30042050	Formulations made of Chloramphenicol
156B	30042061	Formulations made of Erythromycin Salts
156C	30042095	Formulations made of Clindamycin Salts
156D	30043919	Formulations made of Progesterone
156E	30045032	Formulations made of Vitamin B1
156F	30045034	Formulations made of Vitamin B12
156G	30045039	Formulations made of Vitamin B6
156H	30049015	Formulations made of Neomycin
156I	30049021	Formulations made of Ornidazole
156J	30049022	Formulations made of Metronidazole
156K	30049023	Formulations made of Tinidazole
156L	30049099	Formulations made of Acyclovir



## Prohibition on Export of Hydroxychloroquine

7. Whether there is any notification issued by the Government of India to ban the export of key malaria drug amidst the COVID-19 outbreak? If yes, what will be the legal consequences of such notifications?

Answer: As per the notification no 54/2015-2020 dated 25.03.2020 issued by the Directorate General of Foreign Trade (DGFT) the export of key malaria drug Hydroxychloroquine was prohibited albeit with a few exceptions and conditions.

However, the DGFT vide **Notification no. 01/2015-2020 dated 04.04.2020** has amended its earlier notification and has now **completely prohibited the export of Hydroxychloroquine or its formulations, without any exceptions.**

To understand the legal implications on different stakeholders, please get in touch with legal experts.



## Medical Devices

### 8. Whether medical devices would be considered drugs?

Answer: Yes, the National Pharmaceutical Pricing Authority under the Ministry of Chemicals & Fertilizers vide its order dated 31.03.2020 has notified Medical Devices intended for use in human beings or animals **with effect from 01st April, 2020.**

All medical devices shall accordingly be governed under the provisions of the Drug (Price Control) Order, 2013.



## Prohibition on Export of Surgical/Disposable Masks

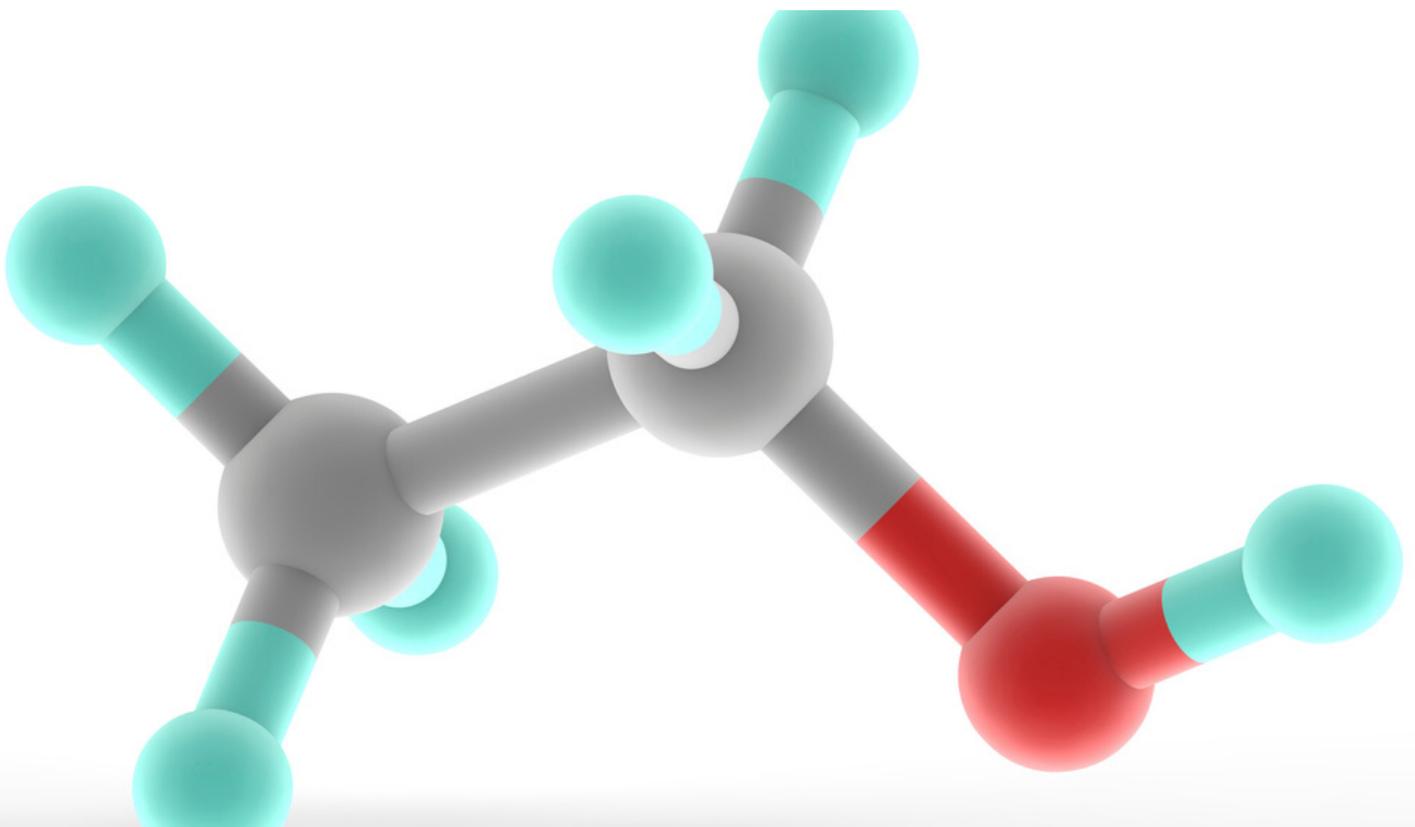
### 9. What are the current notifications under COVID-19 in regard to export of masks and other drugs?

Answer: The Government of India, vide notification no. 52/2015-2020 dated 19.03.2020, has prohibited the export of all surgical/disposable masks and textile raw material used for making masks.

## Force Majeure Clause in Contracts

### 10. Should Pharmaceutical Industries relook the Force Majeure clause in their supply contracts?

Answer: It is advisable to revisit all the on-going contracts especially with respect to the Force Majeure clause as any loophole may lead to litigation in the future concerning the supply or payment criteria.



**The Force Majeure clause should be reviewed in terms of the following questions:**

- Who can invoke it?
- When can it be invoked?
- What are the exceptions to it?
- What is the procedure to invoke it?
- How can a party safeguard itself from the undesirable outcomes of Force Majeure?
- What is the limitation period to invoke it?
- Whether, under the light of the Office Memorandum of the Ministry of Finance, it is only applicable to public contracts or to private contracts as well?
- What recourse does a party have if the contract does not contain any force majeure clause?
- Whether a settlement agreement can be halted by taking the defence of Force Majeure?

**It is important to answer all such questions before deciding to pave your way ahead in Force Majeure.**



## Miscellaneous Questions

### 11. Should Pharmaceutical Industries revisit their Disaster recovery planning in case of prolonged disruptions?

Answer: It is advisable for the Pharmaceutical Industries to revisit their Disaster recovery planning in light of their supply chain, APIs products, production of medicines, etc. and also to restructure the clause if required. An expert's advise should be always suggested to anticipate these aspects and unforeseen situations.

### 12. Whether there are any regulations with regards to ceiling prices of pharmaceutical products and/or permissible increase in process of scheduled / non-scheduled formulations?

Answer: As per the Drug Price Control Order, 2013, specific provisions are mentioned towards compliance of ceiling of prices of pharmaceutical products. It restricts increase in price of products and also contains the provisions for sanctions against the perpetrator in case of violation of the provisions.



### **13. How to get regulatory approval to manufacture COVID-19 testing kit?**

Answer: The Director General of the Indian Council of Medical Research, New Delhi had invited quotations for procurement of FDA / CE-IVD / ICMR-NIV Pune approved Antibody Kit (Serological Test) for diagnosis of COVID-19. Any Manufacturer with Indian based supplier could have submitted the quotations through email by 2:30 pm on 26.03.2020.

### **14. Whether there is any notification by Ministry of Home Affairs exempting Veterinary hospitals, Pharmacies and Research labs from lockdown?**

Answer: The Government vide order no. 40-3/2020-D, dated 24.03.2020 issued by the Ministry of Home Affairs had excluded Veterinary hospitals, Pharmacies and Research labs from the lock down and also exempted it from the Disaster Management Act, 2005.

### **15. Whether pharmaceutical Industries can appoint any institute or dealers for the supply of masks and sanitizers or they would be required to take any mandatory licenses first?**

Answer: Currently, there is no specific bar on the pharmaceutical industries for procuring masks and sanitizers. They can hire any entity which has been authorized and allowed by the Government for manufacture of masks and sanitizers even from the pre COVID-19 era.



## ABOUT US

AMLEGALS is a multi-specialised law firm. We would love to hear your views, queries, feedback and comments on [covid19@amlegals.com](mailto:covid19@amlegals.com) or [rohit.lalwani@amlegals.com](mailto:rohit.lalwani@amlegals.com).

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