

**GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS**

LOK SABHA
UNSTARRED QUESTION NO. 392
TO BE ANSWERED ON 15th September, 2020

Role of NPPA for Drug Availability

**392. SHRI IVINOD KUMAR SONKAR:
SHRIMATI SANGEETA KUMARI SINGH DEO:
DR. JAYANTA KUMAR ROY:
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DR. SUKANTA MAJUMDAR:**

Will the Minister of **CHEMICALS AND FERTILIZERS** be pleased to state:

- (a) whether the National Pharmaceutical Pricing Authority (NPPA) has played a crucial role in ensuring the availability of essential drugs at reasonable prices during the COVID 19 pandemic;
- (b) if so, the details thereof, State-wise including West Bengal;
- (c) whether the NPPA has set up a Control Room to prevent any shortage of medicines during COVID-19 pandemic and resolve public grievances;
- (d) if so, the details thereof;
- (e) whether the NPPA has supplied critical medicines from India during the pandemic to over 120 countries and if so, the details thereof; and
- (f) the details of other steps being taken by the Chemical and Fertilizer Ministry during the COVID 19 pandemic?

ANSWER

MINISTER IN THE MINISTRY OF CHEMICALS & FERTILIZERS

(SHRI D. V. SADANANDA GOWDA)

(a) & (b): Yes Sir. The National Pharmaceutical Pricing Authority (NPPA) played a crucial role in ensuring the availability of essential drugs at reasonable prices during the COVID-19 pandemic. The situation arising due to COVID-19 has been closely monitored by the NPPA. Timely and effective steps were taken to ensure no shortage of drugs during the lockdown period throughout the country. To ensure seamless availability of drugs, the NPPA set up a 'Control Room' with Helpline No. 1800111255 and issues like non-availability of medicines, masks, gloves, hand sanitizers etc., and price violation of medicines, masks, gloves, hand sanitizers, etc., were resolved promptly. Also, a COVID-19 dashboard on the NPPA's website (www.nppaindia.nic.in) having latest office orders, circulars, helpline no., Email for sending grievances etc., was created for convenience of public and other stakeholders.

An Inter-ministerial Empowered Committee was constituted vide order dated 26.03.2020 to make recommendations for export of drugs/items requested by foreign

Governments. This committee also monitors the availability and supply of COVID-19 treatment drugs. The NPPA worked as a Secretariat to this Inter-ministerial empowered committee.

The NPPA has ensured the availability of drugs by coordinating with State Health Authorities like SDCs and Central Govt. Authorities like the Central Drugs Standard Control Organisation (CDSCO), Director General of Health Services (DGHS), Department for Promotion of Industry and Internal Trade (DPIIT) etc. The NPPA collected the critical information from drug manufacturers used in decision making to ensure drug availability.

The NPPA has taken steps to ensure the availability of Heparin used in COVID treatment. Further, on intervention in the issue of price-parity of N-95 Masks by the NPPA, major manufacturers/importers of N-95 Masks have reduced their prices significantly up to 67%.

The NPPA also coordinated issues related to production of raw material, medicines, medical devices, packaging material, etc. by manufacturers and movement of raw material, packing material, finished goods and manpower etc. to availability of life saving essential drugs during the lockdown.

The NPPA has taken various steps to ensure the availability of life saving essential drugs like Hydroxychloroquine, Paracetamol, Vaccines, Anti-Tuberculosis drugs, Anti-diabetic drugs, cardiac drugs, imported Anti-epileptic drugs and COVID-19 drugs like FDC Lopinovir & Ritonavir, Remdesivir, Favipiravir, Zinc Sulphate, Methylprednisolone, Enoxparin, Dexamethasone etc.

Further, on the intervention of the NPPA and the Drugs Controller General of India, DCG(I), manufacturers of Remdesivir have created a Helpline to make available the remdesivir. However, both these drugs are not part of Covid-19 Protocol and continue as under investigational therapy Drugs. The details of various steps taken by the NPPA are at Annexure 1.

The state-wise details of steps taken is not available, however in respect of West Bengal, the NPPA received 34 number of calls on its control room which were resolved promptly.

(c) & (d): The NPPA has set up a Control Room to prevent any shortage of medicines during COVID-19 pandemic and resolve public grievances. The details of the Control Room are at Annexure 2.

(e): Based on information received from the Directorate General of Foreign Trade (DGFT) till 09.06.2020 (Till Hydroxychloroquine and Paracetamol were under export restriction), exemptions were granted to export Hydroxychloroquine to 114 Countries and to export Paracetamol to 24 countries. Details are as following:-

S.No.	Drug	API
1	Hydroxychloroquine	44,783.34 Kgs (44.79 MT), 39,72,10,290 Tablets
2.	Paracetamol	269.9 MT, 9,63,43,534(96.34 Million) Tablets, 4 Lakh Units (Suspension IP), 7,69,000 Bottles (100 ml each)

Details received from DGFT are at Annexure 3.

(f): The details of other steps taken by the Department of Pharmaceuticals/Ministry of Chemicals and Fertilizers during the COVID-19 pandemic are at Annexure 4.

MEASURES TAKEN FOR ENSURING AVAILABILITY OF DRUGS

1. The NPPA vide D.O. letter dated 20th Feb, 2020 requested all Chief Secretaries of States/UTs to closely monitor the production and availability of Active Pharmaceutical Ingredients (APIs) and their formulations, and to take necessary action under the provisions of the Drugs (Prices Control) Order, 2013 (DPCO, 2013) to ensure availability of life saving essential drugs to the consumers at all times.
2. In order to address the issues related to availability and pricing of critical Medical Devices such as Masks, Sanitizers and Gloves to deal effectively with COVID-19 situation, the NPPA, vide letter dated 13th March 2020, requested MoHFW to prepone the effective date of consideration of Medical Devices as Drugs.
3. The NPPA, vide order dated 13th March, in exercise of powers under clause (l) of sub section (2) of section 10 of the Disaster Management Act directed all States/UTs and concerned State Authorities to take necessary steps to ensure sufficient availability of surgical and protective masks, hand sanitizers and gloves at prices not exceeding MRP printed on pack sizes. Ministry of Consumer Affairs had issued order dated 13th March 2020 to regulate the production, quality, distribution, logistics of masks and hand sanitizers.
4. In an effort of continuous monitoring, a letter dated 18th March, 2020 was also issued to all State Drug Controllers (SDCs) directing them to take immediate action through field officers to restrain acts of hoarding of surgical and protective masks, hand sanitizers and gloves and profiteering by manufacturers, distributors, stockists and retailers of these items as well as to ensure availability and distribution of these items at prices not exceeding MRP.
5. In its effort to maintain seamless availability of critical drugs and Medical Devices related to COVID-19, NPPA vide letter dated 19th March, requested Secretary (Textile) to put temporary export restrictions on critical inputs (PP MELTBLOWN Non Woven Fabric, the Nosewire and Loop Elastic non latex) for Masks. Further, at the intervention by NPPA, DCGI vide Order dated 19th March directed all Port Offices of CDSCO to take proactive measures for clearance of imported stock of gloves in coordination with Customs in expedited manner in public interest.
6. The issue regarding availability of N-95 Masks and PPE kits is entrusted to Empowered Group 3 and the issues of 2 ply/3 ply Masks and Hand Sanitizers is being monitored by Ministry of Consumer Affairs and Department of Food respectively. The NPPA undertook database creation in respect of N95 Masks, PPE kits, 2 ply/3 ply Masks and Hand Sanitizers and shared it with concerned Authorities for effective monitoring.
7. The NPPA made efforts to collect information regarding Domestic Manufacturers of Masks, Gloves, Hand Sanitizers, PPE Kits and Ventilators in the Country. In this

regard, various meetings were held at NPPA as well as through Video conferencing with the stakeholders including industry associations. The compiled information was placed on NPPA's website & also disseminated to MoHFW and all States/UTs to assist in procurement of these devices required for treatment of COVID-19.

MEASURES TAKEN FOR ENSURING AFFORDABILITY OF N-95 MASKS

1. In order to ensure availability of N-95 mask at affordable prices in the Country, NPPA vide O.M dated 21.05.2020, directed Manufacturers/ Importers/Suppliers of N95 Mask to maintain parity in prices for non-government procurements and to make available the same at reasonable prices and any violation of the same would invite action under Essential Commodities Act, 1955.
2. After issuing such an Advisory, major manufacturers/importers of N-95 Masks have reduced their prices significantly up to 67%. Further, a Press Release in this regard was released on 25.05.2020 for dissemination of information to the general public.

MEASURES FOR LOGISTIC MANGEMENT FOR AVAILABILTY OF DRUGS

1. NPPA associated with Empowered Group 5 headed by Secretary, Department of Drinking Water and Sanitation, regarding 'Facilitating supply chain & Logistics Management for availability of necessary items such as Food & Medicines' to flag the logistics issues of Pharmaceutical Industry to ensure the seamless availability of drugs across the Country.
2. In lockdown period the Pharmaceutical sector faced serious challenges relating to logistics of raw materials and manpower. In this regard, NPPA took many initiatives in management of logistic disruption faced by the Pharmaceutical Industry which led to increased availability of Medicines and Medical Devices across the Country.
3. The NPPA took measures for availability of Drugs for COVID-19 and other Essential Drugs including HCQ, Paracetamol, Vaccines, TB, Insulin and other cardiac drugs. NPPA is also dealing with issues related to sub-optimal production, logistics, MIS, shortages and exports.
4. The shortage of imported Anti-epileptic drugs (particularly Sabril 500) was reported by MoHFW and some NGO groups. NPPA immediately took necessary action and the issue was addressed promptly. Similarly, the issue of availability of imported drug Acterna of COVID-19 treatment, was facilitated through discussion with Cipla, the importer.
5. NPPA vide D.O. letter No. 37001/2020/Div.-III/NPPA/Part dated 25th April, 2020 to Administrator, Daman & Diu and Chief Secretary Maharashtra, requested to take immediate necessary action in respect of resolution of bottlenecks to mitigate the risk of shortage of Anti-TB medicines in the country.

6. Further, based on communication dated 21st April, 2020 from Joint Secretary (RCH) referring to the letter dated 14th April 2020 of the Secretary (Health), requesting to address transportation issues due to nationwide lockdown to ensure seamless availability of vaccines required to successfully conduct Universal Immunization Programme (UIP), NPPA, vide letter dated 21st April, 2020, requested Ministry of Civil Aviation, GoI to take immediate steps regarding airlifting of necessary supplies of vaccines, at the earliest, as it is critical for the smooth operation of UIP.

7. The grievances received at micro and macro level from individuals as well as from Associations/ Industry and Institutions/ Departments were taken care of to address all issues. During the lockdown, complaints were received regarding non access to critical medicines. These were got home delivered through coordination with SDCs.

8. On 26th March, 2020, NPPA requested all States/UTs to ensure unobstructed movement of Raw material, packing material, finished products and manpower related to manufacturing and distribution of drugs and medical devices.

CREATION OF DASHBOARD FOR COVID-19

NPPA created a COVID-19 dashboard on its website having latest Office orders, circulars, helpline no., Email for sending grievances etc. for convenience of public and other stakeholders. Link: <http://www.nppaindia.nic.in/en/whats-new-about-coronavirus/>.

CREATION OF COVID AND COVID PLUS DRUGS DATABASE

NPPA in coordination with DCGI developed a comprehensive database for COVID & COVID plus (55+97) drugs as a measure of preventive preparedness for fighting COVID-19. This will be immensely useful in current scenario as well as future needs of the organization. DCGI has been directed to create a state-wise mechanism to obtain timely alerts (ring the bell) in case of shortages to take remedial action.

MEASURES TAKEN TO ENSURE AVAILABILITY OF MEDICAL OXYGEN

NPPA also coordinated the issue of availability of Medical Oxygen. The Empowered Group of Secretaries Group-3 (EGoS-3) considered the representation of All India Industrial Gas Manufacturers Association (AIIGMA) regarding cost impact of production of medical oxygen by the major manufacturers on 27th May, 2020. The Tariff Commission was asked to examine the claim.

The NPPA coordinated the supply of data for medical oxygen from companies to Tariff Commission and ensured that examination of claim is done timely. In its report, Tariff Commission has mentioned that the claim of AIIGMA relies mainly on venting of various gases on account of production of oxygen and increase in electricity consumption cost. However both grounds are prima facie not substantiated based on data provided by AIIGMA / manufactures and reject the price increase claim.

MEASURES TAKEN TO ENSURE AVAILABILITY OF DRUGS PLACED UNDER EXPORT RESTRICTIONS

1. Paracetamol and Hydroxychloroquine along with other drugs were put under export prohibition to ensure drug security in the country. NPPA made all out efforts to collect data regarding manufacturing capacity, domestic requirement, current stock, procurement orders of APIs/KSMs/Intermediates in respect these drugs placed under export restriction.
2. Based on detailed examination of the stock position, manufacturing capacity and domestic requirement of Paracetamol, DoP/NPPA vide letter dated 15th May, 2020 recommended to DGFT for lifting of ban on export of Paracetamol API with the condition for major manufacturers to maintain supply of equivalent quantity in the domestic market. The NPPA is regularly monitoring the details regarding manufacturing, stock position and supplies of Paracetamol API made to domestic market by major manufacturers.
3. The NPPA, vide dated 11.06.2020, recommended to DGFT for lifting of ban on export of Hydroxychloroquine API and formulations with the condition for major manufacturers to maintain sufficient availability in the domestic market.
4. The NPPA is regularly monitoring the details regarding manufacturing, stock position and supplies of Hydroxychloroquine made to various authorities/ agencies by major manufacturers.

MONITORING THROUGH SURVEY

The availability of key medicines is also monitored through chemist level surveys conducted by the CDSCO, AIOCD surveys and Pharmatrac reports.

MEASURES TAKEN TO ENSURE AVAILABILITY OF OTHER COVID-19 DRUGS

1. As and when any drug (e.g. FDC Lopinovir & Ritonavir, Remdesivir, Favipiravir, Zinc Sulphate, Methylprednisolone, Enoxparin, Dexamethasone etc) comes under consideration for treatment protocol of COVID-19, NPPA pro-actively initiated task of collection of information to assess availability situation in the Country.
2. NPPA, on receiving of estimated quantity required from MoHFW, vide letter dated 03.07.2020 and 16.07.2020 directed Major manufacturers of Methylprednisolone, Enoxparin, Dexamethasone to ensure sufficient production and availability of these drugs across the country.

MEASURES TAKEN TO COORDINATE WITH SDCs

NPPA conducts regular meeting through VC with SDCs and Drug Manufacturers to monitor the availability of drugs and takes appropriate action. NPPA also coordinates with SDCs through a WhatsApp group created for this purpose.

MEASURES TAKEN TO ENSURE AVAILABILITY OF HEPARIN:

NPPA received representations from several manufacturers for upward revision of ceiling prices of Heparin Injection 5000IU/ ml which has been considered as an essential COVID plus medicine by Ministry of Health & Family Welfare. To ensure the availability, NPPA increased the ceiling price of Heparin for a period of six months.

MEASURES TAKEN TO STOP PRICE RISE OF DRUGS

1. National Pharmaceutical Pricing Authority (NPPA) issued necessary instructions to DCGI, States/ UTs to ensure adequate supply of APIs and formulations including surgical and protective masks, hand sanitizers and gloves at affordable prices in the market and to prevent black marketing and hoarding which could create artificial shortages in the country.
2. The NPPA took cognizance of reports of **black marketing** of Remdesivir and Tocilizumab and directed the DCGI to issue necessary instruction to SDCs to take appropriate action in this respect.
3. Several requests from State Governments, NGOs and general public were received regarding fixation of prices for N-95 masks as the same were available in the market at exorbitant and differential prices. In order to ensure availability of N-95 mask at affordable prices in the Country, NPPA vide O.M dated 21.05.2020, directed manufacturers/ importers/suppliers of N-95 masks to maintain parity in prices for non-government procurements and to make available the same at reasonable prices and any violation of the same would invite action under the Essential Commodities Act, 1955.
4. After issuing such an Advisory, major manufacturers/importers of N-95 Masks have reduced their prices significantly up to 67%. Further, a Press Release in this regard was released on 25.05.2020 for dissemination of information to general public.
5. The NPPA also took cognizance of complaints of black marketing and hoarding of N-95 Masks and directed SDC Maharashtra to take necessary action. SDC conducted raid on the company doing black marketing and hoarding of N-95 Masks.

NPPA's CONTROL ROOM AND HELPLINE

As a measure to deal with the emerging situation arising due to outbreak of COVID-19 pandemic, including to ensure seamless availability of drugs including masks, hand sanitizers and gloves, the NPPA set up a 'Control Room' with Helpline No. 1800111255 and e-mail IDmonitoring-nppa@gov.in on 20th March 2020. The Control Room has attended 1867 calls and addressed all types of the complaints in coordination with the State Drug Control Departments, AIOCD, AIMED etc. till 31.08.2020.

The NPPA's Control Room team worked on 24 x 7 basis, in 3 shifts, on virtual basis through remote locations and has made serious efforts, in coordination with O/o Chief Secretaries of States/UTs, SDCs, District/ State Administration and other State Authorities, for prompt resolution of number of issues. The list of issues resolved through the NPPA Control Room is given below:

Sl. no.	Issues
1	Non-availability of medicines, masks, gloves, hand sanitizers, etc.
2	High price of medicines, masks, gloves, hand sanitizers, etc.
3	Coordination in permission for production of raw material, medicines, medical devices, packaging material, etc. by manufacturers
4	Coordination in movement of raw material, packing material, finished goods and manpower.

Annexure 3

Directorate General of Foreign Trade

Country Specific Exemptions granted by DGFT

(As on 09:00 AM, 09.06.2020)

Table A - All country specific exemptions issued so far for HCQ and Paracetamol(Chronological)

Date: 7 TH April, 2020			
S.No	Country	Item	Quantity allowed
1.	Bahrain	Hydroxychloroquine IP 200 MG	7,70,000 Tablets(Quantity revised on 26.04.2020)
2.	Brazil	Hydroxychloroquine Sulfate	530 Kgs
Date: 8 TH April, 2020			
3.	United States	Hydroxychloroquine Sulfate	11,046.558 Kgs
4.	UK	Paracetamol 500 MG Tablets/Capsules	4,53,58,704 Tablets
5.	Spain	Hydroxychloroquine Sulfate	2,500 Kgs (2320 Kgs issued)
Date: 9 TH April, 2020			
6.	Germany	Hydroxychloroquine	63,36,800 Tablets
7.	New Zealand	Paracetamol 500mg	5 Million Tablets
8.	Nepal	Hydroxychloroquine	2,50,000 Tablets
		Paracetamol	1. Paracetamol 325 mg and Dicyclomine HCl 20 mg - 6,00,000 Tablets 2.Paracetamol Suspension IP 125mg/5ml - 3,00,000 Units
9.	Bhutan	Hydroxychloroquine (HCQ) 200 mg	20,000 tablets
		Paracetamol	(i) Paracetamol suspension IP 125mg/5ml (60ml bottle) – 1 lakh bottles (ii) Paracetamol 325 mg and diclycoamine HCL 20 mg – 1 lakh tablets
Date: 10 TH April, 2020			
10.	Mauritius	Hydroxychloroquine	5,00,000 Tablets

11.	Dominican Republic	Hydroxychloroquine	2,00,000 Tablets
12.	Afghanistan	Hydroxychloroquine	5,00,000 Tablets
13.	Seychelles	Hydroxychloroquine	1,00,000 Tablets
14.	Bangladesh	Hydroxychloroquine	5,00,000 Tablets
15.	South Africa	Paracetamol (500 mg) Tablets	1,49,31,340 Tablets
Date: 11TH April, 2020			
16.	Madagascar	Hydroxychloroquine	1,00,000 Tablets
Date: 12TH April, 2020			
17.	South Africa	Paracetamol (100 – 450 mg tablets)	1,00,33,490 Tablets
18.	Burkina Faso	Hydroxychloroquine (HCQ) 200 mg	1,00,000 Tablets
		Paracetamol (500 mg) Tablets	1,00,000 Tablets
19.	Democratic Republic of Congo	Hydroxychloroquine (HCQ) 200 mg	1,00,000 Tablets
		Paracetamol (500 mg) Tablets	1,00,000 Tablets
20.	Mali	Hydroxychloroquine (HCQ) 200 mg	1,00,000 Tablets
		Paracetamol (500 mg) Tablets	1,00,000 Tablets
21.	Niger	Hydroxychloroquine (HCQ) 200 mg	1,00,000 Tablets
		Paracetamol (500 mg) Tablets	1,00,000 Tablets
22.	Uganda	Hydroxychloroquine (HCQ) 200 mg	1,00,000 Tablets
		Paracetamol (500 mg) Tablets	1,00,000 Tablets
23.	Zambia	Hydroxychloroquine (HCQ) 200 mg	1,00,000 Tablets
		Paracetamol (500 mg) Tablets	1,00,000 Tablets
24.	Chad	Paracetamol (500 mg) Tablets	1,00,000 Tablets
25.	Eswatini	Paracetamol (500 mg) Tablets	1,00,000 Tablets
26.	Republic of Congo	Paracetamol (500 mg) Tablets	1,00,000 Tablets
27.	Senegal	Paracetamol (500 mg) Tablets	1,00,000 Tablets
28.	Sierra Leone	Paracetamol (500 mg) Tablets	1,00,000 Tablets
29.	Zimbabwe	Paracetamol (500 mg) Tablets	1,00,000 Tablets
Date: 13TH April, 2020			
30.	Jamaica	Hydroxychloroquine (HCQ) 200 mg	4,000 Tablets
31.	Ecuador	Hydroxychloroquine (HCQ) 200 mg	1,00,000 Tablets
32.	Myanmar	Hydroxychloroquine (HCQ) 200 mg	2,00,000 Tablets
33.	Egypt	Hydroxychloroquine (HCQ) 200 mg	25,000 Tablets
		Paracetamol (500 mg) Tablets	20,000 Tablets

34.	Armenia	Hydroxychloroquine (HCQ) 200 mg	50,000 Tablets
35.	Kazakhstan	Hydroxychloroquine (HCQ) 200 mg	30,000 Tablets
36.	Syria	Hydroxychloroquine (HCQ) 200 mg	15,000 Tablets
Date: 14TH April, 2020			
37.	Canada	Hydroxychloroquine (HCQ) 200 mg	5 Million Tablets
38.	Belarus	Hydroxychloroquine (HCQ) 200 mg	4,90,000 Tablets
39.	Ukraine	Hydroxychloroquine (HCQ) 200 mg	30,000 Tablets
40.	Poland	Hydroxychloroquine (HCQ) 200 mg	25,00,000 Tablets
41.	Russia	Paracetamol (500 mg) Tablets	1,90,00,000 Tablets
42.	Kuwait	Paracetamol IV Bottles (100 ml each)	7,69,000 Bottles
43.	Afghanistan	Paracetamol (500 mg) Tablets	1,00,000 Tablets
Date: 15TH April, 2020			
44.	Indonesia	Hydroxychloroquine Sulphate	150 Kg
45.	Spain	Paracetamol	28.8 MT
Date: 16TH April, 2020			
46.	Maldives	Hydroxychloroquine	50,000 Tablets
Date: 17TH April, 2020			
47.	Jordan	Hydroxychloroquine	500 Kg
48.	South Africa	Hydroxychloroquine (200 mg)	5,00,000 Tablets
49.	Russia	Hydroxychloroquine (200 mg)	90,00,000 Tablets
50.	UAE	Hydroxychloroquine (200 mg)	54,50,040 Tablets
51.	Uganda	Hydroxychloroquine (200 mg)	3,00,000 Tablets
52.	Ecuador	Hydroxychloroquine (200 mg)	15,00,000 Tablets
53.	Nepal	Paracetamol API	1100 Kgs
Date: 18TH April, 2020			
54.	Oman	Hydroxychloroquine (200 mg)	10,00,150 Tablets
55.	France	Hydroxychloroquine (200 mg)	17,75,000 Tablets
56.	United States	Hydroxychloroquine (200 mg)	3,15,05,000 Tablets
Date: 19TH April, 2020			
57.	United States	Hydroxychloroquine (200 mg)	45,00,000 Tablets
Date: 21st April, 2020			
58.	Ukraine	Hydroxychloroquine (200 mg)	7,80,000 Tablets
59.	Kazakhstan	Hydroxychloroquine (200 mg)	65,000 Tablets
60.	United States	Hydroxychloroquine (200 mg)	17,00,000 Tablets
Date: 22nd April, 2020			
61.	Portugal	Hydroxychloroquine (200 mg)	50,010 Tablets
Date: 23rd April, 2020			

62.	Comoros	Hydroxychloroquine (200 mg)	50,000 Tablets
63.	Colombia	Hydroxychloroquine (200 mg)	9,00,000 Tablets + 1 MT
64.	Germany	Paracetamol API	240 MT
65.	Malaysia	Hydroxychloroquine (200 mg)	1.2 Million Tablets
Date: 24th April, 2020			
66.	Nigeria	Hydroxychloroquine (200 mg)	75,000 Tablets
67.	Kenya	Hydroxychloroquine (200 mg)	3,79,000 Tablets
68.	Tanzania	Hydroxychloroquine (200 mg)	87,000 Tablets
69.	Zimbabwe	Hydroxychloroquine (200 mg)	59,000 Tablets
Date: 25th April, 2020			
70.	Bahrain	Hydroxychloroquine (200 mg)	7,50,000 Tablets
71.	Uruguay	Hydroxychloroquine (200 mg)	77,100 Tablets
72.	Spain	Hydroxychloroquine (200 mg)	9,00,000 Tablets
Date: 29th April, 2020			
73.	United States	Hydroxychloroquine (200 mg)	12.30 Million Tablets
Date: 30th April, 2020			
74.	Mauritius	Hydroxychloroquine (200 mg)	1,92,000 Tablets
75.	Myanmar	Hydroxychloroquine (200 mg)	20,00,000 + 6,90,200 Tablets
76.	West African countries	Hydroxychloroquine (200 mg)	9,43,000 Tablets
77.	Jamaica	Hydroxychloroquine (200 mg)	19,020 Tablets
78.	Malaysia	Hydroxychloroquine (200 mg)	89,010 Tablets
79.	Thailand	Hydroxychloroquine (200 mg)	13,80,000 Tablets
80.	Trinidad & Tobago	Hydroxychloroquine (200 mg)	1,35,000 Tablets
81.	Guyana	Hydroxychloroquine (200 mg)	9,000 Tablets
82.	Morocco	Hydroxychloroquine (200 mg)	60,00,000 Tablets
83.	Australia	Hydroxychloroquine (200 mg)	6 Million Tablets
84.	Singapore	Hydroxychloroquine (200 mg)	2.5 Million Tablets
85.	UK	Hydroxychloroquine Sulphate API	4 MT
86.	Ghana	Hydroxychloroquine (200 mg)	20,00,000 Tablets
87.	Zambia	Hydroxychloroquine (200 mg)	1,00,000 Tablets
88.	Uganda	Hydroxychloroquine Sulphate API	750 Kg
89.	Philippines	Hydroxychloroquine (200 mg)	4,40,000 Tablets
90.	Romania	Hydroxychloroquine (200 mg)	25,00,000 Tablets
Date: 1st May, 2020			
91.	Netherlands	Hydroxychloroquine (200 mg)	1,07,99,990 Tablets
Date: 5th May, 2020			
92.	Germany	Hydroxychloroquine Sulphate API	0.96 MT (50,00,000 Tablets)

93.	United States	Hydroxychloroquine (200 mg)	10.09 Million Tablets
94.	UAE	Hydroxychloroquine (200 mg)	10.5 Million Tablets
95.	Canada	Hydroxychloroquine Sulphate API	3510.13 Kg
96.	South Africa	Hydroxychloroquine (200 mg)	5,53,200 Tablets
97.	Malawi	Hydroxychloroquine (200 mg)	50,000 Tablets
98.	Algeria	Hydroxychloroquine (200 mg)	20,00,000 Tablets
99.	Saudi Arabia	Hydroxychloroquine Sulphate API	520 Kg
100.	Mexico	Hydroxychloroquine Sulphate API	2.5 MT
101.	Italy	Hydroxychloroquine (200 mg)	54,23,580 Tablets
102.	Philippines	Hydroxychloroquine (200 mg)	5,82,000 Tablets
103.	Tajikistan (Grant Basis)	Hydroxychloroquine (200 mg)	70,000 Tablets
104.	Sri Lanka	Hydroxychloroquine (200 mg)	1,20,000 Tablets
Date: 9th May, 2020			
105.	Uzbekistan	Hydroxychloroquine (200 mg)	40,000 Tablets
106.	Brazil	Hydroxychloroquine Sulphate API	1000 Kg
107.	Egypt	Hydroxychloroquine Sulphate API	1500 Kg
108.	Indonesia	Hydroxychloroquine Sulphate API	350 Kg
109.	Argentina	Hydroxychloroquine Sulphate API	1300 Kg
110.	Russia	Hydroxychloroquine Sulphate API	25 Kg
111.	Kazakhstan	Hydroxychloroquine (200 mg)	4,00,020 Tablets
112.	Trinidad and Tobago	Hydroxychloroquine (200 mg)	3,70,020 Tablets
113.	United States	Hydroxychloroquine (200 mg)	20,24,200 Tablets
Date: 12th May, 2020			
114.	South Korea	Hydroxychloroquine Sulphate API	2 MT
115.	Netherlands	Hydroxychloroquine (200 mg)	120,00,000 Tablets
116.	Algeria	Hydroxychloroquine Sulphate API	2 MT
117.	UAE	Hydroxychloroquine (200 mg)	10,00,000 Tablets
Date: 20th May, 2020			
118.	Belgium	Hydroxychloroquine (200 mg)	2,28,000 Tablets
119.	Liberia	Hydroxychloroquine 200 mg	25,000 Tablets
120.	Russia	Hydroxychloroquine API	505 Kg + 10 Crore Tablets

121.	Philippines	Hydroxychloroquine API	210 Kg
122.	Israel	Hydroxychloroquine 200 mg	28.5 Lakh Tablets
123.	Chad	Hydroxychloroquine 200 mg	2,50,000 Tablets
124.	Guinea	Hydroxychloroquine 200 mg	1,00,000 Tablets
125.	Algeria	Hydroxychloroquine 200 mg	9,00,000 Tablets
126.	Tajikistan	Hydroxychloroquine 200 mg	3,93,040 Tablets
127.	Uzbekistan	Hydroxychloroquine 200 mg	24,000 Tablets
128.	United Kingdom	Hydroxychloroquine 200 mg	1,92,00,000 Tablets
129.	Niger	Hydroxychloroquine 200 mg	36,000 Tablets
130.	Zambia	Hydroxychloroquine 200 mg	3,20,000 Tablets
131.	Argentina	Hydroxychloroquine API	600 Kgs
132.	Belarus	Hydroxychloroquine 200 mg	7,00,020 Tablets
133.	Mexico	Hydroxychloroquine API	10 Kgs
134.	Malaysia	Hydroxychloroquine API	100 Kgs
135.	Ghana	Hydroxychloroquine 200 mg	5,00,000 Tablets
136.	Egypt	Hydroxychloroquine API	100 Kgs
137.	Bulgaria	Hydroxychloroquine 200 mg	4,50,000 Tablets
138.	Vietnam	Hydroxychloroquine 200 mg	35,00,000 Tablets
139.	Bangladesh	Hydroxychloroquine API	500 Kg
140.	Eswatini	Hydroxychloroquine 200 mg	1,00,000 Tablets
141.	Zimbabwe	Hydroxychloroquine 200 mg	1,00,000 Tablets
142.	Mozambique	Hydroxychloroquine 200 mg	1,00,000 Tablets
143.	Ethiopia	Hydroxychloroquine 200 mg	1,00,000 Tablets
144.	Malawi	Hydroxychloroquine 200 mg	1,00,000 Tablets
145.	Namibia	Hydroxychloroquine 200 mg	1,00,000 Tablets
146.	Kenya	Hydroxychloroquine 200 mg	1,00,000 Tablets
147.	Cabo Verde	Hydroxychloroquine 200 mg	1,00,000 Tablets
148.	Benin	Hydroxychloroquine 200 mg	1,00,000 Tablets
149.	Chad	Hydroxychloroquine 200 mg	1,00,000 Tablets
150.	Equatorial Guinea	Hydroxychloroquine 200 mg	1,00,000 Tablets
151.	Gambia	Hydroxychloroquine 200 mg	1,00,000 Tablets
152.	Guinea Bissau	Hydroxychloroquine 200 mg	1,00,000 Tablets
153.	Guinea	Hydroxychloroquine 200 mg	1,00,000 Tablets
154.	Liberia	Hydroxychloroquine 200 mg	1,00,000 Tablets
155.	Nigeria	Hydroxychloroquine 200 mg	1,00,000 Tablets
156.	Republic of Congo	Hydroxychloroquine 200 mg	1,00,000 Tablets
157.	Senegal	Hydroxychloroquine 200 mg	1,00,000 Tablets
158.	Sierra Leone	Hydroxychloroquine 200 mg	1,00,000 Tablets

159.	Antigua and Barbuda	Hydroxychloroquine 200 mg	10,000 Tablets
160.	The Bahamas	Hydroxychloroquine 200 mg	20,000 Tablets
161.	Barbados	Hydroxychloroquine 200 mg	10,000 Tablets
162.	Commonwealth of Dominica	Hydroxychloroquine 200 mg	10,000 Tablets
163.	Grenada	Hydroxychloroquine 200 mg	10,000 Tablets
164.	Guyana	Hydroxychloroquine 200 mg	30,000 Tablets
165.	Haiti	Hydroxychloroquine 200 mg	3,00,000 Tablets
166.	St. Kitts & Nevis	Hydroxychloroquine 200 mg	10,000 Tablets
167.	St. Lucia	Hydroxychloroquine 200 mg	10,000 Tablets
168.	St. Vincent & the Grenadines	Hydroxychloroquine 200 mg	10,000 Tablets
169.	Suriname	Hydroxychloroquine 200 mg	20,000 Tablets
170.	Trinidad & Tobago	Hydroxychloroquine 200 mg	40,000 Tablets
171.	Jamaica	Hydroxychloroquine 200 mg	80,000 Tablets
172.	Belize	Hydroxychloroquine 200 mg	20,000 Tablets
173.	Costa Rica	Hydroxychloroquine 200 mg	1,40,000 Tablets
174.	Dominican Republic	Hydroxychloroquine 200 mg	1,00,000 Tablets
175.	El Salvador	Hydroxychloroquine 200 mg	2,00,000 Tablets
176.	Honduras	Hydroxychloroquine 200 mg	2,60,000 Tablets
177.	Nicaragua	Hydroxychloroquine 200 mg	1,70,000 Tablets
178.	Panama	Hydroxychloroquine 200 mg	1,10,000 Tablets
179.	Guatemala	Hydroxychloroquine 200 mg	5,00,000 Tablets
180.	Ecuador	Hydroxychloroquine 200 mg	4,00,000 Tablets
181.	Bolivia	Hydroxychloroquine 200 mg	3,00,000 Tablets
182.	Cuba	Hydroxychloroquine 200 mg	3,00,000 Tablets
183.	Peru	Hydroxychloroquine 200 mg	9,00,000 Tablets
184.	Venezuela	Hydroxychloroquine 200 mg	7,40,000 Tablets
185.	Republic of Paraguay	Hydroxychloroquine 200 mg	2,00,000 Tablets
186.	Oriental Republic of Uruguay	Hydroxychloroquine 200 mg	1,00,000 Tablets
Date: 25th May, 2020			
187.	Hong Kong	Hydroxychloroquine 200 mg	28,00,000 Tablets
Date: 26th May, 2020			
188.	United States	Hydroxychloroquine 200 mg & API	40 Million Tablets + 1800 Kgs

189.	Peru	Hydroxychloroquine 200 mg	3,91,020 Tablets
190.	Brazil	Hydroxychloroquine API	2,461.65 Kg
Date: 28th May, 2020			
191.	United States	Hydroxychloroquine 200 mg	15 Million Tablets
Date: 29th May, 2020			
192.	Philippines	Hydroxychloroquine 200 mg	10,00,000 Tablets
193.	Oman	Hydroxychloroquine 200 mg/API	5,00,100 Tablets + 130 Kg
194.	Mexico	Hydroxychloroquine API	5 Kg
195.	Liberia	Hydroxychloroquine 200 mg	25,000 Tablets
196.	Republic of Congo	Hydroxychloroquine 200 mg	75,000 Tablets
Date: 1st June, 2020			
197.	Kenya	Hydroxychloroquine 200 mg	10,00,000 Tablets
198.	Congo	Hydroxychloroquine 200 mg	11,00,000 Tablets
199.	Germany	Hydroxychloroquine 200 mg	12 Million Tablets
200.	Madagascar	Hydroxychloroquine 200 mg	60,000 Tablets
201.	Guinea	Hydroxychloroquine 200 mg	2,40,000 Tablets
202.	Tchad	Hydroxychloroquine 200 mg	20,00,010 Tablets
203.	Zimbabwe	Hydroxychloroquine 200 mg	3,00,000 Tablets
Date: 4th June, 2020			
204.	Congo	Hydroxychloroquine 200 mg	3,00,000 Tablets
205.	Zimbabwe	Hydroxychloroquine 200 mg	1,00,000 Tablets
Date: 8th June, 2020			
206.	United States	Hydroxychloroquine 200 mg	95,00,000 Tablets
207.	Tajikistan	Hydroxychloroquine 200 mg	2,00,000 Tablets
208.	Algeria	Hydroxychloroquine API	2400 Kg

Table B - Exemptions granted to export Hydroxychloroquine

S.No.	Country	Quantity *
1.	Bahrain	1,520,000 Tablets
2.	Brazil	1530Kgs + 2461.65 Kg
3.	United States	12,846.558 Kgs& 126.61 Million Tablets (Approx.)
4.	Spain	2,320 Kgs & 9,00,000 Tablets
5.	Germany	63,36,800 Tablets + 12 Million Tablets & 0.96 MT
6.	Nepal	2,50,000 Tablets
7.	Bhutan	20,000 tablets
8.	Mauritius	6,92,000 Tablets
9.	Dominican Republic	2,00,000 Tablets + 1,00,000 Tablets
10.	Afghanistan	5,00,000 Tablets
11.	Seychelles	1,00,000 Tablets
12.	Bangladesh	5,00,000 Tablets + 500 Kg
13.	Madagascar	1,60,000 Tablets
14.	Burkina Faso	1,00,000 Tablets
15.	Democratic Republic of Congo	12,00,000 Tablets
16.	Mali	1,00,000 Tablets
17.	Niger	1,36,000 Tablets
18.	Uganda	4 lakh Tablets& 750 Kg(API)
19.	Zambia	5.20 Lakh Tablets
20.	Jamaica	23,020 Tablets + 80,000 Tablets
21.	Ecuador	16 Lakh Tablets + 4,00,000 Tablets
22.	Myanmar	28,90,200 Tablets
23.	Egypt	25,000 Tablets & 1600 Kg
24.	Armenia	50,000 Tablets
25.	Kazakhstan	4,95,020 Tablets
26.	Syria	15,000 Tablets
27.	Canada	5 Million Tablets & 3510.13 Kg
28.	Belarus	11,90,020 Tablets

29.	Ukraine	8,10,000 Tablets
30.	Poland	25,00,000 Tablets
31.	Indonesia	500 Kg
32.	Maldives	50,000 Tablets
33.	Jordan	500 Kg
34.	South Africa	10,53,200 Tablets
35.	Russia	10,90,00,000 Tablets& 530 Kg
36.	UAE	16.9 Million Tablets
38.	Oman	15,00,250 Tablets + 130 Kg
39.	France	17,75,000 Tablets
40.	Portugal	50,010 Tablets
41.	Comoros	50,000 Tablets
42.	Colombia	9,00,000 Tablets & 1000 Kgs
43.	Malaysia	12,89,010 Tablets + 100 Kgs
44.	Nigeria	1,75,000 Tablets
45.	Kenya	4,79,000 Tablets + 10,00,000 Tablets
46.	Tanzania	87,000 Tablets
47.	Zimbabwe	5,59,000 Tablets
48.	Uruguay	77,100 Tablets
49.	Philippines	20,22,000 Tablets+ 210 Kg
50.	Romania	25,00,000 Tablets
51.	West African countries	9,43,000 Tablets
52.	Thailand	13,80,000 Tablets
53.	Trinidad & Tobago	5,05,020 Tablets + 40,000 Tablets
54.	Guyana	9,000 Tablets + 30,000 Tablets
55.	Morocco	60,00,000 Tablets
56.	Australia	6 Million Tablets
57.	Singapore	2.5 Million Tablets
58.	UK	4 MT + 1,92,00,000 Tablets
59.	Ghana	20,00,000 Tablets + 5,00,000 Tablets
60.	Netherlands	1,07,99,990 Tablets + 120,00,000 Tablets#
61.	Malawi	50,000 Tablets + 1,00,000 Tablets
62.	Algeria	29,00,000 Tablet + 4.4 MT
63.	Saudi Arabia	520 Kg
64.	Mexico	2510 Kg + 5 Kg
65.	Italy	54,23,580 Tablets
66.	Tajikistan	6,63,040 Tablets
67.	Sri Lanka	1,20,000 Tablets

68.	Argentina	1900 Kg
69.	Uzbekistan	64,000 Tablets
70.	South Korea	2 MT
71.	Belgium	2,28,000 Tablets
72.	Liberia	1,25,000 Tablets + 25,000 Tablets
73.	Chad	3,50,000 Tablets
74.	Israel	28.5 Lakh Tablets
75.	Guinea	4,40,000 Tablets
76.	Bulgaria	4,50,000 Tablets
77.	Vietnam	35,00,000 Tablets
78.	Eswatini	1,00,000 Tablets
79.	Mozambique	1,00,000 Tablets
80.	Ethiopia	1,00,000 Tablets
81.	Namibia	1,00,000 Tablets
82.	Cabo Verde	1,00,000 Tablets
83.	Benin	1,00,000 Tablets
84.	Equatorial Guinea	1,00,000 Tablets
85.	Gambia	1,00,000 Tablets
86.	Guinea Bissau	1,00,000 Tablets
87.	Republic of Congo	4,75,000 Tablets
88.	Senegal	1,00,000 Tablets
89.	Sierra Leone	1,00,000 Tablets
90.	Antigua and Barbuda	10,000 Tablets
91.	The Bahamas	20,000 Tablets
92.	Barbados	10,000 Tablets
93.	Commonwealth of Dominica	10,000 Tablets
94.	Grenada	10,000 Tablets
95.	Haiti	3,00,000 Tablets
96.	St. Kitts & Nevis	10,000 Tablets
97.	St. Lucia	10,000 Tablets
98.	St. Vincent & the Grenadines	10,000 Tablets
99.	Suriname	20,000 Tablets
100.	Belize	20,000 Tablets
101.	Costa Rica	1,40,000 Tablets
102.	El Salvador	2,00,000 Tablets
103.	Honduras	2,60,000 Tablets
104.	Nicaragua	1,70,000 Tablets
105.	Panama	1,10,000 Tablets

106.	Guatemala	5,00,000 Tablets
107.	Bolivia	3,00,000 Tablets
108.	Cuba	3,00,000 Tablets
109.	Peru	9,00,000 Tablets + 3,91,020 Tablets
110.	Venezuela	7,40,000 Tablets
111.	Republic of Paraguay	2,00,000 Tablets
112.	Oriental Republic of Uruguay	1,00,000 Tablets
113.	Hong Kong	28,00,000 Tablets
114.	Tchad	20,00,010 Tablets
	Total	44,783.34 Kgs (44.79 MT) + 39,72,10,290 Tablets

** Hydroxychloroquine API in Kgs/MT & Hydroxychloroquine Formulations in*

Table C – Exemptions granted to export Paracetamol

S.No.	Country	Quantity
1.	UK	4,53,58,704 Tablets
2.	New Zealand	5 Million Tablets
3.	Nepal	6,00,000 Tablets 3,00,000 Units (Suspension IP)
4.	Bhutan	1 Lakh Tablets 1 Lakh Bottles(Suspension IP)
5.	South Africa	1,49,31,340 Tablets + 1,00,33,490 Tablets = 2,49,64,830 Tablets
6.	Burkina Faso	1,00,000 Tablets
7.	Democratic Republic of Congo	1,00,000 Tablets
8.	Mali	1,00,000 Tablets
9.	Niger	1,00,000 Tablets
10.	Uganda	1,00,000 Tablets
11.	Zambia	1,00,000 Tablets
12.	Chad	1,00,000 Tablets
13.	Eswatini	1,00,000 Tablets
14.	Republic of Congo	1,00,000 Tablets
15.	Senegal	1,00,000 Tablets
16.	Sierra Leone	1,00,000 Tablets
17.	Zimbabwe	1,00,000 Tablets
18.	Egypt	20,000 Tablets
19.	Russia	1,90,00,000 Tablets
20.	Kuwait	7,69,000 Bottles (100 ml each)
21.	Afghanistan	1,00,000 Tablets
22.	Spain(API)	28.8 MT
23.	Nepal(API)	1100 Kgs
24.	Germany (API)	240 MT
	Total	9,63,43,534(96.34 Million) Tablets + 4 Lakh Units (Suspension IP) + 7,69,000 Bottles (100 ml each) + 269.9 MT

Annexure 4

Details of other steps by the Department of Pharmaceuticals in Covid-19 pandemic related response.

Since the onset of the COVID-19 pandemic and through all subsequent lockdown periods, Department of Pharmaceuticals (DoP) has been working on mission mode to address the difficulties and challenges. High import dependence for raw materials to produce critical drugs and supply chain disruption, limited domestic capacities to manufacture health care equipments and diagnostic kits, and the restrictions of lockdown themselves- threw different challenges for ensuring continued production of essential drugs and medical devices and maintaining their supplies. During lockdown periods, it was also challenging to coordinate and cooperate among different central government departments, state governments, industry associations and logistic companies as the manufacturers faced various problems at different levels related to transportation and logistics for carrying both raw materials and finished products, shortage of labour etc.

The various challenges faced and the actions taken by DoP and National Pharmaceutical Pricing Authority (NPPA), an attached office of the Department, including National Institutes of Pharmaceutical Education & Research (NIPERs) and Bureau of Pharma PSUs of India (BPPI) are given as follows;-

1. Department of Pharmaceuticals:

A. Assessing the availability and ensuring adequate stock of essential items.

(i) India, one of the largest manufacturers of drug formulations/medicines is heavily dependent on China for import of critical bulk drugs. India imports around 70% of total imports of bulk drugs from China. The outbreak of the deadly Novel Corona Virus (COVID-19) in China in December 2019 brought out the risk of disruption of supply chain which could jeopardize the Indian pharma sector and could have adverse impact on the drug security in India. DoP was aware of the situation and had been constantly monitoring the availability of medicines to avoid any potential shortage in the country.

(ii) Immediately after the first case of the COVID-19 which was reported on 30.01.2020 in the country, DoP assessed the situation and took fast track actions as a measure of public health preparedness. The Department held a series of meetings on 31st January, 2nd, 3rd and 6th February 2020 with all the relevant stakeholders to assess the domestic availability of (i) Drug Lopinavir+Ritonavir fixed drug combination which was included in the initial protocol of ICMR for treating the COVID-19 disease (ii) Active Pharmaceutical Ingredients (API), intermediates and Key Starting Materials (KSM) for which India was critically dependent on China.

(iii) Further, DoP helped Ministry of External Affairs and Ministry of Health and Family Welfare to procure various supplies needed.

(iv) Meetings were held under the chairmanship of Secretary, Pharmaceuticals on 23.03.2020 and 24.03.2020 to review the status of availability of ventilators, thermometers, PCR machines, diagnostics kits and related logistics issues and to explore manufacturing of ventilators by domestic automobile companies.

(v) DoP conducted series of meetings through Video conferencing with the officers/ officials of Central Government Ministries/ Departments/ Organisations, DCGI/ State Drug Controllers/ Pharma and Medical Device Associations, Pharma/ Medical Device Manufacturers and Air Cargo Units for ensuring availability/ stock of medicines and medical devices (PPE kit, Gloves, Masks, Hand Sanitizers, Face Shield, other essential medicines and logistics issues).

(vi) An inter-ministerial Committee was constituted by DoP on 06.02.2020 under the chairmanship of Dr. Eswara Reddy, Joint Drugs Controller, Central Drugs Standard Control Organization (CDSCO) to address the issue of drug security in the country. The committee submitted its report on 27.02.2020. The Committee reviewed the situation regarding impact on import of APIs and KSMs due to outbreak of Corona virus and identified four core issues viz. (1) Disruption of manufacturing activity in China due to holidays (2) Logistics issues (3) Restriction on movement of personnel, and (4) Availability of raw materials for manufacturing of APIs/KSMs. The committee observed that there could be major impact on import of certain APIs and KSMs which were manufactured in Hubei province in China.

(vii) Based on the recommendations of the Committee, DoP issued necessary instructions to National Pharmaceutical Pricing Authority (NPPA), Drugs Controller General of India (DCGI) and State Governments to ensure adequate supply of APIs and formulations at affordable prices in the market and to prevent black-marketing, illegal hoarding, creating artificial shortages in the country and recommended DGFT to restrict exports of 13 API and formulations made using these APIs. (On 03.03.2020 DGFT notified restriction on exports of 13 APIs and their corresponding formulations as a measure against the implications of COVID-19 outbreak in China.)

B. Historical decision to ensure domestic manufacturing of critical bulk drugs and medical devices.

A Technical Committee was constituted by DoP on 02.03.2020 under the chairmanship of Dr. Eswara Reddy, Joint Drugs Controller, Central Drugs Standard Control Organization (CDSCO) to make recommendations for the revival of fermentation industry, new technologies for manufacturing of APIs including its backward integration, costing of the projects and identification of strategic business models. On the basis of the recommendations of the committee, Department had prepared the following four schemes – two for promoting domestic manufacturing of Bulk Drugs, and two for promoting domestic manufacturing of Medical Devices; which were approved by the Union Cabinet on 20.03.2020.

(i) **Promotion of Bulk Drug Parks:** to provide grant-in-aid to 3 Bulk Drug Parks for creation of Common Infrastructure Facilities (CIF) with a maximum limit of Rs.1000 Crore per park or 70% of the project cost of CIF, whichever is less. The total size of the Scheme is Rs.3000 Crore and tenure of the Scheme will be five years (2020-21 to 2024-25).

(ii) **Production Linked Incentive (PLI) scheme:** Under the scheme, financial incentive is given to eligible manufacturers of 53 KSMs/Drug Intermediates and APIs on their incremental sales over the base year (FY 2019-20) for 6 years. For fermentation based eligible products, incentive for the first four years (2023-24 to 2026-27) would be 20%, for fifth year (2027-28) 15%, and sixth year (2028-29) 5%, on incremental sale of KSMs/ Drug Intermediates/ APIs. For chemically synthesized eligible products incentive would be 10% on incremental sales of KSMs/Drug Intermediates/ APIs for 6 years (2022-23 to 2027-28). A total outlay of Rs. 6,940 Crore has been approved for the scheme.

(iii) **Scheme for Promotion of Medical Device Parks:** The total size of the Scheme is Rs.400 Crore and tenure of the Scheme will be five years (2020-21 to 2024-25). The scheme will provide grant-in-aid to 4 Medical Device Parks with a maximum limit of Rs. 100 Crore per park or 70% of the project cost of Common Infrastructure Facilities, whichever is less. In case of hilly states and North East Region, the grant-in-aid would be Rs. 100 Crore per park or 90% of the project cost of Common Infrastructure Facilities, whichever is less. The assistance under the proposed scheme will be admissible for creation of Common Infrastructure Facilities such as Component Testing Centre, Electro-magnetic interference laboratory, Biomaterial / Biocompatibility testing centre, Medical grade low vacuum moulding, Cabinet moulding, injection moulding centres, 3D designing and printing for medical grade products, Sterilization and Toxicity testing centre, Radiation testing centre etc. The scheme would be implemented through a State Implementing Agency (SIA) to be formed by the concerned state government.

(iv) **Production Linked Incentive Scheme for Promoting Domestic Manufacturing of Medical Devices:** The Cabinet has also approved Production Linked Incentive (PLI) scheme for promoting domestic manufacturing of medical devices with a financial outlay of Rs. 3420 Crore. The medical devices manufacturing sector faces lack of a level playing field vis-à-vis competing economies. The sector suffers from a disability of around 12% to 15% on account of various factors. The recently approved PLI Scheme will provide financial incentive with an objective to boost domestic manufacturing and attract large investments in the Medical Device sector. The Scheme shall extend an incentive of 5% on incremental sales (over base year) of goods manufactured in India and covered under target segments, to eligible companies, for a period of five (5) years. The tenure of the Scheme will be from 2020-21 to 2026-27.

C. Support to Industry during lockdown

The lockdown across the country in the wake of the COVID-19 pandemic had resulted in supply disruptions even though pharmaceutical and medical device industry was exempted by the government from the lockdown as they were included under essential services. The major challenge was with respect to transportation, especially inter-state movement of medicines and medical products and movement of labourers. In addition, there were other challenges in terms of non-availability of ancillary services such as availability of packing materials, courier services etc.

D. Actions initiated in the Department to address Logistics related issues

(i) Regular meetings were held with State Drug Controllers, Drug and medical devices manufacturer's Associations and Chemists and Pharmacists Associations. Issues brought to knowledge of the department were assessed and resolutions given on real time basis. Cases brought out by Industry Associations & general public continuously taken up with the States/UTs over phone calls and e-mails and were resolved.

(ii) Various WhatsApp groups were formed to tackle issues arising out of lockdown e.g. group of associations of pharmaceutical and medical devices manufacturers, group of distributors of AIOCD, group of Drug Controller General of India with the state drug controllers, group of automobile companies interested in manufacturing ventilators, group of glove manufacturers, group of masks manufacturers, overall IMC group on exports of medicines, group of officers from railways and postal services etc. Many issues were brought to the knowledge of department through these WhatsApp groups which were flagged to concerned states/ departments for resolution.

(iii) A Control Room (with Phone No. 011-23389840 and email: helpdeskpharma@gov.in) was set up on 28.03.2020 in Department of Pharmaceuticals for handling transport and logistics services related issues of industry engaged in providing essential services following the lockdown across the country. A total of 277 cases were handled from 29.03.2020 to 20.05.2020. The cases received were related to the following issues viz. transportation of goods/medicines/ medical equipment; cargo/custom related issues; regulatory issues; shortage of workers, issue of e-pass to employees/workers etc.; availability of essential medicines; Inter-state transport issues; medical equipment manufacturing and manufacturing restricted /barred in some states; permission to function printing and packaging units required by drug manufacturers. The issues raised were effectively resolved; required information provided; some issues were forwarded to concerned authorities for redressal.

(iv) DoP requested Ministry of Home Affairs (MHA) to issue necessary instructions to State Authorities for effective resolution of issues faced in production, distribution and management of critical, lifesaving essential medicines and medical devices including non-operational courier services and ancillary suppliers of inputs including packaging materials, excipients, utility consumables and spare parts not recognized as essential services in the wake of lockdown for COVID -19. MHA was further requested to take suitable effective measures to prevent any shortage of medicines and medical devices in future and DoP made certain suggestions for tackling the situation including ferrying back contractual labourers from their native places; treating commercial driving license as a pass during the lock down; sensitizing local authorities of the need to restore production of medicines and medical devices, restoration of courier services etc.

(v) DoP was in constant touch with Key Ministries/Depts. including Civil Aviation, Posts, Air Force, Railways, Customs for effective resolution of transport and logistics services related issues in ensuring availability of medicines across the country.

(vi) DoP conducted various meeting through video conferencing with representatives of major pharma and medical device associations to discuss latest issues/ challenges faced by them following lockdown for COVID -19; to obtain the status updated from the industry regarding their working and to take suggestions from them on tackling the situation.

(vii) DoP had requested all Chief Secretaries of States/UTs to ensure that all district authorities and field agencies were informed that no separate passes were required for through traffic of trucks and goods carriers including empty trucks etc., so that there was no ambiguity at the ground level and movement of through traffic of trucks and goods carriers including empty trucks was allowed without hindrance.

(viii) Further, DoP along with NPPA and CDSCO were regularly monitoring the working status of pharmaceutical and medical device manufacturing units and assessed the situation, pre COVID and post COVID.

E. Letters written to Ministries/ Departments/ States etc. by Secretary (Pharma)

(i) Secretary (Pharma) wrote to all the Chief Secretaries of States and UTs on 23.03.2020 to direct the authorities concerned to make necessary arrangements for issuance of IDs/Entry Passes so as to facilitate movement of the workers engaged in these essential activities.

(ii) Secretary (Pharma) on 02.04.2020 also wrote to Secretary, Ministry of Home Affairs to issue necessary instructions to State authorities in order to ensure availability of life saving essential medicines during this critical time. Further, Secretary (Pharma) vide DO dated 03.04.2020 to Secretary, Ministry of Home Affairs requested for issuing appropriate instructions for urgent intervention of the State authorities in the issues related to the supplies of ancillary goods and operation of courier services.

(iii) Secretary (Pharma) also wrote on 09.04.2020 to Secretary, Ministry of Home Affairs suggesting measures to prevent shortage of medicines in the domestic market, which included allowing pharma and medical device industry to ferry back their contractual labourers from their native places, allowing drivers in possession with driving license of a commercial vehicle to move with or without their vehicle, addressing the apprehensions of drivers regarding ill treatment by the police and to motivate/incentivize (Insurance etc.) them, sensitizing State and District Authorities to the need of bringing back the production of pharma and medical device industry to its pre lockdown level and need to make courier services fully functional for ensuring movement of medicines and medical devices.

(iv) Secretary (Pharma) on 24.04.2020 wrote to Secretary, Ministry of Home Affairs for issuing instructions to State authorities to take effective measures for enabling pharma units to work in full capacity and raise the production to reach the pre-lockdown level and avoid future shortages of medicines and medical devices in the country. List of ancillary services relating to pharma and medical device industry was also provided for circulation to State Authorities for their clarity.

(v) The interventions of the Department had resulted in timely issuance of instructions/ advisories to State/Local authorities ensuring that the production process in the pharmaceutical industry was not hampered and supply of essential medicines in the country was not adversely affected. As per the information provided by CDSCO, of the 5891 manufacturing units operational in the country in the pre Covid-19 situation only 3222 manufacturing units (55.1%) were operational with 39.5% employees working and average daily production of 34.4% during mid-April 2020. However, the situation improved since then. As on 01.07.2020, 4797 manufacturing units (81.4%) were operational with 53.49% employees working and had an average daily production of 50.00%.

F. Empowered Group-3 ensured production, procurement and availability of essential medical equipment:

The Empowered Group-3 took up necessary actions for ensuring availability and production of essential medical equipment, procurement, import and distribution. At the start of the pandemic, the country did not have or have very negligible number of manufactures for PPE suit, N-95 masks, ventilators, and testing kits. The Group worked hard to ensure that demand was increasingly fulfilled by domestic manufacturers with the following outcomes:

(i) **PPE Kits-** Initially the demand was being met through Imports only, but now more than 1200 companies are manufacturing PPE Kits. More testing labs (10 from just one at the beginning of the pandemic) have been added and new types of fabrics developed, supply chain nurtured and more manufacturers helped to validate their products. The daily production capacity of PPEs has crossed more than 5 lakh per day. The country has become the second largest PPE manufacturer in the world. Export permission also has now been given.

(ii) **N-95 Mask-** The production of N-95 Masks in the country was negligible and the demand was being largely met through imports. There is now sufficient number of producers in India. In addition, DRDO has developed two types of masks viz. N-97 & N-99 masks. The production capacity has been enhanced to about 3 lakhs per day.

(iii) **Ventilators-** The country had almost negligible ventilators manufacturing facilities. Now we have a number of domestic manufacturers with production capacity of more than 3 lakh per annum. Government is procuring about 97 per cent of the orders from domestic manufacturers (for 58,850 ventilators out of total 60,848 ventilators). Delivery has started meeting full requirement for management of Covid-19.

(iv) **Diagnostic Kits-** India initially imported testing kits and polymer swabs. Now we have become self-reliant in swab availability as supply chain were identified, nurtured and manufacturing started within India. With no indigenous capacity to manufacture RT-PCR based kits and Rapid Diagnostic kits for COVID-19 diagnosis, today the Indian manufacturers stand by the manufacturing capacity of 1334 million kits per annum and 27 million kits per annum respectively. Good number of domestic companies has also started manufacturing extraction kits, the weak link in testing, first time in India. There is likelihood of allowing exports of these items too.

2. National Institutes of Pharmaceutical Education & Research (NIPERS)

NIPERs were in forefront in sensitizing the various stakeholders and public at large about the precautions to be taken for controlling spread of COVID. The Institutes also undertook various activities like distribution of sanitizers, masks etc.

(i) NIPERs at Ahmedabad, Guwahati and Hajipur have been assisting the State Governments concerned in COVID-19 testing. NIPER Ahmedabad has created a Palliative Care Protocol (PCP), as supportive treatment for COVID-19 In association with M/s Troika Pharma. The institute is developing a device quantum-dots and conductivity-based biosensors for rapid COVID-19 testing, which would reduce the testing time to 5 mins and could be applied in mass screening. It is also developing new formulation of HCQ for delivery to lungs. NIPER Hyderabad has been instrumental in development and validation of homology model of potential targets of COVID-19 for screening of existing drugs and new chemical entities in collaboration with IIT Delhi. It is involved in screening of selected antiviral phytoconstituents and Natural chemical entities from Arisaema Genus against various targets of COVID - 19. NIPER Guwahati has designed, developed & validated a 3D-printed multi-layer antimicrobial face mask to control the spread of novel coronavirus. NIPER Mohali has developed Tisane (Herbal Tea) as an Immune booster. NIPERs have also contributed 11 COVID related publications. NIPERs have signed 3 MoUs for joint collaborative research for Covid19 with the agencies and partners like ESIC Medical College Hyderabad, HAL etc. Various webinars involving different experts organized regarding the challenges posed by the COVID 19 and possible solutions and application of different combination of drugs and supplements for its possible remedies along with immunity boosting.

(ii) Besides these activities, NIPERs have also undertaken various Research activities that are enumerated as under:

a. Ahmedabad

- (i) Established ICMR approved COVID-19 Testing Facility and has conducted quality check & sample testing.
- (ii) Conducted COVID-19 related webinar on "Participation in lifestyle and public awareness program through Electronic Media".
- (iii) In the process of developing "Quantum dot based diagnostic tests for COVID-19".
- (iv) Developing new Nanoformulation of repurposing drugs for COVID-19.
- (v) Research on Grazoprevir as a probable new drug for COVID-19 to target viral as well as host protein.
- (vi) Working on development of Ayurveda based formulation as immunity booster against COVID-19.

b. Hyderabad

- (i) Two Book Chapters were published entitled "COVID-19 Outbreak: Update on Epidemiology, Transmission and Treatment Opportunities" and "Roles of Online Social Media Platforms and Artificial Intelligence in Diffusing the Impact of COVID-19

as Scientists Finds a Cure” in the Elsevier Book Series on “Drug Discovery Updates”.

- (ii) Developed noble effervescent formulation of an anti-aging agent.
- (iii) Cycloencapsulated and rographolide with improved physicochemical and biological characteristics.
- (iv) Toxicity and safety study was conducted in animal model for the formulation by industry LifeActivus Pvt. Ltd. and Supreme Industry for the treatment of COVID-19.
- (v) Technology Transfer Document between NIPER, Hyderabad, and Lifeactivus Private Limited, Hyderabad, for the product “An Improved Process for a Noble Effervescent Formulation of an Anti-Aging Agent”.
- (vi) Technology Transfer Document between NIPER, Hyderabad, and Ambe Phytoextracts Private Limited, New Delhi, for the product “Cycloencapsulated andrographolide with improved physicochemical and biological characteristics”.
- (viii) Published 13 research & review paper in reputed journals.
- (ix) 2 MoUs signed for collaborative research work with BBAU, Lucknow, Tenshi KSM Pvt Ltd. Bangalore and LifeActivus Pvt. Ltd., Hyderabad.
- (x) Filled one Indian patent entitle “A liquid formulation of chlorine for treatment of COVID-19 and other respiratory viral infection” Application No. 202041028506.

c. Raebareli

- (i) In process of preparing a herbal formulation (in tablet) using various herbs as immune-booster during the treatment of Covid -19.
- (ii) New compounds belonging to bisthiourea containing bisguanidine class were synthesized and remaining compounds in this series are being synthesized and purified. These compounds are likely to target the viral RNA of the COVID-19.
- (iii) A cream based different hand sanitizer formulations using naturally occurring essential oils traditionally acclaimed for microbicidal activity including anti-viral activity.
- (iv) Working on the development of a spray based coating solution to form film on surfaces comes in frequent contacts to prevent the growth of microorganisms including SARS-CoV-2.
- (v) Working on identification of promising antiviral phytoconstituents of *Andrographis paniculata* and evaluate their binding affinity against available targets using computational techniques.
- (vi) Filed patent on “**Herbal hand sanitizer hydrogel**” and “**Coating solution containing Sodium Chloride and Cetrimide**”.
- (vii) A manuscript titled as “*Montelukast in combination with Remdesivir may be an Effective Therapeutic Strategy to Control SARS-CoV-2 induced COVID-19*” has been submitted to the European Journal of Pharmacology and is under review.
- (viii) Project entitled “Development and evaluation of immunostimulatory activity of novel herbal formulation” under the scheme “Anti-SARS-CoV-2/nCoV-2 virus studies using botanical ingredients and traditional formulations” in DBT-BIRAC, New Delhi, worth 38 lakhs (approximately) submitted in July, 2020.

d. Mohali

- (i) Worked with Technology Information, Forecasting & Assessment Council (TIFAC), DST for the preparation of the report on ‘Active Pharmaceutical Ingredients-

Status, Issues, Technology readiness and Challenges' which was released by Hon'ble Minister for S&T, Earth Sciences and Health and Family Welfare.

(ii) Research publication on Covid - Structure-Based Virtual Screening to Discover Potential Lead Molecules for the SARS-CoV-2 Main Protease published from the Institute.

(iii) Research on identification and analysis the structural features of enzymes and proteins associated with SARS-CoV-24 initiated.

(iv) Concept note prepared for the synthesis of anti-viral agents and new process development for improved synthesis of anti-viral agents, e.g.; remdesivir.

(v) One extramural research grant for Covid research submitted to a funding agency.

e. Guwahati

(i) Published a review article on progression and treatment against COVID-19 in a peer-reviewed international journal (European journal of Pharmacology) having an impact factor more than 3.0.

(ii) Patented ***"3D printed face protecting device"*** signed for the mutual non-disclosure agreement & finally the technology is licensed to Hindustan Antibiotics Limited (HAL).

(iii) Computation studies: Molecules which showed good docking score against COVID proteins has been submitted for anti-viral screening to RCB laboratories, New Delhi.

(iv) Have Supercomputing facility through remote access with PARAM ISHAN to work on various drug development activities including COVID 19.

f. Kolkata

(i) Hand sanitizer was prepared in the Institute laboratory and distributed among the faculties.

(ii) In-depth Analysis, Phytochemical identification and Network pharmacology-based analysis of three important Indian medicinal plants, *Nyctanthes arbor-tristis*, *Andrographis paniculata* & *Carica papaya* for treating COVID-19 has been carried out by exploiting LC-MS.

(iii) Phytochemical identification and Network pharmacology-based analysis of Biogreen winner Capsules by LC-MS for treating COVID-19.

(iv) Manuscripts related to Covid-19 research submitted to the International journals: a). Protease inhibitory effect of natural polyphenolic compounds on SARS CoV II: An in-silico study (Manuscript ID: molecules-908740) b). Screening of FDA approved drugs of fungal origin that may interfere with SARS CoV II spike protein activation, viral RNA replication and post translational modification: an in silico study (Manuscript Number: JMGM-D-20-00252).

(v) In depth analysis of putative active compounds of three important medicinal plants *Tinospora cordifol* *Ziziphus nummularia* and *Andrographis paniculata* has been carried out using Network Pharmacology based approach focusing.

3. Bureau of Pharma PSUs of India (BPPI)

Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP)

(i) In the wake of COVID-19 crisis, Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) has been rendering essential services to the nation. The stores remained functional during lockdown and maintained operations as part of their commitment to ensure uninterrupted availability of essential medicines. BPPI has clocked appreciable sales turnover of Rs. 198.39 crore in the first four months of 2020-21 despite the lock down and testing times as compared to Rs. 103.92 crore achieved in the first four months of 2019-20.

(ii) BPPI has adequate stock of the medicines currently under demand, viz., Face mask, Hydroxychloroquine, Paracetamol and Azithromycin. BPPI has sold about 16 lacs Face masks, 82 lacs tablets of Hydroxychloroquine in the month of March to August, 2020. Further, orders for 40 lacs Hydroxychloroquine tablets has also been placed. Envisioning current market demand, BPPI has also placed purchase orders for procurement of these medicines so as to have enough stock for the next six months.

(iii) Further, India has always believed in sharing its resources and expertise with its friendly and partnering nations notwithstanding, its own domestic challenges and constraints. The Department has furthered the belief of "Vasudhaiva Kutumbakam" and has so far supported our neighbouring countries in their fight against the pandemic by providing them stocks of many essential medicines through the Ministry of External Affairs. Complete details of the supplies made are as under: -

Supply of medicines through Ministry of External Affairs

Sl. No.	Name of the Country	No. of Medicines supplied	Invoice Value
1	Sri Lanka	19	Rs. 43,65,832/-
2	Mauritius	26	Rs. 39,98,147/-
3	Seychelles	41	Rs. 72,11,341/-
4	Nepal	36	Rs. 75,15,409/-
5	Bhutan	5	Rs. 10,35,811/-

Supply of medicines to embassy of friendly countries directly by BPPI

Sl. No.	Name of the Country	No. of Medicines supplied	Invoice Value
1	Uzbekistan	2	Free Supply

Supply of medicines through HLL Lifecare Limited (HLL) to MEA

Sl. No.	Name of the Party	No. of Medicines supplied	Invoice Value
1	HLL Lifecare Limited	24	Rs. 10,59,58,939/-

(iv) The number of PMBJP stores has increased to 6599 as on 09.09.2020.

(v) The Scheme has been approved with a budget of Rs. 490 cr. for the period 2020-21 to 2024- 25 with amount of incentives increased from existing Rs. 2.5 lakhs to up to Rs. 5 lakh to be given @ 15% of monthly purchase made from BPPI by these JAKs subject to a ceiling of Rs 15,000/- per month. Further, one-time incentives of Rs. 2.00 lakh is to be provided to the stores being opened in aspirational districts, North-Eastern states or by women/ divyang/ weaker sections of the society.
