GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

RAJYA SABHA
UNSTARRED QUESTION NO. 689
TO BE ANSWERED ON 18th September, 2020

Measures to tackle disruption in supply of drugs

689 Shri Mallikarjun Kharge:

Will the Minister of **Chemicals and Fertilizers** be pleased to state:

(a) whether Government has announced a set of measures to tackle possible disruption in supply of drugs and other manufactured goods due to Coronavirus outbreak in China; and
(b) if so, the details thereof?

ANSWER

MINISTER IN THE MINISTRY OF CHEMICALS & FERTILIZERS
(SHRI D. V. SADANANDA GOWDA)

(a) & (b): Yes, Sir. The Department of Pharmaceuticals (DoP) has taken various measures to ensure the availability of essential drugs at reasonable prices during the COVID-19 pandemic. Timely and effective steps were taken to ensure no shortage of drugs during the lockdown period throughout the country. The details are as under:-

(i) To ensure seamless availability of drugs, a 'Control Room' has been set up 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.

(ii) An inter-ministerial committee under the chairmanship of Shri S. Eswara Reddy, Joint Drug Controller, CDSCO has been constituted to monitor trends of export and import of APIs, Formulations and Medical devices to ensure timely availability of these items in the country and to prevent shortages. The committee submits its reports from time to time.

(iii) Availability of drugs has been ensured by coordinating with State Health Authorities like SDCs and Central Govt. Authorities like CDSCO, DGHS, DPIIT etc. National Pharmaceutical Pricing Authority (NPPA) under Department of Pharmaceuticals collected the critical information from drug manufacturers used in decision making to ensure drug availability.

(iv) Steps have been taken to ensure the availability of Heparin used in COVID-19 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%.

(v) The DoP 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 lock down.

(vi) 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, Remidesivir, Favipiravir, Zinc Sulphate, Mythyleprednisolone, Enoxparin, Dexamethasone etc.

(vii) Further, on the intervention of the Department of Pharmaceuticals, manufacturers of Remdesivir have created a Helpline to make available the Remdesivir. However, Remdesivir and Tocilizumab continue as under investigational therapy Drugs under Covid-19 Protocol. The details of various other measures taken by the NPPA are at **Annexure 1**.

Annexure 1

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 ofActive Pharmaceutical Ingredients (APIs) and their formulations, and necessary action should be taken 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 the 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 N95 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. NPPA undertook database creation in respect of said Medical Devices and shared 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 N95 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 procurement 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 general public.

NPPA's CONTROL ROOM AND HELPLINE

1. As a measure to deal with the emerging situation arising due to outbreak of COVID-19, 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 ID monitoring-nppa@gov.inon 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.

2. The NPPA's Control Room team worked vigorously 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 summary of the 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.

MEASURES FOR LOGISTIC MANGEMENT FOR AVAILABILTY OF DRUGS

1. NPPA associated with Empowered Group 5 headed by Shri Parameswaran Iyer, Secretary, DWS, 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 which also includes sealing of State borders at various places, Pharmaceutical sector faced serious challenges relating to logistics raw materials and manpower in an effort to provide seamless availability of drugs and medical devices across country. In this regard, NPPA took many initiatives in management of logistic disruption faced by the Pharmaceutical Industry which has 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 Acterma of COVID treatment, was facilitated through discussion with Cipla, the importer.

5. NPPA vide D.O. letter No. 37001/2020/Div.-III/NPPA/Part dated 25thApril, 2020 to Administrator, Daman & Diu and Chief Secretary Maharashtra, has 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 seamlessavailability 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 DCGIdeveloped 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) considered the representation of All India Industrial Gas Manufacturer Association (AIIGMA) regarding cost impact of production of medical oxygen by the major manufacturers on 27th May, 2020. Tariff Commission was asked to examine the claim.

NPPA coordinated the 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 AVAILABILTY OF DRUGS UNDER EXPORT RESTRICTION

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 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. NPPA is regularly monitoring the details regarding manufacturing, stock position and supplies of Paracetamol API made to domestic market by major manufacturers.

3. Further, also 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**.** Further, NPPA is submitting a daily report to Cabinet Minister, MoC&F regarding Hydroxychloroquine based on reports received from the concerned major manufacturers of the drugs.

MONITORING THROUGH SURVEY

The availability of key medicines is also monitored through CDSCO chemist level surveys, 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, Remidesivir, Favipiravir, Zinc Sulphate, Mythyleprednisolone, Enoxparin, Dexamethasone etc) come into 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 manufactures of Mythyleprednisolone, Enoxparin, Dexamethasoneto 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 WhatsApp group.

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 month.

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. NPPA took cognizance of reports of **black marketing** of Remedesvir and Toclizumab and directed 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-5 Masks as the same were available in the market at exorbitant and differential prices. In order to ensure availability of N95 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.

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.

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