

**F. No.50014/03/2020-CDN**  
Government of India  
Ministry of Chemicals and Fertilizers  
Department of Pharmaceuticals

Shastri Bhawan, New Delhi  
Dated June, 2020

To

The Cabinet Secretary,  
Rashtrapati Bhawan, New Delhi.  
(e-mail :cabinetsy@nic.in, subhag@nic.in)

**Subject: Monthly Report on the significant developments/ achievement of Department of Pharmaceuticals during the month of March, 2020 (in the revised format).**

Sir,

Kindly find enclosed information in prescribed format in respect of significant developments/achievements of Department of Pharmaceuticals for the month of March, 2020

Yours faithfully,



(H.K. Hajong)

Economic Advisor

Tel. No. 011-23381927

Encl: As above.

**1. Important policy decisions taken and major achievements during the month of March, 2020:**

**(A) IMPORTANT POLICY DECISIONS:**

The Union Cabinet in its meeting dated 20.03.2020 has approved two sub-schemes and the brief of these sub-schemes are as under:

**Scheme for Promotion of Bulk Drug Parks**

This scheme has been approved by the Union Cabinet on 20.03.2020. The total size of the Scheme is Rs.3000 Crore and tenure of the Scheme will be five years (2020-21 - 2024-25).

The scheme will provide grant-in-aid to 3 Bulk Drug Parks with a maximum limit of Rs.1000 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.1000 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 Solvent recovery and Distillation Plant, Central Effluent Treatment Plants, Captive Power Plants, Steam and Cooling systems, Incubation facilities, Common Logistic facilities, Advance Common Testing Centre, Regulatory awareness facility Centre, Emergency Response Centre etc. The scheme would be implemented through a State Implementing Agency (SIA).

**Production Linked Incentive (PLI) scheme for promotion of domestic manufacturing of critical Key Starting Materials (KSMS)/ drug intermediates and Active Pharmaceutical Ingredients (APIS) in India**

The Cabinet has also approved Production Linked Incentive (PLI) scheme for promotion of domestic manufacturing of critical Key Starting Materials (KSMS)/ drug intermediates and Active Pharmaceutical Ingredients (APIS) in India to promote their domestic manufacturing and to address their high import dependence. 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. For fermentation based eligible products, the first four years (2022-2023 to 2025-2026) would be 20%, for fifth year (2026-27) 15% and sixth year (2027-2028) 5% on incremental sale of KSMS/Drug Intermediates/APIs. For chemically synthesised eligible products for entire scheme (2021-2022 to 2026-2027) should be 10% on incremental sales of KSMS/Drug Intermediates/APIs. A total outlay of Rs. 6,940 Crore has been approved for the scheme for a period of 07 years subsequent to the base year. The scheme would be implemented through a Project Management Agency (PMA) to be nominated by the Department of Pharmaceuticals. With the successful implementation of this Scheme it is expected that India would be well positioned as a global hub for manufacturing of critical KSMS/Drug Intermediates and APIs along with the final drug formulations.



**b. Scheme for promotion of Medical Device Parks:**

The sub-scheme termed as "Assistance to Medical Device Industry for Common Facility Centre" is a Central Sector Scheme under the umbrella scheme for Development of Pharmaceutical Industry. The total size of the above sub-scheme was Rs.100 Crores for 2018-2020. The sub-scheme proposes to provide a one-time grant-in-aid to the tune of Rs.25 Crore or 70% of the project cost, whichever is less, to be released for creation of identified infrastructure and common facilities to a State Implementing Agency (SIA) set up for the purpose. The purpose of the grant is to render the financial assistance for establishment of common facilities in any upcoming Medical Device Parks promoted by State Governments/State Corporations.

However, it was realized that creation of common facilities requires large investment and the Department proposed revision under the existing sub-scheme. with an outlay of Rs.400 Crore for financing 4 medical device parks from financial year 2020-21 to 2024-25 which has been approved by the Cabinet in its meeting held on 20.03.2020. The new sub-scheme proposes to provide enhanced maximum limit for grant-in-aid of Rs.100 Crore per park.

**Production Linked Incentive Scheme for Promoting Domestic Manufacturing of Medical Devices**

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 Production Linked Incentive Scheme proposes 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 subsequent to the base year 2019-20. The tenure of the Scheme will be from 2020-21 to 2025-26. The expected incentive to the tune of Rs. 3420 Crore will be provided during the tenure of the Scheme. The detailed guidelines of the scheme are being prepared.

**II. Consumer Awareness, Publicity and Price Monitoring Scheme (CAPPM)**

In March, 2020 one PMRU has been set up in the State of Jammu & Kashmir. With this 12 (Twelve) PMRUs have been set up in the States viz. Kerala, Gujarat, Odisha, Rajasthan, Punjab, Haryana, Tripura, Nagaland, Uttar Pradesh, Andhra Pradesh, Mizoram and Jammu & Kashmir up to March 2020.

**III. Action taken by NPPA in the wake of outbreak of COVID-19**

In the wake of outbreak of COVID-19 situation, National Pharmaceutical Pricing Authority (NPPA) had taken immediate action to take stock of the situation and as a measure of public health preparedness has taken following measures in the interest of the public health:

- a. NPPA had requested all Chief Secretaries of States/UTs to closely monitor the production and availability of APIs and their formulations to prevent black



marketing and hoarding and necessary action should be taken under the provisions of DPCO, 2013 to ensure availability of life saving essential drugs to the consumers at all times.

- b. NPPA, 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.
- c. NPPA issued letters 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.
- d. At the intervention by NPPA, DCGI vide Order dated 19<sup>th</sup> March had directed all Port Offices of CDSCO to take proactive measures to help for clearance of imported stock of gloves in coordination with Customs in expedited manner in public interest.
- e. 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, NPPA set up a 'Control Room' with Helpline No. 1800111255 and e-mail ID monitoring-nppa@gov.in on 20<sup>th</sup> March 2020. The Control Room has attended 1805 calls and resolution have been provided to all types of the complaints in coordination with the and Drug Control Departments, etc.
- f. NPPA Control Room team vigorously on 24 x 7 basis 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 varieties of issues. The summary of the issues resolved through 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.

- g. NPPA had made all out efforts to collect data regarding manufacturing capacity, domestic requirement, current stock, procurement orders of APIs/KSMs/Intermediates i.r.o 13 drugs under Export restriction to help the Empowered Committee in examination of the situation and taking informed decisions.



- h. Based on recommendations of Empowered Committee, DoP/NPPA had issued recommendation orders dated 6<sup>th</sup> /7<sup>th</sup> /9<sup>th</sup> /15<sup>th</sup> April, 2020 indicating surplus available for exports during the month of April i.r.o Hydroxychloroquine and Paracetamol. NPPA is constantly monitoring the availability of Hydroxychloroquine and Paracetamol in the domestic market
- i. NPPA along with DCGI has created a master database of 55+97 COVID+ drugs required for ensuring availability of essential medicines for COVID-19 patients admitted to hospitals alongwith other list of essential drugs, in general, that are projected for use during the following three months. NPPA has taken various actions to identify all manufacturers of above referred formulations and their APIs/ KSMs establishing each manufacturers production level, source of API/raw material, level of supply to domestic market, comparing the stated requirement of said drugs with present production levels to check excess or shortages, if any.
- j. NPPA conducted various meeting through video conferencing with SDCs, DCGI and Manufacturer Associations for ensuring availability of Vaccines, Anti-diabetic medicines, Anti-cardiac medicines and other essential medicines.
- k. In the present circumstances arising due to the outbreak of COVID-19, the work of NPPA has increased manifold. The team of NPPA is working in a war mode throughout the lockdown period over weekends and gazetted holidays to meet the challenges of 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.

**(B) MAJOR ACHIEVEMENTS:**

(i) NPPA has fixed retail prices of 33 new medicines during March, 2020 bringing cumulative figure to 1268 till March, 2020. (i.e. 52 in 2013-14, 108 in 2014-15, 124 in 2015-16, 157 in 2016-17, 234 in 2017-18 and 327 up to March, 2019 in 2018-19, 266 in March in 2019-20 in 2020-21).

(iii) Total overcharged amount received during March, 2020 is Rs. 244.05 Lakh.

(iv) 106 Jan Aushadhi Kendras under Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) were opened during **March, 2020** across the country.

2. Important policy matters held up on account of prolonged inter-ministerial consultation.

**NIL**

3. Compliance of CoS decisions:

**NIL**

4. No. of cases of 'sanction for prosecution' pending for more than three months:

**NIL**

5. Particulars of cases in which there has been a departure from the Transaction of Business Rules or established policy of the Government:

**NIL**

6.(a) Status of implementation of e-Governance:

Total No. of files	Total No. of e-file
42	14

6(b). Under the Integrated Pharmaceutical Database management System (IPDMS), Pharmaceutical companies are directed for online filing of returns in Form-II, III and V vide orders dated 11.10.2014 under DPCO, 2013. Details of forms received in IPDMS up to the month of March, 2020 are as follows:

Month	Companies registered	Products registered	Form V filed	Form II filed
March	949	79226	58520	12300

7. Status of Public Grievances:

No. of public Grievances redressed during the month of March, 2020	No. of Pubic Grievances pending at the end of the month (as on 31.03.2020)
93	101

8. Information on the specific steps taken by the Ministry/Department for utilization of the Space Technology based tools and applications in Governance and Development:-

**NIL**

9. Status of FDI Proposals

March, 2020

- a. Pending Proposals: 14
- b. Approved Proposals:3
- c. Rejected Proposals: 0
- d. Closed Proposals: 4