

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

Shastri Bhawan, New Delhi  
Dated: 17<sup>th</sup> December, 2021

**Subject: Monthly Summary Report in respect of Department of Pharmaceuticals for the month of November, 2021-reg.**

The undersigned is directed to circulate herewith a copy of the Monthly Summary pertaining to the Department of Pharmaceuticals for the month of November, 2021 for information.



(Shamim Uddin Ansari)

Under Secretary to the Govt. of India

To,

1. All members of Council of Ministers.
2. Vice Chairman, NITI Aayog, Yojana Bhawan, New Delhi.
3. The Principal information Officer, M/o Information and Broadcasting, Shastri Bhawan, New Delhi.

Copy to:

1. Secretaries to the Govt. of India, All Ministries/Department.
2. The Chairman, UPSC, Shahajahan Road, New Delhi-110069.
3. Secretary to President of India (Rashtrapati Ke Sachiv), Rashtrapati Bhawan, New Delhi-110004.
4. Secretary to Vice- President of India (Uprashtrapati Ke Sachiv), New Delhi-110004.
5. PS to Prime Minister of India, South Block, New Delhi-110004.
6. Director, Cabinet Secretariat, Rashtrapati Bhawan, New Delhi-110004.
7. Sr.PPS to Secretary (Pharma).
8. Director (NIC), Department of Pharmaceuticals, Shastri Bhawan, New Delhi.

**Ministry of Chemicals & Fertilizers**  
**Department of Pharmaceuticals**  
**Monthly Summary for the Month of November, 2021**

Important events for the Month of **November, 2021** are as follows:

**1. IMPORTANT POLICY DECISIONS:**

NIL

**2. MAJOR ACHIEVEMENTS:**

- (i) **Export of Remdesivir and Amphotericin-B:** On 01.06.2021 and 14.06.2021, export policy of remdesivir injection / API and Amphotericin-B injections, respectively, was amended from 'Prohibited' to 'Restricted'. Subsequently, DGFT has been referring applications for export in this regard to DoP and DoHFW for recommendations. During **November 2021**, 4,43,570 vials of Remdesivir and 2,98,800 units of Amphotericin B were recommended for export to DGFT.
- (ii) **Selection of applicants in the PLI Scheme for Pharmaceuticals:** The PLI scheme for Pharmaceuticals with an outlay of Rs 15000 crores provides for selection of 55 applicants. The 278 applications received under the PLI Scheme were considered for ranking as per selection criteria and 55 applicants were finalized on 26.11.2021, including 25 MSMEs, in line with the Scheme guidelines.
- (iii) FDI inflow approved during this month:- ₹552.27 crore.
- (iv) 91 Jan Aushadhi Kendras under Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) were opened during November, 2021 across the country taking cumulative of total to 8536.
- (v) **Activities of NPPA:**
  - (a) Ceiling prices of 02 medicines namely Methylthioninium chloride (Methylene blue) 10mg/ml and Hydroxocobalamin Injection 1mg/ml, have been fixed by NPPA during November, 2021 bringing the cumulative figure to 886 till November, 2021.
  - (b) Retail prices of 47 new medicines have been fixed by NPPA during November, 2021 bringing cumulative figure to 1668 till November, 2021.
  - (c) **Opening of PMRU in West Bengal:** Price Monitoring & research Unit was established in the state of West Bengal, bringing the number of PMRUs to 21 in the country.
  - (d) **Market Research on availability of COVID Management Drugs:** Five (5) market research analysis has been conducted through Price Monitoring and Resource Units (PMRUs) in the eighteen States on weekly basis in November, 2021 to assess the availability of COVID Management Drugs in the market.
  - (e) **Monitoring of COVID drugs for Buffer Stock:** As part of measures being taken to strengthen the preparedness to meet any future surge, MoHFW has released the guidelines for Buffer Stock Management of drugs used for COVID-19 wherein it was emphasized that the States must initiate procurement on priority for building up buffer stock. NPPA, has been assigned the task of coordinating with States / UTs and the manufacturers, if any facilitation is required to monitor the supplies, once the purchase orders are placed. A meeting with the States/UTs convened by MoHFW was attended by MS, NPPA on 22nd November 2021 and it was highlighted that States / UTs need to place orders as per the buffer guidelines

well in advance. A meeting was convened by CDSCO on 30th November 2021, under the chairmanship of Chairperson, NPPA with the manufacturers of Enoxaparin, Heparin and Tocilizumab as well as the API manufacturers, to take account of the production, supply & stock.

(f) **Authority Meeting:** The 225<sup>th</sup> (overall) and 93<sup>rd</sup> meeting of the Authority under DPCO, 2013 was held on 15<sup>th</sup> November 2021 in which in addition to fixing ceiling price of two drugs, the prices of Oxygen Concentrators, as fixed vide S. O. No. 2161(E) dated 03.06.2021 under TMR approach, further extended upto 31.05.2022.

(g) The demand of Medical device industry to permit quarterly submission of information relating to stock details of medical devices namely, (i) Bare Metal Stents, (ii) Drug Eluting Stent, (iii) Orthopaedic Knee Implants, and (iv) Oxygen Concentrators instead of on a monthly basis was agreed to. It will lead to reduction in compliance burden

(vi) **Total overcharged amount received during November, 2021 is Rs. 20.58 Lakhs.**

(vii) **Activities of NIPERs:**

(a) NIPERs has organized 10 Seminars, 6 Workshops and 4 other events during the month of November, 2021.

(b) Out of 455 Research Papers published during the current financial year, 57 papers have been published in the month of November, 2021.

(c) Out of 13 Patents filed during the current financial year, 1 patent has been filed during the November, 2021.

(viii) **Policy related Activities**

(a) **Interaction with the industry to discuss the draft Uniform Code for Medical Devices Marketing Practices:** Department of Pharmaceuticals assigned the task for preparing draft Uniform Code for Medical Devices Marketing Practices (UCMDMP) to Standing Forum of Medical Device Associations having convenor Medical Device Technology Association of India (MTAI). A discussion session was organised under the chairpersonship of Secretary (Pharma), on 10.11.2021 with Industry to discuss various aspects of UCMDMP.

(b) **Interaction with CII to discuss issues on streamlining of the regulatory framework for Medical Devices:** CII was made convenor of the Standing Forum of Medical Device Associations for the specific task to identify the issues on Streamlining of the Regulatory framework for Medical Devices. The report was submitted by CII on 25.10.2021. A discussion session was organised under the chairpersonship of Secretary (Pharma), on 11.11.2021 with the representatives of CII to discuss on the issues of Streamlining of the Regulatory framework for Medical Devices.

(c) **Organized Meeting to discuss the draft National Medical Device Policy:** A meeting was organized on 15.11.2021 under the chairmanship of Dr. N. Yuvraj, Joint Secretary, DoP to discuss the draft National Medical Device Policy with the Medical device Industry associations.

(ix) **Status of API-CF Schemes:**

Meeting of the Scheme Steering Committee (SSC) held under the Chairpersonship of Secretary, Department of Pharmaceuticals on 11.11.2021. The following points were discussed:-

(a) **Kala Amb Infrastructure Development Company (KIDC):** SSC has directed that the bills shall be scrutinized by PMC within a week and a detailed report about the approved components be submitted.

- (b) **MIIs Inducare Pharmaceuticals and Research Foundation (IPRF):** SSC directed the PMC to submit a detailed due diligence report based on progress made and as per Scheme guidelines.
- (c) **Jeedimetla Effluent Treatment Ltd. (JETL):** SSC directed the PMC to do the due diligence, rates such as GeM rates, etc. Further, SSC directed PMC to re-examine the proposal and re-submit.
- (d) **Sirmour Green Environ Limited (SGEL):** SSC directed the PMC to re-submit the project proposal with segregation of the cost for industrial effluent (1.5 MLD) and detailed due diligence report.
- (e) **Bulk Drug Manufactures Association (BDMA):** SSC observed that multiple extension of "in-principle" approval have been given to the project. Hence, the proposal accorded is decided to be canceled.

(x) **Status of PLI Schemes:**

S.No.	Name of Scheme		Total No. of Application Received*	No. Applications approved in the month of November	Total no. of applications approved till November
1	Production Linked Incentive Scheme for Bulk Drug  (Last EC Meeting held on 25.11.2021 on PU Bulk Drugs)*	Round 1	215	0	42
		Round 2	24	08	08
		Total	239	08	50
2	Production Linked Incentive Scheme for Medical Device  (Last EC Meeting held on 25.11.2021 on Medical Devices)*	Round 1	28	0	13
		Round 2	14	08	08
		Total	42	08	21

\*The MoM of EC meeting is under submission for approval of Hon'ble Minister C&F.

2. The details of grievances during the **November, 2021** are as under:

No. of grievances at the start of the month	No. of grievances received during the month	No. of grievances disposed	No. of grievances pending at end of the month
54	85	112	27

3. **FDI proposals: -**

- Pending at beginning of the month:- (15)
- Received during the month:- (3)
- Disposed of during the month:- (2)
- Pending at end of the month:- (16)

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