

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

Shastri Bhawan, New Delhi  
Dated: October, 2021

**Subject: Monthly Summary Report in respect of Department of Pharmaceuticals for the month of September, 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 September, 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. PSO 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 September, 2021**

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

**1. IMPORTANT POLICY DECISIONS:**

**(i) 'In-principle' approval to the States of Himachal Pradesh, Uttar Pradesh, Madhya Pradesh and Tamil Nadu under the scheme "Promotion of Medical Device Park" :-** The Union Cabinet has approved the revision in the sub-scheme from 'Assistance to Medical Device Industry for Common Facility Centre' to 'Promotion of Medical Devices Parks'. Recognizing the need for higher levels of investments for the creation of testing and laboratory facilities, the Department of Pharmaceuticals has notified the scheme "Promotion of Medical Devices Parks" on 21.07.2020. Under the Scheme, a one-time grant-in-aid will be provided for creation of common infrastructure facilities in selected Medical Device Park proposed by a State Government. The parks will provide common testing and laboratory facilities / centre at one place reducing the manufacturing cost significantly and will help in creating a robust ecosystem for medical device manufacturing in the country. The total financial outlay of the scheme is Rs. 400 crore. The tenure of the scheme is from FY 2020-2021 to FY 2024-2025.

Sixteen (16) States/UTs submitted their proposals under the scheme. After evaluation of proposals and approval of Scheme Steering Committee, the Department vide letters dated 24.09.2021 conveyed '**in-principle**' approval to four states i.e. Himachal Pradesh, Uttar Pradesh, Madhya Pradesh and Tamil Nadu under the scheme "Promotion of Medical Device Park".

**2. MAJOR ACHIEVEMENTS:**

**I. MEDICAL DEVICES:**

**(i) Third meeting of Scheme Steering Committee (SSC) of the scheme "Assistance to Medical Device Industry for Common Facility Centre" held on 30.09.2021:** Under the scheme, the project of Andhra Pradesh Medtech Zone Ltd (AMTZ) has been given approval for grant of Rs. 25 crore for creation of common facility centre for superconducting magnetic coils testing & research facility. The Department had released 1<sup>st</sup> installment of Rs. 7.49 crore for the project to AMTZ on 11.09.2020. During the 3<sup>rd</sup> meeting of SSC, the progress of the project was reviewed, for release of 2<sup>nd</sup> installment of Grant-in-aid to AMTZ. The SSC approved the release of second installment of Rs. 7.50 crore to AMTZ. Upon completion of the project, it would enable testing of superconducting magnet in the country and would therefore lead to the manufacturing of MRI machines in the country.

**(ii) Regulatory Roundtable on the issues of medical devices with the medical device industry, held on 30.09.2021:** Medical devices Industry has been representing to the Department regarding the need for simplification or streamlining of various regulatory compliance. It being stated policy of the Government of India to minimize regulatory compliance burden on the business as well as the citizens, this Department in partnership with FICCI has compiled a list of various issues being faced by the industry on the regulatory side and along with suggestions on the same. Accordingly, a virtual Regulatory Round-table was held on 30<sup>th</sup> September 2021, addressing the issues of the industry with the Regulators of medical devices sector. The Round-table meeting was attended by various representatives of Industry and their issues were noted for redressal by the concerned Regulators.

## **II. DRUG MONITORING:**

(i) Two meetings of the Drugs Coordination Committee were held during the month on 01.09.2021 and 27.09.2021 wherein procurement orders placed by States/UTs for Covid drugs buffer stock; adequacy of raw material supply w.r.t. manufacture of drugs used in COVID-19 treatment; New approvals granted by CDSCO or State Licensing Authorities; Update on monoclonal antibodies licenced for import / manufacture / marketing; export of remdesivir and amphotericin B; imports of Tocilizumab; manufacturing and availability of IVIG including coordination with blood banks to boost plasma availability were reviewed. Inter-alia, the early effective functioning of buffer operations was prioritized with an emphasis on eliminating/minimizing bottlenecks w.r.t. raw material availability and eliciting active participation of States/UTs and other concerned stakeholders.

(ii) 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 September, 2021, 55,18,111 vials of remdesivir and 2,53,186 vials of Amphotericin B were recommended for export to DGFT.

(iii) Allocation commercial shipments of Tocilizumab is being undertaken jointly by the Department of Pharmaceuticals and Ministry of Health and Family Welfare amongst States/UTs to ensure equitable distribution of limited availability of this drug since it was not manufactured in the country and sourced through imports from M/s Roche, Switzerland. On 14.09.2021, allocation of 5,311 patient doses was made from fresh imports / reserve stocks. Further, inter-alia, States/UTs have also been requested to utilize the drug judiciously.

## **III. National Pharmaceutical Pricing Authority (NPPA):**

(i) Retail prices of 23 new medicines have been fixed during September, 2021 bringing cumulative figure to 1621 till September, 2021.

(ii) Total overcharged amount received during September, 2021 is Rs. 37.510 thousand.

(iii) **'Consumer Awareness, Publicity and Price Monitoring (CAPPMP)' Scheme:** In the Run-up of India @ 75, 'Bharat ka Amrit Mahotsava', on 30<sup>th</sup> September, 2021, NPPA conducted a Webinar at National Level on 'Survey on availability of COVID Management Drugs'. Representatives of most of the States/UT governments attended the webinar.

(iv) **Special Campaign to dispose of pending references:** An online workshop on "Weeding out of old files/ records" was got conducted under the Special Campaign to dispose of pending references on 28th September, 2021. This workshop was conducted by one of the faculty members of the ISTM. This workshop was attended by about 20 officers and staff from NPPA/ Department of Pharmaceuticals and PMBI (Pharmaceuticals and Medical Devices Bureau of India).

## **IV. Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP):**

217 Jan Aushadhi Kendras under Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) were opened during **September, 2021** across the country taking cumulative of total to 8339.

## **V. National Institutes of Pharmaceutical Education and Research (NIPERs):**

- (i) Common Admission process for the current academic year completed with 988 Masters and 185 PhD fellows selected for the seven NIPERs..
- (ii) Out of 346 Research Papers published during the current financial year, 49 papers have been published in September, 2021.
- (iii) Out of 11 Patents filed during the current financial year, 1 patent has been filed during the September, 2021.
- (iv) NIPERs have organized 20 Seminars, 3 Workshops and 6 other events during the month of September, 2021.

## **VI. COVID-related activities:**

- (i) **Market Research on availability of COVID Management Drugs:** NPPA through Price Monitoring and Resource Units (PMRUs) in the eighteen States have conducted four (4) market research analysis on weekly basis in September, 2021 to assess the availability of COVID Management Drugs and five medical devices in the market.
- (ii) **Activities undertaken to ensure supply of Buffer Drug:** Meetings of Covid Drug Management Committee (CDMC) meetings held on weekly basis under the chairmanship of Secretary (DoP) on 7<sup>th</sup>, 14<sup>th</sup>, 21<sup>st</sup> and 28<sup>th</sup> September 2021. NPPA remained actively in touch with the Liaison officers of manufacturers, Nodal Officers of States/UTs and CDSCO to ensure uninterrupted supply of the buffer drugs. The steps undertaken by the NPPA in the month of September 2021 in coordination with CDSCO are summarized in Table below:

<b>Date</b>	<b>Activities</b>
3 <sup>rd</sup> September 2021	A meeting was held to discuss the production plan, supply and other related issues being faced by the manufacturers /importers of Posaconazole & IVIG Formulation.
4 <sup>th</sup> September 2021	A meeting was held to discuss the production plan, supply and other related issues being faced by the manufacturers /importers of Dexamethasone, Remdesivir, Conventional Amphotericin and Methyl Prednisone.
10 <sup>th</sup> September 2021	A meeting was held with the representatives of the MoHFW, CDSCO and DoP to discuss the road map to place a system for monitoring the procurement of buffer drugs with manufacturers. A meeting was held to discuss the production plan, supply and other related issues being faced by the manufacturers /importers of Baricitinib, Azithromycin, Doxy cycline and Itolizumab.
14 <sup>th</sup> September 2021	A meeting was held with the manufacturers of the IVIG wherein the company representatives were advised to participate in the Govt tenders and supply the drugs at earliest.
17 <sup>th</sup> September 2021	A meeting was held to discuss the production plan, supply and other related issues being faced by the manufacturers /importers of Paracetamol tab/Oral/Suspension, Methyl Prednisolone, Prednisolone. (MoM under process)
23 <sup>rd</sup> September 2021	A meeting was held with the manufacturers/importers of the Infliximib to understand the production/import plan of the drug.
24 <sup>th</sup> September 2021	A meeting was held to discuss the production plan, supply and other related issues being faced by the manufacturers /importers of Liposomal Amphotericin, Heparin, Ivermectin, Budesonide.
29 <sup>th</sup> September 2021	A meeting with manufacturers/importers of Monoclonal Antibodies was held to review their stocks, production plans/imports etc.



30 <sup>th</sup> September 2021	A meeting was called of 11 States/UTs that had shown an increase in number of COVID cases to ascertain the status of placing of POs as per the buffer guidelines of MoHFW. Eight States/UTs attended the meeting. Representatives of Goa, Mizoram and A&N Islands did not attend the meeting.
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#### **VII. Budget Expenditure:**

In the Financial Year 2021-22, the total budget allocated to Department of Pharmaceuticals Rs. 470.41 Cr and the details of expenditure incurred are as below:

(Rs. in Crore)

Total Budget allocated	Expenditure incurred (as on 30.09.2021)	Expenditure incurred in the month of September, 2021 (as on 30.09.2021)
Rs. 470.41	Rs. 258.39	88.99

#### **VIII. Status of PLI Schemes:**

S.No.	Name of Scheme	Total No. of application received	Total no. of application approved during the month of September, 2021	Total no. of application approved till date (30.09.2021)
1	Production Linked Incentive for Bulk Drug	215 in 1st round 24 in 2nd round	0	42
2	Production Linked Incentive for Medical Device ( 28 slots)	28 in 1st round 14 in 2nd Round	0	13
3	Production Linked Incentive scheme for Pharmaceuticals (about 55 slots)	The scheme was notified on 03.03.2021, Operational Guidelines issued on 01.06.2021 Corrigendum issued on 30.06.2021 and 13.08.2021.	Total 278 applications were received as on 31.08.2021 and all are under examination by SIDBI (Project Management Agency)	

3. The details of grievances during the **September, 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
59	236	261	34

4. FDI proposals:-

(a) Pending at beginning of the month	:-	17
(b) Received during the month	:-	1
(c) Disposed of during the month	:-	2
(d) Pending at end of the month	:-	16

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