सं. / No. 50014/03/2020-CDN

भारत सरकार/Government of India

रसायन एवं उर्वरक मंत्रालय / Ministry of Chemicals and Fertilizers

औषध विभाग / Department of Pharmaceuticals

223ए, शास्त्री भवन, नई दिल्ली/ 223A, Shastri Bhawan, New Delhi Dated: //^LNovember, 2023

OFFICE MEMORANDUM

Subject: Monthly Summary Report in respect of Department of Pharmaceuticals for the month of October, 2023-reg.

The undersigned is directed to circulate herewith a copy of the Monthly Summary pertaining to the Department of Pharmaceuticals for the month of October, 2023 for information.

(Sandeep Kumar) 6-X (.2!

(Sandeep Kumar) Under Secretary to the Govt. of India Tel. 011-23387920

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

1. Important policy decisions taken and major achievements during the month of October 2023:

A. National Institutes of Pharmaceutical Education & Research (NIPERs):

New Schemes:

- Cabinet in its meeting held on 25.07.2023 has approved the Scheme for Promotion of Research and Innovation in Pharma-Med Tech (PRIP) with an outlay of Rs.5000 crore for a period of 5 years i.e., 2023-24 to 2027-28. The Scheme was notified on 17.08.2023 and formally launched on 26.09.2023.
 - Application for Request for Proposal from CPSEs/Public Financial Institutions to work as a Project Management Agency (PMA) for PRIP Scheme has been invited.
 - Operational guidelines for the PRIP Scheme have been uploaded on the Department website on 25.10.2023.
- A new scheme on 'Human Resource Development in Medical Devices Sector' has been approved with an outlay of Rs.480 crore for a period of three years envisaging financial assistance to government institutions for running multi-disciplinary dedicated courses in medical technology. Operational guidelines for the Scheme have been uploaded on the Department website on 20.10.2023.

Research Papers, Patents and MoUs:

- Out of 596 research papers published during the current financial year, 89 papers have been published in the month of October 2023.
- Out of 31 Patents filed during the current financial year, 05 patents were filed in the month of October 2023.
- Out of the 24 MoUs signed during the current financial year, one MoU have been signed in the month of October 2023.

Workshops/Seminars/Training and other events:

- NIPER-Mohali organized Hands-on training on High Performance Liquid Chromotography (HPLC) & Nuclear Magnetic Resonance (NMR 600) MHz on October 16, 2023.
- NIPER-Mohali celebrated 14th Convocation on October 14, 2023.
- Atal Incubation Centre NIPER-Guwahati Foundation organized an Expert Talk on "Integration of Evolving Technologies in Healthcare and Surveillance" on 12th October 2023.
- Dr. Pallab Bhattacharya, Associate Professor and Dean, received the "**Best Stroke Researcher of the Year**" award by Hon'ble Health Minister of Gujarat at National Stroke Conclave 2023.

- Top 2% World Scientist: Dr. Rakesh K. Tekade, faculty from NIPER-Ahmedabad, was listed as a Top 2% World Scientist in a recent list published by Stanford University, USA.
- NIPER Ahmedabad hosted a 2-day hands-on training program in "Peptide Synthesis and Characterization" on October 17-18, 2023.

B. National Pharmaceutical Pricing authority (NPPA):

(i) During the month, 29 new drug prices fixed under NLEM 2022 as approved during the 117th Authority meeting held on 13.10.2023. These were notified vide S.O. No. 4660 (E) dated 25.10.2023. The details of drug prices fixed in the financial year 2023-2024 are as under:

S. No.	Prices fixed/ Notified under Revised Schedule I (NLEM		U	Cumulative from 1 st April, 2023 to
	202	22)	1 st October, 2023	31 st October 2023
			to	
			31 st October 2023	
1.	Ret	ail Price of 'New Drug'	29	213
2.	i.	Fixation of ceiling		
		Price under revised	0	40
		scheduled-I (NLEM		
		2022) of DPCO, 2013		
	ii.	Fixation of ceiling		
		price with special	0	2
		features under		
		scheduled - I (NLEM		
		2022) of DPCO, 2013		
	iii.	Exemption under para		
		32 of DPCO, 2013	2	3
		(NLEM 2022)		

(ii) The details of exemption granted under Para 32 of DPCO, 2013 in October 2023 are as follows:

- a) Exemption under Para 32 (i) & (ii) of DPCO 2013 granted to M/s Cadila Pharmaceuticals Limited for their product Cholecalciferol Aqueous Injection 6,00,000 IU /2 ml (Vitamin D3 Injection)
- b) Exemption under Para 32 (i) of DPCO 2013 granted to M/s Panacea Biotec Limited for their product EasyfourPol (DTwP-Hib-IPV) Vaccine

(iii) On the basis of Monitoring & Enforcement activities, One Hundred Twenty-Nine (129) Preliminary Notices (PN) were issued.

(iv) As a result of enforcement activities, during the month of October 2023, **Rs.1,08,09,442**/- (Rupees One crore Eight Lakh Nine Thousand Four Hundred Forty-Two only) was received towards overcharged amount.

(v) NPPA through Price Monitoring and Resource Units (PMRUs) in the States/UTs conducted 5 market surveys in October 2023 to assess the availability of drugs.

(vi) During this period, under the Special Campaign 3.0, NPPA adopted two best practices which are as under:

- a) To ensure the safe and proper disposal of leftover / expiry/ near expiry medicines and to protect our environment, "Guidelines on Storage and Disposal of Drugs" was framed by NPPA in consultation with Lady Hardinge Medical College /Hospital and circulated to SDCs and PMRUs for use.
- b) A box for collection of expired/ unused medicines was installed at Office of NPPA, YMCA Building, Jai Singh Road, New Delhi. Thereafter, the collected medicines will be disposed of by Lady Hardinge Medical College & Hospital & Mediflo.

C. International Cooperation:

(i) DoP participated in the 13th round of India-UK FTA negotiations on 10th October 2023 wherein Goods Market Access between India and UK was discussed.

(ii) A Meeting was convened under chair of Secretary, Department of Pharmaceuticals with Mr.Selby Pillay, Ambassador, Seychelles Foreign Affairs Department; CEO, Health Care Agency; Chief Pharmacist and Procurement Officer for Pharmaceutical Supplies from Seychelles; Director General, Pharmexcil and officers from Ministry of External Affairs (MEA) and Seychelles High Commission on 11th October 2023 wherein the possibility of greater sourcing of medicines by Seychelles from India was discussed.

(iii) DoP participated in the 5th Indo-US Health Dialogue at Washington DC, USA between 10th-13th October and made a presentation related to Pandemic Preparedness and Response (Resilient Supply Chain and Access to Medical Products) as well as Health Safety & Security & Strengthening and Harmonization of Regulatory System session of the meeting.

(iv) DoP participated in the 6th Meeting of the Intergovernmental Commission (IGC) for Commercial, Economic, Scientific and Technological Cooperation between the Republic of Azerbaijan and the Republic of India 25th-26th October, 2023 in Baku, Azerbaijan The Azerbaijan-India IGC was co-chaired by Mr. Mukhtar Babayev, Minister of Ecology and Natural Resources, on behalf of the Government of the Republic of Azerbaijan and Smt. Anupriya Patel, Minister of State for Commerce and Industry, on behalf of the Government of India wherein cooperation in Pharmaceutical Sector through National Institutes of Pharmaceutical Education and Research (NIPERs) was discussed. (v) DoP participated in the USISPF Round-table on Building Resilient Supply Chains for Pharmaceuticals, Medical Devices & Diagnostic Industry held on 25th-26th October. The aim of the industry roundtable was to understand what is needed to further strengthen and create robust supply chains in the pharmaceuticals, medical technology, and diagnostic industry, while addressing the common challenges and understanding the opportunities present in these critical domains, and to explore US-India areas of potential collaboration for the pharmaceutical, medical technology and diagnostic supply chain.

(vi) A Meeting was convened under chair of Secretary, Department of Pharmaceuticals with H.E. Ana Taban, Ambassador of the Republic of Moldova to the Republic of India on 27.10.2023 wherein various aspects of bilateral cooperation between Moldova and India was discussed.

D. Schemes:

	s functional	BJP at ue in R d savi mon m	t MRP Val Rs.crore an ng to com nan during onth of Oc 2023			vidha San itary Nap kins @ Rs .1/- per pa d during t he month October, 2023	ded in the mont h October, 202 3
Octobe r 2023	Cumulative	Sale	Saving	Medicine s	Surgical		
	(As on 31.1 0.2023)		In Rs.(cro re) (Appr ox.)				
96	9998	117.7 9	589.00	1965	293	1.39 crore	1.16 crore

(i) Status of Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP):

(ii) Status of PLI Schemes

S. No.	Name of Scheme		Total No. of Application Received*	Applications	Total No. of applications approved as on date
100000		Round 1	215	0	38
	Incentive Scheme for Bulk	Round 2	24	0	07
	Drug	Round 3	09	0	02
	(Last EC Meeting held on 04.10.2023 on PLI Bulk	Round 4	01	0	01
	Drugs)	Total	249	0	48

2.	Production Linked		28	0	11
	Incentive (PLI) Scheme for	Round 2	14	0	08
	Medical Device	Round 3	18	0	05
	(Last EC Meeting held on	Round 4	04	0	02
	04.10.2023 on Medical Devices)	Total	64	0	26
3	Production Linked Incent Scheme for Pharmaceutical		278	0	55

(iii) The Actual progress made as on June 2023 under the PLI Schemes are as follows:

Defails as on June 2023	PLI Bulk Drugs	PLI Medical Devices	PLI Pharmaceuticals
Actual Investment (Rs.in crore)*	2543.87	851.56	22381.38
Actual Production (Rs.in crore)	695	2467.26	88597.33
Actual Employment (No. of persons)	2431	4217	47286
Project Commissioned	26	14	261 manufacturing locations

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

NIL

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

NIL

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

NIL

5. Status of ongoing Swachhata Abhiyan (progress under Special Campaign):

- All 62 Public Grievances settled.
- No pendency on other parameters also as monitored under Special Campaign.
- All 9648 identified outdoor sites cleaned covering length and breadth of the country. This includes 9600 Jan Aushadhi Kendras cleaned with initiative and support of PMBI creating a far-reaching impact among general public and creating awareness on importance of clean and hygienic environment among all.
- Under 68 premises cleaned by PMRUs in 24 State, participation of 803 people spending more than 1341 man hours achieved.
- 5823 physical files reviewed and 1400 files weeded out. In addition, 3261 recently 'Parked' e-Files have been reviewed and decision taken to retain for future reference.
- Department along with three NIPERs generated revenue of Rs.3,41,387/- from scrap disposal.

- The department has implemented Eight Best Practices (3 from NIPER-Ahmedabad, 1 from NIPER-Guwahati, 1 from HAL, Pune, 1 from NIPER-Hajipur and 1 each from NPPA/PMRUs) focusing on ease of living, reclaiming space for office use and recreation and citizens' participation in betterment of living environment.
- NPPA issued detailed guidelines on 31.10.2023 regarding storage and disposal of Drugs at NPPA and PMRUs to ensure the safe and responsible disposal of expiry/near expiry medicines to protect our environment.
- Active dissemination and propagation of initiatives through PIB and social media like Facebook, X (Twitter), YouTube, LinkedIn, Instagram carried out and 192 posts made on social media by the department and all its organizations.

6. Status of Rationalization of Autonomous Bodies:

Completed

7. 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

8. Vacancy position of senior level appointments in the Ministry/Department, including Autonomous Bodies/PSUs:

(i) Department of Pharmaceuticals:

S. No.	Name of the posts	Sanctioned Strength	In-position	Vacancy	Group
1	JS	02	01	01	А
2	Director/DS	07*	05	02	Α
3	Principal Private Secretary	02	01	01	А
4	Section Officer	16	12	04	В
	Total	27	19	8	

* It includes one newly sanctioned post of Director from Indian Economic Service.

(ii) Public Sector Undertakings:

(a) Karnataka Antibiotics & Pharmaceuticals Limited (KAPL):

S. No.	Designation	Vacant Positions
1	Senior Manager	07
2	Deputy General Manager	03
3	General Manager	06
	Total	16

(b) Hindustan Antibiotics Limited (HAL) (under strategic sale):

S.No.	Designation	Vacant Positions
1	CGM	03
2	GM	03
3	DGM	12
4	Manager	20
	Total	38

S.No.	Designation	Vacant Positions
1	Manager (Legal)	01
2	DGM (Marketing)	01
3	Sr. Manager (Purchase)	01
4	DGM (Finance)	01
5	Factory Head (DGM/AGM)	02
6	AGM (QA/QC)	01
	Total	07

(c) Bengal Chemicals & Pharmaceuticals Limited (BCPL) (under strategic sale):

- (d) Indian Drugs & Pharmaceuticals Limited (IDPL) : NIL
- (e) Rajasthan Drugs & Pharmaceuticals Limited (RDPL) : NIL
- 9. List of cases in which ACC directions have not been complied with:

NIL

10. Details of FDI proposals cleared during the month and status of FDI proposals awaiting approval in the Ministry/Department:

(i)	Pending at beginning of the month	12
(ii)	Received during the month	1
(iii)	Disposed of during the month	3
(iv)	Pending at end of the month	10

FDI inflow approved during this month: Rs.40 crore.
