

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: 13th October, 2023

OFFICE MEMORANDUM

Subject: Monthly Summary Report in respect of Department of Pharmaceuticals for the month of September, 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 September, 2023 for information.



(S.U. Ansari)

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 September 2023:

A. Cabinet decisions/EFC & SFC appraisals

CCEA in its meeting dated 13/09/2023 approved the FDI proposal No. 6438 of M/s Berhyanda Limited, Cyprus for foreign investment of Rs.9,589 crore (appx.) in M/s Suven Pharmaceuticals Limited. Post issue of minutes on 18.09.2023, approval was conveyed on 25.09.2023.

B. Observance of Swachata Pakhwada, Hindi Pakhwada and Swachata Hi Sewa

Department of Pharmaceuticals observed Swachata Pakhwada (1st to 15th September, 2023), Hindi Pakhwada (14th to 29th September, 2023) and Swachata Hi Sewa (15th to 2nd October, 2023). All officers and staff of the Department, as also organisations of the Department actively participated in the events.

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

New Schemes:

- a. The Cabinet has approved the National Policy on Research & Development and Innovation in the Pharma-MedTech Sector in India in its meeting held on 25.07.2023. The Policy was notified on 18.08.2023. Hon'ble Minister had a press briefing on 29.08.2023. The policy was launched by the HMCF on September 26, 2023, in New Delhi in august presence of Dr. V. K. Paul, Member, NITI Aayog.
- b. Cabinet in its meeting held on 25.07.2023 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. The PRIP Scheme was launched by the HMCF on September 26, 2023, in New Delhi in August presence of Dr. V. K. Paul, Member, NITI Aayog.
- c. In pursuance of Budget Speech Announcement 2023-24, a new scheme on 'Human Resource Development in Medical Devices Sector' has been approved by Minister Chemicals and Fertilizers with an outlay of Rs.480 crore for a period of 3 years under which financial assistance to government institutions for running multi-disciplinary dedicated courses in medical devices will be provided.

Inauguration of permanent Campus:

Hon'ble Home Minister inaugurated the permanent campus of the National Institute of Pharmaceutical Education and Research (NIPER) Ahmedabad at Gandhinagar on September 30, 2023.

Research Papers, Patents and MoUs:

- a. Out of 507 research papers published during the current financial year, 72 papers have been published in the month of September 2023.
- b. Out of 26 Patents filed during the current financial year, 4 patents were filed in the

- c. Out of the 23 MoUs signed during the current financial year, 2 MoUs have been signed in the month of September 2023.

Workshops/Seminars/Training and other events:

- a. All NIPERs celebrated Swachhta Pakhwada-2023 and took the Swachhata Pledge in the month of September.
- b. All NIPERs conducted various activities during Swachhta Pakhwada 2023 in the month of September 2023.
- c. All NIPERs celebrated Teacher's Day on September 5, 2023.
- d. NIPER-Mohali organized 'हिन्दी पखवाड़ा' events on September 23, 2023.
- e. NIPER-Mohali organized a seminar on Entrepreneurship- Interaction with the audience on September 23, 2023.
- f. NIPER-Raebareli organised the Orientation Programme 2023 from 13th to 15th September to cordially welcome and congratulate all of its new batch of students.
- g. From 14th to 29th September 2023, NIPER Raebareli celebrated "Hindi Pakhwada" by organizing distinguished lectures, writing competitions, poem competitions and quiz competitions.
- h. NIPER Raebareli celebrated the "3rd Pharmacovigilance Week" on 17th to 23th September 2023.
- i. The "8th convocation ceremony" of the NIPER-Raebareli was held on September 23, 2023
- j. NIPER-Raebareli organised a rally to celebrate the remarkable contributions of "Pharmacists Day" on 25.09.2023.

D. National Pharmaceutical Pricing authority (NPPA):

(i) During the month, 51 new drug prices were fixed under NLEM 2022 during the 116th Authority meeting held on 6.9.2023 and notified vide S.O. No. 4067 (E) dated 15.09.2023. 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 2022)	During the month of 1 st September, 2023 to 30 th September 2023	Cumulative from 1 st April, 2023 to 30 th September 2023
1.	Retail Price of 'New Drug'	51	184
2.	(i) Fixation of ceiling Price under revised scheduled-I (NLEM 2022) of DPCO, 2013	0	40
	(ii) Fixation of ceiling price with special features under scheduled - I (NLEM 2022) of DPCO, 2013	2	2

(iii) Exemption under para 32 of DPCO, 2013 (NLEM 2022)	0	1
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(ii) On the basis of Monitoring & Enforcement activities, sixteen (16) Preliminary Notices (PN) and 03 show cause notices (SCN) were issued.

(iii) As a result of enforcement activities, during the month of September 2023, **Rs.52,29,774/-** (Rupees Fifty-Two Lakh Twenty-Nine Thousand Seven Hundred Seventy-Four only) was received towards overcharged amount.

(iv) As a part of COVID drug management monitoring work, NPPA through Price Monitoring and Resource Units (PMRUs) in the State/UTs conducted four market surveys in September 2023 to assess the availability of drugs.

(v) Swachhata Pakhwada was observed from 1st September 2023 to 15th September 2023.

(vi) In response to the Government of India's 'Swachhata Hi Seva' (SHS) campaign from 15th September -2nd October 2023, NPPA through the PMRUs in different States/UTs conducted cleanliness drives at Office premises as well as in public places. The photographs of the Swachhata activities along with no. of participation of persons, number of hours devoted and locations (the building/ premises name) were uploaded on the SHS Portal.

E. International Cooperation:

(i) Meeting with the Eurasian Economic Commission facilitated by Embassy of India, Moscow was held on 04.09.2023 wherein issues pertaining to Good Manufacturing Practices (GMP) certification, clinical trials and recognition in member countries of Eurasian Economic Union were discussed to explore possibilities to boost export of pharmaceuticals from India to the Eurasian Economic Union and promote access of affordable medical countermeasures therein.

(ii) Ms. Louise Sevel, Counsellor for Health, Embassy of Denmark in Delhi met Ms. Gayatri Nair, Economic Advisor, DoP on 14.09.2023 and shared insights & information about the pharmaceutical industry in India and Denmark. Also potential areas of collaboration, including possibility of co-development of Centre for Excellence in NIPERs, was discussed.

(iii) DoP participated in the meeting between Hon'ble Minister, Health & Family Welfare and Chemicals & Fertilizers with Mrs. Hélène Budliger Swiss State Secretary of Economic Affairs and Dr. Severin Schwan, Chairman of the Board of Directors of Roche Holding Ltd. on 20th September, 2023 wherein issues pertaining to pharmaceutical patents were discussed.

(iv) Department of Pharmaceuticals participated in two-day National Workshop on "Investment Commitments in International Treaties" on 21st and 22nd September 2023, at Vanijya Bhawan, New Delhi organized by DPIIT.

(v) Dr. Robert Califf, Commissioner of the U.S. Food and Drug Administration met Secretary, DoP on 22.09.2023. Issues pertaining to supply chain resilience; monitoring of drug shortages and assurance of continuity of supply chain; nurturing quality ecosystem; and potential of India as a future hub of clinical trials were discussed.

(vi) DoP provided inputs pertaining to pharmaceutical cooperation proposed to be taken up in the Asian Cooperation Dialogue on Bahrain Declaration as well as upcoming meetings with Peru, Paraguay, Dominican Republic facilitated by MEA and with Azerbaijan, Brazil, Peru and Oman facilitated by Department of Commerce and with Cuba facilitated by DPIIT.

F. Schemes:

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

Number of PMBJP Kendras functional		Sales under PMBJP at MRP Value in Rs. Crore and saving to common man during the month of September, 2023		Product basket (As on 30.09.2023)		Sale of Suvidha Sanitary Napkins @ Rs. 1/- per pad during the month of September, 2023	Incentive provided in the month of September, 2023 (Rs. in crore)
Sept 2023	Cumulative	Sale	Saving	Medicines	Surgical		
	(As on 30.09.2023)	In Rs.(crore)	In Rs.(crore) (Approx.)				
169	9996	141.05	705.25	1965	293	1.47 crore	8.12

(ii) Status of PLI Schemes:

S. No.	Name of Scheme		Total No. of Application Received	No. of Applications approved in the month of September 2023	Total no. of applications approved as on date
1.	Production Linked Incentive Scheme for Bulk Drug (Last EC Meeting held on 09.06.2023 on PLI Bulk Drugs)	Round 1	215	0	38
		Round 2	24	0	07
		Round 3	09	0	02
		Round 4	01	0	01
		Total	249	0	48
2.	Production Linked Incentive Scheme for Medical Device (Last EC Meeting held on 09.06.2023 on Medical Devices)	Round 1	28	0	11
		Round 2	14	0	08
		Round 3	18	0	05
		Round 4	04	0	02
		Total	64	0	26
3	Production Linked Incentive Scheme for Pharmaceuticals		278	0	55

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):

Monthly updation of the SCDPM Portal for the month of September, 2023 carried out in respect of SCPDM 2.0 and details in respect of Department uploaded.

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	A
2	Director/DS	07	05	02	A
3	Principal Private Secretary	02	00	02	A
4	Section Officer	16	11	05	B
	Total	27	17	10	

(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

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

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

(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	11
(ii)	Received during the month	4
(iii)	Disposed of during the month	3
(iv)	Pending at end of the month	12

FDI inflow approved during this month

Rs.9,589 crore, including FDI proposal No.6438 of M/s Berhyanda Limited, Cyprus for foreign investment of Rs.9,589 crore (appx.) in MIs Suven Pharmaceuticals Limited, as approved by CCEA.
