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

शास्त्री भवन, नई दिल्ली/ Shastri Bhawan, New Delhi Dated: 12 June, 2023

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

(Shamim Uddin 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 May 2023:

A. Medical Devices:

(i) Export Promotion Council for Medical Devices is established on 22nd May 2023 with Headquarters in YEIDA, Greater Noida, Uttar Pradesh, under the aegis of D/o Pharmaceuticals.

The main objects of Council are as under:

- to carry out all export promotion measures, as well as survey export potential of medical devices from the country.
- to prepare action plans for promotion of exports, development of export markets, setting of export targets generally and in relation to specific countries and commodities on a regular basis.
- to engage in communication with the Chambers of Commerce and/or industry associations, and/or mercantile and public bodies throughout the world with a view to take appropriate and necessary measures ensuring sustainable growth in exports of Medical-devices.
- to carry out various publicity and promotional activities undertaking intensive awareness and outreach programs
- to organize training and development programs to improve the skill of personnel engaged in the sector in India.
- to assist the potential or intended exporters for registration with various authorities, schemes; and, in other procedural aspects in various fields including documentation relating to export and related matters
- to organize and participate in fairs, exhibitions and shows for the promotion of medical devices in India and all parts of the world, so as to maximize the exports of medical devices.

B. National Pharmaceutical Pricing Authority (NPPA):

(i) Retail price fixed for 15 new drugs and ceiling prices fixed for 20 scheduled formulations under NLEM 2022 in the 112th Authority Meeting held on 01.5.2023. The prices were notified vide S.O. No. 2123(E), S.O. No. 2124(E) and S.O. No. 2125(E) dated 04.5.2023. The details of 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 May, 2023 to 31 st May 2023	Cumulative from 1 st April, 2023 to 31 st May 2023
1.	Retail Price of 'New Drug'	15	15
2.	Fixation of ceiling Price under revised scheduled-I (NLEM 2022) of DPCO, 2013	20	20

(ii) On the basis of Monitoring and Enforcement activities, one (1) Preliminary Notice (PN) was issued. **Rs. 20,00,60,810**/- was received during the month towards overcharged amount. Out of this amount, **Rs. 19,75,27,571**/- is received as per the orders dated 25.4.2023 of the Hon'ble High Court of Delhi in WP No. 11349/2015, the same is being deposited as FDR.

(iii) As a part of COVID drug management monitoring work, five market surveys through Price Monitoring and Resource Units (PMRUs) in 20 States/UTs for drugs and six medical devices were conducted during the month to assess the availability of COVID Management Drugs in the States/UTs.

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

Major Achievements of NIPERs during the month are as under:

- a. The Scheme for Promotion of Research and Innovation in Pharma-Med Tech (PRIP) and the National Policy on Research & Development, and Innovation in the Pharma-MedTech Sector were considered by ETG in its meeting held on 24.05.2023.
- b. Out of 177 research papers published during the current financial year, 88 papers were published in the month of May 2023.
- c. Out of seven Patents filed during the current fiscal, one was filed in the month of May 2023.
- d. Out of the eight MoUs signed during the current financial year, one was signed in the month of May, 2023.
- e. NIPER Mohali organised a seminar on Radiation Safety on May 01, 2023.
- f. NIPER Mohali organised a Technical Committee (TC) meeting of the National GLP Compliance Monitoring Authority (NGCMA) on May 01, 2023.
- g. NIPER Mohali organised a seminar on Risk Assessment on May 01, 2023.
- h. NIPER-Mohali organised a one-week HPLC Training Programme during May 15-19, 2023.
- i. NIPER Guwahati organised an event on the ecosystem for healthcare device development and commercialization on May 4, 2023.
- j. NIPER Guwahati organised an event on Secretory Metabolites of Bacteria: untapped pharmaceutical potential on May 04, 2023.
- k. NIPER Guwahati organised an event on Modelling blood cell triggered metastasis of tumors with microfluidic Organ-On-Chips: a translational approach that dissects complex pathophysiology of cancer and evaluates anti-cancer drugs on May 17, 2023.
- 1. NIPER Guwahati organised an event on Saroglitazar: Leading India in the race to address the global problem of NAFLD and NASH on May 23, 2023.
- m. NIPER Raebareli co-organised a symposium on the International Conference on "Formulation in Food and Healthcare (ICFFH 2023)" from May 30 to June 1, 2023.

D. Schemes:

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

		Sales under PMBJP at MRP Value in Rs. Crore and saving to common man during the month of May, 2023		(As on 31.05.2023)		Sale of Suvidha Sanitary Napkins @ Rs. 1/- per pad during the month May, 2023	provided in the
May 2023			Saving	Medicines	Surgical		
	(As on 31.05.2023)	In Rs. (Cr.)	In Rs. (Cr.) (Approx.)				
137	9484	118.43	710.58	1800	285	1.30 Cr.	0.21 Cr.

(ii) Status of PLI Schemes:

S. No		eme	Total No. of Application Received	No. of Applications approved in the month of May 2023	Total no. of applications approved as on date
	Production Linked	Round 1	215	0	39
	Incentive Scheme for	Round 2	24	0	08
	Bulk Drug	Round 3	09	0	03
	(Last EC Meeting held on 24.03.2023 on PLI	Round 4	01	0	01
	Bulk Drugs)	Total	249	0	51
	Production Linked	Round 1	28	0	13
	Incentive Scheme for	Round 2	14	0	08
	Medical Device	Round 3	18	0	05
	(Last EC Meeting held	Round 4	04*	0	0
	on 24.03.2023 on Medical Devices)	Total	64	0	26
	Production Linked Ince Scheme for Pharmaceut		278	0	55

*In^{ℓ} PLI Medical Devices round – IV application window, four applications have been received which are under examination.

E. FDI inflow approved during this month: NIL

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):

The requirement of monthly updation of the SCDPM Portal for the month of May, 2023 has been fulfilled by uploading the information received from various Sections of Department in the 2.0 version of the SCDPM Portal.

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

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

Department of Pharmaceuticals: (i)

S. No.	France of the posts	Sanctioned Strength	In-position	Vacancy	Group
	Director/DS	06	05		
2	Under Secretary			01	A
3	Dringing I D :	10	08	02	Δ
5	Principal Private Secretary	02	0	02	<u>A</u>
4	Section Officer		0	02	A
	Total	16	03	13	B
	10(a)	34	16	18	D

Public Sector Undertakings: (ii)

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

S. No.	Designation	
1	Senior Manager	Vacant Positions
2	Deputy General Manager	06
3 General Manager	General Manager	03
	3 General Manager Total	06
Hindustan Antibiotics Limited (HAL) (under a		15

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

Designation	
CGM	Vacant Positions
	3
	3
	12
	20
Total	38
	Designation CGM GM DGM Manager Total

Bengal Chemicals & Pharmaceuticals Limited (BCPL)(under strategic sale): (c) 6

S.No.	Designation	Verent D 11
1	Manager (Legal)	Vacant Positions
2	DGM (Marketing)	1
3	Sr. Manager (Purchase)	1
4	DGM (Finance)	1
5	Assistant Manager (Company Secretary)	1
6	Factory Head (DGM/AGM)	1
7	AGM (QA/QC)	2
	Total	1

Indian Drugs & Pharmaceuticals Limited (IDPL) (d) : NIL

- Rajasthan Drugs & Pharmaceuticals Limited (RDPL) (e) 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:

(1)	Pending at beginning of the month		10
(ii)	Received during the month	•	10
(iii)	Disposed of 1	:	1
(iv)	Disposed of during the month	:	3
(\mathbf{IV})	Pending at end of the month	:	8

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