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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: 16 May, 2023

Subject: Monthly Summary Report in respect of Department of Pharmaceuticals for the month of April, 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 April, 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 April 2023:

A. Approval of National Medical Devices Policy, 2023:

(i) National Medical Devices Policy, 2023 approved by the Union Cabinet on 26.04.2023. The Policy is expected to promote an orderly growth of the medical device sector and facilitate the achievement of public health objectives of access, affordability, quality and innovation.

(ii) The Policy lays down a roadmap for accelerated growth of the medical devices sector so as to achieve 10-12% share in the expanding global market over the next 25 years while ensuring its Access & Universality, Affordability, Quality, Patient Centricity & Quality Care, Preventive & Promotive Health, Security, and facilitating Research and Innovation and Skilled manpower.

(iii) Medical devices sector will be facilitated and guided through a set of strategies that will cover the following broad areas of policy interventions:

- Regulatory Streamlining would be ensured.
- Establishing and strengthening enabling infrastructure including medical device parks, clusters in proximity to economic zones with requisite logistics connectivity etc.
- Facilitating R&D and Innovation by complementing the Department's proposed *National Policy on R&D and Innovation in the Pharma- MedTech Sector in India* and establishing Centres of Excellence in academic and research institutions, innovation hubs, 'plug and play' infrastructures and support to start-ups.
- Attracting Investments in the Sector by encouraging private investments, funding from Venture Capitalists, and Public-Private Partnership(PPP).
- Human Resources Development through skilling, reskilling and upskilling of professionals in the medical device sector, supporting dedicated multidisciplinary courses for medical devices in existing institutions to ensure availability of skilled manpower for futuristic medical technologies, high-end manufacturing and research, to produce future-ready MedTech human resources
- To develop partnerships with foreign academic/industry organizations to develop medical technologies in order to be in equal pace with the world market.
- Brand Positioning and Awareness Creation: through dedicated Export Promotion Council for the sector under the Department

B. National Pharmaceutical Pricing Authority (NPPA):

(i) On the basis of Monitoring & Enforcement activities carried out by Enforcement Division, 126 Preliminary Notices (PNs) have been issued.

(ii) As a part of COVID drug management monitoring work, following activities were undertaken during the period:

- (a) Inputs on availability of Oseltamivir along with other drugs were presented in the meeting of the COVID Drug Management Committee held on 26.4.2023.
- (b) Four market surveys through Price Monitoring Resource Units were conducted on 3rd April and 10th April in 17 States/ UTs, on 17th April in 19 States/UTs and on 24th April in 24 States/UTs during April 2023 for COVID Management Drugs as well as six medical devices.

(iii) Further, an interactive webinar on the topic "Guidance on effective reporting through IPDMS Software" was organised by NPPA on 28.04.2023 to provide the guidance to PMRUs regarding NLEM -2022 and various activities to be undertaken by PMRUs in an effective manner. The PMRUs in the State/ UTs have actively participated in the webinar.

(iv) Total overcharged amount received during April, 2023 is Rs. 6,73,75,884/-.

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

Major Achievements of NIPERs during the month are as under:

- a. A total of 89 Research papers were published during the first month of the current financial year, i.e. in April, 2023.
- b. Six Patents were filed in the month of April, 2023.
- c. Five MoUs were signed in the month of April, 2023.
- d. Draft SFC Note for Scheme on 'Human Resource Development in medical devices' has been circulated for inter-departmental consultations on 12.04.2023.
- e. A Science 20 (S20) webinar was organized on 18.04.2023 in partnership with the Indian National Science Academy (INSA) on "An Integrated Approach to Combat Neo-Infections: A Way Forward, through Vaccines, Diagnostics and Therapeutics" with eminent speakers across the G-20 countries. The Webinar focused on discussing a need for collaborative models that would help to strengthen and support research and development (R&D) in Vaccines, Therapeutics, and Diagnostics (VTDs).
- f. On April 17, 2023, the 11th Board of Governors meeting was held at NIPER-Ahmedabad.
- g. NIPER Hajipur organised an invited talk (online) on quality and regulatory affairs in the pharmaceutical industry on April 25, 2023.
- h. NIPER-Kolkata organised two Symposiums, one on Pharmacological Approaches for Chronic Inflammation and its Complications product demo session on "JMP Statistical Discovery" on April 12, 2023 and another on "Photocatalysis and Pharmaceuticals" on April 21, 2023.
- i. NIPER-Kolkata invited a talk on "Biological Applications of Carbon Nitride Nano composites on April 22, 2023.
- j. NIPER-Kolkata organised drug discovery at FERRING Pharma on April 24, 2023.
- k. NIPER Raebareli celebrated World Intellectual Property Day and World Creativity Day and held a guest lecture on "Accelerating Innovation, Creativity, and Translational Science from Phenomena in Nature" on April 26, 2023.
- l. NIPER, Raebareli, in association with Rajiv Gandhi National Institute of Intellectual Property Management (RGNIIPM), organised an online workshop on "Intellectual Property Rights (IPR) Patents and Design Filing".
- m. NIPER Raebareli organised a Hands-on training on organic synthesis and characterization on April 10, 2023.
- n. NIPER Raebareli organised a one-day symposium on "Recent Trends and Future Prospects in Biological Sciences".
- o. NIPER Guwahati organised an event on Integrated Approach to Combat Neo-Infections: A Way Forward, Through Vaccines, Diagnostics, and Therapeutics on April 18, 2023.
- p. NIPER Guwahati conducted a session on "Start-Ups in the Knowledge Economy of the Northeast Region" on April 20, 2023.

- q. NIPER Guwahati organised a seminar on "Safety in the Pharma and Chemical Sector" on April 21, 2023.

D. 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 April, 2023		Product basket (As on 30.04.2023)		Sale of Suvidha Sanitary Napkins @ Rs. 1/- per pad during the month April, 2023	Incentive provided in the month April, 2023
April 2023	Cumulative	Sale	Saving	Medicines	Surgical		
	(As on 30.04.2023)	In Rs. (Cr.)	In Rs. (Cr.) (Approx.)				
43	9341	95.89	575.34	1800	285	0.76 Cr.	Nil

(ii) Status of PLI Schemes:

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

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

**In PLI for Pharmaceuticals, the approval of one application has been cancelled due to Merger of the companies. Further, approval letter has been sent to next waitlisted applicant on 17.04.2023.

E. International Cooperation:

(i) DoP participated in the 12th session of India-Spain Joint Commission for Economic Cooperation (JCEC) meeting on 13th April 2023 at New Delhi. It was noted that both the sides are pharmaceutical powerhouse and have considerable potential for mutual collaboration. Both sides enjoy a very healthy bilateral trade. Spain expressed interest in investments in the Bulk Drug Parks since Spain is also looking at diversifying its API supply chains.

(ii) G20 co-branded event on 'strengthening cooperation and enabling sustainable development and manufacturing of effective, quality and affordable diagnostic countermeasures' was organised by the Department of Pharmaceuticals in collaboration with FIND and Unitaaid on 16th April 2023. The meeting provided an opportunity for diagnostics industry-partners to put forward their recommendations to the G20 and its Member States for consideration of G20 Second Health Working Group meeting.

(iii) DoP participated in the 24th Session of the India-Russia Inter-Governmental Commission on Trade, Economic, Scientific, Technical and Cultural Cooperation on 18 April 2023 led by H.E Dr. Subrahmanyam Jaishankar, the Minister of External Affairs, and the Chairperson of the Indian side of the Commission. Both sides acknowledged discussions held in the 2nd JWG on Pharmaceuticals Meeting on 21.12.2022 and agreed to take further steps in this regard.

(iv) Status of de-risking the supply chain of vaccines was reviewed on 19th April 2023 with vaccine manufactures. The need for a strategy for Overseas investment by Indian Manufactures was also deliberated in the meeting.

(v) DoP participated in the stakeholder workshop jointly organized by the EU Delegation to India and the Embassy of Sweden on '*One Health Approach to Antimicrobial Resistance: environment and manufacturing industry*' at the Embassy of Sweden on 24th April 2023. The goal of the workshop was to reduce the impact of antibiotics in the environment and curbing the spread of AMR.

F. 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 April, 2023 has been fulfilled by uploading the information received from various Sections of this 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

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	Director/DS	06	05	01	A
2	Under Secretary	10	08	02	A
3	Principal Private Secretary	02	0	02	A
4	Section Officer	16	03	13	B
	Total	34	16	18	

(ii) Public Sector Undertakings:

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

S. No.	Designation	Vacant Positions
1	Senior Manager	06
2	Deputy General Manager	03
3	General Manager	06
	Total	15

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

S.No.	Designation	Vacant Positions
1	CGM	3
2	GM	3
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)	1
2	DGM (Marketing)	1
3	Sr. Manager (Purchase)	1
4	DGM (Finance)	1
5	Assistant Manager (Company Secretary)	1
6	Factory Head (DGM/AGM)	2
7	AGM (QA/QC)	1
	Total	8

(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	:	(0)
(iii)	Disposed of during the month	:	(2)
(iv)	Pending at end of the month	:	(10)
