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भारत सरकार / Government of India

रसायन एवं उर्वरक मंत्रालय / Ministry of Chemicals and Fertilizers

औषध विभाग / Department of Pharmaceuticals

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शास्त्री भवन, नई दिल्ली / Shastri Bhawan, New Delhi

Dated: 11<sup>th</sup> August, 2023

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

**A. Cabinet decisions/EFC & SFC appraisals**

- a. 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.
- b. Cabinet has approved the Scheme for Promotion of Research and Innovation in Pharma-Med Tech (PRIP) with an outlay of Rs. 5000 cr. for a period of 5 years (2023-24 to 2027-28) in its meeting held on 25.07.2023
- c. In pursuance of the budget announcement in FY 2023-24, the Department of Pharmaceuticals has come up with a new scheme on 'Human Resource Development in Medical Devices Sector'. The scheme has been appraised by the Standing Finance Committee in its meeting held on 14.07.2023 under the chairmanship of Secretary, D/o Pharmaceuticals.

**B. Medical Device:**

**(i) Task Force Report on "The Mapping of Testing Infrastructure for Medical Devices in India":**

DPIIT vide DO letter dated 15.03.2022 requested DoP for a comprehensive review of all laboratories operating under concerned medical device sector to ensure that necessary infrastructure and qualified human resources are available; and applicable processes are followed diligently. Pursuant, a review meeting was held in DoP on 11.04.2022 on the measures to be taken towards strengthening of testing infrastructure to enable smoother transition to licensing for Medical Devices (MDs). A Task Force on "The Mapping of Testing Infrastructure for Medical Devices in India" was set up by DOP on 13.04.2022 with the following mandate to address the need for Quality Testing Infrastructure for medical devices.

- To map the Classification of MDs by CDSCO vis-à-vis the available BIS product standards and arrive the list / category of MDs with different types of standards available.
- To arrive the list of tests and testing equipment that are required to test these standards.
- To map the existing infrastructure of labs available in public / private / institutional set-up towards testing of MDs.
- To submit the recommendations with the specific actionable points in respect of the laboratory resources required under Medical Device Regulations.

The Task Force submitted its Interim Report on 04.07.2022. The Task Force Report was examined by DOP and forwarded to CDSCO on 07.07.2023 for further action.

**C. National Pharmaceutical Pricing Authority (NPPA):**

- (i) The details of prices of drugs 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 <sup>st</sup> July, 2023 to 31 <sup>st</sup> July 2023	Cumulative from 1 <sup>st</sup> April, 2023 to 31 <sup>st</sup> July 2023
1.	Retail Price of 'New Drug'	0	89
2.	i. Fixation of ceiling Price under revised scheduled-I (NLEM 2022) of DPCO, 2013 ii. Ceiling price under para 19 of DPCO, 2013 (NLEM 2022)	0 0	40

(ii) On the basis of Monitoring & Enforcement activities, One Hundred Eighty-Three (183) Preliminary Notices (PN) and two (2) Show-cause notices (by Medical Device Division) were issued.

(iii) As a result of enforcement activities, during the month of July 2023, **Rs. 4,24,56,069.68/-** (Rupees Four Crore Twenty-Four Lakh Fifty-Six Thousand Sixty-Nine and Paise Sixty-Eight only) was received towards overcharged amount.

(iv) The review application filed by M/s Zydus Health Care Limited under Para 31 of Drugs (Prices Control) Order, 2013 against price fixation order issued by NPPA vide S.O. No. 2981 (E) dated 30.6.2022 fixing the retail price of Sitagliptin 50/100 mg & Metformin Hydrochloride 500/1000 mg (ER/SR) tablet was disposed off by DoP in favour of NPPA.

(v) As a part of COVID drug management monitoring work, five market surveys through Price Monitoring and Resource Units (PMRUs) in States/UTs were conducted during July 2023.

(vi) Eleventh issue of NPPA e-Newsletter i.e. **Aushadh Sandesh** covering the article on "Biosimilars - The emerging Wave for the pharma sector" was released.

#### **D. National Institutes of Pharmaceutical Education & Research (NIPERs):**

##### ***Research Papers, Patents and MoUs***

- 95 papers have been published in the month of July 2023, bringing total research papers published during the current financial year to 351.
- 04 patent were filed in the month of July 2023, bringing total patents filed during the current financial year to 18 patents.
- 05 more MoUs have been signed in the month of July, 2023, bringing total MoUs signed during the current financial year to 16.

##### ***Workshops/Seminars/Training and other events***

- NIPER-Ahmedabad organized a Workshop on Patent Drafting, Filing, and Processing on July 13, 2023.
- NIPER Ahmedabad organized a seminar on the topic "Drug Discovery and Unmet medical Need; Medicinal Chemistry Prospective" on 14th July 2023.
- NIPER Ahmedabad has organized One-day seminar on "Challenges and Opportunities in the Development of Plant-Based Medicinal Products" on July 18, 2023.
- Hand-on Training on "Basics of LCMS-TOF, LCMS-TQD and LCMS-ORBITRAP" at NIPER – Ahmedabad on 19th July 2023.

- e. NIPER-Ahmedabad organized the "SSIP Awareness Program and Startup Success Story" event, on July 20, 2023.
- f. NIPER-Ahmedabad organized a one-day seminar on "Translation Research in Drug Discovery from Natural Products" on July 28, 2023.
- g. NIPER-Ahmedabad celebrated "International Plastic Bag Free Day" on 12-July-2023.
- h. NIPER-Hajipur organised 'Two Days National Training Program on Materiovigilance on July 6-7, 2023.
- i. NIPER-Hajipur organised the first International meeting on cancer & immunity employing transdisciplinary approaches on July 24-25, 2023.
- j. NIPER Raebareli organised a workshop on "One Day hands-on training on HPLC" on 04 July 2023.
- k. NIPER Raebareli organised a "One Day workshop on Computer-aided Drug Design" on 10 July 2023.
- l. NIPER- Raebareli organised a workshop on "Certificate Course and Training on Design and Characterization of Nanomaterials" from 17th-21st July, 2023.
- m. NIPER-Mohali celebrated Van Mahotsav Celebrations under Azadi Ka Amrit Mahotsav (AKAM) on July 5, 2023.
- n. NIPER-Mohali organised Pharmaceutical Industrial Training from July 13- August 3, 2023.
- o. NIPER-Mohali organised IPR Training Workshop from July 17-21, 2023.
- p. NIPER-Mohali organised a seminar on small molecule - TB drug discovery on July 14, 2023.
- q. NIPER-Mohali conducted a training course on high performance liquid chromatography (HPLC) from July 10-14, 2023.

#### **E. International Cooperation:**

(i) DoP participated in the 2<sup>nd</sup> Joint Working Group meeting between India and Maldives on health cooperation held on 5<sup>th</sup> July 2023. A presentation was made on "Pharmaceutical and Medical Device Sector in India." The meeting was held under the Co-chairmanship of Mr. Lav Agarwal, Additional Secretary, Ministry of Health and Family Welfare from Indian side.

(ii) DoP participated in the 9<sup>th</sup> Edition of IPHEX held on 6<sup>th</sup> July 2023 at Hitex, Exhibition Center, Hyderabad, Telangana wherein CEO Roundtable & Interactive sessions were held on Biosimilars, Vaccines & Quality Compliance & Patient Safety etc. Presentations of India Pharma Awards for outstanding Export Performance in different regions and Research & development in various therapies were also part of the event.

(iii) DoP participated in the 4<sup>th</sup> Meeting of India-US Counter Narcotic Working Group (CNWG) on 19-20 July, 2023 at Washington D.C. U.S.A wherein Memorandum of Understanding between The United States of America and The Republic of India concerning a Drug Policy Framework was discussed.

(iv) DoP participated in the bilateral meeting between the Hon'ble Minister of Health and Family Welfare of India and the Hon'ble Minister of Health of the United Republic of Tanzania on 25<sup>th</sup> July 2023 wherein the potential areas to strengthen bilateral cooperation

in pharmaceuticals and explore potential collaborations in the Pharmaceuticals sector was discussed.

(v) Meeting with H.E. Mr. Didier VANDERHASSELT, Ambassador of Belgium to India was held on 10.07.2023 to further explore possibilities w.r.t. sourcing more medicines by Belgium from India, and discussions about Technology of Transfer on specific products.

(vi) DoP proposed areas of cooperation w.r.t National Institute of Pharmaceutical Education and Research (NIPER), Recognition of Indian Pharmacopoeia, Bilateral Trade, Investments for the 3rd India and Laos FOC, forthcoming India and Ukraine FOC, 22nd session of India and Italy Joint Commission for Economic Cooperation and 2nd meeting of India and Ecuador Joint Economic Trade Committee.

#### 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 July, 2023		Product basket (As on 31.07.2023)		Sale of Suvidha Sanitary Napkins @ Rs. 1/- per pad during the month July, 2023	Incentive provided in the month July, 2023
July 2023	Cumulative	Sale	Saving	Medicines	Surgical		
	(As on 31.07.2023)	In Rs. (Cr.)	In Rs. (Cr.) (Approx.)				
156	9668	123.89	619.00	1800	285	1.93 Cr.	9.15 Cr.

##### (ii) Status of PLI Schemes

S. No.	Name of Scheme	Total No. of Application Received	No. of Applications approved in the month of July 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
		<b>Total</b>	<b>249</b>	<b>0</b>	<b>48*</b>
2.	Production Linked Incentive Scheme for Medical Device	Round 1	28	0	11
		Round 2	14	0	08
		Round 3	18	0	05
		Round 4	04	2	2

	(Last EC Meeting held on 09.06.2023 on Medical Devices)	Total	64	2	26**
3	Production Linked Incentive Scheme for Pharmaceuticals		278	0	55

\* Under PLI for Bulk Drugs three applications have been withdrawn and same was considered in the 15<sup>th</sup> EC meeting held on 09.06.2023.

\*\* Under PLI for Medical devices two applications (Category-A) have been withdrawn and two new applications (Category-B) have been selected and same was considered in the 15<sup>th</sup> EC meeting held on 09.06.2023.

**G. 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):**

**A. Response to DARPG Initiatives:**

- a. Inputs were uploaded on the SCDPM Portal for the month of June 2023, within the due date. Information in respect of July has been sought from all Divisions which shall also be uploaded as stipulated in August, 2023.
- b. As per DARPG report on CPGRAMS for the month of June'23; D/o Pharmaceuticals is ranked as 6<sup>th</sup> among 58 Departments, a further improvement from May 2023. DOP had only 20 PG cases pending by third week of July, out of which only 03 were between 15-30 days. No case was pending beyond 30 days.
- c. Disposal of one unserviceable Staff Car is under process.

**B. Response to MEITY Initiatives:**

The Department is in the process of engaging a Professional Agency for upgrading its Website as per GIGW 3, for which the tendering process is completed and file is awaiting administrative approval for issuing work order.

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	07	04	03	A
2	Under Secretary	11	09	02	A
3	Principal Private Secretary	02	0	02	A
4	Section Officer	16	7	09	B
	<b>Total</b>	<b>36</b>	<b>20</b>	<b>16</b>	

(ii) **Public Sector Undertakings:**

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

S. No.	Designation	Vacant Positions
1	Senior Manager	05
2	Deputy General Manager	03
3	General Manager	06
	<b>Total</b>	<b>14</b>

(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
	<b>Total</b>	<b>38</b>

(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
	<b>Total</b>	<b>8</b>

(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 : 09  
(ii) Received during the month : 02  
(iii) Disposed of during the month : 01  
(iv) Pending at end of the month : 10

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