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: 19 September, 2023

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

Sanduping

(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 August 2023:

A. India MedTech Expo (IMTE) 2023: India MedTech Expo (IMTE) 2023, 1st edition, was organized by the Department of Pharmaceuticals, from 17th-19th August 2023 at Helipad Exhibition Center, Gandhinagar, with the theme "India: The Next MedTech Global Hub" Future of Devices, Diagnostics and Digital. The event was organised by the Department with FICCI as an organising partner and as a cobranded event to the G 20 Health Working Group Meeting. The event showcased the strength and potential of Indian Medical Devices ecosystem. Some of the major features of the event are as below:

- a) The Event brought all stakeholders on one platform, creating opportunities to network and explores collaborations for sector's growth in India.
- b) In the Event, more than 4000 Buyer-Seller meetings were organized and more than 10000+ visitors visited EXPO-2023. About 47 countries participated in the Buyer-Seller Meet.
- c) The Expo witnessed large participation from Global and Indian companies including MSMEs, Startups, Academic and Research Institutions, State Governments, Central and state procurement agencies, Regulatory Agencies etc.

B. National Pharmaceutical Pricing Authority (NPPA):

(i) During the month, 44 new drug prices as approved in the 115th Authority meeting were fixed and notified vide S.O. No. 3560 (E) dated 08.08.2023. The number of drug prices fixed in the financial year 2023-2024 are as under:

S. No.	Prices fixed/ Notified under Revised Schedule I (NLEM 2022)	and a second sec	Cumulative from 1 st April, 2023 to 31 st August 2023
1.	Retail Price of 'New Drug'	44	133
2.	i. Fixation of ceiling Price under revised scheduled-I (NLEM 2022) of DPCO, 2013	0	40

(ii) On the basis of Monitoring & Enforcement activities, One Hundred Twenty-Four (124) Preliminary Notices (PN) were issued.

(iii) As a result of enforcement activities, during the month of August 2023, **Rs.10,49,083**/-(Rupees Ten Lakh Forty-Nine Thousand Eighty-Three 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 04 market research analysis in August 2023 to assess the availability of drugs.

(v) On the eve of NPPA foundation day, a presentation competition on 'Price Regulation Practices of Medicines in other countries' was organized.

- (vi) Towards celebration of Azadi Ka Amrit Mahostav following activities were carried out:
 - a) The Price Monitoring and Resource Unit (PMRU) of Goa, J&K, Karnataka, Ladakh, Madhya Pradesh and Tripura organised one Day State/UT level seminar on "Fixation of ceiling price under NLEM- 2022- Ensuring affordability". The seminars were attended by stakeholders from Pharma Industry/ Associations, Consumer Groups, Medical Educations Institutes, NGOs and officers from State/UT.
 - b) A webinar on "How to handle medicines nearing expiry date or already expired" was organised on 14.8.2023, wherein officials from NPPA and PMRUs of States/UTs also participated.
 - c) As part of the on-going G-20 related activities the NPPA, Department of Pharmaceuticals brought out a **Coffee Table Book** titled: 'Serving Humanity: Indian Pharmaceutical Sector सर्वे भवन्तु सुखिन: सर्वे सन्तु निरामया: " The Book was released by Hon'ble Chief Minister of Gujarat and Hon'ble Union Minister of Health & Family Welfare and Chemical & Fertilizers in Gandhinagar, Gujarat on 17.8.2023.
 - d) NPPA participated in the three (3) days 'India MedTech Expo 2023', wherein various creatives on NPPA functions, IPDMS, Pharma Sahi Daam, Pharma Jan Samadhan and PMRU's were displayed. Brochures on NPPA activities were distributed to visitors to create awareness and on the role of NPPA in ensuring affordability and availability of drugs.

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

New Schemes

- 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 held a press briefing on 29.08.2023.
- 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. Hon'ble Minister held a press briefing on 29.08.2023.
- A new scheme on 'Human Resource Development in Medical Devices Sector' has been approved with an outlay of Rs.480 cr. 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.

Research Papers, Patents and MoUs

- Out of 435 research papers published during the current financial year, 84 papers have been published in the month of August 2023.
- Out of 22 Patents filed during the current financial year, 04 patent were filed in the month of August 2023.

• Out of the 21 MoUs signed during the current financial year, 05 MoUs have been signed in the month of August, 2023.

Workshops/Seminars/Training and other events

- NIPER-Mohali organized NIPER Students Research Symposium-2023 from August 10-12, 2023.
- NIPER-Mohali organized Seminar on "National Intellectual Property Awareness (NIPAM)- Role in Pharmaceutical Sciences" on August 23, 2023.
- NIPER-Mohali organized One-week extensive training ITEC Programme entitled "Developing Training and Capacity Building Program on Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP)" from August 28- September 1, 2023.
- NIPER-Ahmedabad conducted Hands on Electrospinning Workshop on August 11, 2023.
- NIPER-Ahmedabad conducted Hands on 3D Bioprinting Workshop on August 17, 2023.
- Dr.Manoj Dandekar, Assistant Professor, NIPER-Hyderabad delivered a talk at the renowned APC Microbiome Institute, University of Cork, Ireland.
- Dutch pharma regulatory officials visited NIPER Hyderabad on August 17, 2023.
- NIPER Raebareli organized a one-day workshop on "WESTERN BLOTTING" on August 21st, 2023.
- NIPER Raebareli participated in the "India MedTech Expo 2023" held from 17th to 19th August 2023 in Gandhinagar, Gujarat.
- Foundation stone for the campus of NIPER-Kolkata laid by Hon'ble Minister on 25.08.2023.

D. International Cooperation:

(i) The 2nd meeting of the India-Belarus Joint Working Group (JWG) on Pharmaceuticals was held on 4th August 2023 at 11.30 A.M. through video conference. The Belarus delegation was led by Mr. Androsyuk B.N., Deputy Minister of Health from the Republic of Belarus, and the Indian delegation was led by Ms. Gayatri Nair, Economic Adviser, Department of Pharmaceuticals. Possible collaboration in bilateral trade, capacity building & research, issues of convergence of regulatory approaches, Ayurveda pharmacopeia and investments were discussed.

(ii) DoP held a meeting with Seychelles High Commissioner on 07.08.2023 to discuss pharma cooperation between the two countries and greater sourcing of medicines from India by Seychelles.

(iii) DoP participated in the session of the 4th and 5th round of India-Australia CECA negotiations on Rules of Origin on 11th August 2023 and 29th August, 2023, respectively, in Vanijya Bhawan, New Delhi.

(iv) Secretary, DoP led discussions related to pharmaceutical cooperation in dedicated bilateral meetings led by Dr. Mansukh Mandaviya, Hon'ble Minister for Health & Family Welfare and Chemicals & Fertilizers, with Netherlands, UK, Germany, Japan, WHO, Indonesia, Egypt, EU, Saudi Arabia, Sri Lanka, USA, Singapore, Australia and Nepal, on the sidelines of the 4th Health Working Group meeting under Indian G20 Presidency during 15th August 2023 to 21st August 2023 in Delhi and Gandhinagar. The key areas of pharma cooperation that were discussed included strengthening supply chain & boosting investments; manufacturing in India for the globe; R&D, skilling and capacity building; boosting global affordable healthcare across pharmaceuticals, vaccines and medical devices.

(v) DoP in collaboration with the Indian Pharmaceutical Association (IPA), organized an industry interaction event on 20th August 2023 in Hotel Leela, Gandhinagar on the sidelines of the 4th Health Working Group meeting. This event was graced by the presence of esteemed individuals, including Dr. Mansukh Mandavia, the Honorable Union Minister of Health and Family Welfare, Budi Gunadi Sadikin, the Indonesian Minister of Health, Ernst Kuipers, the Minister of Health, Welfare, and Sport of the Netherlands, Ms. S Aparna, the Secretary of DoP, Sudarshan Jain, the Secretary General of IPA, and Dr. Viranchi Shah, the Promoter & Director of IDMA. Furthermore, the event witnessed the participation of Indonesian delegates, numerous Indian pharmaceutical companies, various associations, as well as officials from DoP, IPA, IDMA, and others.

(vi) DoP participated in the reception programme on "US-India Partnership: Bridging the Skill Gap" organized by USISPF on the occasion of the B-20 Summit, 2023 in New Delhi on 24th August 2023. The Reception was chaired by Amb. Harsh Vardhan Shringla, Chief Coordinator for India's G-20 Presidency & Johnny C. Taylor, Jr. Co-Chair, B-20 Task Force on Future of Work, Skilling & Mobility; President & CEO, Society for Human Resource Management and Board Member, USISPF.

(vii) Ambassador of the Republic of Cuba, H.E Mr. Alejandro Simancas Marin met Secretary, DoP on 28.08.2023 and discussed areas of cooperation in pharma including recognition of Indian Pharmacopoeia, bilateral exchange between regulators and sourcing greater medical supplies from India.

E. Schemes:

Number of PMBJP Kendras functional		PMBJ Valu Cro sav comr dur mc	es under P at MRP ie in Rs. ore and ving to non man ring the onth of ust, 2023	Product (As on 31.		Sale of Suvidha Sanitary Napkins @ Rs. 1/- per pad during the month August, 2023	Incentive provided in the month August, 2023
August 2023	Cumulative	Sale	Saving	Medicines	Surgical		
	(As on 31.08.2023)	In Rs. (Cr.)	In Rs. (Cr.) (Approx.)				
159	9827	103.93	520	1800	285	1.75 Cr.	3.43 Cr.

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

(ii) Status of PLI Schemes:

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

F. FDI inflow approved during this month: 218.31 crore

G. Participation in activities.

(i) Officers and staff of the Department and its organisations were encouraged to take Panch Pran Oath and upload Selfie with Mitti in hand to make the campaign "Meri Maati-Mera Desh" successful.

(ii) Officers and staff of the Department and its organisations actively participated in hoisting National flag at their home and uploading of selfies at www.harghartiranga.com.

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:

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

Monthly updating of the SCDPM Portal for the month of August, 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	Director/DS	07	04	03	Α
2	Under Secretary	10	09	01	Α
3	Principal Private Secretary	02	00	02	A
4	Section Officer	16	10	06	В
	Total	35	23	12	

(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
100.00	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):

 s^{-3}

. . . .

(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	10
(ii)	Received during the month	03
(iii)	Disposed of during the month	02
(iv)	Pending at end of the month	11
