

फा.सं. F. No.50014/03/2020-CDN
भारत सरकार / Government of India
रसायन एवं उर्वरक मंत्रालय / Ministry of Chemicals & Fertilizers
औषध विभाग / Department of Pharmaceuticals

Shastri Bhawan, New Delhi
Dated: 19 April, 2022

Subject: Monthly Summary Report in respect of Department of Pharmaceuticals for the month of March, 2022-reg.

The undersigned is directed to circulate herewith a copy of the Monthly Summary pertaining to the Department of Pharmaceuticals for the month of March, 2022 for information.



(Shamim Uddin Ansari)
Under Secretary to the Govt. of India

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 March-2022:

A. Medical Devices:

(i) The sub-scheme termed as “Assistance to Medical Device Industry for Common Facility Centre” was a Central Sector Scheme under the then umbrella scheme for Development of Pharmaceutical Industry to provide a one-time grant-in-aid of ₹ 25 crore or 70% of the project cost, whichever was less, to be released for creation of identified infrastructure and common facilities to a State Implementing Agency (SIA) set up for the purpose. The Department has supported the proposal of Andhra Pradesh Medtech Zone Ltd. (AMTZ), Andhra Pradesh under the said sub-scheme to provide grant-in-aid of Rs. 25 crore. Under the scheme, the Department has released **Rs. 7.5 Crore** as third installment of GIA to AMTZ.

(ii) Recognizing the need for higher levels of investments for the creation of testing and laboratory facilities, the scheme “Promotion of Medical Devices Parks” has been approved and is currently under implementation. The parks will provide common testing and laboratory facilities/centre at one place reducing the manufacturing cost significantly and will help in creating a robust ecosystem for medical device manufacturing in the country. The ‘Final Approval’ was accorded by SSC to the proposals from Himachal Pradesh, Uttar Pradesh, Madhya Pradesh and Tamil Nadu. An amount of Rs. 30 Crores each has been released as 1st installment of GIA to the State Governments of Tamil Nadu, Madhya Pradesh, Himachal Pradesh & Uttar Pradesh.

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

(i) During the months of March, 2022, NIPERs have organized 12 Seminars, 9 Workshops/Training and 11 other events. The important events organized by NIPERs include:

- i. Guest Talk on Chemical Biology of Lipids: From Target to Drug held on 2nd March, 2022 by NIPER Hyderabad.
- ii. Gender Equality Today for a Sustainable Tomorrow held on 8th March, 2022 by NIPER Hyderabad.
- iii. Entrepreneurship Talk Series held on 11th March, 2022 by NIPER Hyderabad.
- iv. Heartfulness Meditation held from 14th to 16th March, 2022 by NIPER Hyderabad.
- v. FIPS International E-Conference IX Annual Symposium of Federation of Indian Physiological Societies-2022 Reconnecting Physiology and Nature for A Healthy Life held from 25th to 27th March, 2022 by NIPER Hyderabad.
- vi. Academic Opportunities in North America: The Application Process and Key Challenges held on 26th March, 2022 by NIPER Hyderabad.
- vii. Six Month Entrepreneurship Development Program held on 28th March, 2022 by NIPER Hyderabad.
- viii. FDP Workshop on Molecular Docking, Virtual Screening & Computational Biology held from 28th March to 5th April, 2022 by NIPER Hyderabad.
- ix. Short Term course on Awareness Course on Recent Changes in Indian and Global Regulatory Landscape” for MSMEs, Startups, Industry Professionals and Students held on 29th March, 2022 by NIPER Hyderabad.
- x. Guest lecture on Pharmacoepidemiology in Drug Development held on 16th March, 2022 by NIPER Hajipur
- xi. Guest Lecture held on 11th March, 2022 by NIPER Hajipur.

- xii. Webinar on quality by design (QbD) in Pharma & Inauguration of Industry Sponsored QbD Software Facility held on 4th March, 2022 by NIPER Hajipur.
- xiii. Student of Atmiya University Visited Biopharma Incubation Center and NIPER-AHMEDABAD on 23rd March, 2022 by NIPER Ahmedabad.
- xiv. Webinar on Government scheme for startups held on 31st March, 2022 by NIPER Ahmedabad.
- xv. Hands – on training with Confocal Microscope held from 22nd to 25th March, 2022 by NIPER Kolkata.
- xvi. E-Symposium on Topical Product Development held on 25th March, 2022 by NIPER Kolkata.
- xvii. Hands-on training and workshop on in vivo small animal imaging techniques held from 28th to 30th March, 2022 by NIPER Kolkata.
- xviii. Patent Analytics and Innovation Growth Inaugural Speech Introduction to IPR and filling of India patent application Product and process patent application in the field of pharma and chemistry held on 29th March, 2022 by NIPER Kolkata.
- xix. Online workshop on Improving research writing using on Grammarly held on 30th March, 2022 by NIPER Kolkata.
- xx. Drugs-Discovery to Delivery (DDD-2022) held on 4th March, 2022 by NIPER Guwahati.
- xxi. Funding Opportunities at BIRAC held on 8th March, 2022 by NIPER Guwahati.
- xxii. FOSTERING RESEARCH CULTURE IN NORTH-EAST REGION OF INDIA under Ministry of Science & Technology, Govt. of India Science and Engineering Research Board (SERB)-Scientific Social Responsibility Policy held on 16th March, 2022 by NIPER Guwahati.
- xxiii. Health Camp at Bonda Narangi Guwahati held on 28th March, 2022 by NIPER Guwahati.
- xxiv. The industry Perspectives on Translational Challenges in Drug Discovery & Development held on 11th March, 2022 by NIPER Raebareli.
- xxv. Biomarker identification held on 4th March, 2022 by NIPER Mohali.
- xxvi. Application of Lubrizol Polymers in Oral Solid Formulations and Solubilization held on 4th March, 2022 by NIPER Mohali.
- xxvii. Aptamers as therapeutic agents held on 11th March, 2022 by NIPER Mohali.
- xxviii. International Women's Day celebrated held on 8th March, 2022 by NIPER Mohali.
- xxix. DBT Sponsored Skill Vigyan Training Programme (online phase) held from 14th March to 5th April, 2022 by NIPER Mohali.
- xxx. DBT Sponsored Skill Vigyan Training Programme (Hands on training phase) held from 14th March to 5th April, 2022 by NIPER Mohali.
- xxxi. NIPER SAS Nagar celebrated Foundation Day on 15th March, 2022.
- xxxii. Technical Applications of EUDRAGIT and RESOMER Polymers in Oral and Parenteral Dosage Forms held on 16th March, 2022 by NIPER Mohali.

(ii) Out of 795 Research Papers published during the current financial year, 75 papers have been published in the month March, 2022.

(iii) Out of 30 Patents filed during the current financial year, 9 patents have been filed during the March, 2022.

C. National Pharmaceutical Pricing Authority (NPPA):

(i) The details of notifications issued in respect of price fixed in financial year 2021-22 are as below:

Sr. No.	Fixed Price/ Notified under Revised Schedule I (NLEM 2015)	During the month of March, 2022	Cumulative from 1 st April, 2021 to 31 st March, 2022
*1	Retail Price of 'New Drug'	56	302
*2	i) Ceiling Price fixed under para 19 ii) Ceiling Price fixed under para 4&6	2 1	8
*3	Exemption granted under para 32 of DPCO 2013	1	2
4	Revision of Ceiling price based on WPI a. Scheduled formation which were fixed under NLEM 2015 b. Ceiling Price with special features c. Scheduled formation which were fixed under NLEM 2011	874 15 9	898

* Notification in respect of Sl. No. 1, 2 and 3 are under issuance.

(ii) Retail price fixed for 56 new drugs and ceiling price of 3 formulations fixed during the 96th Authority Meeting held on 24.03.2022. The notification would be issued after a period of 10 working days as recorded in the minutes.

(iii) The prices of 'Liquid Medical Oxygen' (LMO) and 'Oxygen Inhalation (Medicinal Gas) in cylinder' fixed under Para 19 of the DPCO 2013 vide Notification S.O. 3322(E) dated 25.09.2020 issued by National Pharmaceutical Pricing Authority as extended from time to time are further extended upto 30.06.2022 vide S.O. no. 1508 (E) dated 30.03.2022.

(iv) The ceiling prices of 'Heparin Injection 1000IU/ml and 'Heparin Injection 5000IU/ml' fixed under Para 19 of the DPCO 2013 vide Notification S.O. 2151(E) dated 30.06.2020 issued by National Pharmaceutical Pricing Authority as extended from time to time are further extended upto 30.09.2022 vide S.O. no. 1507 (E) dated 30.03.2022.

(v) On the basis of Monitoring & Enforcement activities carried out by Enforcement Division, 90 Preliminary Notices (PNs) have been issued. Also, an amount of Rs. 18, 65,072/- towards the overcharged amount has been received in 3 cases.

(vi) Also Demand notices for Overcharged Receipts of Rs. 21,532,162/- (Rs 1,387,648 under DPCO 1995 & Rs 2,01,44,514 under DPCO 2013) were raised during the month: -

(vii) Under the CAPP Scheme, Twenty-Three (23) Price Monitoring and Resource Unit (PMRU) have been set up in the States till 31.03.2022 viz., Kerala, Gujarat, Odisha, Rajasthan, Punjab, Haryana, Tripura, Nagaland, Uttar Pradesh, Andhra Pradesh, Mizoram, Jammu & Kashmir, Karnataka, Telangana, Maharashtra, Goa, Madhya Pradesh, Chhattisgarh, Jharkhand, Puducherry, West Bengal, Ladakh and Himachal Pradesh. Setting up of PMRUs in the Other States are in progress.

(viii) In the Run-up of India @ 75, 'Bharat ka Amrit Mahotsav', five webinars were conducted in the month of March, 2022

(ix) Availability surveys of COVID Management Drugs at the State/UT level: NPPA through Price Monitoring and Resource Units (PMRUs) in the States/ UTs have conducted seven (7) market research analysis in March, 2022 to assess the availability of COVID Management Drugs in the States/ UTs.

(x) Grievances redressed under PMOPG (13 numbers) and information provided for RTI (Two numbers).

(xi) NPPA is encouraging the use of e-office to reduce the use of paper and in this regard 66 new files have been opened digitally on E-Office. 46 new hard files have been opened during the month (including volumes).

D. 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 March 2022		Product basket (As on 31.03.2022)		Sale of Suvidha Sanitary Napkins @ Rs. 1 per pad during the March 22	Incentive provided in the month of March 2022
March 2022	Cumulative	Sale	Saving	Medicines	Surgical		
45	8610 (As on 31.03.2022)	81.26 Crore (approx.)	488.00 Crore (approx.)	1616	250	1.35 (Crore)	4.04 Cr.

E. Policy:

(i) An interactive session with the Technical Committee of the Production Linked Incentive Scheme for Pharmaceuticals was facilitated by the Department of Pharmaceuticals and SIDBI, the Project Management Agency of the Scheme, with the selected applicants of the Scheme. The objective of the session was to reiterate the Broad Vision of the PLI Scheme and Expectation from the Applicants; and Present the Overview, Process & Approach adopted by the Technical Committee w.r.t. determining admissibility of eligible products submitted by applicants under the Scheme. The session helped enhance clarity and sensitise applicants to take forward scheme implementation in a more meaningful manner to achieve desired outcomes.

(ii) Further, Department of Pharmaceuticals and Invest India had organized an interactive session on 11.03.2022 on Direct Taxation in India, Highlighting the benefits of the Tax Regime for Pharmaceutical & Medical Devices Sectors in India. The session was led by the CA firm, Cyril Amarchand Mangaldas and witnessed participation of several industry members. Overall, it was an informative and insightful program.

(iii) The 1st meeting of the India-Egypt Joint Working Group (JWG) was held on 14th March 2022 at 2.30 P.M. through video conference. The Egyptian delegation was led by Dr. Sondos Mohamed Moshtohry, International Cooperation Officer – Chairman of EDA Office and the Indian delegation was led by Dr. Sumit Garg, Deputy Secretary, Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers, Government of India. The meeting was fruitful and it was mutually agreed to take forward areas of cooperation in pharmaceutical trade, regulatory cooperation, AYUSH and pharmaceutical education and research.

(iv) Indian Delegation led by HMCf hosted H.E.Mr. Marcelo Ebrard Casaubón, Foreign Minister of Mexico on 30.03.2022. Further, a separate meeting with Business Delegation from Mexico was also held on the same day to explore areas of joint research, joint production and expansion in bilateral trade. In the said meeting, the Indian Delegation comprised of Officials from Department of Pharmaceuticals, Department of Biotechnology, Central Drugs Standard

Control Organization, Invest India, Pharmexcil and industry representatives of the Indian Pharmaceutical and Medical Devices Sectors.

(v) The Department also actively engaged with the Department of Commerce on the matter of treatment of tariff lines pertaining to the Pharmaceutical and Medical Devices Sectors in the ongoing negotiations of the India-Australia Economic Cooperation and Trade Agreement.

(vi) **FDI inflow approved during this month: - Rs. 1172.06 crore**

F. Status of PLI Schemes:

S. No.	Name of Scheme		Total No. of Application Received*	No. of Applications approved in the month of March 22	Total no. of applications approved till date
1.	Production Linked Incentive Scheme for Bulk Drug (Last EC Meeting held on 25.11.2021 on PLI Bulk Drugs)	Round 1	215	0	41
		Round 2	24	08	08
		Total	239	08	49
2.	Production Linked Incentive Scheme for Medical Device (Last EC Meeting held on 25.11.2021 on Medical Devices)*	Round 1	28	0	13
		Round 2	14	08	08
		Total	42	08	21
3.	Production Linked Incentive Scheme for Pharmaceuticals		278	N/A	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 Swachhta Abhiyan (progress under Special Campaign):

(i) Monthly updation of New SCDPM Portal of DARPG: The information on Pending Matters and other parameters included in the revised SCDPM Portal updated for the month of March, 2022 within the timeline stipulated by DARPG.

(ii) **National Pharmaceutical Pricing Authority (NPPA):** NPPA is having bio-medical wastes comprising of outdated, contaminated and discarded medicines, which requires their disposal by way of incineration/destruction and drugs disposal in secured landfills. As NPPA is not equipped with the required bio-medical waste treatment facilities like incinerator, autoclave or microwave system for treatment of biomedical waste nor is having any expertise for management and handling of Biomedical wastes, the matter has been taken up with Lady

Hardinge Medical College, New Delhi for making necessary arrangements for disposal of old and unused drugs.

(iii) Public Sector Undertakings:

(a) Indian Drugs & Pharmaceuticals Limited (IDPL): Following activities were carried out under Swachhta Abhiyan in the month of March, 2022:

- i) Regular and dedicated cleaning drive of office premises and plant campuses.
- ii) Maintenance of parks and removal of dead leaves.
- iii) Insecticide spray was carried out to prevent spread of diseases.

(b) Karnataka Antibiotics & Pharmaceuticals Limited (KAPL): As a routine practice, swachhta/cleaning activities are undertaken both at Corporate Office and factory daily. Company observes Swachhata Pakhwada annually during the month of September. As a part of Swachhata Pakhwada, Campaign on special activities like clearing old files/records, cleaning the entire surroundings of both Factory and Corporate Office are undertaken.

(c) Hindustan Antibiotics Limited (HAL): The activities like: cleanliness of building/premises, disposal of wastes, garbage, condemned furniture, e-waste and cleaning/maintaining of sitting area etc. is carried out. Also work pertaining to disposal of long pending files, representation etc. and weeding out of old records as per Record Retention Schedule is carried out.

6. Status of Rationalization of Autonomous Bodies: Rationalization not required for the Autonomous Bodies (NIPERs) of the Department, as they are institutes of national importance and there is demand for more of such institutes.

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	Vacancy
1	Director/Deputy Secretary	1
2	Under Secretary	2
3	Principal Private Secretary	2

(ii) National Institute of Pharmaceutical Education & Research:

NIPER	Vacant Position
NIPER- Raebareli	Director
NIPER- Ahmedabad	Director

NIPER – Hajipur, Director - Under Suspension

(iii) **Public Sector Undertakings:**

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

S.No.	Designation	Vacant Positions
1	Senior Manager	04
2	Deputy General Manager	03
3	General Manager	07
	Total	14

(b) **Hindustan Antibiotics Limited (HAL):**

S.No.	Designation	Vacant Positions
1	CGM	2
2	GM	3
3	DGM	12
4	Manager	19
	Total	36

(c) **Bengal Chemicals & Pharmaceuticals Limited (BCPL):**

S.No.	Designation	Vacant Positions
1	DGM/AGM	3
2	Sr. Manager	3
3	DGM (Marketing)	1
4	DGM(Finance)	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	:	11
(ii)	Received during the month	:	2
(iii)	Disposed of during the month	:	4
(iv)	Pending at end of the month	:	9
