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IDMA BULLETIN

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INDIAN PHARMA - GLOBAL HEALTH CARE

INDIAN DRUG MANUFACTURERS' ASSOCIATION

HIGHLIGHTS

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IDMA BULLETIN

Vol. No. 53 **Issue No. 16** **22 to 30 April 2022**

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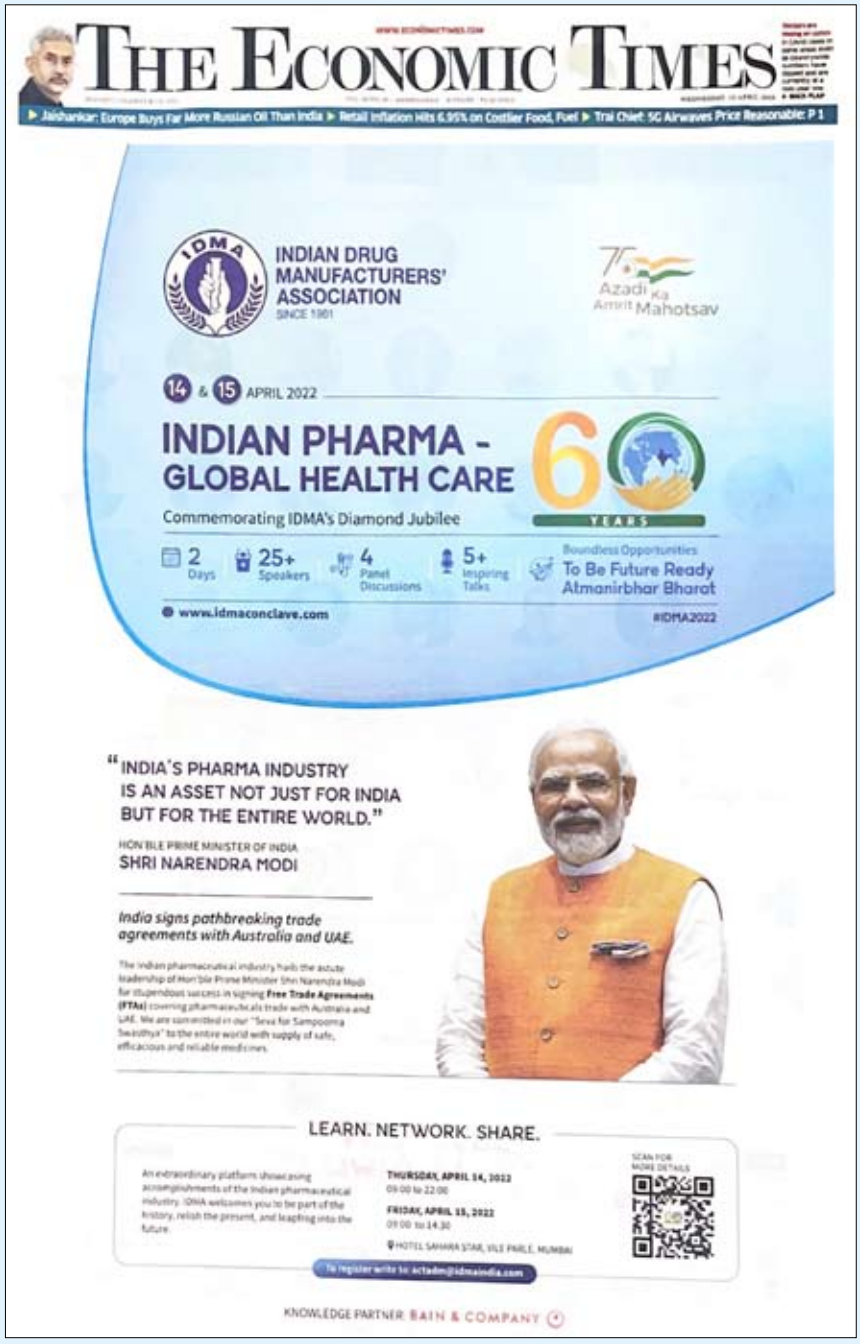
IDMA's 60th Year Diamond Jubilee Celebrations 2022- A Huge Success

IDMA thanks all the members for the huge success of IDMA's 60th Year Diamond Jubilee Celebrations 2022.

Await "Bumper Special Issue"

IDMA's Diamond Jubilee Year Celebrations 2022 - Announcement in The Economic Times dated 13th April 2022 First Time Ever.




CHIEF GUEST - INAUGURAL CEREMONY
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Hon'ble Minister of Health & Family Welfare and Chemicals & Fertilizers, Government of India
CHIEF GUEST - VALEDICTORY CEREMONY
SHRI PIYUSH GOYAL
Hon'ble Minister of Commerce & Industry, Consumer Affairs, Food & Public Distribution and Textiles, Government of India
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S APARNA, IAS
Secretary, Department of Pharmaceuticals, Government of India
Dr. MANDEEP KUMAR BHANDARI, IAS
Joint Secretary, Ministry of Health & Family Welfare, Government of India
Dr. V G SOMANI
Drugs Controller General of India, Government of India
AJITH PAI
COO, Dellivery
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Managing Partner, Quadria Capital
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BAKUL
DWD
ELAN PHARMA
GCCPL
Galentic
Shga
MACLEODS
MJ SHAH
NATCO
NEON
WALLACE
Zuventus
Conclave managed by: stageextslive

Invitation to IDMA's MSME member companies to participate in the 12th edition of KOREA PHARM & BIO 2022, scheduled to be held in KINTEX-II, Seoul, South Korea during JUNE 14-17, 2022

Indian Drug Manufacturers' Association (IDMA) & Kyungyon Exhibition Corporation, South Korea invite IDMA's MSME member companies to participate in the 12th edition of **KOREA PHARM & BIO 2022,** scheduled to be held in KINTEX-II, Seoul, South Korea during **JUNE 14-17, 2022**.

IDMA has submitted an application to MSME Ministry to organize Indian National Pavilion in the aforesaid exhibition by which exhibitors from MSME categories can avail reimbursement of up to 100% on booth cost and economy class airfare for 1 person from the exhibiting company as per the guidelines.

KOREA PHARM has been the most preferred platform for the last 8 years for Indian exporters of Pharmaceuticals, APIs, Intermediates, Natural Ingredients. PHARMEXCIL has been a regular participant by organizing national pavilion. **PHARMEXCIL has confirmed participation of 20+ exhibitors for this year as well.**

The exhibition, organized by Kyungyon Exhibition Corporation, is the oldest Exhibition focused on Pharmaceuticals and Pharmaceutical Ingredients. This is the only Exhibition supported by Ministry of Food & Drug Safety, and Korea Pharmaceuticals & Bio-Pharmaceuticals Manufacturers Association. KOREA PHARM & BIO 2022 will be co-held with 6 other exhibitions with participation expected to have 1,500 exhibitors.

EXHIBIT PROFILE : Pharmaceuticals, Pharmaceutical Ingredients, APIs, Bulk Drugs, Intermediates, Excipients, Bio-Pharmaceuticals, Functional Ingredients, Natural Extracts.

Participation Cost: Rs. 2.70 lakh / 9 sqm Standard Booth
Corner Booth to be charged at Rs. 2.75 lakh
To be paid to IDMA

Participants from Non-MSME categories are welcome to participate but financial subsidies from MSME Ministry is not possible.

To register your participation, please send your Udyam Registration Certificate and Participation Cost to IDMA by **3rd May 2022**. Please hurry up as limited booths available.

CONTACTS

Exhibition & MSME Reimbursement related Queries:
Mr. Susanta Mahapatra / md@3smg.in / 91-9971988322
IDMA: Mr. Melvin Rodrigues / actadm@idmaindia.com / 91-9821868758

Requesting all IDMA MSME Members to participate and take benefit from this Exhibition.

Looking forward to your usual excellent support and prompt action.

Thanking you,

With Best regards,

Daara B Patel, Secretary - General

Jan Aushadhi – Medicines for the Masses*

Dr. Nagaraj Rao, *Associate Editor, Indian Drugs*

Dear Reader,

Universal health care is a goal which most nations are striving to achieve. Brazil can boast of showing the way – it is perhaps the only country today where any individual within Brazilian jurisdiction is deemed eligible to receive free, instant and complete healthcare without any formalities and covers treatments, surgeries and medicines.

As far as medicines in India are concerned, the first Jan Aushadhi Kendra (Centre, Store) was set up in 2008 by the Department of Pharmaceuticals under the Ministry of Chemicals and Fertilizers, with the active participation of central public sector undertakings. The Jan Aushadhi Plan received great impetus in 2016, when the Indian government decided to open 3000 stores during 2017. More than 8675 Jan Aushadhi Kendras were thriving across the country at the end of January 2022, covering all the 739 districts – with many of them providing self-employment, especially to women entrepreneurs. The government has set a target of 10,000 such Kendras by the March 2024, which appears to be easily realisable. Jan Aushadhi Week is celebrated across the country from 1st to 7th March every year, and the first Jan Aushadhi Store on an IIT campus was inaugurated very recently at IIT-Indore during its 13th Foundation Day celebrations. The state of Uttar Pradesh has more than 1185 such Kendras, while a small state like Goa already has more than 10.

The declared aim of this mission is to ensure that high quality generic medicines are procured from WHO GMP, CGMP and CPSU manufacturers. Quality, safety and efficacy of medicines and conformance with required standards is ensured by strict checking procedures by NABL-accredited laboratories. Only after the batches are approved by these laboratories can the medicines be released for despatch.

Dr. Nagaraj Narayan Rao obtained Bachelor's degrees in Science (Chemistry) and in the Technology of Pharmaceuticals and Fine Chemicals from the University of Mumbai. After working with Colgate-Palmolive (India) for two years as a laboratory chemist, he obtained his doctorate in science with magna cum laude from the University of Tuebingen, Germany, under the guidance of Prof. Dr. H. J. Roth. He carried out post-doctoral research at the Institute of Biotechnology of the Research Center Juelich, Germany. He was a member of the Editorial Board for the first official German-language version of the European Pharmacopoeia. He was a visiting scientist at Juelich and a visiting faculty at the Institute of Chemical Technology Mumbai from 1993 to 2007 in the field of bioprocess technology. He has authored several original research articles, a patent, review articles and book chapters in the fields of pharmaceuticals, biotechnology, brewery and surface coatings. He was Chief Editor of the "Transactions of the MFAI" for a few years. He contributes a monthly 'Report from India' to a leading German technical journal since fourteen years and is a distinguished alumnus of the Research Center Juelich.

Dr. Rao is co-founder of the RRR group of small and medium enterprises, manufacturing organic fine chemicals, formulations for surface coating technologies and fertilizers, process sensors and process units for life sciences, brewery and chemical process industries, as well as representing select overseas companies for cell culture media, bulk drugs and used chemical equipment and plants.

The product basket of the Pradhan Mantri Bharatiya Janaushadhi Pariyojana comprises currently of 1451 drugs and 240 surgical instruments. These medicines are priced significantly lower than branded medicines and are anywhere between 50% and 90% cheaper. The initial hesitation of cheaper medicines being also lower in quality has been dispelled. New medicines and nutraceuticals products, besides sanitizers, masks, glucometer and oximeter have been added to the ever-increasing portfolio. As far as logistics is concerned, three IT-enabled warehouses are functioning in Gurugram, Chennai and Guwahati and the fourth one will be starting operations in the western city of Surat. Around 40 distributors have the responsibility of supporting the supply of medicines, especially to rural and remote areas, to ensure reasonable stock levels. The enterprising Kendras also often sell OTC drugs, sanitary napkins and general items to increase footfalls. There are several examples of hospitals which have allowed such Kendras to be run without having to pay rent.

It is estimated that in the financial year 2021-2022 itself, the citizens saved up to Rs. 4000 crores of rupees. Especially for those who have chronic ailments and need to take medicines regularly and for long durations, the Jan Aushadhi Yojana is a huge blessing. However, it must be noted that Indian citizens still largely pay directly to the health care provider, without a third-party insurer, and this often leads to financial ruin of families. The connected mission of Jan Arogya Yojana, launched in 2018, aims at providing a health insurance cover of Rs. 5.00 lakhs per family per year for secondary and tertiary care hospitalization to 11 crore poor and vulnerable families. Under the Indian Constitution, public health, sanitation, hospitals and dispensaries are state subjects and budgetary allocations vary from state to state. Indian citizens still pay on an average for half of the total health expenditure, which is termed as Out of Pocket Expenditure.

The Jan Aushadhi Kendras cannot assume to have a cake-walk though. There is competition here too since 2018 - and that too from a then 16-year-old boy named Arjun Deshpande. His startup, named Generic Aadhar, is hogging the limelight. Its declared aim is also to make affordable low-cost generic medicines to one and all. Generic Aadhar, like the Jan Aushadhi Kendras, also delivers high-quality medicines at up to 80% lower price than branded counterpart from manufacturers to end-users directly, thereby eliminating middle-chain costs of advertising, marketing, distribution, stocking and supply chain through its unique pharmacy-aggregator franchise business model. In today's ever-increasing digital world, Generic Aadhar provides local pharmacies with user-friendly software and uses traditional transaction methods, thereby enabling the business to grow in offline and online models, invoicing and more through the B2B and B2C franchise model. As far as consumers are concerned, online ordering and doorstep delivery within two hours from nearby Generic Aadhar franchisees is ensured. Till date, it has empowered more than a million retailers, 1500 micro-entrepreneurs and 1500 service providers across India, who together are in the fray competing with medical malls and online pharmacies. The Generic Aadhar start-up is backed by the Industrialist Ratan Tata.

Several milestone decisions taken by the government in the last decades have taken us towards the goal of better health care for all. Not to be missed is the change in the patent law for manufacturing APIs in the early 'seventies of the last century, which led to the dramatic growth of the Indian pharmaceutical industry. The then industry leaders and associations like the IDMA, the publisher of Indian Drugs, made it happen.

Happy reading!

Courtesy: Indian Drugs, Editorial, 59 (02), February 2022

**Dedicated to Dr. Abraham Patani, Founder Editor of Indian Drugs, on the occasion of his 90th Birthday*

DGFT Helpdesk support now available on 24x7 basis - reg.

DGFT Trade Notice No.02/2022-23, dated 22nd April 2022

To,

1. All Exporters/Members of Trade,

2. DGFT Regional Authorities,

3. Export Promotion Councils/Commodity Boards.

1. In order to facilitate trade and extend more proactive helpdesk support to the exporting community, it is informed that the services of DGFT Helpdesk will now be available on a 24x7 basis.

2. Stakeholders may use any of the below channels to flag any issues, suggestions or feedback on matters related to DGFT as follows -

i. Call the Helpdesk support on Toll Free numbers 1800-572-1550 or 1800-11-1550

ii. Raise a Helpdesk ticket by navigating to DGFT website (https://dgft.gov.in) → Services → DGFT Helpdesk Service. Users may also see their earlier ticket(s) status on real-time basis or search previously filed requests.

iii. Write an email to dgftedi@nic.in

3. Trade Community may also refer to the Help manuals, FAQs and educational videos for suitable guidance. The same is available on the DGFT Website → Learn → 'Application Help & FAQs' for perusal of the trade community.

This issues with the approval of the competent authority.

File No. 01/02/107/AM22/EG&TF[E-30138]

Md. Moin Afaque, Deputy Director General of Foreign Trade, Ministry of Commerce and Industry, Department of Commerce, Directorate General of Foreign Trade, New Delhi.

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Extension of Date for Mandatory electronic filing of Non-Preferential Certificate of Origin (CoO) through the Common Digital Platform to 1st August 2022 – reg.

DGFT Trade Notice No.04/2022-23, dated 27th April 2022

To,

1. All Exporters/Members of Trade,

2. All Designated Issuing Agencies.

1. In continuation to the earlier Trade Notice 24/2021-22 dated 15.11.2021, Trade Notice 42/2020-2021 dated 19.02.2021, 48/2020-2021 dated 25.03.2021, 10/2021-2022 dated 19.07.2021, 19/2021-2022 dated 01.10.2021, 21/2021-22 dated 18.10.2021 and 32/2021-22 dated 24.01.2022, it is informed that the transition period for mandatory filing of applications for Non-Preferential Certificate of Origin through the e-CoO Platform has been further extended till **01st August 2022.**

2. While the exporters and NP CoO Issuing Agencies would have the option to use the online system, the same shall not be mandatory till 01st August 2022. The existing systems of processing non-preferential CoO applications in manual/paper mode is being allowed. For guidance on registration and online application submission process, the Help Manual & FAQs may be seen on the landing page at https://coo.dgft.gov.in

3. All stakeholders may note that issuing agencies who do not use the Online System for issue of non-preferential CoOs after 1st August 2022 will invite penal action and can be subject to 'de-listing' as an authorised agency. The authorised agencies are therefore required to sensitize the exporting community and their constituents regarding the Online system and its registration requirements well in time. Any issues relating to the IT system and its

implementation may also be brought to our notice for appropriate action.

This issues with the approval of the competent authority.

File No. 01/02/82/AM-19/EDI[E-14047]

Md. Moin Afaque, Deputy Director General of Foreign Trade, Ministry of Commerce and Industry, Department of Commerce, Directorate General of Foreign Trade, New Delhi.

● ● ●

Application for recognition as Pre-Shipment Inspection Agency (PSIA) and issuance and electronic Verification of Pre-Shipment Inspection Certificate (PSIC) – reg.

Trade Notice No. 03/2022-23, 26th April, 2022

1. Reference is invited to paragraph 2.55 and 2.56 of Handbook of Procedures 2015-20 regarding recognition as Pre-Shipment Inspection Agency (PSIA) for metal scrap and issuance of Pre- Shipment Inspection Certificate (PSIC).

2. As a part of IT Revamp, this Directorate proposes a new online module for filing of application for recognition as Pre-Shipment Inspection Agency (PSIA), electronic issuance of Pre-shipment Inspection Certificates (PSICs) and electronic verification of authenticity of the PSICs **with effect from 01.05.2022.**

3. In this regard, it is submitted that all existing PSIAs as recognised under Appendix 2G of the FTP are required to register online on the DGFT Website (https://dgft.gov.in) → My Dashboard → Register and selecting 'Register User As' -'Pre-Shipment Inspection Agency'. The said PSIA official shall thereafter navigate to Services → Pre-Shipment Inspection → Apply for PSIA and submit required details for activation of their specific online account.

4. Further, any application for amendment in instruments and/or areas of operation of existing PSIA may also be made online post-login as PSIA by navigating to the DGFT website → Services → Pre-Shipment Inspection → Amendment in Area of Operation/ Instruments.

5. Further, on successful activation of account, the PSIA may generate and upload Pre-Shipment Inspection Certificates (PSIC) online through the following navigation:

DGFT website → Services → Pre-Shipment Inspection → Generate and upload PSIC. The PSIC shall may be generated by the PSIA after the required inspection has been carried out. Required Video and photographic evidence is to be uploaded by the PSIA during this online PSIC process.

6. Further, the PSIC generated online can be downloaded by the Indian Importer by navigating to the DGFT website → Services → Pre-Shipment Inspection → Download Pre-shipment Inspection Certificate (PSIC). The Importer would be required to enter the PSIC certificate number and the name of PSIA to download any such PSIC.

7. The Customs Authorities at the Indian Port may also consider verifying the genuineness of online PSIC generated using the steps as summarised under para 6 above. The Importer or the Customs Authorities shall not be required to login to the DGFT Website to access the PSIC download or PSIC verification services.

8. The given online process shall not be mandatory in the initial period of go-live and the PSIAs as well as the importers are provided time till 30.06.2022 to onboard and familiarise with the said online process. All PSICs shall be mandatorily generated online through the DGFT Website w.e.f. 01.07.2022. PSICs dated on or after 01.07.2022 not generated using the DGFT online systems may not be accepted by the Indian Customs Authorities.

9. For any help and guidance on this new process, the Help manual & FAQs may be accessed on the DGFT Website → Learn → Application Help & FAQs. For

any further assistance, guidance and resolution of issues faced, any of the following channels may be assessed –

i. Raise a service request ticket through the DGFT Helpdesk Service on DGFT Website → Services → DGFT Helpdesk Service

ii. Call the toll-free-Helpline number

iii. Send an email to the Helpdesk on dgftedi@gov.in

10. This issues with the approval of the Competent Authority.

File No. 01/53/8/E/AM22/PSIA/ImportCell)

Md. Moin Afaque, Deputy Director General of Foreign Trade, Ministry of Commerce and Industry, Department of Commerce, Directorate General of Foreign Trade, New Delhi.

● ● ●

Electronic filing and Issuance of Preferential Certificate of Origin (CoO) for India's Exports under India-UAE Comprehensive Economic Partnership Agreement (India-UAE CEPA) w.e.f. 01st May 2022

DGFT Trade Notice No.05/2022-2023, dated 29th April 2022

1. In continuation to the earlier Trade Notice(s) 34/2015-2020 dated 19.09.2019, 41/2019-2020 dated 12.12.2020, 53/2019-2020 dated 02.03.2020, 01/2020-2021 dated 07.04.2020, 30/2020-2021 dated 13.10.2020, 43/2015-2020 dated 23.02.2021 and 01/2021-22 dated 01.04.2022, it is informed that the electronic platform for Preferential Certificate of Origin (CoO) is being expanded further to facilitate electronic application of Preferential Certificates of Origin under the India-UAE Comprehensive Economic Partnership Agreement.

2. The Preferential Certificate of Origin for Exports to UAE under India-UAE CECPA shall be issued from the CoO e-platform with effect from 01st May 2022.

3. It is informed that applications under the above-mentioned Trade Agreement may be submitted on the eCoO Website (https://coo.dgft.gov.in). The eCoO generated shall bear the image signature of the officer and stamp of the issuing agency. The eCoO shall also bear a Quick-Response(QR) code for electronic verification and authenticity of eCoO so issued. The authenticity of the eCoO may additionally be verified by keying in the Certificate Number on the 'Verify Certificate' link on the eCoO Website.

4. On issue, the e-CoO system shall generate an original copy and a duplicate copy besides the electronic copy. Accordingly, paper copies of the eCoO may also be collected by post or in person, from the concerned issuing agency, after necessary ink-signatures/stamping, if required.

5. The concerned Indian Exporters may please take note of the following points with regard to the process being notified herewith:

- Digital Signature Certificate (DSC) would be required for the purpose of electronic submission. The digital signature would be the same as used in other DGFT applications; and should be a Class III DSC;
- Any new applicant exporter would be required to initially register at the portal. The password would be sent on the email and mobile number of the IEC holder. In case the IEC holder desires to update their email on which communication is to be sent, the same may be done by using the 'IEC Profile Management' service on the DGFT website https://dgft.gov.in
- Once registration is completed, the IEC branch details would be auto-populated as per the DGFT-IEC database. Applicant is required to ensure that updated IEC details are available in the DGFT system. Necessary steps may be taken to modify the IEC details online, whenever required.

6. For further guidance on registration and application submission, the Help manual & FAQs may be

accessed on the landing page at https://coo.dgft.gov.in. For any further assistance you may utilize any of the following channels -

- Raise a service request ticket through the DGFT Helpdesk Service on DGFT Website -- > Services -- >DGFT Helpdesk Service
- Send an email to DGFT CoO Helpdesk at coo-dgft@gov.in
- Call the Toll-Free DGFT Helpdesk Numbers

This issues with the approval of the competent authority.

File No. 01/02/82/AM-19/EDI[E-14047]

Md. Moin Afaque,
Deputy Director General of Foreign Trade,
Ministry of Commerce and Industry,
Department of Commerce,
Directorate General of Foreign Trade, New Delhi.

● ● ●

FSSAI MATTERS

State Food Safety Index 2021-2022-reg.

File No. RCD-04/2 12022-Regulatory-FSSAI, dated 26th April 2022

To,

The Commissioner of Food Safety of all States/UTs

1. As you are aware, FSSAI has been evaluating the performance of State/UTs based on compliance to food safety parameters through State Food Safety Index to create a positive competitiveness among States /UTs to improve Food safety ecosystem and ensure availability of safe and healthy wholesome food to general public.

2. FSSAI has initiated the process for State Food Safety Index for 2021-2022. In this regard the online portal (www.fssai.qov.in/sfsi) for uploading data for State Food Safety Index 2021-2022 will be made Live from 27.04.2022. You are requested to provide the requisite data of financial year 2021-2022 for State Food Safety Index on the SFSI portal positively by 10.05.2022. The login credential for uploading the data are the same as provided earlier at the time of SFSI-2020-2021.

3. The evaluation will be done by a Team of Evaluators comprising of members from FSSAI as well as external experts for which deliberations may be held through video conferencing for necessary verification and obtaining further information as required.

Kindly ensure an early action in this matter.

Parveen Jargar, Joint Director (RCD), Food Safety and Standards Authority of India, (Regulatory Compliance Division-State Unit), (A Statutory Authority under Ministry of Health and Family Welfare), FDA Bhawan, Kotla Road, New Delhi

● ● ●

NPPA fixes the Retail Price of Specified 15 Formulation/ Brand Name under the Drugs (Price Control) Order, 2013

NPPA Order S.O.1833(E), dated 18th April 2022

In exercise of the powers conferred by paragraphs 5, 11 and 15 of the Drugs (Prices Control) Order, 2013, read with S.O. 1394(E) dated the 30th May, 2013 and S. O. 701(E) dated 10th March, 2016 issued by the Government of India in the Ministry of Chemicals and Fertilizers, the National Pharmaceutical Pricing Authority (hereinafter referred as NPPA), hereby fixes, the price as specified in column (6) of the table herein below as the retail price, exclusive of Goods and Services Tax, if any, in relation to the formulation specified in the corresponding entry in column (2) of the said Table with the strength, unit and name of manufacturer & marketing company, as specified in the corresponding entries in columns (3), (4) and (5) thereof;

TABLE

Sl. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
1.	Metformin (extended-release) + Teneligliptin Tablet	**Each uncoated bilayered tablet contains:** Metformin Hydrochloride IP 500mg (as Extended-Release) Teneligliptin Hydrobromide hydrate eq. to Teneligliptin 20mg	1 Tablet	M/s Associated Biotech / M/s Dales Laboratories	7.14
2.	Dapagliflozin + Metformin Hydrochloride Extended release Tablet	**Each film-coated tablet contains:** Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg, Metformin Hydrochloride IP 1000mg (As Extended release form)	1 Tablet	M/s Exemed Pharmaceuticals / M/s Emcure Pharmaceuticals Limited	10.70
3.	Dapagliflozin + Metformin Hydrochloride (As Extended release form) Tablet	**Each film-coated bilayered tablet contains:** Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg, Metformin Hydrochloride IP 1000mg (As Extended release form)	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Natco Pharma Ltd.	7.97
4.	Dapagliflozin + Metformin Hydrochloride (As Extended release form) Tablet	**Each film-coated bilayered tablet contains:** Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg, Metformin Hydrochloride IP 1000mg (As Extended release form)	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Apex Laboratories Private Limited	10.70
5.	Dapagliflozin + Metformin Hydrochloride Extended release Tablet	**Each film-coated tablet contains:** Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg, Metformin Hydrochloride IP 500mg (As Extended release form)	1 Tablet	M/s Exemed Pharmaceuticals / M/s Emcure Pharmaceuticals Limited	9.18

6.	**Dapagliflozin + Metformin Hydrochloride (As Extended release form) Tablet**	**Each film-coated bilayered tablet contains:** Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg, Metformin Hydrochloride IP 500mg (As Extended release form)	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Natco Pharma Ltd.	7.30
7.	Dapagliflozin + Metformin Hydrochloride (As Extended release form) Tablet	**Each film-coated bilayer tablet contains:** Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg, Metformin Hydrochloride IP 500mg (As extended release form)	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Apex Laboratories Private Limited	9.18
8.	Dapagliflozin + Metformin Hydrochloride Extended release Tablet	**Each film-coated tablet contains:** Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 5mg, Metformin Hydrochloride IP 1000mg (As extended release form)	1 Tablet	M/s Exemed Pharmaceuticals / M/s Emcure Pharmaceuticals Limited	7.29
9.	Dapagliflozin + Metformin Hydrochloride Extended release Tablet	**Each film-coated tablet contains:** Dapagliflozin 5mg, Metformin Hydrochloride IP/USP 1000mg (As extended release form)	1 Tablet	M/s MSN Laboratories Pvt. Ltd. / M/s USV Limited	7.29
10.	Dapagliflozin + Metformin Hydrochloride Extended release Tablet	**Each film-coated tablet contains:** Dapagliflozin 5mg, Metformin Hydrochloride IP/USP 500mg (As extended release form)	1 Tablet	M/s MSN Laboratories Pvt. Ltd. / M/s USV Limited	6.16
11.	Human Normal Immunoglobulin for Intravenous use IP 5% (Ig M Enriched)	**Each vial contains:** Total Protein 50 g/L, Immunoglobulin M 6g/L, Immunoglobulin A 6g/L, Immunoglobulin G 38g/L, Glucose Monohydrate (as stabilizer) 27.5g/L, Sodium Chloride 4.56g/L, Water for injection q. s. Distribution of Ig G subclass is approx. 62%IgG1,27%IgG2,1%IgG3,10 %IgG4	Per 1 ml (for 10 ml vial)	M/s Intas Pharmaceuticals Ltd	177.85
12.	Medroxyprogesterone Acetate sustained release Tablet	**Each uncoated sustained release tablet contains:** Medroxyprogesterone Acetate IP 30mg	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Serum Institute of India Pvt. Ltd.	14.04

13.	Medroxyprogesterone Acetate SR Tablet	**Each uncoated sustained release tablet contains:** Medroxyprogesterone Acetate IP 30mg	1 Tablet	M/s Synokem Pharmaceuticals Limited / M/s Torrent Pharmaceuticals Ltd.	14.04
14.	Glycopyrrolate + Formoterol Fumarate + Budesonide Inhalation	**Each actuation delivers:** Glycopyrrolate IP 9mcg Formoterol Fumarate Dihydrate IP eq. to Formoterol Fumarate 4.8mcg Budesonide IP 160mcg	1 MDI	M/s Zydus Healthcare Ltd.	8.63
15.	Folic Acid, Pyridoxine Hydrochloride, Methylcobalamin & Vitamin D3 Tablet	**Each uncoated mouth dissolving tablet contains:** Folic Acid IP 5mg Pyridoxine Hydrochloride IP 3mg Methylcobalamin IP 1500mcg Vitamin D3 IP 1000 IU	1 tablet	M/s Unison Pharmaceuticals Pvt. Ltd.	6.70

Note:

(a) The manufacturer of above mentioned formulations i.e. "new drug" under paragraph 2(u) of the DPCO, 2013 shall fix the retail price as specified in column (6) of the table hereinabove.

(b) The manufacturer may add Goods and Services Tax only if they have paid actually or it is payable to the Government on the retail price mentioned in column (6) of the above said table.

(c) The retail price for a pack of the aforesaid formulation shall be arrived at by the concerned manufacturer in accordance with the retail price specified in column (6) of the above table as per provisions contained in paragraph 11 of the DPCO, 2013. The manufacturer shall issue a price list in Form–V from date of Notification as per paragraph 24 of the DPCO, 2013 to NPPA through IPDMS and submit a copy to State Drug Controller and dealers.

(d) As per para 24(4) of DPCO 2013, every retailer and dealer shall display price list and the supplementary price list, if any, as furnished by the manufacturer, on a conspicuous part of the premises where he carries on business in a manner so as to be easily accessible to any person wishing to consult the same.

(e) The above mentioned retail price is applicable only to the individual manufacturer / marketer as mentioned above i.e. who have applied for the same by submitting Form-I for price fixation / revision as stipulated under DPCO, 2013 and subject to fulfilment of all the applicable statutory requirements as laid down by the Govt. under relevant statutes/ rules, including manufacturing license permission from the Competent Authority i.e. the Central/State Licensing Authority, as may be applicable, by the concerned manufacturer/marketing companies.

(f) In case the retail price of any of the aforesaid formulations is not complied with, as per instant price notification and notes specified hereinabove, then the concerned manufacturer/marketing company shall be liable to deposit the overcharged amount along with the interest thereon under the provisions of the DPCO, 2013 read with the Essential Commodities Act, 1955.

(g) Consequent to the issue of ceiling price of such formulation as specified in column (2) of the above table in this notification, the price order(s) fixing ceiling or retail price, if any, issued prior to the above said date of notification, stand(s) superseded.

PN/228/96/2022/F/
F. No. 8(96)/2022/D.P./NPPA-Div.-II

Prasenjit Das,
Deputy Director,
Ministry of Chemicals and Fertilizers,
Department of Pharmaceuticals,
National Pharmaceutical Pricing Authority,
New Delhi

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NPPA fixes the Ceiling Price of "Framycetin" Scheduled Formulation Name under the Drugs (Price Control) Order, 2013

NPPA Order S.O.1834(E), dated 18th April 2022

In exercise of the powers conferred by paragraphs 4, 6, 10, 11, 14, 16, 17 and 18 of the Drugs (Prices Control) Order, 2013, read with S.O. 1394(E) dated the 30th May, 2013 and S.O. 701(E) dated 10th March, 2016 issued by the Government of India in the Ministry of Chemicals and Fertilizers and in supersession of the Order of the Government of India in the Ministry of Chemicals and Fertilizers (National Pharmaceutical Pricing Authority) at Sl.No.6 of SO 1503(E) dated 30th March, 2022 in so far as it relates to formulation packs mentioned in the table below, except in respect of things done or omitted to be done before such supersession, the National Pharmaceutical Pricing Authority (hereinafter referred as NPPA) hereby fixes the price as specified in column (5) of the table herein below as ceiling price exclusive of goods and services tax applicable, if any, in respect of the Scheduled formulation specified in the corresponding entry in column (2) of the said Table with the dosage form & strength and unit specified respectively in the corresponding entries in columns (3) and (4) thereof:

TABLE

Sl. No.	Name of the Scheduled Formulation	Dosage form & Strength	Unit	Ceiling Price (Rs.)
(1)	(2)	(3)	(4)	(5)
1.	Framycetin	Cream 0.5%	1 GM	1.19

Note:

(a) All manufacturers of scheduled formulation, selling the branded or generic or both the versions of scheduled formulations at a price higher than the ceiling price (plus Goods and Services Tax as applicable) so fixed and notified by the Government, shall revise the prices of all such formulations downward not exceeding the ceiling price specified in column (5) in the above table plus goods and services tax as applicable, if any.

(b) All the existing manufacturers of above mentioned scheduled formulations having MRP lower than the ceiling price specified in column (5) in the above table plus goods and services tax as applicable, if any, shall continue to maintain the existing MRP in accordance with paragraph 13 (2) of the DPCO, 2013.

(c) The manufacturers may add goods and services tax only if they have paid actually or if it is payable to the Government on the ceiling price mentioned in column (5) of the above said table.

(d) The ceiling price for a pack of the scheduled formulation shall be arrived at by the concerned manufacturer in accordance with the ceiling price specified in column (5) of the above table as per provisions contained in paragraph 11 of the Drugs (Prices Control) Order, 2013. The manufacturer shall issue a price list in Form–V from date of Notification as per paragraph 24 of the DPCO, 2013 to NPPA through IPDMS and submit a copy to State Drug Controller and dealers.

(e) As per para 24(4) of DPCO 2013, every retailer and dealer shall display price list and the supplementary price list, if any, as furnished by the manufacturer, on a conspicuous part of the premises where he carries on business in a manner so as to be easily accessible to any person wishing to consult the same.

(f) Where an existing manufacturer of scheduled formulation with dosage or strength or both as specified in the above table launches a new drug as per paragraph 2 (u) of the DPCO, 2013 such existing manufacturer shall apply for prior price approval of such new drug to the NPPA in Form I as specified under Schedule-II of the DPCO, 2013.

(g) The manufacturers of above said scheduled formulations shall furnish quarterly return to the NPPA, in respect of production / import and sale of scheduled formulations in Form-III of Schedule-II of the DPCO, 2013 through IPDMS. Any manufacturer intending to discontinue production of above said scheduled formulation shall furnish information to the NPPA, in respect of discontinuation of production and / or import of scheduled formulation in Form-IV of Schedule-II of the DPCO, 2013 at least six months prior to the intended date of discontinuation.

(h) The manufacturers not complying with the ceiling price and notes specified hereinabove shall be liable to deposit the overcharged amount along with interest thereon under the provisions of the Drugs (Prices Control) Order, 2013 read with Essential Commodities Act, 1955.

(i) Consequent to the issue of ceiling price of such formulation as specified in column (2) of the above table in this notification, the price order(s) fixing ceiling or retail price, if any, issued prior to the above said date of notification, stand(s) superseded.

PN/228/96/2022/F/
F. No. 8(96)/2022/D.P./NPPA-Div.-II

Prasenjit Das, Deputy, Director, Ministry of Chemicals and Fertilizers, Department of Pharmaceuticals, National Pharmaceutical Pricing Authority, New Delhi

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CDSCO MATTERS

Procedure to be followed for regularization of FDCs with respect to 294 FDCs examined, by the DTAB which were licensed to manufacture and market by State Licensing Authority without prior approval from DCG(I) - reg.

F.No.04-146/ 2007-DC (Part-I), dated 28th April 2022

To
All State/UT Drugs Controllers,

1. *This Directorate letter no 04-14612007-DC (Part-I) dated 27.02.2019.*
2. *This Directorate letter no 04-146/2007-DC (Part-I) dated 19.08.2019.*
3. *This Directorate letter no 04-146/2007-DC (Part-I) dated 08.09.2020.*
4. *This Directorate 02 letters no 04-14612007-DC (Part-I) dated 27.08.2021.*

1. This is with reference to this Directorate's various above letters w.r.t. FDCs falling under 294 category. As per the said letters, manufacturers who are already holding licenses from State Licensing Authorities for such FDCs and did not apply to DCG(I) were required to submit their applications to this Directorate as per the defined pathways. The date for filing such applications of various categories has already expired.

2. Meanwhile in the wake of Covid 19 pandemic, this Directorate has received various representations requesting for extension of time for submission of such applications. Accordingly, it has been decided that manufacturers/stakeholders who are holding licenses from State Licensing Authorities and have not yet applied to this Directorate may submit their applications w.r.t these FDCs **by 31.10.2022.**

3. In view of above, you are requested to direct all the concerned manufacturers/stakeholders who are already holding manufacturing permissions for manufacturing these FDCs to submit their application to this Directorate alongwith requisite fees by 31.10.2022 positively.

Dr. V G Somani,
Drugs Controller General (India),
Directorate General of Health Services,
Central Drugs Standard Control Organization,
(FDC Division),
FDA Bhawan,
Kotla Road,
New Delhi.

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1, 3 Phenylenediamine (Quality Control) Order, 2022 published

Chemicals & Fertilizers Order S.O.1960(E), dated 27th April 2022

In exercise of the powers conferred by section 16 of the Bureau of Indian Standards Act, 2016 (11 of 2016) (hereinafter referred to as the said Act), the Central Government being of the opinion that it is necessary or expedient so to do in the public interest and after consultation with the Bureau of Indian Standards , hereby makes the following order, namely:-

1. Short title, commencement and application

(1) This order may be called the **1, 3 Phenylenediamine (Quality Control) Order, 2022.**

(2) It shall come into force on the one hundred and eighty- first day from the date of its publication in the Official Gazette.

(3) It shall apply to goods or articles specified in column (1) of the Table below, but shall not apply to such good or articles meant for export.

2. Conformity to standard and compulsory use of Standard Mark

Goods or articles specified in column (1) of the said Table shall conform to the corresponding Indian Standard specified in column (2) of the said Table and shall bear the Standard Mark under a licence from the Bureau of Indian Standard as per Scheme-I of Schedule-II of the Bureau of Indian Standards (Conformity Assessment) Regulations, 2018.

3. Certification and enforcement authority

The Bureau of Indian Standards shall be the certifying and enforcing authority in respect of the goods or articles specified column (1) of the said Table.

4. Penalty for contravention

Any person who contravenes the provisions of this order shall be punishable under the provisions of the said Act.

Table

Goods or articles	Indian Standard	Title of Indian Standard
(1)	(2)	(3)
1, 3 Phenylenedi-amine	IS 17450 : 2020	1,3 Phenylenediamine - Specification

F.No.C-II-13012/01/2021-Chem. II

N K Santoshi, Deputy Director General, Ministry of Chemicals and Fertilizers, Department of Chemicals and Petrochemicals, New Delhi.

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Lauric Acid (Quality Control) Order, 2022 published

Chemicals & Fertilizers Order S.O.1961(E) dated 27th April 2022

In exercise of the powers conferred by section 16 of the Bureau of Indian Standards Act, 2016 (11 of 2016) (hereinafter referred to as the said Act), the Central Government being of the opinion that it is necessary or expedient so to do in the public interest and after consultation with the Bureau of Indian Standards, hereby makes the following order, namely:-

1. Short title, commencement and application

(1) This order may be called the **Lauric Acid (Quality Control) Order, 2022.**

(2) It shall come into force on the one hundred and eighty- first day from the date of its publication in the Official Gazette.

(3) It shall apply to goods or articles specified in column (1) of the Table below, but shall not apply to such good or articles meant for export.

2. Conformity to standard and compulsory use of Standard Mark

Goods or articles specified in column (1) of the said Table shall conform to the corresponding Indian Standard specified in column (2) of the said Table and shall bear the Standard Mark under a licence from the Bureau of Indian Standard as per Scheme-I of Schedule-II of the Bureau of Indian Standards (Conformity Assessment) Regulations, 2018.

3. Certification and enforcement authority

The Bureau of Indian Standards shall be the certifying and enforcing authority in respect of the goods or articles specified column (1) of the said Table.

4. Penalty for contravention

Any person who contravenes the provisions of this order shall be punishable under the provisions of the said Act.

Table

Goods or articles	Indian Standard	Title of Indian Standard
(1)	(2)	(3)
Lauric Acid	IS 10931:1984	Lauric Acid - Specification

F.No.C-II-13012/01/2021-Chem. II

N K Santoshi, Deputy Director General, Ministry of Chemicals and Fertilizers, Department of Chemicals and Petrochemicals, New Delhi.

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Acid Oil (Quality Control) Order, 2022 published

Chemicals & Fertilizers Order S.O.1962(E), dated 27th April 2022

In exercise of the powers conferred by section 16 of the Bureau of Indian Standards Act, 2016 (11 of 2016) (hereinafter referred to as the said Act), the Central Government being of the opinion that it is necessary or expedient so to do in the public interest and after consultation with the Bureau of Indian Standards, hereby makes the following order, namely:-

1. Short title, commencement and application

(1) This order may be called the **Acid Oil (Quality Control) Order, 2022.**

(2) It shall come into force on the one hundred and eighty- first day from the date of its publication in the Official Gazette.

(3) It shall apply to goods or articles specified in column (1) of the Table below, but shall not apply to such good or articles meant for export.

2. Conformity to standard and compulsory use of Standard Mark

Goods or articles specified in column (1) of the said Table shall conform to the corresponding Indian Standard specified in column (2) of the said Table and shall bear the Standard Mark under a licence from the Bureau of Indian Standard as per Scheme-I of Schedule-II of the Bureau of Indian Standards (Conformity Assessment) Regulations, 2018.

3. Certification and enforcement authority

The Bureau of Indian Standards shall be the certifying and enforcing authority in respect of the goods or articles specified column (1) of the said Table.

4. Penalty for contravention

Any person who contravenes the provisions of this order shall be punishable under the provisions of the said Act.

Table

Goods or articles	Indian Standard	Title of Indian Standard
(1)	(2)	(3)
Acid Oil	IS 12029:1986	Acid Oil - Specification

F.No.C-II-13012/01/2021-Chem. II

N K Santoshi, Deputy Director General, Ministry of Chemicals and Fertilizers, Department of Chemicals and Petrochemicals, New Delhi.

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In Rajya Sabha & In Lok Sabha

In Rajya Sabha

Interest Equalisation Scheme

Rajya Sabha Unstarred Question No. 2588

Shri P. Wilson:

Q. Will the Minister of **COMMERCE & INDUSTRY** be pleased to state:

(a) whether the Ministry has plans to extend the Interest Equalisation Scheme on pre and post shipment export credit with retrospective effect;

(b) whether the Ministry has plans on providing compensation to the exporters that suffered a lot due to demonetisation, advent of GST and reduction in the duty draw back making them less competitive resulting in loss of business from the years 2017-2021; and

(c) if so, the details thereof, if not, the reasons therefor?

Answered on 25th March 2022

A. (a) : Interest Equalisation Scheme on pre and post shipment export credit has already been extended upto 31.03.2024 with effect from 01.10.2021. RBI has issued the necessary circular dated 08.03.2022 in this regard.

(b) and (c) : India's export is impacted by several factors both, endogenous and exogenous, including structural, external, fiscal and monetary factors. During 2021-22, exports of goods and services are likely to touch the highest ever figure of US$ 600 billion. Till date, in 2021-22, Merchandise exports from India has crosses historic high of $400bn.

The Minister of State in the Ministry of Commerce and Industry (Smt. Anupriya Patel)

Industrial effluent samples checking in Punjab

Rajya Sabha Unstarred Question No. 4032

Shri Rajendra Gehlot:

Q. Will the **Minister of ENVIRONMENT, FOREST AND CLIMATE CHANGE** be pleased to state:

(a) whether surprise checks are being carried out after collecting samples from the effluent exit points of industrial units Common Effluent Treatment Plant (CETP) and Sewage Treatment Plant (STP) in the country;

(b) if so, the number of samples of chemicals-laden waste taken from industrial units of leather, foundry, electroplating and hosiery located at Ludhiana and Jalandhar in Punjab during the last three years along with the outcomes thereof; and

(c) whether Government proposes to take action against industrial units of Punjab under the Environment Protection Rules, 1986 and the Water (Prevention and Control of Pollution) Act, 1974, if so, by when and if not, the reasons therefor?

Answered on 7th April 2022

A. (a) to c) Regulation of industrial pollution is implemented through various provisions of the Water (Prevention and Control of Pollution) Act, 1974 and the Air (Prevention and Control of Pollution) Act , 1981 under Consent mechanism by the respective State Pollution Control Board (SPCB) in the States and Pollution Control Committee (PCC) in the Union Territories.

Central Pollution Control Board (CPCB) had carried out inspection of 14 Sewage Treatment Plants (STPs) in the catchment of river Satluj during 23rd June to 25th June, 2021 and 12 STPs were found non-complying. Out of 12 non – complying STPs, 05 STPs (Balloke –II, Ludhiana, Bhattian-I, Bhattian-II, Muktsar Sahib-I and Muktsar Sahib-II) were noncomplying in respect of BOD, TSS and Fecal Coliform and remaining 09 STPs were noncomplying in respect of Fecal Coliform.

CPCB has issued directions to Punjab Pollution Control Board (PPCB) under Section 18(1) (b) of the Water (Prevention and Control of Pollution) Act, 1974 and also to Municipal Corporation of Ludhiana and Muktsar under Section 5 of Environment (Protection) Act, 1986 for the compliance of sewage discharge standards.

PPCB has collected more than 600 effluent samples of hosiery(dyeing / printing / washing)

units at Jalandhar and Ludhiana from 01.04.2019 to 31.03.2022. All the Common Effluent Treatment Plants (CETPs) and STPs are monitored on monthly basis by the PPCB.

As informed by PPCB, no trade effluent is generated by foundry units located at Jalandhar and Ludhiana; as such no effluent sampling is required.

All the electroplating units located in Jalandhar and Ludhiana either get trade effluent lifted for treatment in the CETP installed at Ludhiana or have installed Zero liquid discharge treatment systems.

In any industrial unit is found to be violating the provisions of Environment Protection Rules, 1986 and Water (Prevention & Control of Pollution) Act, 1974, strict action including closure, bank Guarantee imposition/ encashment and Environment Compensation imposition in accordance with the provisions prescribed under the respective laws, is taken against the industry.

Minister of State in the Ministry of Environment, Forest and Climate Change
(Shri Ashwini Kumar Choubey)

Disposal of bio-medical wastes

Rajya Sabha Unstarred Question No. 4039

Shri Neeraj Shekhar:

Q. Will the Minister of **ENVIRONMENT, FOREST AND CLIMATE CHANGE** be pleased to state:

(a) whether Government has issued any instruction to hospitals under the Central Government and to various State Governments for proper disposal of bio-medical wastes in view of huge waste being generated by hospitals due to COVID-19;

(b) if so, the details thereof;

(c) if not, the reasons therefor;

(d) whether Government has made any assessment of bio-medical waste generated during 2020-21 and 2021-22 till date; and

(e) if so, the details thereof, State-wise?

Answered on 7th April 2022

A. (a) to (c) The Central Pollution Control Board (CPCB) has issued separate guidelines under Bio-Medical Waste Management Rules, 2016 in March, 2020 for "Handling, Treatment and Disposal of Waste Generated during Treatment/ Diagnosis/ Quarantine of COVID-19 Patients".

These guidelines were circulated to States/ Union Territories (UTs) through concerned State Pollution Control Bodies/ Pollution Control Committees (SPCBs/ PCCs) for implementation as per the provisions of BMW Management Rules, 2016. The Ministry of Environment, Forest and Climate Change has also issued advisory to the States/ UTs for implementation of CPCB guidelines. The guidelines facilitate and streamline the segregation, collection, transport and disposal of COVID-19 waste and specify the duties of various stakeholders like healthcare facilities, sample collection centres, laboratories, quarantine centres/ camps/ home quarantine facilities, Common Biomedical Waste Treatment Facilities (CBWTFs), SPCBs/ PCCs and Urban Local Bodies (ULBs).

Public awareness material has also been shared with stakeholders to support them in management of BMW like BMW tool-kit, flyers on Do's and Don'ts in BMW management, waste segregation posters, videos etc. The CPCB had also developed a mobile application namely 'COVID19BWM' to monitor the biomedical waste generation and treatment on daily basis.

(d)&(e) The CPCB compiles nationwide data on BMW generation based on the Annual Report(s) submitted by SPCBs/ PCCs as per the provisions of BMWM Rules, 2016. Further, the COVID-19 BMW data is compiled through the COVID19BWM application. The State/ UT-wise COVID and non-COVID BMW generation data is annexed.

Minister of State in the Ministry of Environment, Forest and Climate Change
(Shri Ashwini Kumar Choubey)

In Lok Sabha

Janaushadhi Kendras

Lok Sabha Starred Question No. 332

Shri Patel Hasmukhbhai Somabhai

Q. Will the Minister of **CHEMICALS AND FERTILIZERS** be pleased to state:

(a) whether the Government has received any requests from the private players seeking their participation in setting up of Janaushadhi Kendras;

(b) if so, the details thereof; and

(c) the action taken/proposed to be taken by the Government in this regard?

Answered on 25th March 2022

A. (a) to (c): A Statement is laid on the Table of the House.

Statement Referred to in Reply to Parts (A) to (C) of the Lok Sabha Starred Q.No. 332 (12th Position) for Answer on 25.03.2022 Regarding Janaushadhi Kendras

(a) to (c): Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) is being implemented mainly through individual entrepreneurs. Till 28.02.2022, about 8,689 Pradhan Mantri Bhartiya Janaushadhi Kendras (PMBJKs) have been opened covering all the districts in the country. Out of these, about 1,064 kendras have been opened in government premises, while remaining 7,625 PMBJKs have been opened by the private players, viz., individuals/ societies/NGOs/institutions etc.

In order to encourage receipt of applications from individual entrepreneurs/private players for opening of PMBJK, the normal incentive under the scheme has been enhanced from Rs. 2.50 lakhs to Rs. 5.00 Lakh, subject to a ceiling of Rs. 15,000/- per month. Further, additional one-time incentive of Rs. 2.00 lakh has been introduced for Kendras opened in aspirational districts, Himalayan, Island territories & North-Eastern States or for the Kendras opened by women entrepreneurs, divyangs, SC & ST.

Pharmaceuticals & Medical Devices Bureau of India (PMBI), the implementing agency of the scheme, regularly organizes workshops and seminars to encourage private entrepreneurs/NGOs/Civil Societies and unemployed pharmacists for opening of PMBJKs. Further, PMBI has recently invited applications for opening of PMBJKs in 265 districts of the different States where the coverage of Kendras is relatively less.

Minister in the Ministry of Chemicals and Fertilizers (Dr. Mansukh Mandaviya)

Establishment of Pharma Parks

Lok Sabha Starred Question No. 336

Shri Rajiv Ranjan Singh Alias Lalan Singh:

Shri Satyadev Pachauri:

Q. Will the Minister of **CHEMICALS AND FERTILIZERS** be pleased to state:

(a) whether the Government has announced to establish a number of pharma parks in the country;

(b) if so, the details thereof;

(c) the details of such pharma parks established, so far, State/UT-wise; and

(d) the details of investment made in all those pharma parks, so far, park-wise?

Answered on 25th March 2022

A. (a) to (d): A statement is laid on the table of the house.

Statement Reffered to in Reply to Parts (A) to (D) of Starred Question No. *336 For Reply On 25.03.2022

(a) to (d): The Department of Pharmaceuticals is implementing a scheme namely "Promotion of Bulk Drug Parks" which provides for grant-in-aid towards creation of Common Infrastructure Facilities (CIF) in the bulk drug parks to be developed by the States. The total financial outlay of the Scheme is Rs. 3,000 Crore with maximum grant-in-aid for one bulk drug park limited to Rs 1,000 crore or 70% of the project cost of CIF, whichever is less. In case of North Eastern states and Hilly States (Himachal Pradesh, Uttarakhand, Union Territory of Jammu & Kashmir and Union Territory of Ladakh), the maximum limit of financial assistance is Rs 1,000 crore or 90% of the project cost of CIF, whichever is less. The Guidelines of the scheme are available on the website of the Department of Pharmaceuticals, i.e., http://pharmaceuticals.gov.in.

Department has received proposals from 13 States, viz., Uttar Pradesh, Tamil Nadu, Telangana, Karnataka, Maharashtra, Gujarat, Madhya Pradesh, Rajasthan, Punjab, Haryana, Himachal Pradesh, Andhra Pradesh and Odisha under the scheme.

Minister in the Ministry of Chemicals and Fertilizers (Dr. Mansukh Mandaviya)

Study on Drug Pricing Policy

Lok Sabha Unstarred Question No. 3742

Shri Gnanathiraviam S.:

Q. Will the Minister of **CHEMICALS AND FERTILIZERS** be pleased to state:

(a) whether any study has been conducted by the Government to ascertain the effectiveness of the New Drug Policy and the Drug Price Control Order in increasing the drug production and ensuring the availability of life saving drugs at reasonable prices besides restraining the drug manufacturing companies in making reckless profiteering;

(b) if so, the details thereof along with the deficiency, if any, identified in the implementation of the New Drug Policy and the Price Control Order; and

(c) the steps contemplated to be taken by the Government in this regard?

Answered on 25th March 2022

A. (a) to (c): The extant National Pharmaceutical Pricing Policy (NPPP), notified on 7th December, 2012, has been formulated with an objective to put in place a regulatory framework for pricing of drugs so as to ensure availability of essential medicines at reasonable prices while providing sufficient opportunity for innovation and competition to support the growth of pharma industry. In pursuance of NPPP, 2012, the Government has notified the Drugs (Prices Control) Order, 2013 (DPCO-2013). As per the provisions of DPCO, 2013, the ceiling price of all scheduled formulations appearing in the National List of Essential Medicines (NLEM) are fixed and all manufacturers of these drugs are required to sell their product equal to or lower than the ceiling price. As regard non-scheduled drugs, while manufacturers are free to fix their Maximum Retail Price (MRP), but they cannot increase the same more than 10% of what was prevalent during the preceding twelve months. No study has been conducted regarding effectiveness of the Drug Pricing Policy and/ or the Drug Prices Control Order.

Minister of State in the Ministry of Chemicals and Fertilizers (Shri Bhagwanth Khuba)

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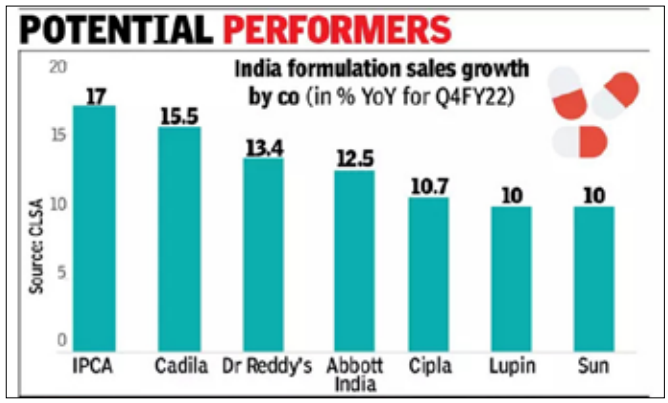
Rising costs may shrink earnings of domestic pharma companies

MUMBAI: Domestic pharma companies are facing headwinds from rising input and logistics costs, which could impact earnings over the next few quarters. Already reeling from a jump in costs on account of freight, logistics and raw materials over last few months, the companies now face even higher expenses due to the ongoing geopolitical tensions, shutdowns and supply disruptions from China. To add to the woes, drug launches in the US — the most lucrative market for domestic firms — have been limited, resulting in muted sales. Overall, the pharma market grew at a robust 12% year-on-year (YoY) in the first two months of Q4FY22, according to research firm IQVIA.

A majority of companies are expected to report a high single- to double-digit revenue growth but with weaker margins due to the pressure on costs, a note from investment group CLSA said. Industry experts said operating margins for companies in the fourth quarter could decline from 100bps to 300bps (100 basis points = 1 percentage point). A muted quarter in the US along with margin headwinds due to cost pressures would result in ebitda (earnings before interest, taxes, depreciation & amortisation) margins declining cumulatively for the industry by 100bps, the note added.

"Biocon is the only company where we expect a mid-20s growth, mainly driven by pickup in its Glargine sales to the US. Cadila Health and Dr Reddy's are likely to grow 3-5% due to weak US and decline in Russia business respectively. Aurobindo is the only company likely to report a YoY growth decline," the analyst added.

Over the last two years, vital raw materials imported from China witnessed supply disruptions and huge price hikes since the start of the pandemic. Prices of key starting materials and solvents were likely to cool off by the fourth quarter as production in China was expected to normalise. However, the ongoing geopolitical tension due to the Russia-Ukraine war has led to a sharp rise in crude, impacting all inputs.



"The price of a key ingredient used for a widely-sold antibiotic has skyrocketed around 40% in the last month. Once the inventory is exhausted, we will have to procure it at the steep price," a company official told TOI.

Larger players like Sun Pharma, Torrent Pharma, Cipla and Abbott India, with a higher branded market exposure and chronic therapy focus, may be better placed to protect margins through gradual price hikes, analysts said.

Further, foreign exchange reversion could help in mitigating the impact for certain companies. "Sequentially, spot average Indian rupee has appreciated against key trading currencies, at -16.6% vs the Russian rouble, -1.7% vs the Japanese yen and -1.5% vs the euro. The Indian rupee has depreciated for the rest of the currencies, namely, 0.4% vs US dollar (75.18), +1.5% vs South African rand, and +2.4% vs LatAm currencies (Brazil, Mexico, Argentina). Dr Reddy's has the highest exposure to Russia/ Ukraine (around 12% of sales), but resilient drug demand, foreign exchange reversion and currency hedges should mitigate the impact," a note from Morgan Stanley said.

Source: TNN, 25.04.2022

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Gujarat: Generic medicines sales up 50% in 2 years

AHMEDABAD: With greater awareness of alternatives to branded medicines and more willingness to try them

out, sales of generic medicine in Gujarat are estimated to have grown by 50% in the past two years, i.e., since the pandemic hit, according to government and industry sources. According to generic medicine retailers, the most of their sales come in five categories — diabetes, oncology,

cardiovascular, nutraceuticals and anti-infectives. Generic medicines worth Rs 60 crore were sold in Gujarat in FY 2022, up from around Rs 25 crore in FY 2020, industry estimates show.

"Awareness of generic medicines is growing, which has propelled sales higher. Once people shift to generics, the money they save for the same quality of medicines gives them confidence," said Dr H G Koshia, Commissioner, Food and Drug Control Administration (FDCA), Gujarat.

Private and government players in the generic medicine segment are also offering a wider range of medicines, drawing more customers, Koshia added.

FDCA data shows that generic medicines accounted for barely 3% of the market in India in 2015-16, and this has now increased to 8%.

Shortage of medicines during the Covid pandemic also took large numbers of customers to generic medicine stores, industry sources said.

"Our customer base increased from roughly 2 lakh in FY 2020 to 4.2 lakh in FY 2022. During the Covid-19 pandemic when the case load rose, there were times when drug shortages prevailed. People turned to generic stores in large numbers. After they there was easy availability and a reduction in their bills, demand really picked up," said Ankur Agarwal, co-founder, Medkart, a private generic medicines brand, which saw sales grow by 51% in volume terms and 70% in value terms in the last two years.

"The volume of generic drugs sales is driven by patients suffering from chronic diseases such as cardiovascular disease, cancer, kidney ailments, diabetes, etc. This is because branded medicines for these diseases are more expensive and customers can save up to 75% with generic alternatives," said Agarwal.

Wider adoption of generic drugs is seen in lower and middle-income groups, according to a pharma consultant. With greater awareness and better-quality generics, the public perception is also changing, industry stakeholders say. "Several major pharmaceutical companies have started rolling out generic alternatives for different molecules. This has increased people's faith in generic drugs on the quality front. Private players in generic drug retail are also walking the extra mile on quality, which helps them to retain customers," said Hari Natarajan, founder, Pronto Consult.

Source: TNN, 25.04.2022

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Sri Lanka sends SOS for lifesaving and emergency medicine supplies

A mother and her child wait for medicines at the pharmacy in Lady Ridgeway Hospital for Children in Colombo, Sri Lanka ***(Photo: AFP)***

NEW DELHI : Sri Lanka has reached out to the Indian Drug Manufacturers' Association (IDMA) seeking supplies of emergency medicines and lifesaving drugs as hospitals run out of stocks because of the economic crisis that has engulfed the nation.

"We have received a communication from Sri Lankan counterparts requesting medical supplies. There are very few companies who do business with Sri Lanka, and only those who have the licence can supply the material there," said Daara Patel, secretary-general, IDMA. "They have given us the list of medicines which we have circulated to all our members. As and when our members respond

to us, we will see how best we can help Sri Lanka. I think some of them would definitely come forward to support Sri Lanka."

Sri Lanka is seeking emergency aid to secure lifesaving drugs amid its worst economic crisis. The island nation, which imports 85% of its medicine requirements, has run out of dollars to pay for imports, putting its healthcare system on the brink of collapse. The Sri Lankan government has also appealed to other countries to donate lifesaving drugs.

"I wish to inform you that the government of Sri Lanka, via its diplomatic missions abroad, has circulated an international appeal for the donation of emergency and lifesaving drugs that are not manufactured in Sri Lanka and which cannot be procured through the line of credit extended by India," Niluka Kadurugamuwa, the deputy high commissioner and spokesman of Sri Lanka's high commission in New Delhi, said in an email response to a query.

An 8 April communication from the island nation's state ministry of production, supply and regulation of pharmaceuticals to its foreign ministry said, "There is a considerable amount of vital medical supplies such as orthopaedic implants, anti-cancer drugs, reagents and consumables used at blood banks, HLA (human leukocyte antigen) testing, HIV-AIDS testing reagents and laboratory reagents that are imported from the US, Europe and Australia. Due to the prevailing foreign reserve crisis, it has been extremely difficult to maintain the supply chain of above mentioned extremely important medical supplies imported from Europe."

While giving a list of 273 such items, the ministry said, "We would be extremely grateful if you could assist state ministry in coordinating with foreign missions and any other interested donors to maintain the medical supplies which are not manufactured in Sri Lanka and could not be imported using the Indian credit line."

Sri Lanka is India's 18th largest partner in terms of pharma trade. India exported pharma goods worth more than $274.4 million to Sri Lanka in FY21, marking a 25% growth over the previous year. However, exports fell to $234.56 million in the following year.

Earlier, the State Pharmaceuticals Corp. of Sri Lanka said it had asked the Pharmaceuticals Export Promotion Council of India to "sensitize" its members on the need to ensure medical supplies to the crisis-hit country. Given the financial crisis, Indian manufacturers are worried about payments for their exports to Sri Lanka.

In a separate communication dated 11 April to donors reviewed by Mint, the state ministry of production, supply and regulation of pharmaceuticals said, "the state ministry is utilizing the maximum capacity of the local production and has also initiated to utilize the Indian credit line to the maximum effect to purchase medical supplies for Sri Lanka."

The 11 April letter said donations could either be sent in dollars or goods.

Source :Priyanka Sharma, HT Mint, 25.04.2022

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Drug used for asthma and allergies drug blocks protein crucial to COVID-19 replication, IISc study reveals

Hussain also said that some clinicians were using montelukast to treat COVID-19 patients because of its known role in making breathing easier in asthma patients.

The drug, montelukast, is consumed orally to prevent wheezing, breathing difficulty, chest tightness, and coughing caused by asthma

A drug, commonly used for the treatment of asthma and allergies, can also block an important protein that is necessary for the replication of SARS-CoV-2, scientists at the Indian Institute of Science (IISc) have found. The findings of this crucial study have been published in the journal eLife.

The drug, montelukast, is consumed orally to prevent wheezing, breathing difficulty, chest tightness, and coughing caused by asthma. According to the US National Library of Medicine, it is also used to prevent breathing difficulties during exercise.

"Montelukast is prescribed in India by physicians.

It is readily available as tablets and syrup (for kids) in pharmacy shops under different brand names," IISc Assistant Professor Tanweer Hussain, senior author of the study, told The Indian Express.

Hussain also said that some clinicians were using montelukast to treat COVID-19 patients because of its known role in making breathing easier in asthma patients. He also informed that it was not known that this drug also has antiviral activity, which we have figured out in this study.

According to the researchers, when the COVID-19 virus infects the human cell, it releases a protein called Nsp1, which is essential for its replication. Then, the protein sticks to the host cell's ribosome.

If this protein, Nsp1, is targetted, then the damage caused by the virus can be reduced. Moreover, the researchers found that montelukast binds strongly to Nsp1, and blocks its access to the ribosome. The scientists also informed that Nsp1's mutation rate is very low as compared to other viral proteins. This means Nsp1 is likely to remain largely unchanged in any virus variants that emerge. Consequently, drugs targeting this region are expected to work against all such variants.

The scientists first used computational modelling to screen more than 1,600 drugs approved by the US Food and Drug Administration (FDA). Then they shortlisted a dozen drugs that bind to Nsp1, among which they zeroed in on montelukast and saquinavir which is an anti-HIV drug. However, lab tests on cultured human cells found that only montelukast was able to rescue Nsp1's inhibition of protein synthesis.

Source: Financial Express, 27.04.2022

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Himachal pharma firms battle higher input costs

A steep increase in the price of raw material coupled with the rising logistics and packaging cost has unnerved the pharmaceutical industry in Himachal, especially micro, small and medium enterprises (MSME), which are the major sufferers.

Availability of APIs affected

- Following Covid-induced shutdown in China, the availability of APIs has been affected and its price has increased considerably.
- Rise in the price of packaging material has burdened the industry.
- Increase in the price of diesel has added to the woes of the industry

The Covid lockdown in China has further hit the industry, as the availability of active pharmaceutical ingredients (APIs) has been affected and its price has increased considerably. The domestic pharmaceutical industry imports around 67 per cent of APIs from China.

The price of the key APIs like cefixime has increased from Rs 11,000 per kg to Rs 13,000 per kg while that of cefpodoxime proxetil has gone up from Rs 10,200 to Rs 14,100 per kg.

The price of paracetamol, which is a key API used in a number of formulations, continues to increase and is available at Rs 650 per kg now against Rs 350 per kg about three months ago. The price of ofloxacin has also increased from Rs 2,800 to Rs 3,100 per kg, say sources in the Baddi pharmaceutical industry.

The National Pharmaceutical Pricing Authority has increased by 10.7 per cent the prices of more than 800 essential drugs falling under the National List of Essential Medicines, as per the Wholesale Price Index, from April 1, but this will not offset the exponential rise in the prices, say the sources.

The rise in the prices of packaging material has further burdened the industry. "The packaging cost has risen by nearly 35 per cent in the past 70 to 80 days due to the rise in the prices of input materials such as kraft paper, white box, stitching wire, starch, ink as well as fuel cost," says Rajiv Gulati, vice-president, HP Corrugation Box Manufacturers Association. He adds that the MSME industry is bearing the brunt due to low margins.

The increase in the price of diesel has added to the woes of the industry. "As against Rs 3 lakh incurred on a container earlier, the cost has now gone up to Rs 10 lakh and one had to wait for nearly three to four weeks to arrange a container," says SL Singla, Adviser, Himachal Pradesh Drug Manufacturers Association.

With shrinking margins and low availability of inputs, smaller players are finding it difficult, says Singla.

Source: Ambika Sharma, Tribune News Service, 29.04.2022

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