

# IDMA BULLETIN

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*IDMA Secretariat and Editorial Team  
Wishes all our Members and Readers  
A Very Happy Navratri & Dussehra*

## Indian APIs & Formulations for Global Healthcare

INDIAN DRUG MANUFACTURERS' ASSOCIATION



### IDMA 60TH YEAR CELEBRATIONS 2022

Friday, 7<sup>th</sup> & Saturday, 8<sup>th</sup> January 2022, Hotel Sahara Star, Mumbai

*(Details on Page: 4)*



### IDMA & APTAR PHARMA - WEBINAR



on "Accelerating & De-risking your Injectable Product Development with PremiumCoat®"

Tuesday, 12th October 2021 from 3.00 pm to 4.00 pm

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## HIGHLIGHTS

- ★ **IDMA Congratulates Our Hon'ble Minister of Health & Family Welfare and Chemicals and Fertilizers of India, Shri Mansukh Mandaviya for being conferred with Doctorate in Political Science** *(Page No. 10)*
- ★ **Dilip Shanghvi: In a year and a half, pharma has darted ahead by a decade in terms of digital tools** *(Page No. 29)*
- ★ **WTO estimates global merchandise trade volume growth at 10.8% in 2021** *(Page No. 33)*

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# IDMA BULLETIN

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## INDIAN DRUG MANUFACTURERS' ASSOCIATION (IDMA) 1961 – 2021 (60 Glorious Years)

102, Poonam Chambers, A Wing, 1st Floor, Dr. Annie Besant Road, Worli,  
Mumbai - 400 018. Maharashtra, India.

Tel: +91-22-24974308 / 24944624 E-mail: actadm@idmaindia.com / Website: www.idma-assn.org

Dear Member,

### **IDMA 60TH YEAR CELEBRATIONS 2022**

Friday, 7th & Saturday, 8th January 2022

Hotel Sahara Star, Mumbai

We are happy to inform you that our Association will be completing 60 glorious years in 2022. The 60th Year Celebrations will be organized on 7th & 8th January 2022 in Mumbai. We intend to commemorate this historic occasion of the completion of 60 years of our Association, with a two day long celebration consisting of Panel Discussions, Technical Sessions and Entertainment Program to boost the image of our Association as the Premier Association of the Indian Pharmaceutical Industry. The main objectives of the celebrations are:

- Showcasing Pharmaceutical and Allied Industries across the Globe
- Disseminating knowledge on various subjects
- Highlighting the achievements of IDMA

This year at the 60th Year Celebrations, we have invited Eminent National and International personalities to address our members over two days. We will also be recognizing Top Achievers in the Indian Pharmaceutical Industry, who have made India Proud and respected world over as providers of affordable quality medicines.

As part of the Celebrations, the winners of the:

1. IDMA Margi Memorial Best Patent Awards
2. IDMA ACG-SCITECH Research Paper Awards
3. IDMA Corporate Citizen Awards

would be announced and the Awards would be presented.

Your Association has come a long way and many milestones have been met in the last 60 Years and specially the last two years which have been different, difficult and trying times. You would be pleased to note that during Covid-19 Pandemic, IDMA Secretariat has played an important role in facilitating uninterrupted supply of quality medicines with excellent coordination between the Industry, Government and Regulators. Nevertheless, it is due to your untiring efforts and commitment to the wellbeing and prosperity of our Association that we will be completing 60 years of glorious service to our Pharma Industry and to our great Nation.

**We are sure you will be an integral part of the Grand Celebrations.**

#### **IDMA 60th ANNUAL PUBLICATION 2022**

The IDMA 60th Annual Publication 2022, an up-to-date and most informative compendium will be released at the Annual Celebrations. This Annual Publication will present statistics, vital data and information on the Pharmaceutical industry. This Publication has also come to be recognized as the indispensable reference book of the Indian Pharmaceutical Industry.

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### REGISTRATION FEES:

To participate in the 60th Year Celebrations, the registration fee would be as under:

Reception Committee Member	Rs.7,500/- plus GST @ 18%
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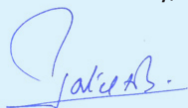
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Your active participation & interaction with the cream of the Pharmaceutical Industry as well as Ministry Officials and Bureaucrats, from the Centre as well as States, will not only add value to your business but also ensure that the flag of our Association continues to fly higher in the Global Pharmaceutical Industry.

Looking forward to your usual fine cooperation in making this historic event a 'सुपर से भी ऊपर' Success.

Thanking you,

Yours faithfully,



Daara B Patel  
Secretary-General





**INVITATION ~ IDMA & APTAR PHARMA - Webinar on  
“Accelerating & De-risking your Injectable Product Development with  
PremiumCoat®” for Tuesday, 12th October 2021 from 3.00 pm to 4.00 pm**

Dear Member,

**~ REGISTER NOW ~**

**IDMA & APTAR PHARMA - Webinar on “Accelerating & De-risking your Injectable Product Development with PremiumCoat®” for Tuesday, 12th October 2021 from 3.00 pm to 4.00 pm**



**Aptar Pharma and Indian Drug Manufacturers' Association (IDMA)** is organizing a Webinar on “Accelerating & De-risking your Injectable Product Development with PremiumCoat®” for Tuesday, 12th October 2021 from 3.00 pm to 4.00 pm

**The abstract of the webinar is given below :**

Aptar Pharma is a global leader in the design and manufacturing of a broad range of pharmaceutical delivery, consumer product dispensing and active material science solutions. Our portfolio of Vial Stoppers, Pre-Filled Syringe components and Services support our customer’s drug development process to ensure their successful launch and life-cycle management. Our PremiumCoat® platform combines a market-proven ETFE film-coating with a pure rubber formulation and best-in-class process to accelerate and derisk your drug development. Aptar Pharma’s expert demonstrated PremiumCoat® stoppers’ ability to reduce Extractables and Leachables, their performance in multipiercing situation and compatibility with different vial sizes and designs.

**Moderator : Mr. S R Vaidya, Chairman, MSME Committee**

**International Speakers for this webinar are**

<p>1. <b>Mr. Jean-Edouard Rabier</b> Mr. Rabier has over 20 years of Sales experience in the pharmaceutical industry, including 11 years in injectable primary packaging. After a decade spent working at West Pharmaceutical Services, Jean-Edouard joined the Aptar Pharma Injectables division in September 2020, where he is Business Director responsible for the Vial Containment Stoppers product portfolio.</p>	
<p>2. <b>Mr. Sébastien Cordier</b> Mr. Sébastien is the Technical Product Manager for PremiumCoat® projects at Aptar Pharma’s Injectables division. A graduate of MINES ParisTech and EDHEC Business School in France, Mr. Sébastien spent over 15 years in the automotive industry, where he developed a strong expertise in plastics and elastomers, before joining Aptar Pharma in 2020. In his current role as Technical Product Manager at Aptar Pharma, Sébastien is responsible for the PremiumCoat® platform of vial stoppers and syringe plungers, and is dedicated to supporting customer development projects involving coated elastomeric solutions.</p>	

**Join us in our webinar on October 12th at 3pm to discover more about the Premium Coat platform and our Injectables solutions.**

Please find the registration link to the webinar below:

<https://teams.microsoft.com/registration/PkrXX3rVDkGNfALE3wYiNA,VjPgRYWeX0GWg7qPokPKGw,vhU8TNwV5kqyzLgXOBFrTg,JOrcacfx-kyEnekq9cfLGA,VcR1XY6SXei8slB8KPNqCA,iuHPd4H6QU2Y4x3Bwfd-mA?mode=red&tenantId=5fd74a3e-d57a-410e-8d7c-02c4df062234>

Kindly note that there are no registration fees for this webinar but prior registration is compulsory.

Members are requested to participate in this webinar in large numbers and avail benefits from the same.

Thanks & regards,

<b>Daara B Patel</b> Secretary – General	<b>Prachi Singhai</b> Manager-Marketing & Communication, India & SE Asia
<b>Indian Drug Manufacturers' Association</b> 102, A Wing, Poonam Chamber, A Wing, 1st Floor, Dr. A. B. Road, Worli, Mumbai-400018. Maharashtra. India. Tel No. 022 24974308 / 24944624 <b>Cell:</b> +91 9821868758 <b>Email :</b> idma2@idmaindia.com/ actadm@idmaindia.com <b>Website:</b> www.idma-assn.org	<b>Aptar Mumbai</b> part of Aptargroup, Inc., Crystal, Lake, Illinois, USA, and having, Registered Office at R - 854, TTC Industrial Estate Thane, Belapur Road, MIDC RABALE, Navi Mumbai, 400701 Mumbai, India. <b>Tel. :</b> 61951900 / Cell # 9892026098 <b>Email:</b> prachi.singhai@aptar.com <b>Website :</b> www.aptar.com



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## Press Note : NPC & IDMA GSB jointly organised "Post Energy Audit Study meeting" on 17<sup>th</sup> September 2021

National Productivity Council (NPC) had conducted a technical study to identify Energy conservation opportunities both in electricity and thermal energy used in the production process of the formulation industries. Energy Audit Studies in MSME Member units of IDMA Gujarat State Board located in Ahmedabad Region namely **Swefn Pharmaceuticals, Accretion Pharmaceuticals, Halewood Laboratories, Edkem Pharmaceuticals, Neuron Pharma, Reino Remedies, Aan Pharma, ACME Diet Care, West Coast Pharmaceutical Works, & Swiss Pharma** were carried out.

NPC & IDMA GSB jointly organised "Post Energy Audit Study Meeting" on 17<sup>th</sup> September, 2021, 06:00 PM at Hotel Crowne Plaza, S. G. Highway, Ahmedabad.

Mr. Milan Patel, Chairman, IDMA GSB welcomed members present and shared brief details of the meeting. Mr. Shirish Paliwal, NPC Regional Director, introduced speakers of the event and delivered a welcome address, and also highlighted the need for saving energy waste, not only to increase the profits but also to reduce national wastage. A presentation was then given by

Mr. Amitosh Gautam Dy. Director, NPC, Gandhinagar, Gujarat on "Detailed Energy Audit Brief & Findings for Ahmedabad Pharma Cluster". He further elaborated about benefits received in energy bills & production cost in the 10 MSME Pharma units audited by them.

The study identified certain measures that can be adopted by any MSME pharma unit to save on its energy bills and production cost, which are shared below :

1. Improve Contract Demand to avoid Excess Demand charges in your electricity bill or Install Maximum Demand Controllers.
2. Replacement of faulty Capacitor in APFC Panel to improve the Power Factor and KVA at Main Incomer - LT Panel
3. Install Lighting Voltage Controller.
4. Install VFD for Blowers/Pumps - with pressure transducer for plant circulation pumps – Chiller condenser pump, plant RT Pump and chiller secondary pumps
5. Install FRP type fans for chiller cooling tower
6. Replace water jet vacuum pump with a new pump





7. Improve HVAC Energy Performance - Install Auto tube cleaning system for chiller condensers or through MAX R100 HVAC Fluid.
8. Recover return hot water / condensate and use it as boiler feed water or use it to increase feed water temperature input to the boiler to save fuel consumption.
9. Insulation for steam pipe line from boiler to Plant.
10. Retrofit existing boiler for using Multiple fuel e.g. (Pallet fired instead of diesel fired) to save cost per kg of steam.
11. Install Solar PV Panels at the Rooftop Building.
12. Use time of day tariff as defined by the electricity supplier to reduce electricity bill by scheduling production operation during Non-Peak Hours, when price/unit of electricity is cheap.
13. Install water savers/ occupancy sensors / BLDC Ceiling fans/ 5 star rated AC and other equipment in the unit to conserve electricity and water.
14. Adopt IOT devices and sensors to capture equipment's energy consumption pattern.

In addition to the above, following organisation made

presentation on Interesting Topics relating to Energy Conservation:

1. Gujarat Energy Development Agency (GEDA) – “Energy Conservation Activities by Gujarat Govt.” by Ms. Amita Pandya
2. AMNYK India – “Energy Saving in HVAC System in Pharma Plants” by Mr. Ramesh Natarajan
3. Green Ops Pvt. Ltd.-“Benefits & Schemes Available for Solar PV implementation in MSME” by Mr. Gurpreet Singh Walia
4. Energy Efficiency Services Ltd. (EESL) – “EESL initiatives” by Mr. Sumit Solanki

Dr. Shrenik Shah Felicitated Ms. Amita Pandya Asst. Project Executive (Energy Conservation) - GEDA with Flowers Bouquet and proposed a vote of thanks to NPC, BEE, GEDA and all EC members of IDMA GSB.

It was indeed a very nice evening wherein 45+ Participants including Ex. Chairmen of IDMA GSB were in attendance. The attendees got tips on Energy conservation for their pharma unit and showed their interest in adopting applicable Energy conservation methods in their unit. The programme concluded with a Networking Dinner.



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**INVESTIGATION OF OUT OF SPECIFICATION (OOS) TEST RESULTS**

TECHNICAL MONOGRAPH NO. 5  
**ENVIRONMENTAL MONITORING IN CLEANROOMS**

TECHNICAL MONOGRAPH NO. 7  
**DATA INTEGRITY GOVERNANCE**

TECHNICAL MONOGRAPH NO. 2  
**PRIMARY & SECONDARY CHEMICAL REFERENCE SUBSTANCES**

TECHNICAL MONOGRAPH NO. 4  
**PHARMACEUTICAL PREFORMULATION ANALYTICAL STUDIES**

TECHNICAL MONOGRAPH NO. 6  
**CORRECTIVE/PREVENTIVE ACTIONS (CAPA) GUIDELINE**

TECHNICAL DOCUMENT NO. 8  
**QUALITY 4.0 DIGITAL TECHNOLOGY OF THE FUTURE**

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CONGRATULATIONS

**IDMA Congratulates Our Hon'ble Minister of Health & Family Welfare and Chemicals and Fertilizers of India, Shri Mansukh Mandaviya for being conferred with Doctorate in Political Science**

**IDMA Congratulates Mr Nikhil Chopra, CEO/ Whole Time Director, JB Chemicals & Pharmaceuticals Ltd, on his successful completion of 365 glorious days of Stewardship in JBCPL**

We wish him Many Many more years of success and accomplishments with good health and cheer!

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No. Acad/Ph.D./1374 / 1420 / 2021. Date: -01-10-2021

**Declaration of the Result of Doctor of Philosophy**  
 Notification No. : UGC Regulation 2016 / 15

(This notification is issued under provisions of UGC (Minimum standards and procedure for awards of M.Phil./Ph.D. degree) Regulation 2016)

The Vice Chancellor in exercise of the powers given to him under O.Ph.D. of this University has accepted the thesis of following candidate for the degree of Doctor of Philosophy in the subject and faculty shown against his name. He is accordingly declared qualified to receive the degree of Doctor of Philosophy.


Name of the Candidate	Title	Subject, Faculty & Deptt. /Insti./College	Name of the Guide/ Co-Guide
Mr. Mandaviya Mansukh Lakhmanbhai	ROLE OF GRAM VIDHYAPITHS IN COMMUNITY DEVELOPMENT AND FUTURE CHALLENGES	Political Science Arts, Gujarat Institute of Development Research Near Gota Flyover, Sarkhej Gandhinagar Highway, Ahmedabad, 380060.	Dr.R.Parthasarathy, Dr.Madhusudan Bandi, Gujarat Institute of Development Research Near Gota Flyover, Sarkhej Gandhinagar Highway, Ahmedabad, 380060.



Registrar

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 (1) Mr. Mandaviya Mansukh Lakhmanbhai, C/o Amar Acharya, Plot No. ...

**J.B. CHEMICALS & PHARMACEUTICALS LTD.**



Dear Team,

Today is a very humbling day for me! It reminds me of my very first day at J B Chemicals & Pharmaceuticals, exactly one year ago! I joined this great organisation because I truly believed JBCPL has a rich legacy with strong fundamentals and character; the incremental opportunities & bright future that this company offers - it would be an honour to **serve the company and its people, to lead them through the next journey of excellence!**

Strengthened by a strong, committed field-force on ground, unique world class manufacturing capabilities, a strategically focused international business and people, deep international business relationships with our clients and above all, a passionate team at the core of it - **the potential that JBCPL has, is immense!**

**Our 'One JBCPL' family has completed its 44<sup>th</sup> year!** Being one of the fastest-growing pharmaceutical companies in India, we have good reason to be pleased. Even so, we are not content. We are already looking ahead and accelerating towards our 50th year in 2026. In this journey, we will focus on strengthening our core capabilities to build an organisation that is agile and resilient to uncertain times. We will be focusing on these 5 key areas for the next year, to make a difference and add value;

- **Strengthen our core therapy segments** i.e., Cardiology, Nephrology, Gastroenterology, Respiratory and Paediatrics.
- **Scale up R&D and business development initiatives** towards building a progressive portfolio for our international markets, API and CMO businesses.
- **Consolidate existing business areas** through deeper penetration in key international markets.
- Establish a **'beyond the pill' culture** with tech-enabled services and a 'phygital' approach to innovatively meet the diverse needs of stakeholders
- 5<sup>th</sup> and most important area of work - **'People First'** - to ensure development, well-being, health and safety initiatives for our 4500 strong JBCPL team.

So, to summarize, our focus will be to **strengthen portfolio, processes, people, places (geography) and plans** and I feel though we have rapidly achieved so much in last 1 year, we have miles to go, in order to fulfil our **ultimate purpose of doing more good for more people!**

We have done it before, we're doing it today, and we are the team that will do it again!

While we keep our eyes on the stars, we keep our feet firmly on the ground! We need to rigorously and continuously demonstrate the **key JBCPL values of integrity, passion and clarity of purpose** to improve quality of lives of patients. Like we make new year resolutions at the end of each year, similarly, we will be revealing **"OUR GOOD RESOLUTIONS"** shortly, that will enable JBCPL to thrive in a digitally connected and dynamic environment.

Finally, none of this would be possible, without a **passionate and committed team**. I must mention that the quality, commitment, knowledge and expertise that each JBCPLite brings to the organisation is truly amazing. We are very grateful for your continued support. Together we will build a company that will thrive and be sustainable for the future! This is just the beginning of a long and fruitful journey ahead.

**Nikhil Chopra.**

www.jbcpl.com

## **Mandating the mentioning of FSSAI License/ Registration number on receipts /invoices /cash memo/ bills etc. by food businesses on sale of food products- reg.**

**ORDER Dated 30<sup>th</sup> September, 2021**

Reference FSSAI order vide no. 15(31)2020/FoSCoS/RCD/FSSAI dated 8<sup>th</sup> June, 2021 on the above mentioned subject (Copy enclosed).

*(A Statutory Authority established under the Food Safety & Standards Act, 2006)  
(Regulatory Compliance Division)  
FDA Bhawan, Kotla Road, New Delhi-110002*

In view of representation from various Industries Association & Stakeholders, it has been decided with the approval from Competent Authority that the enforcement of said order will come into effect from **1<sup>st</sup> Jan 2022**.

Encl: As stated

File No. 15(31)2020/FoSCoS/RCD/FSSAI

*(Inoshi Sharma)  
Executive Director (CS)  
Email: ed-office@fssai.gov.in  
Food Safety and Standards Authority of India*

To,

1. All Food Businesses Operators, Associations, Food Safety Mitra and other stakeholders
2. Commissioner of Food Safety of All States/ UTs
3. Directors of all Regional Offices, FSSAI
4. CITO- to upload on FSSAI's website

Copy for information to -

1. PPS to Chairperson, FSSAI- For information
2. PS to CEO, FSSAI - For information

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## **Mandating the mentioning of FSSAI License/ Registration number on receipts /invoices /cash memo/ bills etc. by food businesses on sale of food products- reg.**

**ORDER Dated, the 8<sup>th</sup> June, 2021**

Section 3I of Food Safety and Standards Act, 2006 mandates that every food business operator is required to obtain FSSAI license or registration prior commencing any food business. The implementation of FSS Act 2006 and Rules and Regulations made thereunder depends upon the FSSAI License and Registration number.

2. The food business ecosystem is large and the FSSAI number of any food business operator is not easily visible and available to consumer/service recipient. Any credible regulatory structure depends upon a robust customer grievance system wherein service product recipients can complaint for redressal. However, if the

FSSAI number is not available to him, expecting him to complain with complete coordinates is an uphill task. Even regulators find it difficult to trace the origin of complaint and attend to it promptly with approximate addresses. No database can be created without a unique locator code, which in case of food safety is the FSSAI number.

3. Presently, FSSAI number is compulsory to be displayed on packaged food labels but the issue lies especially in case of establishments such as restaurants, mithai shops, caterers, even retail stores etc. FSS (Licensing and Registration of Food Businesses)

Regulations are being amended to mandate display of Food Safety Display Boards' at all times at prominent places in case of Restaurants. However there remains a deficit of mechanism for consumer to know the FSSAI number of the service/ product provider.

4. Now, with the approval of Food Authority, it has been decided to mandate declaration of 14-digit FSSAI License or Registration number on cash receipts/ purchase invoices/cash memo /bills etc. by all food businesses. When any operator issues 2 transaction documents such as in case issuing transport challan/ Bill etc and an invoice, then FSSAI number needs to be mentioned on both documents. The only exemption will be GST e-way bill and such other govt documents which are system generated.

5. It shall enable the consumers to have access to information about a particular food business which is publically available at FSSAI's portals. Consumers can visit the FSSAI's portal and Food Safety Connect app for accessing information about FSSAI License or Registration by inputting the 14 digit FSSAI License/ Registration number.

6. In case of any grievance, a consumer can lodge an online complaint against a particular food business using the FSSAI number. Many complaints remain unresolved due to lack of specific information.

7. Mentioning of FSSAI number shall also improve the overall awareness of FSSAI. If not mentioned, it shall indicate non-compliance or non-registration/licensing by the food business. The requirement is expected to generate public demand and pressure for all FBOs to seek FSSAI license/ registration.

8. Even in case of pre-packaged food where the manufacturer's FSSAI number is printed on the pack, there exist a deficit of track and trace mechanism whereby the path of the package from a manufacturer to consumer can be traced. The invoice helps establishing

this trail. With mentioning of the FSSAI number will help in improving traceability for food products.

9. No new transaction document is being mandated to be issued. The policy seeks to leverage the existing commercial transaction practice and the regulatory requirement under tax laws. Thus FSSAI seek to maintain the minimum compliance cost and still have enhanced data dissemination and disclosure.

10. In the view of the above, Food Businesses shall be required to mention FSSAI License or Registration number on cash receipts/ purchase invoices/cash memo /bills etc. Licensing and Registrations Authorities are directed to widely publicise the policy and shall ensure its implementation mandatorily wef 1st Oct 2021.

11. This issues with the approval of the competent authority.

Yours sincerely,

File No. 15(31)2020/FoSCoS/RCD/FSSAI

*(Inoshi Sharma)  
Director (RCD)*

*Email: enforcement1@fssai.gov.in  
Food Safety and Standards Authority of India  
(A Statutory Authority established under the Food Safety &  
Standards Act, 2006)  
(Regulatory Compliance Division)  
FDA Bhawan, Kotla Road, New Delhi-110002*

To,

1. All Food Businesses Operators, Associations, Food Safety Mitra and other stakeholders
2. Commissioner of Food Safety of All States/ UT's
3. Directors of all Regional Offices, FSSAI
4. CITO- to upload on FSSAI's website

Copy for information to -

1. PPS to Chairperson, FSSAI- For information
2. PS to CEO, FSSAI For information
3. Head (RCD)



CDSCO MATTERS

## Module for online processing of applications for registration of BA BE study centres (CT-08)-reg.

To,  
All stakeholders through CDSCO Website

CDSCO in pursuance to implementation of the e-Governance mechanism has launched various online services through the SUGAM portal on 14.11.2015. In continuation to same. CDAC in collaboration with CDSCO has developed a module for online processing of applications for registration of BA BE study centres (CT-08) in accordance with New Drugs and Clinical Trial Rules, 2019.

The module is finalized and has been made functional, which can be accessed through <https://cdscoonline.gov.in>. All concerned stakeholders are requested to avail this facility and any comments/suggestions to help improve the module shall be welcomed and addressed properly.

Thereafter, the BA BE centre registration applications processing will be online and physical applications may not be accepted after 15.10.2021 in this regard.

7-5/2015/Misc/034 (e-Governance)

*Dr. V.G. Somani  
Drugs Controller General (India)  
Government of India  
Directorate General of Health Services  
Central Drugs Standard Control Organisation  
(International Cell Division)*

Copy to

1. All Zonal and Sub-Zonal Offices of CDSCO
2. CDAC Team



DGTR MATTERS

## DGTR Final findings notification wrt Isopropyl alcohol-reg.

### Attention Members

DGTR (DIRECTORATE GENERAL OF TRADE REMEDIES) **released notification** File No. 22/6/2019-DGTR dated 30<sup>th</sup> September 2021 on **Safeguard investigation concerning imports of 'Isopropyl Alcohol' into India – Final Findings – Proceedings under Foreign Trade (Development and Regulation) Act, 1992 and the Safeguard Measures (Quantitative Restrictions) Rules, 2012.**

Notification is available on <https://www.dgtr.gov.in> under Safeguard Investigation in India section. Interested members are requested to visit their website for complete information.







**PHARMACEUTICALS EXPORT PROMOTION COUNCIL OF INDIA**

(Set up by Ministry of Commerce and Industry, Government of India)

PXL/HO/BEC-021/2021-22

Date: 05.10.2021

Hyderabad

To,

IDMA (Indian Drug Manufacturer'S Association)

Dear Sir/Madam,

**Subject: Trade Enquiry - Ho Chi Minh City, Vietnam**

Pharmexcil is in receipt of enquiry from M/s. ADPharco, a Vietnamese pharmaceutical company, Ho Chi Minh City, Vietnam, through our Consulate General of India at Vietnam for **procurement of Medicines**. They are looking for Indian Suppliers for the following products;

1. Remdesivir
2. Favipiravir
3. Molnupiravir
4. 2DG
5. Actemra (Tocilizumab)
6. Methotrexate 2.5mg & 5mg (oral medicine)

Interested companies may contact them directly

Mr. Duong Can Thanh  
Information & Cultural Assistant  
Consulate General of India  
Villa Orchid 14, An Phu Superior Compound,  
36 Thao Dien, Thao Dien ward, District 2, Ho Chi Minh City  
Tel: +84-28-3744 2400/ Ext.17  
Fax: +84-28-3744 2405  
Email: ica.hcm@mea.gov.in | Web: www.cgihcmc.gov.in  
FB: facebook.com/cgihcm | Twitter: India in HCMC @cghcm

With regards,

Udaya Bhaskar, Director General

Disclaimer: Members may please note that the above information is circulated on the basis of information received from M/s. ADPharco, Ho Chi Minh City, Vietnam, through Indian Consulate, Vietnam, Members are advised to make their own decisions before finalizing their business transactions.

## FICCI - MAHARASHTRA BUSINESS DELEGATION TO DUBAI WORLD EXPO 2020- NOV 18-23, 2021

### FOR THE ATTENTION OF MAHARASHTRA MEMBERS

Dear Sir/Madam,

#### Maharashtra Business Delegation to World Expo 2020, Dubai November 18 – 23, 2021

World Expo 2020 - a marquee global event, will be hosted in Dubai from 1st October 2021 to 31st March 2022 and will see participation of businesses and multilateral organizations from 191 countries. Over 25 million visitors are expected to participate during 6-month duration.

Participation from India will be hosted at the India Pavilion, of which FICCI is the exclusive Industry Partner. The India pavilion will remain a vibrant place for Business and Cultural activities throughout the six months through the participation of state governments, central government ministries and corporates on rotation basis.

Maharashtra Government will be participating in the India Pavilion from November 19 to December 02, 2021. The state will showcase its best to the world across multiple areas of importance including Industries, Infrastructure, Tourism and Culture as few key pillars of state economy.

With this background, we are pleased to invite you to share your interest to be part of FICCI Maharashtra Business Delegation, which will coincide with the participation of Maharashtra government as per following schedule:

- **Dates: November 18 – November 23, 2021 (Inclusive of Travel Dates)**
- **Sector Focus: Diversified**

Senior ministers and secretaries from the state government are likely to participate in various activities including Policy launch, Sectoral conferences, MoU signing, B2G meetings etc.

To register online, please go to <https://bit.ly/3obDaZ5>, where additional details are given.

The participation number in the Maharashtra delegation is limited and will be confirmed on first come first serve basis. In case of multiple nominations, registration form for Each Delegate needs to be submitted separately.

Since Final list, having details of delegation members, needs to be submitted to Expo Authority by October 18, to complete the Accreditation process, we request you to submit your interest positively by **October 08, 2021** to complete other formalities.

For any additional information on participation, you may get in touch with Ms. Purva Shetye on +91-9769667378 or Mr. Pradeep Ahire: +91-9594933131 or write an email to [msc@ficci.com](mailto:msc@ficci.com).

I look forward to receiving your online confirmation at the earliest for a successful visit to Dubai..

With best regards,

Deepak Mukhi,  
Director  
Federation of Indian Chambers of Commerce and Industry, Maharashtra State Council  
Industry's Voice for Policy Change, 33-B,  
Krishnamai, Sir Pochkhanwala Road, Worli, Mumbai  
- 400 030  
T: +91-22-24968000, F: +91-22-24966631 / 32, Web:  
[www.ficci.in](http://www.ficci.in), Email: [deepak.mukhi@ficci.com](mailto:deepak.mukhi@ficci.com)  
ISO 9001:2015 certified  
FB: [www.facebook.com/ficciindia](https://www.facebook.com/ficciindia) | Twitter: [www.twitter.com/ficci\\_india](https://www.twitter.com/ficci_india) | Blog: [blog.ficci.com](http://blog.ficci.com)

Maharashtra Meets the World at Dubai World Expo 2020  
Inviting Interest from Maharashtra Inc. to Join  
**BUSINESS DELEGATION TO  
WORLD EXPO 2020, DUBAI**  
November 18 - 23, 2021 | Ex. Mumbai

Registration Closes  
October 08, 2021

Coinciding with Maharashtra's Participation at the World Expo 2020

- Connect with 191 Participating Countries
- Visit to Industrial Towns and Free Trade Zone
- Flexible Participation Packages

- B2B & B2G Meetings
- Explore Cultural Events
- All inclusive Packages

- High Profile Conferences
- City Sightseeing
- Travel Facilitation

Register your interest: Scan QR Code or Visit: <https://bit.ly/3obDaZ5> Contact: Mr. Pradeep: +91-95949 33131 / Ms. Purva - +91-97696 67378

## In Rajya Sabha and In Lok Sabha

### Rajya Sabha

#### CSR EXPENDITURE

#### Rajya Sabha Unstarred Question No. 2412 Dr. Kirodi Lal Meena:

**Q.** Will the Minister of **CORPORATE AFFAIRS** be pleased to state:

- (a) whether many companies have not made their mandatory Corporate Social Responsibility (CSR) expenditure;
- (b) if so, the details thereof and the number of cases of defaults every year during the last three years, the details thereof, company-wise;
- (c) whether Government has taken any step for complying with the recommendations made by the high level committee on CSR; and
- (d) if so, the details thereof and, if not, the reasons therefor?

#### Answered on 10<sup>th</sup> August, 2021

- (a) & (b): The CSR architecture is disclosure based and CSR mandated companies are required to file details of CSR activities annually in the MCA21 registry. The Government monitors the compliance of CSR through the disclosures made by the companies. The existing legal provisions such as mandatory disclosures, accountability of the CSR Committee and the Board, provisions for statutory audit of accounts of the company etc. provide sufficient safeguards. Whenever any violation of CSR provisions is reported, action against such non-compliant Companies are initiated as per provisions of the Act after due examination of records and following due process of law. So far, sanction for prosecution has been accorded in 366 cases. Of these, 148 applications for compounding have been made and 75 cases have been compounded. Further, the non-compliance of CSR provisions have been made civil wrong w. e. f. 22<sup>nd</sup> January, 2021.
- (c) & (d): The High Level Committee on CSR (HLC-2018) submitted its report to the Government on 07.08.2019 which is available in the public domain at [www.mca.gov.in](http://www.mca.gov.in).

gov.in. Based on the recommendations of HLC-2018, the Ministry carried out amendments in the Section 135 of the Companies Act, 2013 ('Act') through Companies (Amendment) Act, 2019 and Companies (Amendment) Act, 2020 and amendments in the Companies (CSR Policy) Rules, 2014 vide notification dated 22<sup>nd</sup> January, 2021

#### Minister of State (Independent Charge) of The Ministry of Statistics and Programme Implementation; Minister of state (Independent Charge) of the Ministry of Planning and Minister of State in the Ministry of Corporate Affairs [Rao Inderjit Singh]

#### Revision of investment limit to classify MSMEs

#### Rajya Sabha Unstarred Question No. 2345 Smt. Jharna Das Baidya:

**Q.** Will the Minister of *Micro, Small and Medium Enterprises* be pleased to state:

- (a) whether Government proposes to revise investment limits to classify Micro, Small and Medium Enterprises (MSMEs);
- (b) if so, the details thereof; and
- (c) the criteria likely to be adopted for the purpose, State-wise?

#### Answered on 09.08.2021

- (a) to (c): The Government, vide notification no. S.O. 2119(E) dated 26.06.2020, has already notified composite criteria of classification of MSMEs based on investment in plant and machinery or equipment and turnover of the enterprise. The new criteria became applicable to all States/UTs in the country effective from 1.7.2020. It has also been decided that the turnover with respect to exports will not be counted in the limits of turnover for any category of MSME units, whether micro, small or medium.

#### Minister of Micro, Small and Medium Enterprises (Shri Narayan Rane)

## Status of MSMEs and SMEs

### Rajya Sabha Unstarred Question No. 2344 Shri Vivek K. Tankha:

**Q.** Will the Minister of *Micro, Small and Medium Enterprises* be pleased to state:

- (a) the details of the Micro, Small and Medium Enterprises (MSMEs) and Small and Medium Enterprises (SMEs) which have been shut down post March, 2020; and
- (b) the details of the number of MSMEs and SMEs which have availed the benefits of the various economic packages announced by Prime Minister in May, 2020?

### Answered On 09.08.2021

- (a): COVID-19 epidemic has temporarily affected various sectors including Micro, Small and Medium Enterprises in the country. Economic activity contracted due to the strict lockdown measures imposed by the Government. This contraction has also had impact on the MSME sector.
- (b): The Ministry of MSME implements various schemes and programmes for growth and development of MSME Sector in the country. These schemes and programmes include Prime Minister's Employment Generation Programme (PMEGP), Scheme of Fund for Regeneration of Traditional Industries (SFURTI), A Scheme for Promoting Innovation, Rural Industry & Entrepreneurship (ASPIRE), Interest Subvention Scheme for Incremental Credit to MSMEs, Credit Guarantee Scheme for Micro and Small Enterprises, Micro and Small Enterprises Cluster Development Programme (MSE-CDP), Credit Linked Capital Subsidy and Technology Upgradation Scheme (CLCS-TUS). Achievements under some of them are:
1. Achievements regarding Credit Guarantee Scheme during 2019-20 to 2021-22

Financial Year	No. of Credit Facilities Approved	Amount of Guarantees Approved (Rs in crore)
2019-20	8,46,650	45,851.22
2020-21	8,36,065	36,954.72
2021-22*	2,44,300	13,315.95

\*Till June 2021 Source: CGTMSE

2. The performance of the PMEGP during the last three years are:

Year	Margin Money Disbursed (Rs. Crore)	Micro units assisted (Number)	Estimated Employment Generated (Number)
2018-19	2070	73,427	5,87,416
2019-20	1950.82	66,653	5,33,224
2020-21	2188.80	74,415	5,95,320
2021-22	453.77*	14,820	1,18,560*

\*upto 30.06.2021

Source: KVIC

3. A brief performance of Emergency Credit Guarantee Line Scheme (ECLGS) as on 02.07.2021 is as under:

Type of Borrower	Guarantee (In nos.)	Guarantees Issued (Amt. In crore)
Micro Enterprises	1,01,92,105	63,524.57
Small Enterprises	4,64,086	63,243.36
Medium Enterprises	2,58,970	39,097.63
Other Business Enterprises	5,16,680	82,906.96
TOTAL	1,14,31,841	2,48,772.52

Source: NCGTC

3. No. of Projects approved under Infrastructure Development (ID) and Common Facility Centres (CFC) under Cluster Development Programme:
4. An online Portal "Champions" has been launched on 01.06.2020 by Hon'ble Prime Minister. This covers many aspects of e-governance including grievance redressal and handholding of MSMEs. Through the portal, total 36,373 grievances have been redressed upto 01.08.2021.

Year	Projects Approved			Projects completed		
	Com-mon Facility Centres (CFC) – Final Ap-proval	Infra-structure Develop-ment Cen-tres (ID) – Final Approval	Total (Final Ap-proval)	Com-mon Facil-ity Cen-tres (CFC)	Infra-struc-ture Devel-opment Centres (ID)	To-tal
2020-21	26	42	68	8	12	20
2021-22	6	1	7	1	1	2
Total	32	43	75	9	13	22

**Minister of Micro, Small and Medium Enterprises (Shri Narayan Rane)**

**Allocation of funds to MSMEs**

**Rajya Sabha Unstarred Question No. 2343  
Shri P Wilson**

**Q.** Will the Minister of *Micro, Small and Medium Enterprises* be pleased to state:

- the details of the special packages announced under the 'Aatma Nirbhar Bharat Abhiyaan' (ABA) to strengthen the Micro, Small and Medium Enterprises (MSMEs) sector in the country;
- the details of the loans sanctioned/disbursed to the MSMEs sector in the country under the ABA especially in Tamil Nadu;
- whether Government has received any complaints from MSMEs about denial of collateral free loans from banks and if so, the details thereof; and
- the details of demands raised by MSMEs and met by Government so far, during the last three years, State/UT-wise?

**Answered On 09.08.2021:**

- (a) & (b): Government of India has taken various measures to strengthen the MSME sector under Aatmanirbhar Bharat Abhiyan (ABA), which includes Rs.3 Lakh crore Collateral-Free Automatic Loans for businesses, Rs. 20,000 crore subordinate debt for stressed MSMEs, Rs. 50,000 crore equity infusion through MSME Fund of Funds, no global tenders for procurement upto Rs. 200 crores along with revision of definition of MSME, etc.

Further, as on 02.07.2021, an amount of Rs. 2.73 lakh crore have been sanctioned under Emergency Credit Line Guarantee Scheme (ECLGS) in the country, including Tamil Nadu, of which an amount of Rs. 2.14 lakh crore has been disbursed.

- (c) & (d): All proposals that are eligible under the relevant guidelines for a collateral free loan are generally accepted. However, Ministry of Micro, Small and Medium Enterprises (MSME) sometimes receives complaint regarding denial of collateral free loan by the banks. As there is a prescribed procedure for obtaining a collateral free loan, such complaints received in the Ministry of MSME, are accordingly forwarded to concerned bank for consideration as per the rule/procedure.

**Ministry of Micro, Small and Medium Enterprises (Shri Narayan Rane)**

**Environmental standards for polluting industries**

**Rajya Sabha Unstarred Question No. 2300  
Dr. Ashok Bajpai**

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

- whether Government has laid environmental standards for compliance by the various polluting industries, if so, the details thereof;
- the details of the industries identified for violating pollution standards and details of the complaints received against them, area-wise and State-wise; and
- the steps being taken by Government to check pollution emitting from other industrial units?

**Answered On 09.08.2021:**

- The Ministry has issued notifications from time to time laying down standards for various sectors of industries under Environmental Protection Act (EPA), 1986. Industry specific environmental standards, for more than 80 industrial sectors have been notified. The list of industrial sectors covered by industry specific notification is given at Annexure-I.
- There are total 4,354 highly polluting industries (17-categories, Annexure-II) in the country. Out of which, 3,708 units are operational and 646 are not operational. Out of 3,708 operational units, 3,386 units are complying with the prescribed environmental standards and 322 units are non-complying. Show-cause notices to 190 units and closure directions to 88 units were issued for non-compliances. Legal actions were initiated against 6 units and action is in process against 38 units. State-wise status of 17 categories of highly polluting industries is given at Annexure-III.
- For strengthening monitoring and effective compliance through self-regulatory mechanism, Central Pollution Control Board (CPCB) directed all 17 categories of highly polluting industries, Grossly Polluting Industries (GPIs) of Ganga basin, Common Effluent Treatment Plants (CETPs), biomedical waste management facilities and common hazardous waste facilities to install Online Continuous Effluent/ Emission Monitoring Systems (OCEMS) for constant vigil on pollution levels. On the basis of SMS alerts generated due to violations of environmental norms, CPCB started inspection-cum-monitoring of 17 categories of highly polluting industries on random basis for appropriate actions.



CPCB has developed the criteria for categorization of industrial sectors into red, orange green and white category and directed all State Pollution Control Boards (SPCBs)/ Pollution Control Committees (PCCs), on 07.03.2016, to adopt the same. The categorization is based on Pollution Index (PI) which is a function of water pollution, air pollution, hazardous waste generation, fuel consumption and amount of waste water generation.

The purpose of the categorization is to ensure that the industry is established in a manner consistent with the environmental objectives and to prompt industrial sectors to adopt cleaner technologies, ultimately resulting in generation of no or minimum pollutants. So far, CPCB has categorized 253 industrial sectors into red, orange, green and white categories. The categorization is used by SPCBs/PCCs for consent management and deciding priority/frequency for environmental surveillance.

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

**Annexure-I List of Industrial Sectors for which  
effluent/emission standards are notified**

**Sl. No. Name of the Industrial Sector**

1	Aluminium	21	Common Hazardous Waste Incinerator
2	Asbestos	22	Copper, Lead and Zinc smelting
3	Bagasse fire Boilers	23	Cotton Textile Industries (Composite and Processing)Composite woolen)
4	Battery Manufacturing industries	24	Cupola furnaces
5	Beehive Hard coke oven	25	Dairy Industry
6	Boilers(Agro waste as fuel)	26	Dye & Dye Industry
7	Boilers(small)	27	Edible Oil & Vanaspati
8	Brick Kilns	28	Electroplating
9	Briquette(Coal)	29	Emission limits for diesel engine more than 0.8 MW for power plant
10	Bullion Refining	30	Emission limits for new diesel engine up to 800 kw for generator sets
11	Calcium Carbide	31	Emission standards for new DG Sets up to 19 KW
12	Carbon Black	32	Fermentation (Distillation, Maltry, Brewery)
13	Cashew seed processing	33	Fertiliser
14	Caustic Soda	34	Flour Mills, Paddy Processing, Pulse Making or Grinding
15	Cement	35	Food & Fruit Processing
16	Ceramics	36	Foundries
17	Coal mines	37	Furnaces (Reheating)
18	Coal Washery	38	Gas/Naptha Based Power Plants
19	Coffee Processing	39	Glass Manufacturing
20	Common Effluent Treatment Plants	40	Guidelines for Pollution control measures in Ginning mill
		41	Hotel Industry
		42	Inorganic Chemicals
		43	Integrated Iron & Steel And coke oven
		44	Jute Processing Industry
		45	Leather Tannery
		46	Lime kiln
		47	Manmade Fibre
		48	Natural Rubber & Synthetic Rubber
		49	Nitric Acid
		50	Noise Generated by Domestic Appliances
		51	Noise limits for generator sets run with Diesel
		52	Noise limits for generator sets run with petrol/ kerosene
		53	Noise standards for fire crackers
		54	Oil Drilling and Gas Extraction
		55	Oil Refinery
		56	Organic Chemicals
		57	Paints

58	Pesticides
59	Petrochemicals
60	Pharmaceuticals
61	Plaster of Paris
62	Primary water quality criteria for bathing water
63	Pulp & Paper (small)
64	Pulp & Paper(Large)
65	Refractory Industry
66	Slaughter House, Meat & Sea Food Processing
67	Soda Ash
68	Soft coke industry
69	Sponge Iron Plants
70	Starch (Maize)
71	Stone crushing
72	Sugar
73	Sulphuric Acid
74	Thermal Power plant
75	Vehicular Noise
76	(a) Viscose Staple Fibre (VSF) Plant(b) Viscose Filament Yarn (VFY) Plant(c) Nylon Polyester(d) Acrylic- (i) Wet Process(ii) Dry Process
77	Water quality standards of costal water marine water falls
78	Sewage Treatment Plants (STPs)
79	Industrial Boilers

80	Airports
81	Automobile Service Station, Bus Depot or Workshop

**Annexure-II**

**List of 17-categories of highly polluting industries**

1. Distillery including Fermentation Industry
2. Sugar (excluding Khandsari)
3. Fertiliser
4. Pulp & Paper (Paper manufacturing with or without pulping)
5. Chlor Alkali
6. Pharmaceuticals (Basic) (excluding Formulation)
7. Dyes and Dye Intermediates
8. Pesticides (Technical) (excluding Formulation)
9. Oil Refinery (Mineral oil or Petro refineries)
10. Tanneries
11. Petrochemicals (manufacture of and not merely use of raw material)
12. Cement
13. Thermal Power Plants
14. Iron & Steel (Involving processes from ore/scrap, and Integrated Steel Plants)
15. Zinc Smelter
16. Copper Smelter
17. Aluminum Smelter

**Annexure-III**

Compliance Status of 17 Category of Industries (as received from SPCBs/PCCs)										
Sl. No.	SPCB/PCC	Total no. of industries	No. of industries closed by their own	No. of industries operational	No. of industries complying with environmental standards	No. of industries non-complying with environmental standards	No. of industries against which action is taken for non-complying with environmental standards			
							Show cause notice issued	Closure directions issued	Legal cases filed	Action under process
1	Andaman & Nicobar	0	0	0	0	0	0	0	0	0
2	Andhra Pradesh	282	23	259	243	16	1	0	1	14
3	Arunachal Pradesh	5	0	5	5	0	0	0	0	0
4	Assam	51	11	40	36	4	2	2	0	0
5	Bihar	43	26	17	17	0	0	0	0	0
6	Chandigarh	0	0	0	0	0	0	0	0	0
7	Chhattisgarh	163	20	143	137	6	5	1	0	0
8	Daman & Diu	4	0	4	4	0	0	0	0	0
9	Delhi	0	0	0	0	0	0	0	0	0
10	Goa	4	0	4	4	0	0	0	0	0
11	Gujarat	517	76	441	344	97	72	24	0	1

12	Haryana	174	8	166	161	5	0	1	0	4
13	Himachal Pradesh	21	2	19	19	0	0	0	0	0
14	Jammu and Kashmir	55	0	55	52	3	3	0	0	0
15	Jharkhand	81	2	79	54	25	13	1	0	11
16	Karnataka	246	47	199	184	15	2	12	0	1
17	Kerala	25	5	20	20	0	0	0	0	0
18	Lakshadweep	0	0	0	0	0	0	0	0	0
19	Madhya Pradesh	96	5	91	88	3	1	0	1	1
20	Maharashtra	506	32	474	434	40	29	11	0	0
21	Manipur	0	0	0	0	0	0	0	0	0
22	Meghalaya	23	1	22	21	1	1	0	0	0
23	Mizoram	0	0	0	0	0	0	0	0	0
24	Nagaland	0	0	0	0	0	0	0	0	0
25	Odisha	186	43	143	126	17	14	3	0	0
26	Puducherry	7	3	4	4	0	0	0	0	0
27	Punjab	98	22	76	71	5	5	0	0	0
28	Rajasthan	161	12	149	129	20	17	2	0	1
29	Sikkim	1	0	1	0	1	0	1	0	0
30	Tamil Nadu	239	41	198	194	4	0	1	0	3
31	Telangana	329	37	292	274	18	0	14	4	0
32	Tripura	5	0	5	4	1	0	1	0	0
33	Uttar Pradesh	855	196	659	646	13	6	5	0	2
34	Uttarakhand	46	0	46	42	4	4	0	0	0
35	West Bengal	131	34	97	73	24	15	9	0	0
	Total	4354	646	3708	3386	322	190	88	6	38

## Environment (Protection) Amendment Rules, 2020

### Rajya Sabha Un-Starred Question No. 2284 Shri K.J. Alphons

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

- whether the post-facto approval of the projects, which the Bill allows, is in violation of the "precautionary principle" and whether there can be a possibility that the environmental damage caused by any such project is likely to be waived off by Government;
- whether the suggestions and recommendations by the public and those affected were considered and taken into account; and
- whether certain irreversible environmental, social or health consequences of the project could go unnoticed because of the change in the submission time since the compliance report by the promoter will now be submitted yearly instead of half-yearly?

**Answered On 09.08.2021**

- No bill is proposed by the Government that allows *post-facto* environmental approval of projects. However, Ministry had published draft Environment Impact Assessment (EIA) Notification, 2020 dated 11.04.2020 for seeking comments from public. The said draft EIA Notification 2020 also does not provide for *ex post facto* clearance to violation cases. Environmental Clearance can be refused also after consideration on merit. The said draft notification *inter alia* provided that the Environment Clearance, if issued after consideration on merit & with such modifications as may be imposed, to the project shall only be prospective and shall be effective from the date of its issuance. Further in such cases, the said notification specifically laid down that the project proponent shall be liable to action under Section 15 of the Environment (Protection) Act, 1986 in addition to liability for bearing the costs towards mitigation of environmental damage through appropriate remedial action and community augmentation plans. There is no such provision for waiving off the environmental damage caused by any such project confirmed as a violation case.

(b) & (c) The draft EIA Notification, 2020 was published in the Official Gazette on 11 April, 2020 with the purpose of seeking public comments. Several comments/suggestions have been received from various stakeholders across the country. The notification has not been finalized.

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

**Lok Sabha**

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**Price of Generic Drugs**

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**Unstarred Question No. 3485  
Shri Hemant Tukaram Godse**

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

- (a) whether the Government has introduced generic drugs in the country;
- (b) if so, whether the prices of generic drugs are cheaper than other drugs available in the open market with the same composition;
- (c) the reasons behind the price variation of the same products;
- (d) whether the Government proposes to fix the price by "one product-one price" method in the country; and
- (e) if so, the details thereof and if not, the reasons therefor?

**Answered On 10<sup>th</sup> August, 2021:**

- (a): Yes Sir. The generic medicines, along with branded ones, are available in the country, subject to compliance to provisions of the Drugs and Cosmetics Act, 1940 and Rules made thereunder. Central Drugs Standards Control Organization (CDSCO) under the Ministry of Health & Family Welfare and the State Drug Controllers grants necessary permissions in this regard.
- (b) & (c): Both generic and branded drugs are treated alike for fixation of ceiling price under provisions of the Drugs (Prices Control) Order (DPCO). As per provisions of DPCO, all manufacturers of scheduled medicines (branded or generic) have to sell their products within the ceiling price fixed by the Government. As regards non-scheduled formulations, whether branded or generic, manufacturers are free to fix their Maximum Retail Price (MRP), but are not allowed to increase the price by more than 10 % per annum during what was prevailing in the preceding 12 months. While the

National Pharmaceutical Pricing Authority (NPPA) under the Department of Pharmaceuticals fixes and monitor the prices of scheduled medicines, it monitors the same in case of non-scheduled medicines.

(d) and (e): No such proposal is under consideration of the Government.

**Minister in the Ministry of Chemicals &  
Fertilizers (Shri Mansukh Mandaviya)**

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**Guidelines for FDCs**

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**Lok Sabha Unstarred Question No. 3493**

**Shri Bhola Singh:  
Shri Jagdambika Pal:  
Shri Arjun Lal Meena:  
Shri Ranjeetsingh Hindurao Naik  
Nimbalkar:  
Dr. Sukanta Majumdar  
Dr. Jayanta Kumar Roy:  
Shri P.P. Chaudhary:  
Shri Vinod Kumar Sonkar:  
Shri Rajveer Singh (Raju Bhaiya):  
Shrimati Sangeeta Kumari Singh Deo:  
Shri Sunil Kumar Singh:  
Shri Sangam Lal Gupta:  
Shri Raja Amareshwara Naik:**

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

- (a) whether the Government has framed guidelines for the approval and use of Fixed Drugs Combinations (FDC) in the country and if so, the details thereof;
- (b) whether the Government plans to increase monitoring of the usage of FDC drugs in the country and if so, the details thereof;
- (c) whether the Government asked National Pharmaceuticals Pricing Authority (NPPA) and Indian Council of Medical Research (ICMR) to study the usage and prescription of FDC medicines in the country and if so, the details thereof;
- (d) whether the Government has banned some FDC medicines on the recommendations of Prof C K Kokate Committee; and
- (e) if so, the list of such FDC medicines?

**Answered on the 10<sup>th</sup> August, 2021.**

(a): The Central Drugs Standard Control Organisation (CDSCO) under MoHFW has informed that the New Drugs and Clinical Trial Rules, (NDCT) 2019 have been

published, vide Gazette notification no. G.S.R.227(E) dated 19.03.2019. The Second Schedule of the NDCT Rules 2019, provides detailed requirements for approval of Fixed Dose Combinations in the country.

(b) to (d): The manufacture, sale and distribution of drugs in the country are regulated under the provisions of the Drugs & Cosmetics Act, 1940 and Rules thereunder through a system of licensing and inspection. Licenses for manufacture, sale and distribution of drugs are granted by the State Licensing Authorities (SLAs) appointed by respective State Governments. Under the said Rules, for manufacture of any New Drug, permission is required from Central Drugs Standard Control Organisation (CDSCO) before obtaining manufacturing license for the New Drug from the concerned State Licensing Authority. Under the afore-said Act, manufacture/sale/distribution of any banned drug is a punishable offence. State Licensing Authorities are empowered to take action in this regard. Some cases of grant of manufacturing license of new drugs including Fixed Dose Combinations (FDCs) falling under the purview of Rule 122E of the Drugs & Cosmetics Rules, 1945 by some of the State Licensing Authorities (SLAs) without due approval of the Drugs Controller General (India) [DCG (I)] came to the notice of the Government.

Apart from issuing repeated statutory directions under Section 33P of the Drugs & Cosmetics Act, 1940 to the State Governments in this regard, the Central Government constituted an Expert Committee under the chairmanship of Prof C.K. Kokate to examine the safety and efficacy of such FDCs. Based on the recommendations of the Prof. C. K. Kokate Expert Committee, the Central Government prohibited 344 FDCs vide notification dated 10.03.2016. Further, the Central Government also prohibited 5 FDCs vide notification dated 08.06.2017. However, with respect to the said 344 FDCs, several writ petitions were filed in different High Courts across the country challenging the ban of the FDCs. After that, the High Court of Delhi vide its order dated 01.12.2016 quashed the said notification. The Union of India challenged the said order of Delhi High Court before the Supreme Court by way of filing Special Leave Petition (SLP). Further, 20 cases against 5 FDCs prohibited on 08.06.2017 which were pending before various High Courts across the country, were also transferred to Hon'ble Supreme Court. Hon'ble Supreme Court vide its order dated 15.12.2017 directed that an analysis be made in greater depth and these cases of (344+5) FDCs should go to the Drugs Technical Advisory Board (DTAB) and/or a Sub-Committee formed by the DTAB for the purpose of having a relook into these cases.

Accordingly, a Sub-Committee of DTAB was constituted which, after providing hearing to all the petitioners/ appellants, submitted its report to DTAB which was accepted by DTAB. Based on the recommendations of DTAB, the Central Government vide notifications dated 07.09.2018 prohibited 328 FDCs for manufacture, sale or distribution as there was no therapeutic justification for these FDCs and they could involve risk to human beings. The Government also restricted 06 FDCs for manufacture, sale or distribution with certain conditions vide notifications issued on the same date. However, various firms/stakeholders have filed writ petitions in various High Courts across the country including the Hon'ble Supreme Court against the said notifications dated 07.09.2018.

(e): The list of such banned FDCs is given in the Annexure.

## **Minister in the Ministry of Chemicals & Fertilizers (Shri Mansukh Mandaviya)**

### **Annexure**

S. No	Name of FDC
1	Aceclofenac + Paracetamol + Rabeprazole
2	Nimesulide + Diclofenac
3	Nimesulide + Cetirizine + Caffeine
4	Nimesulide + Tizanidine
5	Paracetamol + Cetirizine + Caffeine
6	Diclofenac + Tramadol + Chlorzoxazone
7	Dicyclomine + Paracetamol + Domperidone
8	Diclofenac + Tramadol + Paracetamol
9	Diclofenac + Paracetamol + Chlorzoxazone + Famotidine
10	Naproxen + Paracetamol
11	Nimesulide + Serratiopeptidase
12	Paracetamol + Diclofenac + Famotidine
13	Nimesulide + Pitofenone + Fenpiverinium + Benzyl Alcohol
14	Omeprazole + Paracetamol + Diclofenac
15	Nimesulide + Paracetamol Injection
16	Tamsulosin + Diclofenac
17	Paracetamol + Phenylephrine + Chlorpheniramine + Dextromethorphan + Caffeine
18	Diclofenac + Zinc Carnosine
19	Diclofenac + Paracetamol + Chlorpheniramine Maleate + Magnesium Trisilicate
20	Paracetamol + Pseudoephedrine + Cetirizine
21	Phenylbutazone + Sodium Salicylate
22	Lornoxicam + Paracetamol + Trypsin
23	Paracetamol + Mefenamic Acid + Ranitidine + Dicyclomine
24	Nimesulide + Dicyclomine
25	Heparin + Diclofenac



26	Glucosamine + Methylsulfonylmethane + Vitamin D3 + Manganese + Boron + Copper + Zinc
27	Paracetamol + Tapentadol
28	Tranexamic Acid + Proanthocyanidin
29	Lornoxicam + Paracetamol + Tramadol
30	Lornoxicam + Paracetamol + Serratiopeptidase
31	Diclofenac + Paracetamol + Magnesium Trisilicate
32	Paracetamol + Domperidone + Caffeine
33	Ammonium Chloride + Sodium Citrate + Chlorpheniramine Maleate + Menthol
34	Combikit of 3 Tablets of Serratiopeptidase (Enteric Coated 20000 units) + Diclofenac Potassium & 2 Tablets of Doxycycline
35	Nimesulide + Paracetamol Suspension
36	Aceclofenac + Paracetamol + Famotidine
37	Aceclofenac + Zinc Carnosine
38	Paracetamol + Disodium Hydrogen Citrate + Caffeine
39	Paracetamol + DL- Methionine
40	Disodium Hydrogen Citrate + Paracetamol
41	Paracetamol + Caffeine + Codeine Phosphate
42	Aceclofenac (SR) + Paracetamol
43	Diclofenac + Paracetamol injection
44	Azithromycin + Cefixime
45	Amoxicillin + Dicloxacillin
46	Azithromycin + Levofloxacin
47	Cefixime + Linezolid
48	Amoxicillin + Cefixime + Potassium Clavulanic Acid
49	Ofloxacin + Nitazoxanide
50	Cefpodoxime Proxetil + Levofloxacin
51	Combikit of Azithromycin Dihydrate, Secnidazole and Fluconazole
52	Levofloxacin + Ornidazole + alpha-Tocopherol Acetate
53	Nimorazole + Ofloxacin
54	Azithromycin + Ofloxacin
55	Amoxicillin + Tinidazole
56	Doxycycline + Serratiopeptidase
57	Cefixime + Levofloxacin
58	Ofloxacin + Metronidazole + Zinc Acetate
59	Diphenoxylate + Atropine + Furazolidone
60	Combikit of Fluconazole Tablet, Azithromycin Tablet and Ornidazole Tablets
61	Ciprofloxacin + Phenazopyridine
62	Amoxicillin + Dicloxacillin + Serratiopeptidase
63	Azithromycin + Cefpodoxime
64	Lignocaine + Clotrimazole + Ofloxacin + Beclomethasone
65	Cefuroxime + Linezolid
66	Ofloxacin + Ornidazole + Zinc Bisglycinate
67	Metronidazole + Norfloxacin
68	Ciprofloxacin + Fluticasone + Clotrimazole + Neomycin

69	Metronidazole + Tetracycline
70	Cephalexin + Neomycin + Prednisolone
71	Azithromycin + Ambroxol
72	Cilnidipine + Metoprolol Succinate + Metoprolol Tartrate
73	L-Arginine + Sildenafil
74	Atorvastatin + Vitamin D3 + Folic Acid + Vitamin B12 + Pyridoxine
75	Metformin + Atorvastatin
76	Clindamycin + Telmisartan
77	Olmestartan + Hydrochlorothiazide + Chlorthalidone
78	L-5-Methyltetrahydrofolate Calcium + Escitalopram
79	Paracetamol + Promethazine
80	Betahistine + Ginkgo Biloba Extract + Vinpocetine + Piracetam
81	Cetirizine Dihydrochloride + Diethylcarbamazine
82	Doxylamine + Pyridoxine + Mefenamic Acid + Paracetamol
83	Drotaverine + Clidinium + Chlordiazepoxide
84	Flupentixol + Escitalopram
85	Gabapentin + Mecobalamin + Pyridoxine + Thiamine
86	Imipramine + Chlordiazepoxide + Trifluoperazine + Trihexyphenidyl
87	Chlorpromazine + Trihexyphenidyl
88	Ursodeoxycholic Acid + Silymarin
89	Metformin 1000/1000/500/500 mg + Pioglitazone 7.5/7.5/7.5/7.5 mg + Glimepiride 1/2/1/2 mg
90	Gliclazide 80 mg + Metformin 325 mg
91	Voglibose + Metformin + Chromium Picolinate
92	Pioglitazone 7.5/7.5 mg + Metformin 500/1000 mg
93	Glimepiride 1mg/2mg/3mg + Pioglitazone 15mg/15mg/15mg + Metformin 1000mg/1000mg/1000mg
94	Glimepiride 1mg/2mg + Pioglitazone 15mg/15mg + Metformin 850mg/850mg
95	Metformin 850 mg + Pioglitazone 7.5 mg + Glimepiride 2 mg
96	Metformin 850 mg + Pioglitazone 7.5 mg + Glimepiride 1 mg
97	Metformin 500mg/500mg + Gliclazide SR 30mg/60mg + Pioglitazone 7.5mg/7.5mg
98	Voglibose + Pioglitazone + Metformin
99	Metformin + Bromocriptine
100	Metformin + Glimepiride + Methylcobalamin
101	Pioglitazone 30 mg + Metformin 500 mg
102	Glipizide 2.5 mg + Metformin 400mg
103	Pioglitazone 15 mg + Metformin 850 mg
104	Metformin ER + Gliclazide MR + Voglibose
105	Chromium Polynicotinate + Metformin Hydrochloride
106	Metformin Hydrochloride + Gliclazide + Pioglitazone + Chromium Polynicotinate

107	Metformin + Gliclazide + Chromium Polynicotinate
108	Metformin (sustained release) 500 mg + Pioglitazone 15 mg + Glimepiride 3mg
109	Metformin (SR) 500mg + Pioglitazone 5mg
110	Chloramphenicol + Beclomethasone + Clotrimazole + Lignocaine
111	Clotrimazole + Ofloxacin + Lignocaine + Glycerine and Propylene Glycol
112	Chloramphenicol + Lignocaine + Betamethasone + Clotrimazole + Ofloxacin + Antipyrine
113	Ofloxacin + Clotrimazole + Betamethasone + Lignocaine
114	Gentamicin Sulphate + Clotrimazole + Betamethasone + Lignocaine
115	Clotrimazole + Beclomethasone + Ofloxacin + Lignocaine
116	Beclomethasone + Clotrimazole + Chloramphenicol + Gentamycin + Lignocaine Ear drops
117	Flunarizine + Paracetamol + Domperidone
118	Rabeprazole + Zinc Carnosine
119	Magaldrate + Famotidine + Simethicone
120	Cyproheptadine + Thiamine
121	Magaldrate + Ranitidine + Pancreatin + Domperidone
122	Ranitidine + Magaldrate + Simethicone
123	Magaldrate + Papain+ Fungal Diastase + Simethicone
124	Rabeprazole + Zinc + Domperidone
125	Famotidine + Oxetacaine + Magaldrate
126	Ranitidine + Domperidone + Simethicone
127	Alginic Acid + Sodium Bicarbonate + Dried Aluminium Hydroxide + Magnesium Hydroxide
128	Clidinium + Paracetamol + Dicyclomine + Activated Dimethicone
129	Furazolidone + Metronidazole + Loperamide
130	Rabeprazole + Diclofenac + Paracetamol
131	Ranitidine + Magaldrate
132	Norfloxacin+ Metronidazole + Zinc Acetate
133	Zinc Carnosine + Oxetacaine
134	Oxetacaine + Magaldrate + Famotidine
135	Pantoprazole (as Enteric Coated Tablet) + Zinc Carnosine (as Film Coated Tablets)
136	Zinc Carnosine + Magnesium Hydroxide + Dried Aluminium Hydroxide + Simethicone
137	Zinc Carnosine + Sucralfate
138	Mebeverine Hydrochloride & Inner HPMC capsule (Streptococcus Faecalis +Clostridium Butyricum + Bacillus Mesentricus + Lactic Acid Bacillus)
139	Clindamycin + Clotrimazole + Lactic Acid Bacillus
140	Sildenafil + Estradiol Valerate
141	Clomifene Citrate + Ubidecarenone + Zinc + Folic Acid + Methylcobalamin + Pyridoxine + Lycopene + Selenium + Levocarnitine Tartrate + L-Arginine

142	Thyroxine + Pyridoxine + Folic Acid
143	Gentamycin + Dexamethasone + Chloramphenicol + Tobramycin + Ofloxacin
144	Dextromethorphan + Levocetirizine + Phenylephrine + Zinc
145	Nimesulide + Loratadine + Phenylephrine + Ambroxol
146	Bromhexine +Phenylephrine + Chlorpheniramine Maleate
147	Dextromethorphan + Bromhexine + Guaiphenesin
148	Paracetamol + Loratadine + Phenylephrine + Dextromethorphan + Caffeine
149	Nimesulide + Phenylephrine + Caffeine + Levocetirizine
150	Azithromycin + Acebrophylline
151	Diphenhydramine +Terpine + Ammonium Chloride + Sodium Chloride + Menthol
152	Nimesulide + Paracetamol + Cetirizine + Phenylephrine
153	Paracetamol+ Loratadine + Dextromethorphan + Pseudoephedrine + Caffeine
154	Chlorpheniramine Maleate + Ammonium Chloride + Sodium Citrate
155	Cetirizine + Phenylephrine + Paracetamol + Zinc Gluconate
156	Ambroxol + Guaiphenesin + Ammonium Chloride + Phenylephrine + Chlorpheniramine Maleate + Menthol
157	Dextromethorphan + Bromhexine + Chlorpheniramine Maleate + Guaiphenesin
158	Levocetirizine + Ambroxol + Phenylephrine + Guaiphenesin
159	Dextromethorphan + Chlorpheniramine + Chlorpheniramine Maleate
160	Cetirizine + Ambroxol + Guaiphenesin + Ammonium Chloride+ Phenylephrine + Menthol
161	Chlorpheniramine + Phenylephrine + Caffeine
162	Dextromethorphan + Triprolidine + Phenylephrine
163	Terpin Hydrate+ Dextromethorphan + Menthol
164	Dextromethorphan + Phenylephrine + Zinc Gluconate+ Menthol
165	Chlorpheniramine + Codeine + Sodium Citrate + Menthol syrup
166	Enrofloxacin + Bromhexine
167	Bromhexine + Dextromethorphan + Phenylephrine + Menthol
168	Levofloxacin + Bromhexine
169	Levocetirizine + Ranitidine

170	Levocetirizine + Phenylephrine + Ambroxol + Guaiphenesin + Paracetamol
171	Cetirizine + Dextromethorphan + Phenylephrine + Zinc Gluconate + Paracetamol + Menthol
172	Paracetamol+ Pseudoephedrine + Dextromethorphan + Cetirizine
173	Diphenhydramine + Guaiphenesin + Ammonium Chloride + Bromhexine
174	Chlorpheniramine + Dextromethorphan + Phenylephrine + Paracetamol
175	Dextromethorphan + Promethazine
176	Diethylcarbamazine Citrate + Cetirizine + Guaiphenesin
177	Pseudoephedrine + Dextromethorphan + Cetirizine
178	Chlorpheniramine + Phenylephrine + Dextromethorphan + Menthol
179	Ambroxol + Terbutaline + Dextromethorphan
180	Dextromethorphan + Chlorpheniramine + Guaiphenesin
181	Terbutaline +Bromhexine + Guaiphenesin + Dextromethorphan
182	Dextromethorphan + Triprolidine + Phenylephrine
183	Paracetamol + Dextromethorphan + Chlorpheniramine
184	Pholcodine + Phenylephrine + Promethazine
185	Codeine + Levocetirizine + Menthol
186	Dextromethorphan + Ambroxol + Guaifenesin + Phenylephrine + Chlorpheniramine
187	Cetirizine + Phenylephrine + Dextromethorphan + Menthol
188	Roxithromycin + Serratiopeptidase
189	Paracetamol + Phenylephrine + Triprolidine
190	Acetaminophen + Loratadine + Ambroxol + Phenylephrine
191	Cetirizine + Acetaminophen + Dextromethorphan + Phenylephrine + Zinc Gluconate
192	Diphenhydramine + Guaifenesin + Bromhexine + Ammonium Chloride + Menthol
193	Cetirizine + Dextromethorphan + Zinc Gluconate + Menthol
194	Paracetamol + Phenylephrine + Desloratadine + Zinc Gluconate + Ambroxol
195	Levocetirizine + Montelukast + Acebrophylline
196	Dextromethorphan + Phenylephrine + Ammonium Chloride + Menthol
197	Dextromethorphan +Bromhexine +Guaiphenesin + Menthol

198	Acrivastine + Paracetamol + Caffeine + Phenylephrine
199	Naphazoline + Carboxymethyl Cellulose + Menthol + Camphor + Phenylephrine
200	Dextromethorphan + Cetirizine
201	Nimesulide + Paracetamol + Levocetirizine + Phenylephrine + Caffeine
202	Terbutaline + Ambroxol + Guaiphenesin + Zinc + Menthol
203	Codeine + Chlorpheniramine + Alcohol Syrup
204	Dextromethorphan + Phenylephrine + Guaifenesin + Triprolidine
205	Diethylcarbamazine + Cetirizine + Ambroxol
206	Ethylmorphine + Noscapine + Chlorpheniramine Maleate
207	Cetirizine + Dextromethorphan + Ambroxol
208	Ambroxol + Guaifenesin + Phenylephrine + Chlorpheniramine
209	Paracetamol +Phenylephrine + Chlorpheniramine + Zinc Gluconate
210	Dextromethorphan + Phenylephrine + Cetirizine +Paracetamol + Caffeine
211	Levocetirizine + Dextromethorphan + Zinc
212	Paracetamol + Phenylephrine + Levocetirizine + Caffeine
213	Chlorpheniramine + Ammonium Chloride + Sodium Chloride
214	Paracetamol + Dextromethorphan + Bromhexine + Phenylephrine + Diphenhydramine
215	Salbutamol + Bromhexine + Guaiphenesin + Menthol
216	Chlorpheniramine + Ammonium Chloride + Noscapine + Sodium Citrate
217	Cetirizine + Dextromethorphan + Bromhexine + Guaifenesin
218	Diethylcarbamazine + Chlorpheniramine + Guaifenesin
219	Ketotifen + Cetirizine
220	Terbutaline +Bromhexine + Etofylline
221	Ketotifen + Theophylline
222	Ambroxol + Salbutamol + Theophylline
223	Cetirizine + Nimesulide + Phenylephrine
224	Chlorpheniramine + Phenylephrine + Paracetamol + Zinc Gluconate
225	Acetaminophen + Guaifenesin + Dextromethorphan + Chlorpheniramine

226	Cetirizine + Dextromethorphan + Phenylephrine + Tulsii
227	Cetirizine + Phenylephrine + Paracetamol + Ambroxol + Caffeine
228	Guaifenesin + Dextromethorphan
229	Levocetirizine + Paracetamol + Phenylephrine + Caffeine
230	Ketotifen +Levocetirizine
231	Paracetamol + Levocetirizine + Phenylephrine + Zinc Gluconate
232	Paracetamol + Phenylephrine +Triprolidine + Caffeine
233	Caffeine + Paracetamol + Phenylephrine + Cetirizine
234	Dextromethorphan + Phenylephrine + Guaifenesin
235	Ambroxol + Levocetirizine + Phenylephrine + Guaifenesin + Menthol
236	Pseudoephedrine + Cetirizine
237	Dextromethorphan + Chlorpheniramine + Ammonium Chloride + Menthol
238	Paracetamol + Caffeine + Phenylephrine + Chlorpheniramine
239	Salbutamol + Aminophylline + Guaifenesin
240	Salbutamol +Theophylline + Bromhexine
241	Chlorpheniramine + Dextromethorphan + Guaifenesin + Phenylephrine
242	Caffeine + Paracetamol + Chlorpheniramine
243	Ammonium Chloride + Dextromethorphan + Cetirizine +Menthol
244	Dextromethorphan +Paracetamol + Cetirizine + Phenylephrine
245	Chlorpheniramine +Terpin + Antimony Potassium Tartrate + Ammonium Chloride + Sodium Citrate + Menthol
246	Terbutaline Sulphate + Etofylline + Ambroxol
247	Paracetamol + Codeine + Chlorpheniramine
248	Paracetamol + Pseudoephedrine + Cetirizine +Caffeine
249	Chlorpheniramine + Ammonium Chloride + Menthol
250	N-Acetyl Cysteine + Ambroxol + Phenylephrine + Levocetirizine
251	Dextromethorphan + Phenylephrine +Triprolidine + Menthol
252	Salbutamol + Cetirizine +Ambroxol
253	Dextromethorphan + Phenylephrine + Bromhexine + Guaifenesin + Chlorpheniramine
254	Nimesulide + Cetirizine + Phenylephrine

255	Naphazoline + Chlorpheniramine +Zinc Sulphate + Boric Acid + Sodium Chloride + Chlorobutol
256	Dextromethorphan + Phenylephrine + Guaifenesin + Cetirizine + Acetaminophen
257	Guaifenesin + Bromhexine + Chlorpheniramine + Paracetamol
258	Chlorpheniramine + Ammonium Chloride + Chloroform + Menthol
259	Salbutamol + Choline Theophyllinate + Ambroxol
260	Pseudoephedrine + Bromhexine
261	Cetirizine + Phenylephrine + Paracetamol + Caffeine + Nimesulide
262	Dextromethorphan + Cetirizine + Guaifenesin + Ammonium Chloride
263	Ambroxol + Salbutamol + Choline Theophyllinate + Menthol
264	Paracetamol + Chlorpheniramine + Ambroxol + Guaifenesin + Phenylephrine
265	Chlorpheniramine + Vasaka + Tolu Balsam + Ammonium Chloride + Sodium Citrate + Menthol
266	Bromhexine + Cetirizine + Phenylephrine IP + Guaifenesin + Menthol
267	Dextromethorphan + Ambroxol + Ammonium Chloride +Chlorpheniramine + Menthol
268	Dextromethorphan + Phenylephrine + Cetirizine + Zinc + Menthol
269	Terbutaline + N-Acetyl L-Cysteine + Guaifenesin
270	Calcium Gluconate + Levocetirizine
271	Paracetamol + Levocetirizine + Pseudoephedrine
272	Salbutamol + Choline Theophyllinate + Carbocysteine
273	Chlorpheniramine + Vitamin C
274	Calcium Gluconate + Chlorpheniramine +Vitamin C
275	Chlorpheniramine + Paracetamol + Pseudoephedrine + Caffeine
276	Guaifenesin + Bromhexine + Chlorpheniramine + Phenylephrine + Paracetamol + Serratopeptidase (as enteric coated granules) 10000 SP Units
277	Paracetamol + Pheniramine
278	Betamethasone + Fusidic Acid + Gentamycin + Tolnaftate + Idochlorhydroxyquinoline (ICHQ)
279	Clobetasol + Ofloxacin + Miconazole + Zinc Sulphate
280	Clobetasol + Gentamicin + Miconazole + Zinc Sulphate
281	Levocetirizine + Ambroxol + Phenylephrine + Paracetamol

282	Permethrin + Cetrimide + Menthol
283	Beclomethasone + Clotrimazole + Neomycin + Iodochlorohydroxyquinone
284	Neomycin + Doxycycline
285	Ciprofloxacin + Fluocinolone + Clotrimazole + Neomycin + Chlorocresol
286	Clobetasol + Ofloxacin + Ketoconazole + Zinc Sulphate
287	Betamethasone + Gentamicin + Tolnaftate + Iodochlorhydroxyquinoline
288	Clobetasol + Gentamicin + Tolnaftate + Iodochlorohydroxyquinone + Ketoconazole
289	Allantoin + Dimethicone + Urea + Propylene + Glycerin + Liquid paraffin
290	Acriflavine + Thymol + Cetrimide
291	Betamethasone + Neomycin + Tolnaftate + Iodochlorhydroxyquinoline + Chlorocresol
292	Clobetasol + Neomycin + Miconazole + Clotrimazole
293	Ketoconazole + Tea Tree Oil + Allantoin + Zinc Oxide + Aloe Vera + Jojoba Oil + Lavender Oil + Soap Noodles
294	Clobetasol Propionate + Ofloxacin + Ornidazole + Terbinafine
295	Clobetasol + Neomycin + Miconazole + Zinc Sulphate
296	Beclomethasone Dipropionate + Neomycin + Tolnaftate + Iodochlorhydroxyquinoline + Chlorocresol
297	Betamethasone + Gentamycin + Zinc Sulphate + Clotrimazole + Chlorocresol
298	Borax + Boric acid + Naphazoline + Menthol + Camphor + Methyl Hydroxybenzoate
299	Bromhexine + Dextromethorphan
300	Dextromethorphan + Chlorpheniramine + Bromhexine
301	Menthol + Anesthetic Ether
302	Dextromethorphan + Chlorpheniramine + Ammonium Chloride + Sodium Citrate + Menthol
303	Ergotamine Tartrate + Belladonna Dry Extract + Caffeine + Paracetamol

304	Gliclazide 40 mg + Metformin 400 mg
305	Paracetamol + Ambroxol + Phenylephrine + Chlorpheniramine
306	Oflaxacin + Ornidazole suspension
307	Albuterol + Etofylline + Bromhexine + Menthol
308	Albuterol + Bromhexine + Theophylline
309	Salbutamol + Hydroxyethyl Theophylline (Etofylline) + Bromhexine
310	Paracetamol + Phenylephrine + Levocetirizine + Sodium Citrate
311	Paracetamol + Propyphenazone + Caffeine
312	Guaifenesin + Diphenhydramine + Bromhexine + Phenylephrine
313	Dried Aluminium Hydroxide Gel + Propantheline + Diazepam
314	Bromhexine + Phenylephrine + Chlorpheniramine + Paracetamol
315	Beclomethasone + Clotrimazole + Gentamicin + Iodochlorhydroxyquinoline
316	Telmisartan + Metformin
317	Ammonium Citrate + Vitamin B 12 + Folic Acid + Zinc Sulphate
318	Levothyroxine + Pyridoxine + Nicotinamide
319	Benfotiamine + Metformin
320	Thyroid + Thiamine + Riboflavin + Pyridoxine + Calcium Pantothenate + Tocopheryl Acetate + Nicotinamide
321	Ascorbic Acid + Manadione Sodium Bisulphate + Rutin + Dibasic Calcium Phosphate + Adrenochrome Monosemicarbazone
322	Phenylephrine + Chlorpheniramine + Paracetamol + Bromhexine + Caffeine
323	Clotrimazole + Beclomethasone + Lignocaine + Ofloxacin + Acetic Acid + Sodium Methylparaben + Propylparaben
324	Nimesulide + Levocetirizine
325	Ofloxacin + Ornidazole Injection
326	Gemifloxacin + Ambroxol
327	Glucosamine + Ibuprofen
328	Etodolac + Paracetamol





# Dilip Shanghvi: In a year and a half, pharma has darted ahead by a decade in terms of digital tools

**Dilip Shanghvi,**  
*founder and managing director, Sun Pharmaceuticals*

## Synopsis

Sun Pharma's founder says tech and biosimilars will be among the key drivers of new-age pharma. To keep pace, India needs a supportive ecosystem to nurture innovative research across all levels, he believes. This presents a big opportunity for collaboration between the industry, academia, and the government.

***“Cell and gene therapies are a subset of innovation, and each company will have to decide how to move on the innovation game. Companies can take a more classical approach to innovation, or they can take the cutting-edge route.”***

— Dilip Shanghvi, managing director, Sun Pharma

Sun Pharma's emergence as a global generic drug maker has been a journey of successes and setbacks, with the last decade being the most eventful. Founder and managing director **Dilip Shanghvi**, known for his poise, has steered India's largest pharma company past USD4 billion in annual revenue. The expectations are high. At roughly USD26 billion, Sun Pharma tops in market capitalisation among its pharmaceutical peers in the country. Its business strategies are watched closely by Street analysts more sharply than ever in its four decades of existence. In an exclusive interview with ET Prime, Dilip Shanghvi, who rarely opens up to the media, shares his views on some of the pressing issues in the industry and how Sun Pharma is readying for the future.

**The last year has been full of uncertainties. How do you see the Indian pharmaceutical industry moving from here?**

The share of Indian companies in the global pharmaceutical supply chain is increasing year after year and the industry is bound to play a larger role. In the next five years, the impact of patent expiries is estimated to be about USD166 billion. This is a big opportunity for the industry. On the India front, the economy will continue to grow because of the macroeconomic climate. The Indian government has committed to increasing public-healthcare spending as a percentage of GDP from the existing 1.15% to 2.5% by 2025. With an increasing focus on public health and the government's goal of achieving universal

healthcare across India, the domestic pharmaceutical industry will continue to grow.

**But there is a fundamental shift in the way drugs are sold now, like the larger role of online pharmacies. Do you think it may impact big brands if online pharmacies start substituting them with cheaper options or launch white-label products?**

Online pharmacies have existed in several countries for a long time and in none of those markets, they have captured a share of more than 15%. In countries such as Brazil and **Russia**, there are substitution laws, but brands continue to grow. With that as a background, I don't think there will be any major disruption. What may happen is that a certain share (of the market) will go to online pharmacies because they will grow faster.

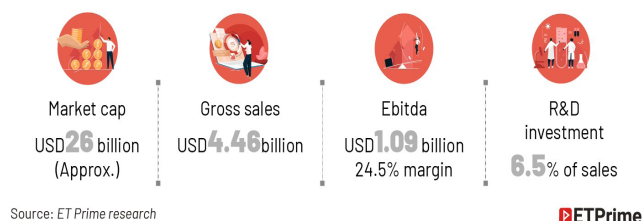
**But over time will it not mean that some big brands may get replaced with cheaper options from online pharmacies?**

This is also possible at present by the (traditional) pharmacies. If you look at the pharmacy chains run by large companies, they have their generic brands. But in my understanding, in all the pharmacy chains, the substitution component is very small. Also, the large private-distribution chains in various parts of the country are our partners and they buy our products. Therefore, the situation does not change for us.

## How do you see the reach of pharmaceutical companies to the doctors changing and what role can technology play?

In terms of digital tools, the pharmaceutical industry has been fast-forwarded a decade in the last one and a half year. Apart from virtual interactions, technology has helped us in training and connecting doctors with global experts for knowledge sharing. Some of these things are expected to continue, but there is no substitute for a face-to-face interaction with doctors.

### Sun Pharma: key numbers for FY21



## Particularly for Sun Pharma, what could have been done better since the outbreak of Covid-19?

All our businesses have done well, and we have grown in a year in which the business environment was significantly impacted because of the pandemic. There is always an opportunity to improve, and we continuously look at ways to create more value for shareholders. Looking at our performance in the first quarter of this year, I am quite happy with the overall progress.

## How do you see the Indian pharmaceutical market from the lens of global drug makers? They have been focusing on bringing their innovative products and alliances with Indian companies.

I have little understanding of how MNCs work because generally when I interact with senior MNC executives, I see that they don't look at India in the same way as they look at China. China is central and critical to their long-term growth objectives. India is not comparable, even though both countries have a similar population size.

Part of it is because of the size of the market; part of it is because of our approach to the pricing of medicines and the restrictions we have. In India, we also have a high out-of-pocket expenditure on healthcare. All of this has an impact on the growth of MNCs in India. So, I am not taking the view that MNCs are not growing because they can't, but they have to find the market attractive. Generally, in my interaction, I don't see them to be very excited about India.

## That takes me to the subject of the biosimilars opportunity that you spoke about a few months ago. How do you see this for Sun Pharma and what led to the decision now?

I see gradual clarity about substitution in biosimilars and it will become an attractive opportunity in the next few years. We are evaluating development of biosimilars which can be classified among the third wave of launches. It is a long-term initiative.

## Do you see that also as a factor of the quality perception of biosimilars?

Unfortunately, in some countries, there is still a perception that brands are better than generics. In my view, biosimilars are in no way inferior to a branded biologic product. In Europe, biosimilars are becoming substitutable. I hope that at some point, there will be a situation when biosimilars become substitutable in all major markets. Hence, the patient will have an affordable option.

## Can you please tell us a little more about your biosimilars plans?

All I can say is that it is a big and attractive segment, and we are making a conscious effort to get our feet wet.

### Bestselling drugs of 2020

Brand	Sales	Key indications	Maker/seller
Humira	20.39	Rheumatoid arthritis	AbbVie
Keytruda	14.38	Cancers	Merck, US
Revlimid	12.15	Cancers	Bristol Myers Squibb
Eliquis	9.17	Cancers	Bristol Myers Squibb/Pfizer
Imbruvica	8.43	Cancers	AbbVie/J&J
Eylea	8.36	Wet-AMD, diabetic retinopathy	Regeneron/Bayer
Stelara	7.94	Plaque psoriasis	J&J
Opdivo	7.92	Cancers	Bristol Myers Squibb
Biktarvy	7.26	HIV	Gilead
Xarelto	6.93	Stroke	Bayer/J&J

Figures in USD billion  
Source: Fierce Pharma

ETPrime

## With six of the 10 highest-selling drugs in the world coming from biotechnology research, do you see the shift steadily coming away from small molecules?

The importance of biologics has increased, and as you rightly mentioned, it is also reflected in the rankings. However, small molecules also have an important role

to play. Many indications, which in the past could be addressed only with biologics, are now being treated with small molecules, and this will continue to evolve.

**Chinese companies have moved fast on developing cell and gene therapies. Do you think Indian companies have lagged and must push harder on innovation in these areas?**

Cell and gene therapies are a subset of innovation, and each company will have to decide how to move on the innovation game. Companies can take a more classical approach to innovation, or they can take the cutting-edge route. Generally, these types of treatment options become more and more focused on a narrow set of diseases. The choice has to be made by individual companies because the opportunity will reside only in select therapy areas and those are priced in the range of a hundred thousand dollars.

**Indian companies have made joint efforts for the clinical development of molnupiravir. Will this show the way to collaborate more for research?**

All the companies that have come together are licensees of Merck, and it makes sense to work together. We are today seeing innovation across all levels of the pharmaceutical value chain. I strongly believe that collaboration between pharmaceutical companies, universities, research institutes, and the government is the way forward. This will help in creating innovation hubs across the world. Many developed nations are following this model. The recent examples are Russia's Gamaleya Research Institute and UK's Oxford University in developing Covid-19 vaccines.

**How do you see the academic side of research in India?**

There is more collaboration required between the industry, academia, and the government. We need enabling policies and a supportive ecosystem that encourages the mindset of innovative research versus iterative research — across all levels. There is also an opportunity for academic research institutes in India to collaborate with institutes abroad in basic research.

Source : Economic Times, 06.10.2021



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## An illusion that is touching

### Synopsis

The sense of touch that our brains register is actually electron repulsion and the electromagnetic field that permeates everything and everyone.

This year's Nobel Prize in Physiology, or Medicine, is truly touching. David Julius and Ardem Patapoutian have been



Ardem Patapoutian and David Julius

rewarded for their groundbreaking work on how the human nervous system senses heat, cold and mechanical stimuli. This may be something we take for granted - flinch when the fire on the

matchstick nears our fingers, flinch again when an ice cube is slid down our shirt front, scream when the hammerhead lands on our thumb instead on the nail. But how the message from that point of contact is sent to our brain, and then back again to activate our reaction, fills many gaps on how this machine called the body works. Kudos

But, as usual, we would like to think ourselves to be wiser than Nobel laureates. Thus, the question - a scientific, not a mumbo-jumbo mystical, one - do we really touch? Electrons that exist in every atom of our bodies push other electrons in every atom of other bodies or things. This electron repulsion ensures that we never touch anything, unless it punctures our body. So, what is non-pricking tactile responses? The sense of touch anything, unless it punctures our body. So, what is non-pricking tactile responses? The sense of touch that our brains register is actually electron repulsion and the electromagnetic field that permeates everything and everyone. So, don't worry about getting too close to someone or something. In the truest sense, it's nothing but an illusion, Julius and Patapoutian notwithstanding

Source : *Economic Times*, 04.10.2021



## Exporters worried about competitiveness challenge: Survey

The survey, conducted in partnership with TATA Power and ICICI Bank, pointed to energy prices, demand conditions, changes in government policies, and problems faced on refunds from government bodies as the biggest challenges in the next 6-12 months.



*Over a third of those polled said cheaper imports are acting as a hindrance to business, as per the report.*

As global trade picks up pace after the ravages of the pandemic, an industry lobby's survey has found that an overwhelming number of exporters are worried about competitiveness.

Eighty-three per cent of the respondents felt the issue of competitiveness with respect to the export market is one of the most important business challenges at present, the Bombay Chamber of Commerce and Industry said on Tuesday, pointing to a recent survey of 121 members from 11 sectors.

Over a third of those polled said cheaper imports are acting as a hindrance to business, as per the report. The report also revealed that over half of the respondents feel that the business will be impacted for a quarter as a result of the second wave.

The survey, conducted in partnership with TATA Power and ICICI Bank, pointed to energy prices, demand conditions, changes in government policies, and problems faced on refunds from government bodies as the biggest challenges in the next 6-12 months.

Banks' risk assessments of borrowers seem to have tightened, the survey report said, pointing to findings which had 46 per cent of the borrowers saying access to credit has become more difficult.



“Supportive regulatory measures by the government and providing a healthy business environment are critical for fuelling our economic growth,” the chamber’s president Anjali Bansal said.

Source : PTI, 05.10.2021



## WTO estimates global merchandise trade volume growth at 10.8% in 2021

“The WTO is now predicting global merchandise trade volume growth of 10.8 per cent in 2021-up from 8 per cent forecasted in March-followed by a 4.7 per cent rise in 2022,” it said.



It added that the large annual growth rate for merchandise trade volume in 2021 is mostly a reflection of the previous year’s slump, which bottomed out in the second quarter of 2020.

New Delhi: The World Trade Organization (WTO) has projected that the global merchandise trade volume will grow 10.8 per cent this year, higher than 8 per cent estimated in March.

Growth should moderate as merchandise trade approaches its pre-pandemic long-run trend and supply-side issues such as semiconductor scarcity and port backlogs may strain supply chains and weigh on trade in particular areas, the WTO said.

“The WTO is now predicting global merchandise trade volume growth of 10.8 per cent in 2021-up from 8 per cent forecasted in March-followed by a 4.7 per cent rise in 2022,” it said.

It added that the large annual growth rate for merchandise trade volume in 2021 is mostly a reflection of the previous year’s slump, which bottomed out in the second quarter of 2020.

“Due to a lower base, year-on-year growth in the second quarter of 2021 was 22 per cent, but the figure is projected to fall to 10.9 per cent in the third quarter and 6.6 per cent in the fourth quarter, in part because of the rapid recovery in trade in the last two quarters of 2020,” it said.

Reaching the forecast for 2021 only requires quarter-on-quarter growth to average 0.8 per cent per quarter in the second half of this year, equivalent to an annualized rate of 3.1 per cent, it added.

It also said that risks to the forecast remain on the downside, but the relative importance of those risks is difficult to gauge.

“They include spikes in inflation, longer port delays, higher shipping rates, and extended shortages of semiconductors, with supply-side disruptions being exacerbated by the rapid and unexpectedly strong recovery of demand in advanced and many emerging economies,” it said.

The pandemic itself presents potentially even bigger risks to world trade and output, particularly if more deadly variants were to emerge, the WTO said adding the highly contagious Delta variant has already prompted governments to reinstate some containment measures.

Source: PTI, 05.10.2021



## Manufacturers urge govt to lift export restrictions on non-Covid syringes

They say India’s reputation as dependable producers will be in tatters

The Centre’s decision to restrict syringe exports will put the domestic industry in an awkward situation, where international health agencies will view them as being undependable, said a nodal body for local producers.

### Notification issued

Earlier this week, the Directorate General of Foreign Trade (DGFT) had issued a notification, saying the export policy for syringes with or without needles had been amended from ‘free’ to ‘restricted’.

“It takes lots of effort and years to build credibility as a global supplier and India’s reputation as (a) manufacturing hub of syringes will be tarnished as being undependable,” said the All India Syringe & Needle Manufacturers Association, adding: “We will always prioritise domestic



needs.” To ensure there are no local shortages, on a voluntary basis, many Indian syringe manufacturers have not accepted new business export opportunities from many overseas buyers, they pointed out. In fact, HMD, for example, had advanced supply commitments to the Health Ministry and diverted the supply of 100 million pieces from a UNICEF order to the Indian government from September to December, they said.

Rajiv Nath, president of the association, urged the government to lift restrictions on non-Covid sizes of syringes like insulin syringes, 5 ml and larger syringe sizes or 0.3 ml auto-disable (AD) syringes, developed for Pfizer, which cannot be used in India for vaccination and will be a wasted capacity otherwise.

“At least 50 per cent of the quantity shipped to a country last year in October-January period of 0.5 ml / 1 ml / 2 ml & 3 ml may be allowed to be maintained,” he said, urging that a historical past performance benchmark be catered to, if rationing needed to be done.

Importantly, he said clarity was required from the Health Ministry on India’s quarterly needs for 2022, “as we can’t plan on 2-4 months window horizon basis”, he said.

“Countries are counting on India to support global immunisation / vaccination projects mainly for children for Yellow Fever or Measles, Hepatitis B, Pentavalent or BCG. Those are not the syringes used for Covax supplies of 0.5 ml AD. We cannot deprive those children from those immunisation commitments as those syringes will

anyways not be used for Covid vaccination in India and will lie unused in our factories causing us huge losses. This is our ongoing global contractual commitments to support global vaccination projects,” said Nath.

Supply chain management is currently challenged temporarily due to peak seasonal spike in demand for standard disposable syringes for dengue and typhoid, he said, adding this would ease by mid-November.

It is important for the 20-odd Indian syringe manufacturers to focus on non-Covid curative care as its first priority, followed by preventive care oriented vaccination and honour export commitments, said Vimal Khemka, Association-secretary, adding that “turning off the tap” suddenly was disruptive and would create problems for the producers choking their production lines.

“Such a situation could have been easily avoided. Now business commitments will need to be dishonoured and credibility painstakingly built over the years and India’s reputation as a dependable supplier and manufacturing hub of syringes will be in tatters,” said Khemka.

“We wish Government had called for joint meetings between vaccine manufacturers, Government and syringes and needle manufacturers to create a balance between demand and supply,” he said, besides providing timely support for capacity creation of Covid critical medical devices with PLI schemes to incentivize capacity increase.

*Source : The Hindu Business Line, 05.10.2021*



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