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Indian APIs & Formulations for Global Healthcare

INDIAN DRUG MANUFACTURERS' ASSOCIATION

HIGHLIGHTS

- ★ **A Report on the Webinar - Global Bharat = Digital Transformation Discover how you too can join the program and expand your reach to Global Markets held on 26th August 2021 from 3 p.m. to 4 p.m. (Page No. 5)**
- ★ **Central Goods and Services Tax Rules, 2017 amended (Seventh Amendment of 2021) (Page No. 20)**
- ★ **CRAMS segment boosts Indian pharma cos amid pricing pressure (Page No. 33)**
- ★ **Indian exporters allege global shipping companies are forming cartels (Page No. 39)**
- ★ **India works on multi-variant vax (Page No. 40)**

UNWAVERING ATTENTION TO DETAIL. FOR ABSOLUTE **PRECISION.**

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CASTER SUGAR (Screened Sucrose)
ALVEOSUCRE (Agglomerated Sucrose)



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NATURAL COLOURS



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IDMA BULLETIN

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IDMA's Proud Moment – Mr. B G Barve, Mr. Satish Kumar Singh and Mr. Daara B Patel being honoured by the Governor of Maharashtra

Shri Bhagat Singh Koshyari, Governor of Maharashtra, honoured the distinguished members of the society who contributed immensely during this covid-19 pandemic with **Maharashtra State Champion Awards for Corona Warriors 2020-21** at the Raj Bhavan, Mumbai on Friday 3rd September 2021.

Rotarian Mr. B G Barve, Jt. Managing Director, Blue Cross Laboratories Ltd., Mr. Satish Kumar Singh, Managing Director, Cachet Pharmaceuticals Ltd. along with Mr. Daara B Patel, Secretary – General, IDMA were felicitated by the Honourable Governor of Maharashtra.

Glimpses of the Award Ceremony:



A Report on the Webinar - Global Bharat = Digital Transformation Discover how you too can join the program and expand your reach to Global Markets held on 26th August 2021 from 3 p.m. to 4 p.m.



Global Bharat = Digital Transformation

Join us for an exclusive webinar | 26th August, 2021 | 3:00 PM - 4:00 PM

 Daara B Patel Secretary General IDMA	 Dinesh Chindarkar Co-Founder and Director MediaMedic Communications Pvt. Ltd.	 B G Barve Excise & Taxation Committee IDMA & Joint Managing Director Blue Cross Laboratories Pvt. Ltd.	 Rajendra Yeola Manager-IT Applications Shalina Laboratories Pvt. Ltd.	 Ravi Shankar Prasad Senior Manager Sales YASH Technologies Pvt. Ltd.	 Ajitkumar Salunkhe Regional Manager SAP
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 Global Bharat Movement
 



Indian Drug Manufacturers' Association and SAP organized the webinar **“Global Bharat = Digital Transformation”** on Thursday, 26th August 2021 from 3.00 p.m. to 4.00 p.m.

The webinar had an panel of elite speakers such as Mr. Daara B Patel, Secretary – General, IDMA, Mr. Dinesh Chindarkar, Co-founder & Director, MediaMedic Communications Pvt. Ltd., Mr. B G Barve, Chairman, Excise & Taxation Committee, IDMA and Joint Managing Director, Blue Cross Laboratories Pvt. Ltd., Mr. Rajendra Yeola, Manager – IT Applications, Shalina Laboratories Pvt. Ltd., Mr. Ravi Shankar Prasad, Senior Manager – Sales, YASH Technologies Pvt. Ltd. and Mr. Ajitkumar Salunkhe, Regional Manager, SAP.

There were about 75 plus participants for this webinar. Excellent & elaborate addresses by the speakers led by wonderful deliberations were the hallmark of the Webinar and indeed the success of the webinar.

Mr. Daara B Patel, Secretary – General welcomed the participants for this webinar. Mr. Patel’s welcome address is reproduced for your kind information.

Mr. Dinesh Chindarkar by his address set the tone for this exciting webinar wherein digital transformation is the key focus during this pandemic situation.

Mr. Ajitkumar Salunkhe, Regional Manager, SAP along with Mr. Rajendra Yeola, Manager – IT Applications,

Shalina Laboratories Pvt. Ltd. and Mr. Ravi Shankar Prasad, Senior Manager – Sales, YASH Technologies Pvt. Ltd. explained in the detail the benefit of the SAP's Global Bharat Program and why it is necessary to be digitally transformed so as to enable companies to reach global markets. Their Presentation is reproduced for your information.

Mr. B G Barve, Chairman, Excise & Taxation Committee, IDMA and Joint Managing Director, Blue Cross Laboratories Pvt. Ltd. summed up the proceedings very well and thanked IDMA's National President, Mr. Mahesh Doshi and Secretary – General, Mr. Daara B Patel for having innovative webinars and encouraging members to go digital. Mr. Barve's vote of thanks is reproduced for your kind information.

We reproduce the addresses / presentations made by the speakers at the webinar.

1. **Welcome address by Mr. Daara B Patel, Secretary – General, IDMA**

Good Afternoon Ladies and Gentleman!

Greetings from Indian Drug Manufacturers' Association (IDMA)& SAP.

It gives me great pleasure and honour to address the august gathering & on behalf of our National President, Mr. Mahesh H Doshi and Ms. Stella Bonela from SAP, I welcome you all to this very interesting & innovative webinar titled "**Global Bharat = Digital Transformation**". This webinar will give us insights on SAP's new initiative Global Bharat Program wherein we will discover how you too can join the program and expand your reach to global markets.

Indian Drug Manufacturers' Association (IDMA) has successfully completed 59 glorious years of its existence, providing support to its members for supplying affordable quality medicines, not only to the people of India, but also to people all over the world. The IDMA Membership consists of over 1000 plus wholly-owned Indian large, medium and small companies manufacturing Formulations & APIs. At present, we have 8 State Boards located in Tamil Nadu, Kerala & Puducherry, Gujarat, West Bengal, Haryana, Himachal Pradesh & Uttarakhand, Madhya Pradesh, Telangana & Karnataka.

IDMA publishes the IDMA Bulletin - a weekly publication for the past 51 years. Indian Drugs – a

Monthly Scientific and research publication– now in its 57th year and IDMA Annual Publication –released annually at Annual Celebrations & has completed 58 Editions.

IDMA Annual Awards

- IDMA Quality Excellence Awards
- IDMA Margi Memorial Best Patent Awards
- IDMA ACG-SCITECH Research Paper Awards
- IDMA J B Mody Best Student Awards
- IDMA Corporate Citizen Awards
- IDMA Eminent Analyst Award
- IDMA Young & Outstanding Analyst Award

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.

Global Bharat Program is the next big wave of Digital Transformation in MSME Segment in Pharma Industry.

The global crisis has forced a lot of businesses to reassess their strategies and include '**out of the box**' reforms and solution to not just sustain but grow their business.

In order to be Globally competitive, MSMEs need to think of reinventing their business models. Therefore, technology adoption should be the first step for MSMEs to be globally competitive. **Global Bharat will prove an important milestone in this journey.**

SAP has launched Global Bharat, a program designed to enable Indian MSMEs become globally competitive by equipping them with digital technologies.

The program further compliments Government of India's vision to empower MSME sector by providing them access to global marketplace, digital skilling for the workforce and transforming business processes.

We have excellent speakers from SAP, Yash Technologies and Shalina Laboratories who would give us a meticulous & all-encompassing information on this Global Bharat Program. Not to forget our own Experts, Mr. Dinesh Chindarkar & Mr. B G Barve.

I wish you all fruitful deliberations and I am sure at the conclusion of this webinar we would all be more

eager to join the program and expand our reach to global markets.

Till Then, Stay Safe, Stay Well and Stay Connected.

Thank you & Welcome

- (2) **Presentation by Mr. Dinesh Chindarkar, Co-founder & Director, MediaMedic Communications Pvt. Ltd.** (Reproduced in the following pages)
- (3) **Presentation by Mr. Ajitkumar Salunkhe, Regional Manager, SAP.** (Reproduced in the following pages)
- (4) **Summing up and Vote of Thanks by Mr. B G Barve, Chairman, Excise & Taxation Committee, IDMA and Joint Managing Director, Blue Cross Laboratories Pvt. Ltd.,**

Good Evening Everyone.

I have always felt honoured and proud to be a part of this Association which has so many various events happening for the development of its members. Today's event Global Bharat = Digital Transformation according to me is very important to the MSMEs who are planning to expand their reach to global markets.

I am privileged and glad to propose a vote of thanks on behalf of our National President, Mr. Mahesh Doshi and IDMA to the eminent speakers – Mr. Dinesh Chindarkar,

Mr. Rajendra Yeola, Mr. Ravi Shankar Prasad, Mr. Ajit Kumar Salunkhe and our dynamic & vibrant Secretary – General, Mr. Daara B Patel.

I thank Ms. Stella Bonela and her dedicated & diligent team from SAP for organising such a motivating webinar for our members. I am sure they all would now be interested to join the Global Bharat Program.

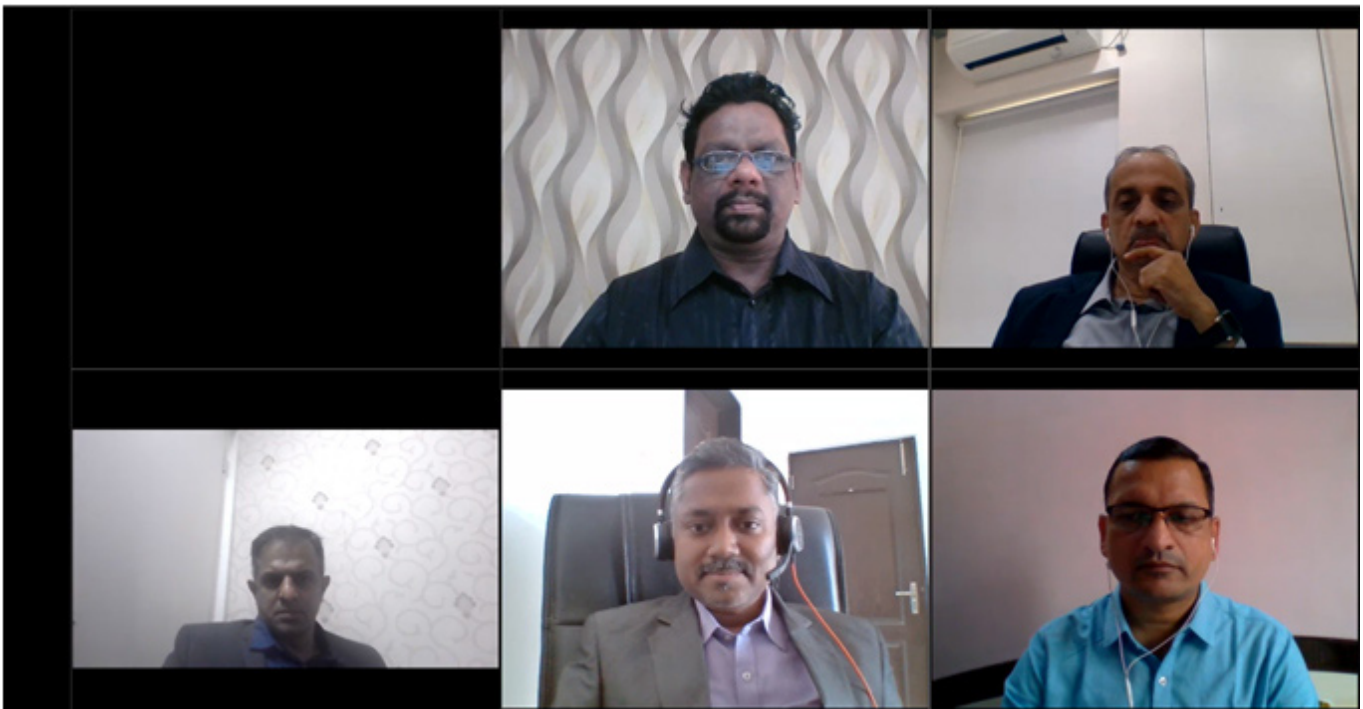
I would specially like to thank Mr. Daara B Patel for always thinking out of the box and giving IDMA members such thought provoking, innovative and educative webinars / conferences for the development of IDMA Members.

A very special thanks to all the participants for taking out valuable time and attending this webinar. I am sure you all would be enriched by the same.

We were looking forward to have physical seminars but it is not possible due to covid-19 pandemic. Till then let's enjoy the new world of **Phygital** (a combination of Physical & Digital) World.

Thank you.

For any clarifications / assistance, please free to write to IDMA Secretariat at publications@idmaindia.com / actadm@idmaindia.com





Global Bharat = Digital Transformation

Join us for an exclusive webinar |  26th August, 2021 | 3:00 PM - 4:00 PM



Daara B Patel
Secretary General
IDMA



Dinesh Chindarkar
Co-Founder and Director
MediaMedic
Communications Pvt Ltd.



B G Barve
Excise & Taxation Committee
IDMA & Joint Managing Director
Blue Cross Laboratories Pvt Ltd.



Rajendra Yeola
Manager-IT Applications
Shalina Laboratories Pvt. Ltd.



Ravi Shankar Prasad
Senior Manager- Sales
YASH Technologies Pvt Ltd.



Ajitkumar Salunkhe
Regional Manager
SAP








Global Bharat Program – For globally competitive MSMEs

Creating Robust Supply Chain




Global Market Access

Developing Talent




Workforce Skilling

Enabling Better Products




Digital Transformation



Collaboration with Partners & Government for Outreach

Onboard Indian SME's as suppliers on SAP Ariba Network that is host to transactions worth \$3.2T annually. Also help buyers find alternate suppliers.

Supply Chain Resilience with Global B2B Commerce Platform

Skill SME workforce digitally with over 150 courses on Soft Skills, Productivity, Technology etc. with Nasscom Foundation & Pratham. Delivery through 'Code Unnati Mobile App'.

Skill Workforce on Topical Content to increase their relevance & readiness in evolving environment

Affordable Cloud ERP – SAP PCE or Business ByDesign

Digital Transformation with Global Standards Systems & Processes to drive greater efficiency

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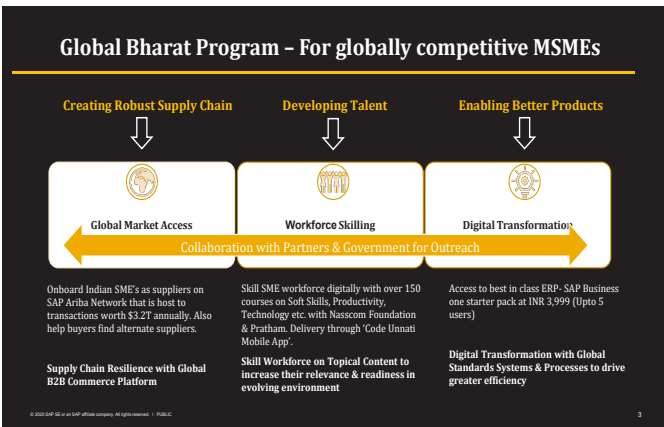
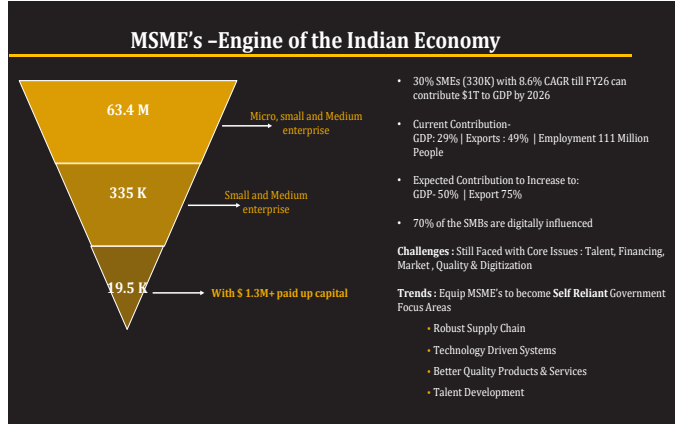
Global Bharat Program

Mr. Ajitkumar Salunkhe, *Regional Manager, SAP*



GLOBAL BHARAT PROGRAM
SAP India

THE BEST RUN SAP



Creating a Robust Supply Chain

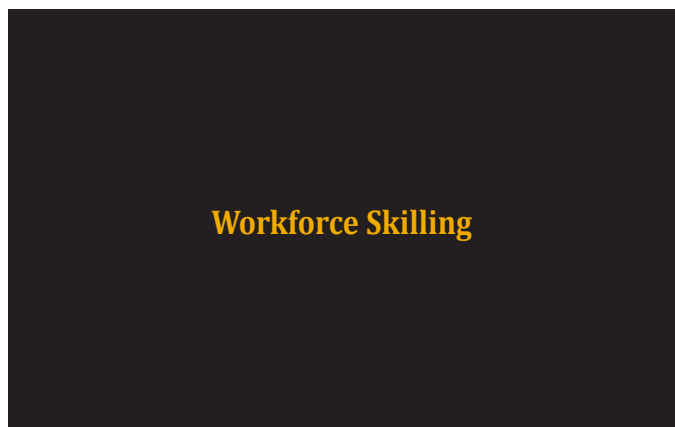
Buyers are looking for new suppliers

Disruption is the reality. Let's deal with it. Together.

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Ariba Network is the largest digital B2B marketplace where more than USD \$3.3 trillion in global commerce

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Digital Transformation

SAP Business One starter package

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Reduce IT complexity in Your Business

To reduce complexity of IT in your business, SAP Business One is offered to you on cloud which is powered by Microsoft and offered & managed by our hosting partner Uneecops Business Solutions.

SAP Business One starter package

Product Offering



SAP Business One Starter Package

SAP Business One starter package addresses fundamental business requirements with basic finance, sales, purchasing, customer relationship management, and inventory functionality.



Analytics on SAP Business One

Integrated analytics, dashboards, and reporting tools powered by SAP HANA to gain insights across financials, sales, customers, inventory, and operations.




SAP Business One Mobile App

SAP Business One mobile app helps in managing alerts & approvals, opportunities, prospects, customers, vendors, sales documents; monitoring inventory levels & price lists & viewing reports


SAP Business One starter package

Pricing




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Rs. 3,999 per user per month
Min -1 user | Max -5 Users



Implementation of SAP Business One starter


Rs.49,000 one time



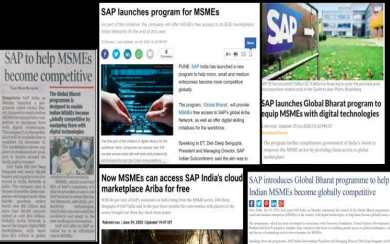
Standard Ongoing Support

Built into Pricing

Global Bharat program Launch: Globally competitive MSMEs



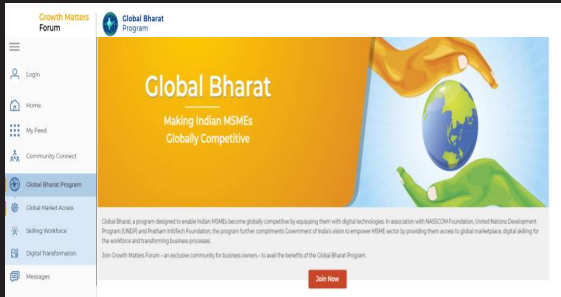
Union minister Shri Nitin Gadkari at SAP SapphireNow



Coverage by leading newspapers.

Access Global Bharat Offerings on Growth Matters Forum

An exclusive community for MSME business owners



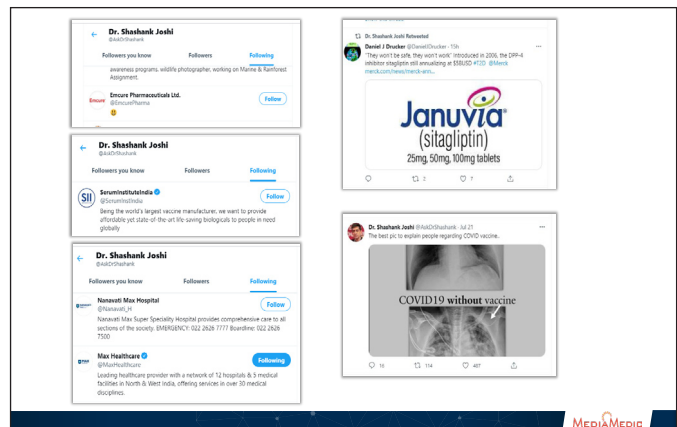
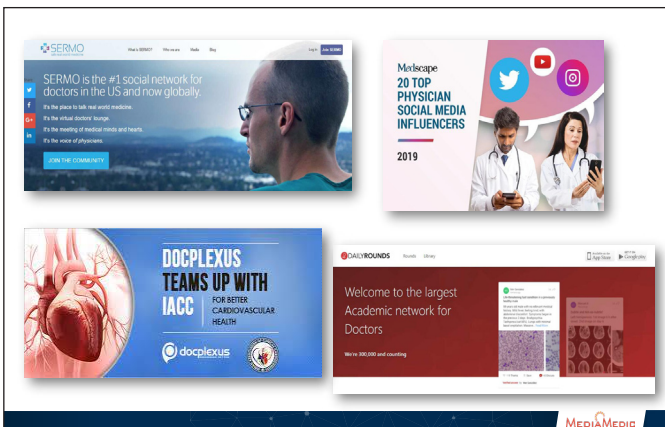
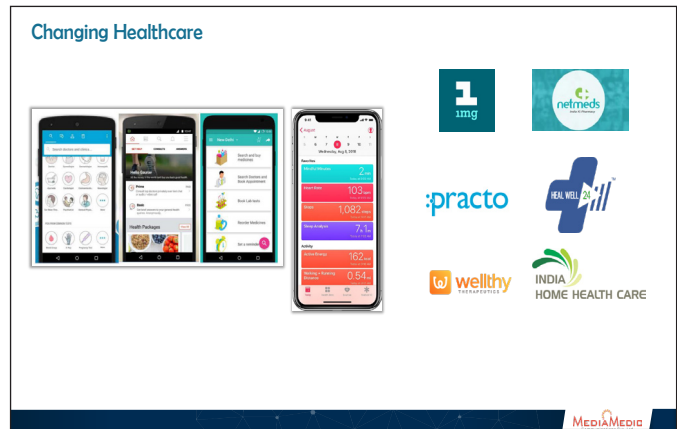
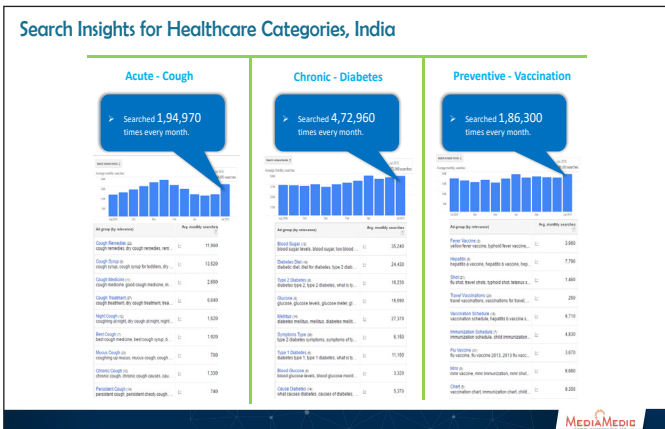
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Digital Transformation

Mr. Dinesh Chindarkar, Co-Founder & Director, MediaMedic Communications



Re-Tweets

Tweets related to newer techniques & treatments

Available brands **Associated Hospitals** **Share cases** **Collaborations**

MediaMedic

Pharmaceutical Landscape on digital media-2020

	Overall score	Aliso traffic rank	Website score (2020)	No. of country websites	Blog (27)	Asso (276)	Facebook (26)	Twitter (31)	LinkedIn (31)	YouTube (31)	Teeka (31)	Pinterest (32)	FlipK (32)	Instagram (33)	Tumblr (33)	Social channel combined (202)	
1	Abbott	4055	25361	155	19	7	125	9	7	3.5	7	0	0	1	4	0	1565
2	Pfizer	3925	28392	192.5	24	9	57	21	15	11	15	0	0	0	6	0	125
3	AbbVie	3795	51512	170	21	5	79	11	13	2.5	8	0	0	0	7	0	1205
4	AstraZeneca	3795	43688	185	23	5	72	10	13	5.5	4	0	0	0	5	0	1095
5	Novo Nordisk	373	152883	162.5	20	5	90	6	6	2.5	3	0	0	0	3	0	1105
6	MSD	3725	165888	185	23	9	53	12	20	16.5	11	0	0	0	4	0	1165
7	Sandoz	3675	93871	200	25	10	47	8	14	5.5	10	0	2	0	8	0	945
8	Boehr	3475	25482	185	23	7	45	15	13	12.5	12	0	0	0	6	0	1035
9	Roche	335	48938	197.5	24	11	17	24	14	4.5	11	0	2	0	14	0	865
10	GlaxoSmithKline	290	23961	187.5	24	6	26	10	10	5.5	7	0	1	5	4	0	845
11	Novartis	290	62566	177.5	22	7	25	11	12	8.5	7	0	0	2	8	0	755
12	Amgen	280	40067	172.5	22	6	25	11	10	7.5	5	0	1	0	8	0	675
13	Teva Pharmaceutical	255.5	221955	155	19	7	35	13	6	5.5	6	0	0	0	1	0	565
14	Boehringer Ingelheim	243.5	77980	155	19	5	13	15	14	3.5	7	0	7	0	6	0	655
15	Takeda	237.5	114357	140	17	6	35	0	6	6.5	2	0	0	0	1	0	505
16	Johnson and Johnson	236	12584	162.5	20	2	17	15	6	3.5	5	0	1	1	4	0	525
17	Biogen Inc	234	143444	132.5	16	2	40	6	6	2.5	2	0	0	0	1	0	575
18	Amgen	224.5	116181	150	19	7	15	8	9	4.5	6	0	0	0	3	0	455
19	Astellera Pharma	217.5	277770	155	19	4	19	0	4	6.5	0	0	0	0	0	0	295
20	Merck	217.5	222248	170	21	6	19	2	4	5.5	3	0	0	0	0	0	235
21	Cellgene	212	79599	142.5	18	3	16	8	8	5.5	5	0	0	0	0	0	425
22	Actavis International	211.5	129621	162.5	20	4	0	8	5	5	3	0	1	0	1	0	32
23	Intand Myers Squibb	206	48719	142.5	18	5	13	4	7	3.5	2	0	1	0	3	0	355
24	Glaxo Sciences	87	65101	52.5	6	1	9	5	5	2.5	2	0	0	0	0	0	235

MediaMedic

Traditional sales model needs a revamp

Increasing number of reps and brands is reducing access to time-stapped physicians. Thus, commanding a high share of voice is becoming increasingly difficult.

Digital economy changing behavior

Patients and physicians translate their experiences from online consumerism into expectations for pharma services.

Personalized
Convenient
Engaging

"Customer engagement is the new battle ground"

Transparent
Trustworthy
Easy to deal with
Relevant

New competitive environment

Increasing number of players engaging via digital. Rise of digital start-ups may challenge pharma's value creation story in the healthcare ecosystem.

Expanding customer landscape with distinct needs

There is now a broader and more diverse group to engage with, moving from only physicians to also including patients, pharmacists and hospital chains.

MediaMedic

MediaMedic

The Challenge

MIGRAINE STATUS IN INDIA

90 million Migraine sufferers in India <20% seek medical treatment Only 8 million complete treatment

INSIGHTS

I am not myself when I get migraine issues:

- People equate Migraine to mere headache and self-medicate
- Lack of awareness and apathy are main barriers towards treatment
- Lot of myths exist with respect to migraine

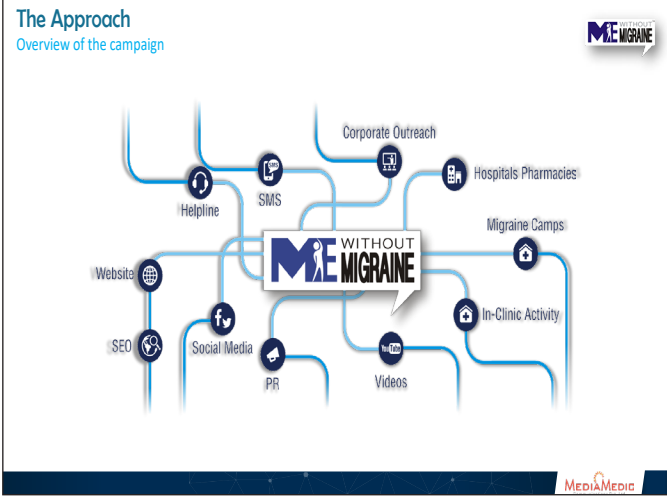
CAMPAIGN INTRODUCTION

- Company leader in Migraine Prophylaxis entered in India. Wanted to increase the size of the pie, expand category, consolidate and grow their position.
- MediaMedic Communications was appointed to expand category, consolidate and grow their position
- Launched Me without Migraine by integrating the digital medium for a medical category for the first time in India.

OBJECTIVES

- Create awareness on Migraine and importance of treatment
- Add value by providing access to information to facilitate call for action
- Create a network to influence the thoughts and actions of those who are seeking help

MediaMedic



1. Virtual Reality & Augmented Reality

Logo: **Uhlmann**

Text: **VIRTUAL REALITY AND AUGMENTED REALITY**
SPECIFIC APPLICATIONS IN PHARMACEUTICAL PACKAGING

Logo: **MEDIA MEDIC**

2. Artificial Intelligence

Novartis uses AI to predict untested components researchers should explore to find new cures

Verge Genomics uses AI to predict the effect of new treatments for patients suffering from ALS & Alzheimer's

AstraZeneca and Alibaba build AI to help patients with automated cancer diagnostics

Bayer and Merck & Co uses AI algorithms to identify pulmonary hypertension

Logo: **MEDIA MEDIC**

3. Omnichannel Marketing

Logo: **MEDIA MEDIC**



Thank You

Logo: **MEDIA MEDIC**

National Safety Calendar & HSE Diary- 2022

राष्ट्रीय सुरक्षा परिषद्
मुख्यालय, एवं संस्थान भवन
98-ए, सेक्टर 15, संस्थान क्षेत्र
सीबीडी बेलापुर, नवी मुंबई – 400 614



National Safety Council
Hqs. & Institutional Building,
98-A, Sector-15, Institutional Area,
C.B.D. Belapur, Navi Mumbai - 400 614.

Ref.No.NSC/Cal-Dia/2022

Date: 27st July, 2021

TO ALL MEMBERS AND PATRONS

Sub: National Safety Calendar & HSE Diary – 2022

Dear Sir(s),

National Safety Council was set up by Ministry of Labour, Government of India on 4th March 1966 to generate, develop and sustain a voluntary movement of Safety, Health and Environment (SHE) at national Level. NSC has been developing and producing **National Safety Calendar** and **HSE Diary**, which has been well recognised by Industry, Govt. Departments and other institutions as an effective and unique medium of promoting safety awareness and enhancing safety culture throughout the year amongst workers and others.

You will be happy to know that the **National Safety Calendar** (for the 43rd consecutive year), **Desk Calendar** (for the 3rd consecutive year) and **HSE Diary** (for the 25th consecutive year) for the year 2022.

NSC has decided to dedicate the National Safety Calendar- 2022 on safety measures for on **Infectious Diseases at Workplace** and would accordingly depict important aspects related to safety, health, hygiene at workplace..

As in past, the Diary-2022 will also have information on important HSE areas.

For placing orders in advance, 'Order Forms' for **National Safety Calendar & Desk Calendar** and **HSE Diary-2022** along with rates, an early bird discount, terms & conditions, printed on its overleaf are enclosed. Kindly place your firm order immediately by returning the Order Form duly filled in along with full advance payment.

The **last date** for accepting the orders **with early bird discount is 31st October, 2021** and **without discount 30th November, 2021**.

Thanking you and looking forward to receive your valuable order.

Yours faithfully,

R. R. Deoghare
Director

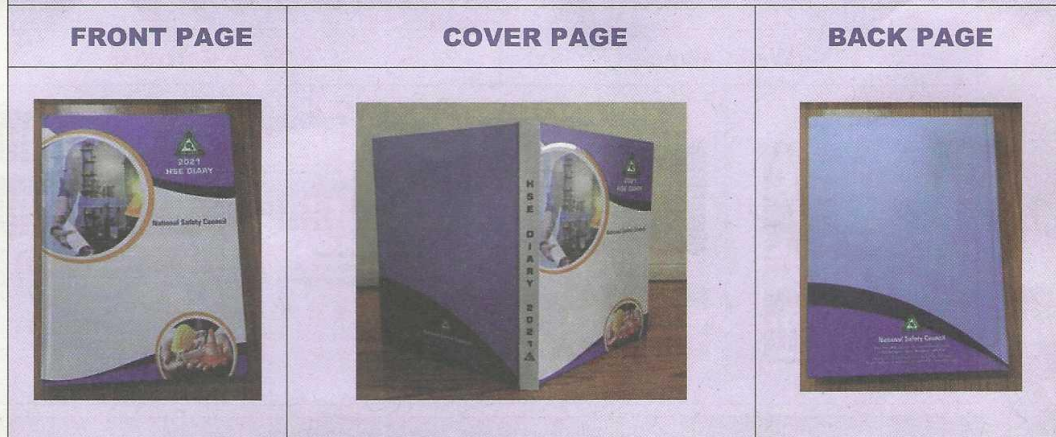
Encl: As Above

RUSH YOUR ORDER

Contacts Numbers ■ Tel. : 022-27522875 / 27522878 / 27522871 ■ Email : safetypromotion@nsc.org.in
Tel. Board No. : 022-2757 9924 / 25 / 26 / 27522801 ■ Fax No. : 022-2757 6411 ■ Website : <https://nsc.org.in>

HEALTH, SAFETY & ENVIRONMENT (HSE) DIARY- 2022

IMAGES OF LAST YEAR DIARY



TOPICS OF INFORMATION SECTION

- List of Laws & Regulations Relating to HSE
- The Occupational Safety, Health and Working Conditions Code, 2020 – Highlights
- Drone Use – Safety & Legal Requirements
- Remedial measures suggested by the Committee of Styrene Gas Leak to avoid such accidents
- Safety Signs and Colours – Communication Tools
- Safety in Commercial & Retail Sectors
- Industry 4.0 and OSH Challenges
- Use of Virtual Reality in Safety
- Safety in Hotel Kitchens
- Electrical Maintenance Work – Safety Procedure
- Electrical Safety at Construction Sites
- Prevention of Covid-19 at Workplace
- Preventive Medical Check-up during Covid-19 Pandemic
- Hospital Fire Safety
- Safe Usage of Oxygen in Hospitals – Tips
- IS 17512 : 2021 - Requirement for Electrical Installations in Medical Locations – Highlights
- Medical Surveillance Guidelines for Food Handlers
- Electrical Safety at Home
- Causes wise Road Accidents during the year 2019
- Accident Trends in Factories from 2016 to 2019

PRINTING OF COMPANY NAME AND LOGO ON HSE DIARY

Organisation's name (2 lines only) and logo will be printed only on the Cover Page of the Diary for the order exceeds 200 Nos. of Diaries. Please refer the terms and conditions Pt. No.4c & 4d.

MECHANICAL DATA

Binding :	Head-bound section sewing with page marker	Cover :	Hard Board with velvet lamination
Size :	:9½" x 7"	Process :	Multicolour Photo Offset
Paper :	Super sunshine	No. of Pages :	Approx. 230 out of which 70 text pages including HSE information & balance of Dates (2 on each page)

National Safety Calendar- 2022

IMAGES OF LAST YEAR CALENDAR



SALIENT FEATURES

	Wall Calendar	Desk Calendar
Technical Themes	Messages on Safety measures for Infectious Diseases at Workplace and would accordingly depict important aspects related to safety, health, hygiene at workplace.	
Information Sheet	On topic “Control of Infectious Diseases at the Workplace”	-
Language	In bi-lingual i.e. English & Hindi	
<ul style="list-style-type: none"> • Date Pads, Dialog in Cartoon/Picture and Safety Information Sheet • Messages / Caption 	In bi-lingual i.e. in English-Hindi. For more details see our terms and conditions.	
Printing of Company Name and Logo	Organisation's name (2 lines only) and logo will be printed only on the “Flyleaf and Information Sheet” for the order exceeds 500 Nos. of Wall Calendar	Organisation's name (2 lines only) and logo will be printed only on the “Plain Stand” for the order exceeds 100 Nos. of Desk Calendar.

MECHANICAL DATA

	Wall Calendar	Desk Calendar
Flyleaf / Information Sheet Size (14" x 22")	One Sheet Printed in one colour	-
Other Sheets Size	14" x 19"	8.5" x 7.7"
No. of Sheets	3 Sheets Printed in multi colour cartoons on both sides with date pads	4 Sheets Printed in multi colour cartoons on both sides with date pads
Paper	Art Paper (White)	Art Card
Printing Process	Offset	Offset
Binding	Metal Strip	Plain stand with Metal Wiro Binding
Plain Stand	-	Tuffex Board

NOTE: Please fill the details of "Billing & Delivery Address, Delivery Option, Quantity, Details of Printing Matter & Logo, etc." in the provided blank field.

ORDER FORM - NATIONAL SAFETY WALL CALENDAR, DESK CALENDAR AND HSE DIARY - 2022										Page - 1			
BILLING ADDRESS (* Fields are Mandatory)					DELIVERY ADDRESS (* Fields are Mandatory)								
Name of the Person					Name of the Person								
Designation					Designation								
Organisation Name*					Organisation Name								
Address *					Address								
Post Office *					Post Office *					STD Code			
Pin *					Pin *					Phone No.			
District *					District *					Mobile No. *			
State *					State *					E-mail ID			
NSC Membership No. *					NSC Membership No. *					Organisation's GST No. *			
NOTE: If the organisation is local under SEZ area and exempted from GST then provide the SEZ certificate along with the order and if the SEZ certificate not provided along with the order, GST will be applicable and payable by you.													
1) Special Early Bird Discount: For the orders whose orders received before 31st October, 2021 with full advance payment. a) For NSC Members: 10% discount will be applicable on orders whose Cost of Material (Calendar and or Diary) exceeds Rs.20,000/- (i.e. Total of Column No.8 of the Order From) b) For NSC Non-Members: 5% will be applicable on orders whose Cost of Material (Calendar and or Diary) exceeds Rs.20,000/- (i.e. Total of Column No.8 of the Order From) c) Kindly note that no discount will be admissible if the cost of material is less than Rs.20,000/- or full advance payment is not made along with the order and the received after 31st October, 2021.													
2) Collection Discount: A collection Discount of 5% will be applicable on 'Cost of the Calendars & or Diary' (total of Column No.8) only if the Calendars/Diary are collecting from the Council's Office at CBD Balapur. Also on receipt of our intimation, arrange to collect the same from Council's office.													
3) Packing and Forwarding Charges: The rates of the items are inclusive of packing and forwarding charges.													
QUANTITY REQUIRED DETAILS													
Sl. NO.	ITEM NAME	LANGUAGE	HSN CODE	QUANTITY REQUIRED	UNIT	PRICE [Rs.]	COST OF MATERIAL [5 x 7]	DISCOUNT [Refer T & C for applicability] (%)	DISCOUNT Amount [8 x 9]	NET COST [8 - 10]	GST %	GST AMOUNT [11 x 12]	TOTAL AMOUNT [11 + 13]
1	National Safety Wall Calendar - 2022 : - Orders should be for minimum quantity of 10 Nos. and in multiples of 10 Nos. - The Captions for the Pictures / Cartoons and date pad will in English and Hindi language only.	Eng. Hindi	49100010	5	6	7	55.00	9	10	11	12	13	14
2	National Safety Wall Calendar - 2022 with Printing of Company's Name & Logo : - Orders should be for minimum quantity of 500 Nos. and in multiples of 10 Nos. - Organisation's name (2 lines only) and logo will be printed only on the 'Flyleaf and Information Sheet'.	Eng. Hindi	49100010	1	1	65.00					12%		

ORDER FORM - NATIONAL SAFETY WALL CALENDAR, DESK CALENDAR AND HSE DIARY - 2022

QUANTITY REQUIRED DETAILS

SL. NO.	ITEM NAME	LANGUAGE	HSN CODE	QUANTITY REQUIRED	UNIT	PRICE [Rs.]	COST OF MATERIAL [₹ x 7]	DISCOUNT [Refer T & C for applicability (%)]	DISCOUNT Amount [₹ x 9 / 100]	NET COST [8 - 10]	GST %	GST AMOUNT [11 x 12]	TOTAL AMOUNT [11 + 13]
1													
2													
3	National Safety Desk Calendar - 2022 : - Orders should be for minimum quantity of 10 Nos. and in multiples of 10 Nos.	Eng. Hindi	49100010			100.00					12%		
4	National Safety Desk Calendar - 2022 With Printing of Company's Name & Logo - Orders should be for minimum quantity of 100 Nos. and in multiples of 10 Nos. - Organisation's name (2 lines only) and logo will be printed only on the "Plain Stand".	Eng. Hindi	49100010			110.00					12%		
5	HSE DIARY - 2022 (size - 9 x 7") : Logo : - Organisation's name (2 lines only) and logo will be printed only for the order exceeds 200 Nos. of HSE Diaries..	Eng.	48209090			280.00					15%		
6	HSE DIARY - 2022 with printing of Company Name & Logo : - Organisation's name (2 lines only) and logo will be printed only for the order exceeds 200 Nos. of HSE Diaries..	Eng.	48209090			300.00					15%		
TOTAL						B/F ...							

PAYMENT DETAILS :	Mode (Cheque / DD / Bank Transfer / Cash)	Cheque / DD / UTR or Transaction No.	Date	Amount Paid	Less : TDS (if deducted) - Refer T & C clause 2 (iii-c) :	TOTAL AMOUNT :

Amount in words (Rupees) -

PRINTING OF COMPANY'S NAME & LOGO : Printing matter (in two lines only). Also separately provide soft copy of the logo preferably in JPEG or PDF format.

Line 1

For Wall Calendar

For Desk Calendar

For HSE Diary

Line 2

For Wall Calendar

For Desk Calendar

For HSE Diary

Order Placed by:

Signature :

Name & Design:

Office Stamp & Full Address:

MAIL THIS COPY TO

National Safety Council,
Plot No.96/A, Institutional Area,
Sector 15, C.B.D. Belapur
Navi Mumbai - 400 614
Maharashtra

NSC Contact Details :

Telephone No. : 022-2757 99 24
Direct No. : 022-2752 2879 / 2878 / 2871
Fax No. : 022-2757 64 11
E-mail : safetypromotion@nsc.org.in
Web site : https://nsc.org.in
GST No. : 27AAATN3068N1Z4

Terms and Conditions

1) GENERAL :

- a) The order once placed cannot be cancelled.
- b) **The minimum quantity order should be 10 Numbers and in multiples of 10 Nos. for Wall Calendars and Desk Calendars.**
- c) The dispatch of orders for Calendars and Diaries will start from first week of December, 2021 and will be executed on 'first-come-first-served' basis.
- d) Any complaint regarding non-receipt/short supply of the materials should be made within a month from the date of dispatch of materials. Also complaint of receipt of damaged material should be informed immediately along with photo copies of the damaged material & a copy of Invoice/Delivery Challan received along with material. Complaints received thereafter will not be entertained.
- e) The last date for receipt of orders with full advance payment is 30th November, 2021. The orders received thereafter may be executed subject to availability of the Calendar and Diaries.

2. PAYMENT, DISCOUNT & TAXES :

i) PAYMENT :

- a) Orders will be executed only after receipt of payment.
- b) The order must be accompanied with full advance payment accompanied with applicable GST by Demand Draft or at par Cheque drawn in favour of "National Safety Council" payable at Mumbai. Payment will also be accepted by EFT or RTGS, in such case details of the payment made must be submitted along with the Order Form or to be sent to NSC by email (safetypromotion@nsc.org.in). Our Bank details for EFT Payment is as follows :

Name & Address of Bank	Title of Account in the Bank : National Safety Council
Bank of India	Account type & Code : Current Deposit (11)
Plot No.11, Sector11,	Bank Account Number : 01162010005233
C.B.D. Belpaur,	Bank Branch MICR Code : 400013106
Navi Mumbai-400614	Bank Branch IFSC Code : BKID0000116
	Permanent Account Number : AAA TN 3069 N
	GST Number : 27AAATN3069N1Z4

- c) In case of receipt of less/excess payment, the quantity of the Calendar and Diary ordered will be adjusted accordingly.

ii) DISCOUNT :

- 1) **Special Early Bird Discount** : For the orders whose orders received before 31st October, 2021 with full advance payment.

a) For NSC Members :

10% discount will be applicable on orders whose Cost of Material (Calendar and or Diary) exceeds Rs.20,000/- (i.e. Total of Column No.8 of the Order Form)

b) For NSC Non-Members : 5% will be applicable on orders whose Cost of Material (Calendar and or Diary) exceeds Rs.20,000/- (i.e. Total of Column No.8 of the Order Form)

Kindly note that no discount will be admissible if the cost of material is less than Rs.20,000/- or full advance payment is not made along with the order is received after 31st October, 2021.

- 2) **Collection Discount : 5% will be applicable on 'Cost of the Calendars & or Diary' (total of Column No.8) only if the Calendars/Diary are collecting from the Council's Office.** In case you are collecting the Calendar & Diary from Council's office please mention 'Y' in column provided in the Order Form. Also on receipt of our intimation, arrange to collect the same from Council's office.

iii) TAXES :

- a) GST will be applicable as per the GST rates mentioned in the 'Order Form'.
- b) If the organisation is locating under SEZ area and exempted from GST then provide the SEZ certificate along with the order. If the SEZ certificate not provided along with the order GST will be applicable and will be paid by you.
- c) If TDS is deducted, the TDS certificate should be sent within a period of one month from the end of the month during which the credit has been given or the payment has been made.

3. MODE OF DESPATCH & POSTAGE :

- a) All rates are inclusive of packing and forwarding charges.
- b) The Calendars/Diaries will be sent by surface mode through our official courier i.e. Blue Dart, TCI Express and Professional Couriers and if their services are not available in your region it will be sent by Registered Post.
- c) Bulk or voluminous orders will be dispatched through road transport.

4. PRINTING OF COMPANY'S NAME & LOGO :

- a) **Wall Calendar** : Printing of **Company's name (2 lines only) & logo will be done on the 'Flyleaf and Information Sheet' for the order exceeds 500 nos.** of the National Safety Wall Calendar. Printing of Company's name and logo will not be done on the orders less than 500 Nos. of National Safety Wall Calendar and for the captions in other languages.
- b) **Desk Calendar** : Printing of **Company's name (2 lines only) & logo will be done on the "Plain Stand" of the Desk Calendar (Print Area - 1.5' x 7.5" inches only at the bottom) for the order exceeds 100 nos.** Printing of Company's name and logo will not be done on the orders less than 100 Nos. for Desk Calendar.
- c) **HSE Diary** : Screen Printing of **Company' name (2 lines only) & logo will be done on the 'Cover Page' of the HSE Diary for the order exceeds 200 nos.** of Diary. Printing of Company's name and logo will not be done on the orders less than 200 Nos. for HSE Diary.
- d) Company's name & Logo should be sent along with the order (preferably a soft copy in PDF / JPEG format).

Central Goods and Services Tax Rules, 2017 amended (Seventh Amendment of 2021) - reg.

Notification No. G.S.R.598(E), 32/2021-Central Tax, dated 29th August, 2021

In exercise of the powers conferred by section 164 of the Central Goods and Services Tax Act, 2017 (12 of 2017), the Government, on the recommendations of the Council, hereby makes the following rules further to amend the Central Goods and Services Tax Rules, 2017, namely:-

1. Short title and commencement.

- (1) These rules may be called the Central Goods and Services Tax (Seventh Amendment) Rules, 2021.
- (2) Save as otherwise provided in these rules, they shall come into force on the date of their publication in the Official Gazette.

2. In the Central Goods and Services Tax Rules, 2017,-

- (i) in sub-rule (1) of rule 26, -
 - (a) in the fourth proviso, for the figures, letters and words "31st day of August, 2021", the figures, letters and words "31st day of October, 2021" shall be substituted;
 - (b) with effect from the 1st day of November, 2021, all the provisos shall be omitted;
- (ii) with effect from the 1st day of May, 2021, in rule 138E, after the fourth proviso, the following proviso shall be inserted, namely:-

"Provided also that the said restriction shall not

apply during the period from the 1st day of May, 2021 till the 18th day of August, 2021, in case where the return in FORM GSTR-3B or the statement of outward supplies in FORM GSTR-1 or the statement in FORM GST CMP-08, as the case may be, has not been furnished for the period March, 2021 to May, 2021.";

(iii) in FORM GST ASMT-14, -

- (a) after the words, "with effect from -----", the words, "vide Order Reference No. -----, dated -----" shall be inserted;
- (b) the words, "for conducting business without registration despite being liable for registration" shall be omitted;
- (c) at the end after "Designation", the word "Address" shall be inserted.

F.No.CBIC-20006/24/2021-GST

Rajeev Ranjan, Under Secretary, Central Board of Indirect Taxes and Customs, Ministry of Finance, Department of Revenue, New Delhi.

Note: The principal rules were published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i) vide notification No.3/2017-Central Tax, dated the 19th June, 2017, published vide number G.S.R. 610(E), dated the 19th June, 2017 and were last amended vide notification No.30/2021-Central Tax, dated the 30th July, 2021 vide number G.S.R. 517 (E), dated the 30th July, 2021.



Seeks to extend FORM GSTR-3B late fee Amnesty Scheme from 31.08.2021 upto 30.11.2021 - reg.

Notification No. G.S.R.599(E), 33/2021-Central Tax, dated 29th August, 2021

In exercise of the powers conferred by section 128 of the Central Goods and Services Tax Act, 2017 (12 of 2017), the Government, on the recommendations of the

Council, hereby makes the following further amendments in the notification of the Government of India in the Ministry of Finance (Department of Revenue), No.76/2018-Central

Tax, dated the 31st December, 2018, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i) vide number G.S.R.1253(E), dated the 31st December, 2018, namely:–

In the said notification, in the ninth and tenth provisos, for the figures, letters and words “31st day of August, 2021”, where ever they occur, the figures, letters and words “30th day of November, 2021” shall be substituted.

F.No.CBIC-20006/24/2021-GST

Rajeev Ranjan, Under Secretary, Central Board of Indirect Taxes and Customs, Ministry of Finance, Department of Revenue, New Delhi.

Note: The principal notification No.76/2018-Central Tax, dated 31st December, 2018 was published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i) vide number G.S.R.1253(E), dated the 31st December, 2018 and was last amended vide notification number 19/2021-Central Tax, dated the 1st June, 2021, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i) vide number G.S.R. 363(E), dated the 1st June, 2021.



Seeks to extend timelines for filing of application for revocation of cancellation of registration to 30.09.2021, where due date for filing such application falls between 01.03.2020 to 31.08.2021, in cases where registration has been canceled under clause (b) or clause (c) of section 29(2) of the CGST Act - reg.

Notification No. G.S.R.600(E), 34/2021-Central Tax, dated 29th August, 2021

In partial modification of the notifications of the Government of India in the Ministry of Finance (Department of Revenue), No.35/2020-Central Tax, dated the 3rd April, 2020, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), vide number G.S.R.235(E), dated the 3rd April, 2020 and No.14/2021-Central Tax, dated the 1st May, 2021, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), vide number G.S.R. 310(E), dated the 1st May, 2021, in exercise of the powers conferred by section 168A of the Central Goods and Services Tax Act, 2017 (12 of 2017) (hereafter in this notification referred to as the said Act), read with section 20 of the Integrated Goods and Services Tax Act, 2017 (13 of 2017), and section 21 of the Union Territory Goods and Services Tax Act, 2017 (14 of 2017), the Government, on the recommendations

of the Council, hereby notifies that where a registration has been cancelled under clause (b) or (c) of sub-section (2) of section 29 of the said Act and the time-limit for making an application of revocation of cancellation of registration under sub-section (1) of section 30 of the said Act falls during the period from the 1st day of March, 2020 to 31st day of August, 2021, the time-limit for making such application shall be extended up to the 30th day of September, 2021.

F.No.CBIC-20006/24/2021-GST

*Rajeev Ranjan,
Under Secretary,
Central Board of Indirect Taxes and Customs,
Ministry of Finance,
Department of Revenue,
New Delhi.*



In Lok Sabha & In Rajya Sabha

Lok Sabha

Measures announced for MSME Sector

Lok Sabha Starred Question No. *185

Shri Annasaheb Shankar Jolle

Shri B.Y Raghavendra

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

- a) whether the measures announced so far to boost diverse sectors of economy also benefit Micro, Small and Medium Enterprises (MSMEs) sector which has been hit hard by the COVID-19 Pandemic;
- (b) if so, the details thereof;
- (c) the exact measures taken for MSMEs rejuvenation including the exports;
- (d) whether integrating MSMEs into larger industries' logistical chains has been envisaged for efficiency gains; and
- (e) if so, the details thereof and if not, the reasons therefor?

Answered on 02nd August 2021

A. (a) to (e): A statement is laid on the Table of the House

Statement as referred to in reply to Lok Sabha Starred Question No. *185 for answer on 02.08.2021 regarding "Measures announced for MSME Sector" by SHRI ANNASAHEB SHANKAR JOLLE and SHRI B.Y RAGHAVENDRA

(a) to (c):

- I. Yes sir, the measures announced so far include various long-term schemes/ programmes/ policies, which aim to benefit Micro, Small and Medium Enterprises (MSMEs) also which are affected by COVID-19. Outcomes of these measures will be visible over a period of time. Details of key schemes recently announced so far related to MSME under Atmanirbhar Bharat, Budget for 2021-22 and recent financial package announced by Government in June 2021 are provided at Annex-1.

- II. Multiple measures have been taken to support MSMEs, including their exports. MUDRA provides refinance support to Banks / MFIs / NBFCs for lending to micro units having loan requirement upto 10 lakh under the Scheme of Pradhan Mantri MUDRA Yojana. Government has launched schemes such as Credit Guarantee Scheme for providing access to credit to Micro and Small Enterprises, SFURTI scheme to organize the traditional industries and artisans into clusters to make them competitive, Cluster Development Programme for providing infrastructure support and enhance the competitiveness of Micro and Small Enterprises, providing skilled manpower to the industry, design and manufacturing of quality tools through Tool Rooms/Technology Centres etc. In addition to this, Ministry of MSME is implementing International Cooperation scheme to facilitate the MSMEs business delegations to visit / participate in international exhibitions/ trade fairs etc., of other countries for exploring new areas of technology infusion/ up-gradation, facilitating of joint ventures, improving market for MSMEs products, foreign collaborations amongst others. Government is also implementing the Niryat Bandhu Scheme for mentoring new and potential exporter on the intricacies of foreign trade through counselling, training and outreach programmes. MSME clusters' have been identified, based on the export potential of the product and the density of industries in the cluster, for focused interventions to boost exports.

- III. Interest Equalization Scheme (IES) provides exporters a cheaper source of rupee credit for pre-shipment and post-shipment activities. Presently IES covers 416 ITC-HS tariff lines at 4 digits at 3% subvention rates for merchants and manufacturer exporters, and all tariff lines with 5% rates for MSMEs. The Scheme has been extended till September 30, 2021.

- IV. RBI has taken several monetary and liquidity measures to keep the flow of credit uninterrupted to the productive sectors of the economy, including MSMEs. Some of these measures are listed in Annex-1 (D). Overall, the RBI has since February 2020 announced liquidity enhancing measures worth ₹17.2 lakh crore (8.7 per cent of nominal GDP of 2020-21).

(d) to (e):

MSMEs in general and especially in the manufacturing sector are linked to the logistical supply chain of larger industries as most of such units function as ancillary suppliers or vendors. This is also evident from the fact that the concentration of MSME is generally higher in the areas with higher industries base. Government of India is also working in this direction of integrating MSMEs with logistical supply chain of larger industries, by organizing Vendor Development Programmes in large organization/PSUs, helping MSMEs in the procurement of raw material, implementation of Public Procurement Policy, etc. In this regard, the Public Procurement Policy for Micro and Small Enterprises (MSE) Order 2012 had mandated every Central Ministry/Department/PSU to set an annual goal for procurement of minimum 25% from the MSE sector. Total number of 149 CPSEs have uploaded details for 2020- 2021. The share of purchases from all MSEs amounts to Rs. 40442.86 crore (174701 MSEs benefited) which work out to be 28.12% of the total procurement. In addition, the Public Preference (Make in India) Order 2017 has mandated manufacturing, production of goods and services in India, in which preference for local manufacturers and service providers and local content requirement is supporting public procurement from local suppliers, especially by MSMEs.

Annex – I

Measures taken so far to support MSMEs

A. Atmanirbhar Bharat

1. ₹ 3 lakh crores Collateral-free Automatic Loans for Businesses, including MSMEs: The Emergency Credit Line Guarantee Scheme (ECLGS) has been formulated as a relief measure to MSMEs by providing them additional funding of up to ₹ 3 lakh crore in the form of a fully guaranteed emergency credit line. Borrowers with up to ₹ 25 crore outstanding and ₹ 100 crore turnover are eligible. This scheme provides 100 per cent credit guarantee cover to Banks and NBFCs on principal and interest. No guarantee fee, no fresh collateral is required.
2. ₹ 20,000 crore Subordinate Debt for Stressed MSMEs: Provision made for ₹ 20,000 crore subordinate debt for MSMEs which are NPAs or are stressed. Government to support them with ₹4,000 crore to Credit Guarantee Trust for Micro and Small enterprises (CGTMSE). Banks are expected to

provide the subordinate-debt to promoters of such MSMEs equal to 15 per cent of the existing stake in the unit subject to a maximum of ₹ 75 lakhs.

3. ₹50,000 crores equity infusion through MSME Fund of Funds: Government to set up a Fund of Funds with a corpus of ₹ 10,000 crore that will provide equity funding support for MSMEs. The Fund of Funds shall be operated through a mother and a few daughter funds. It will provide equity funding for viable MSMEs. This scheme will help MSMEs to expand its size and capacity and will also encourages them to get listed on stock exchanges.
4. New definition of MSME: Low threshold in MSME definition have created a fear among MSMEs of graduating out of the benefits. Hence, government has revised definition of MSME by raising the Investment limit. An additional criteria of turnover has been introduced and distinction between manufacturing and service sector stands removed.
5. Global tenders to be disallowed upto ₹ 200 crores: General Financial Rules (GFR) of the Government amended to disallow global tender enquiries in government procurement of goods and services of value of less than ₹ 200 crores. This is a step in support of the Make in India initiative and will promote MSMEs to grow.
6. Other Measures for MSMEs: e-market linkage for MSMEs to act as a replacement for trade fairs and exhibitions. MSME receivables from Government and CPSEs are to be released in 45 days. Since May 2020 and upto 26.07.2021, pending payments of Rs 55863.30 crore have been made to MSMEs. This would help MSMEs to solve the problems of marketing and liquidity.
7. Income Tax Refund: Income tax refunds to nearly 8.2 lakh small businesses worth ₹ 5,204 crore has been issued with the objective to help MSMEs to carry on their business activities without pay cuts and layoffs in these challenging times.
8. Relief of ₹1500 crores to MUDRA- Shishu loans: GoI to provide Interest subvention of 2 per cent to prompt payees for a period of 12 months. Small business under MUDRA to be benefited.
9. Ease of doing business for business including MSMEs: Government announced further enhancement of Ease of Doing business through Insolvency and Bankruptcy Code (IBC) related measures which include (a). raising of the minimum threshold to

initiate insolvency proceedings to Rs. 1 crore from Rs. 1 lakh (which largely insulates MSMEs), (b) special insolvency resolution framework for MSMEs under Section 240A of the Code, (c) suspension of fresh initiation of insolvency proceedings up to one year depending upon the pandemic situation and (d) empowering Central Government to exclude COVID 19 related debt from the definition of "default" under the Code for the purpose of triggering insolvency proceedings.

10. Credit Guarantee Scheme for Micro Finance Institutions: Guarantee to be provided to Scheduled Commercial Banks for loans to new or existing NBFC-MFIs or MFIs for on lending upto Rs 1.25 lakh to approximately 25 lakh small borrowers. Loans from banks to be capped at Marginal Cost of Funds based Lending Rate (MCLR) plus 2%. Maximum loan tenure will be 3 years, and 80% of assistance to be used by MFI for incremental lending. Interest rates will be at least 2% below maximum rate prescribed by RBI. Guarantee cover will be available for funding provided by MLIs to MFIs/NBFC-MFIs till March 31, 2022 or till guarantees for an amount of Rs. 7,500 crore are issued, whichever is earlier.
11. Udyam Registration Portal- The Udyam registration Portal has facility through which an entrepreneur can opt for linking itself with Government e-market (GeM) place. With this facility, MSEs can link themselves with the Government's procurement system and can participate in Government's mandatory procurement program from MSEs. In addition to it, the portal has linkages with IT, GST and TReDs portals.
12. Government of India on 02.07.2021 decided to include Retail and Wholesale Trade as MSMEs. However, benefits to the MSMEs engaged in Retail and Wholesale Trade would be restricted to availing credit under Priority Sector Lending only. This measure will benefit a large number of trading entities.
13. Amendments to the Factoring Regulation Act 2011 have been approved by Parliament which will enhance supply of credit to MSMEs from NBFCs.
14. Government, on 23.10.2020, approved the Scheme for grant of ex-gratia payment of difference between compound interest and simple interest for six months, to borrowers in specified loan accounts.

B. Union Budget for 2021-22

1. To ensure faster resolution of cases, NCLT framework to be strengthened, e-Courts system

shall be implemented and alternate methods of debt resolution and special framework for MSMEs shall be introduced.

2. Budgetary allocation for MSMEs of Rs. 15,700 crores provided in 2021-22, which is more than double of BE for 2020-21.
3. Customs duty have been reduced uniformly to 7.5% on semis, flat, and long products of non-alloy, alloy, and stainless steels to provide relief to metal recyclers, mostly MSMEs, Duty on steel scrap has been exempted for a period up to 31st March, 2022.
4. Basic Customs Duty rates have been uniformly reduced on caprolactam, nylon chips and nylon fiber & yarn to 5%. This will help the textile industry, MSMEs, and exports, too.
5. Certain customs duty changes to benefit MSMEs have been made. Duty increased from 10% to 15% on steel screws and plastic builder wares. On prawn feed it is increased from 5% to 15%. Exemption on import of duty-free items is rationalised as an incentive to exporters of 36 garments, leather, and handicraft items. Almost all these items are made domestically by MSMEs. Exemption are withdrawn on imports of certain kind of leathers as they are domestically produced in good quantity and quality, mostly by MSMEs. Customs duty on finished synthetic gem stones is increased to encourage their domestic processing.

C. Announcements related to MSMEs in Relief Package announced on 28 June 2021

1. 1.1 Lakh Cr Loan Guarantee Scheme for COVID Affected Sectors which includes Rs. 50,000 crore for health sector to scale up medical infrastructure targeting under-served areas and Rs. 60,000 crore for other sectors. Interest rate capped at 8.25% p.a. for other sectors and further decisions to be taken at later stage based on evolving needs.
2. Additional 1.5 lakh Cr for Emergency Credit Line Guarantee Scheme (ECLGS) Launched as part of Atma Nirbhar Bharat Package in May, 2020. Limit of admissible guarantee and loan amount increased above existing level of 20% of outstanding on each loan. Overall cap of admissible guarantee raised from Rs. 3 lakh crore to Rs. 4.5 lakh crore.
3. Extension of Atmanirbhar Bharat Rozgar Yojana Launched on 1st Oct, 2020. Scheme extended from 30.6.2021 to 31.03.2022. Incentivizes employers for

creation of new employment, restoration of loss of employment through EPFO. Approved outlay Rs. 22,810 crore for 58.50 lakh estimated beneficiaries. Last date for registration is 30.06.2021. Subsidy provided for two years from registration for new employees drawing monthly wages less than Rs. 15000 for:

- (i) Both Employer's and Employee's share of contribution (total 24% of wages) for establishment strength upto 1000 employees.
 - (ii) Only Employee's share (12% of wages) in case of establishment strength of more than 1000.
4. Rs. 88,000 crore Boost to Export Insurance Cover Export Credit Guarantee Corporation (ECGC) promotes exports by providing credit insurance services. Proposed to infuse equity in ECGC over 5 years to boost export insurance cover by Rs. 88,000 crore.
- D. Measures taken by Reserve Bank of India
1. As credit facilities to MSME borrowers, extended under the emergency credit line guarantee scheme of Gol guaranteed by national credit guarantee trustee company (NCGTC), are backed by an unconditional and irrevocable guarantee provided by the Gol, member lending institutions, viz., SCBs (including scheduled RRBs), NBFCs (including HFCs as eligible under the scheme) and AIFIs, permitted to assign zero per cent risk weight on the credit facilities extended under the ECLGS scheme to the extent of guarantee coverage.
 2. In view of the need to support viable MSME entities on account of the fallout of COVID-19, the scheme of one-time restructuring of loans to MSMEs without an asset classification downgrade, was extended where the borrower's account was a standard asset' as on March 1, 2020 and the aggregate exposure of banks and NBFCs was not more than Rs.25 crore. The restructuring had to be implemented by March 31, 2021, subject to certain conditions.
 3. Scheduled Commercial Banks allowed to deduct credit disbursed to new MSME borrowers from their net demand and time liabilities (NDTL) for calculation of the cash reserve ratio. To further incentivize the inclusion of the MSMEs into the banking system, this exemption, available for exposures up to Rs 25 lakh and credit disbursed up to October 1, is being allowed until December 31, 2021.

4. Special liquidity facility of Rs 16,000 crore to Small Industries Development Bank of India (SIDBI) for on-lending/refinancing through novel models and structures available at the prevailing policy repo rate for a period of up to one year.
5. Restructuring of MSME Accounts under Resolution Framework 2.0: Individual borrowers, small businesses and MSMEs having aggregate exposure of up to Rs 25 crore and classified as Standard' as of March 31, 2021, are eligible for the latest framework. They, however, shouldn't have availed restructuring under any of the earlier frameworks (including the August 2020 resolution). Restructuring under the latest framework needs to be invoked up to September 30, 2021 and shall have to be implemented within 90 days after invocation.

The Finance Minister (Smt. Nirmala Sitharaman)

Inclusion In Schedule Vii of the Companies Act, 2013

Lok Sabha Unstarred Question No. 2080

Adv. A.M. Ariff:

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

- (a) details of the items included in the Schedule VII of the Companies Act, 2013, which lists the areas and activities where Corporate Social Responsibility (CSR) contributions can be made;
- (b) whether the Government intends to include more items in the said Schedule to qualify them as admissible CSR expenditure;
- (c) whether the Government has received any representation from the State of Kerala on including donations to the Chief Minister's Distress Relief Fund in the said Schedule; and
- (d) if so, the action taken thereon?

Answered on 02nd August 2021

- A.** (a): The Government provides the broad framework for Corporate Social Responsibility (CSR) through Section 135 of the Companies Act, 2013 ('Act'), Schedule VII of the Act and Companies (CSR Policy) Rules, 2014. Schedule VII of the Act indicates the activities that can be undertaken as CSR which broadly relates to Health, sanitation, education, environment, sports, heritage, art and culture, rural

development, slum area development, Disaster management, including relief, rehabilitation, and reconstruction activities, setting up old age homes, day care centers, measures for reducing inequalities faced by socially and economically backward groups etc. The Ministry vide General Circular no. 21/2014 dated 18th June, 2014 clarified that items mentioned in Schedule VII are broad based and can be interpreted liberally. A copy of Schedule VII of the Act is given at Annexure.

(b): There is no proposal, at present, to include more items in the Schedule VII of the Act.

(c) & (d): Yes, Sir. The representations from the State of Kerala for inclusion of the contribution to the 'Chief Minister's Distress Relief Fund' in Schedule VII of the Act were received in the year 2018 and 2020 respectively, and the same were duly replied by the Ministry.

Annexure

ANNEXURE REFERRED TO IN REPLY TO LOK SABHA UNSTARRED QUESTION NO. 2080 FOR 02.08.2021

Activities which may be included by companies in their Corporate Social Responsibility Policies Activities relating to:

- (i) eradicating hunger, poverty and malnutrition; promoting health care including preventive health care and sanitation including contribution to the 'Swachh Bharat Kosh' set-up by the Central Government for the promotion of sanitation and making available safe drinking water;
- (ii) promoting education, including special education and employment enhancing vocation skills especially among children, women, elderly, and the differently abled and livelihood enhancement projects;
- (iii) promoting gender equality and empowering women, setting up homes and hostels for women and orphans; setting up old age homes, day care centres and such other facilities for senior citizens and measures for reducing inequalities faced by socially and economically backward groups;
- (iv) ensuring environmental sustainability, ecological balance, protection of flora and fauna, animal welfare, agro forestry, conservation of natural resources and maintaining quality of soil, air and water including contribution to the 'Clean Ganga Fund' set-up by the Central Government for rejuvenation of river Ganga;

- (v) protection of national heritage, art and culture including restoration of buildings and sites of historical importance and works of art; setting up public libraries; promotion and development of traditional arts and handicrafts;
- (vi) measures for the benefit of armed forces veterans, war widows and their dependents, Central Armed Police Forces (CAPF) and Central Para Military Forces (CPMF) veterans, and their dependents including widows;
- (vii) training to promote rural sports, nationally recognized sports, paralympic sports and Olympic sports;
- (viii) contribution to the Prime Minister's National Relief Fund or Prime Minister's Citizen Assistance and Relief in Emergency Situations Fund (PM CARES Fund) any other fund set up by the Central Government for socio-economic development and relief and welfare of the Scheduled Castes, the Scheduled Tribes, other backward classes, minorities and women;
- (ix) (a) Contribution to incubators or research and development projects in the field of science, technology, engineering and medicine, funded by the Central Government or State Government or Public Sector Undertaking or any agency of the Central Government or State Government; and
(b) Contributions to public funded Universities; Indian Institute of Technology (IITs); National Laboratories and autonomous bodies established under Department of Atomic Energy (DAE); Department of Biotechnology (DBT); Department of Science and Technology (DST); Department of Pharmaceuticals; Ministry of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy (AYUSH); Ministry of Electronics and Information Technology and other bodies, namely Defense Research and Development Organisation (DRDO); Indian Council of Agricultural Research (ICAR); Indian Council of Medical Research (ICMR) and Council of Scientific and Industrial Research (CSIR), engaged in conducting research in science, technology, engineering and medicine aimed at promoting Sustainable Development Goals (SDGs).
(x) rural development projects.
(xi) slum area development.

Explanation- For the purpose of this item, the term 'slum area' shall mean any area declared as such by the Central Government or any State Government

or any other competent authority under any law for the time being in force.

(xii) disaster management, including relief, rehabilitation and reconstruction activities.

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

Insolvency and Bankruptcy Code

Lok Sabha Unstarred Question No. 2097

Shri Margani Bharat:

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

- (a) whether it is not true that it has been more than five years since Insolvency and Bankruptcy Code (IBC) was notified and if so, the details thereof;
- (b) whether it is also not true that only 8 resolution plans for real estate sector have been approved in spite of admitting more than 200 cases;
- (c) if so, the reason behind this unacceptable process of resolution plans by IBC;
- (d) whether fall in price of real estate and COVID have any reason behind this; and
- (e) if so, the details thereof?

Answered on 02nd August 2021

A. (a): Insolvency and Bankruptcy Code (the Code) was enacted on 28th May, 2016 and the Insolvency and Bankruptcy Board of India was established on 1st October, 2016 to exercise regulatory functions under the Code. Further, the provisions for corporate insolvency resolution process (CIRP) were notified w.e.f. 1st December, 2016.

(b) to (e) : 212 applications pertaining to real estate sector were admitted for CIRP under the Code, of these, 8 cases were resolved, 65 cases have been settled or withdrawn and 23 cases were ordered for liquidation and for rest, process is ongoing. Further, the insolvency resolution process is market driven and the outcome depends on market forces.

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

Rajya Sabha

Upgradation of emission control equipment by companies

Rajya Sabha Starred Question No. 146

Dr. Vikas Mahatme:

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

- (a) whether Government has taken cognizance of the lack of action by companies, which are using diesel generators, to upgrade to emission control equipment; and
- (b) the steps that Government has undertaken to ensure speedy upgradation to the same?

Answered on 02nd August 2021

A. (a) and (b): A Statement is laid on the Table of the House.

STATEMENT REFERRED TO IN REPLY TO PARAS (a) TO (b) OF THE RAJYA SABHA STARRED QUESTION NO. 146 DUE FOR REPLY ON 02.08.2021 REGRADING 'UPGRADATION OF EMISSION CONTROL EQUIPMENT BY COMPANIES' RAISED BY DR. VIKAS MAHATME, HON'BLE MEMBER OF PARLIAMENT

(a)& (b) Government is aware of the issue of emissions from in-use diesel generator sets. Upgradation of in-use diesel generator for emission control requires installation of Retro-fit Emission Control Devices (RECD). For this purpose, RECD must be type approved from Certification Agencies as per System & Procedure. As on date, there is no type approved RECD.

Government has taken following steps to ensure speedy up gradation:

- i. MoEFCC notified emission norms for diesel generator set engines vide GSR 771E dated 11.12.2013 under Environment (Protection) Act, 1986.
- ii. Central pollution Control Board (CPCB) is the Nodal Agency for coordination and implementation of provision of said GSR related to control of emissions

- from DG sets of capacity less than 800 KWs at manufacturing stage.
- iii. Central pollution Control Board (CPCB) has constituted a Standing Committee comprising of national level experts and stake-holders to look into matters pertaining to enforcement of Diesel Generator (DG) set emission rules.
 - iv. A dedicated Sub-Committee has been constituted for development of Standard Operating Procedure (SOP) for RECD. This Sub-Committee is headed by Head of R&D Division of Indian Oil Corporation, Faridabad and members from Automotive Research Association of India (ARAI), International Centre for Automotive Technology (ICAT), Indian Institute of Petroleum (IIP), Indian Diesel Engine Manufacturers Association (IDEMA), Maharashtra SPCB, Tamil Nadu SPCB, Uttar Pradesh SPCB and CPCB.
 - v. The System & Procedure for Testing of RECD had been put up on CPCB web site for inviting suggestion(s). The suggestions received so far have been examined by the Sub-committee for finalization of System & Procedure.
 - vi. Government has awarded a pilot study to ICAT to assess baseline emissions from inuse DG sets having capacity less than 800 KW and to also assess the efficacy of RECD.

Minister for Environment, Forest and Climate Change (Shri Bhupender Yadav)

**Ban on plastic less than
50 micron thickness**

Rajya Sabha Unstarred Question No. 1477

Shri Brijlal:

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

- (a) whether it is a fact that the use of bags, sheets made of plastic and other such materials with thickness less than 50 microns have been banned;

- (b) whether all the States, Government and Non-Government Organizations have been instructed to implement this strictly; and
- (c) the details of the steps being taken in order to prevent the use of plastic with less than 50 microns of thickness?

Answered on 02nd August 2021

- A.** (a) to (c): The Plastic Waste Management (PWM) Rules, 2016, prohibits manufacture, import, stocking, distribution, sale and use of carry bags and plastic sheets less than fifty microns in thickness in the country. There is complete ban on sachets using plastic material used for storing, packing or selling gutkha, tobacco and pan masala. The Plastic Waste Management Rules provide the regulatory framework for management of plastic waste generated in the country. All the stakeholders including State / Union Territory Governments, and Nongovernmental organizations, from time to time, are made aware about the effective implementation of the provision contained in the Rules including those on the restriction on thickness of plastic sheets and carry bags.

Directions under Section 5 of Environment (Protection) Act, 1986, have been issued to all States/Union Territories for setting up for institutional mechanism for strengthening enforcement of PWM Rules. Guidelines for assessment of Environmental Compensation for Violation of PWM Rules, 2016, have also been issued.

These Guidelines have provisions for penal action including seizure of goods and levy of environmental compensation for violation of Plastic Waste Management Rules, 2016, which restricts thickness of carry bags/plastic sheets to 50 microns. States and Union Territories, where required, take action on noncompliance of Plastic Waste Management Rules.

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



New list of essential medicines: 39 new drugs added, 16 dropped

Viswanath Pilla

(Author is a business journalist with 14 years of reporting experience. Based in Mumbai, Pilla covers pharma, healthcare and infrastructure sectors for Moneycontrol)

Most of the new drugs added to the list were anti-cancer like Azacitidine and Fludarabine antiretroviral such as Dolutegravir, Darunavir+Ritonavir, new generation TB medications such as Bedaquiline and Delamanid, anti-allergy Montelukast, anti diabetes drugs like Tenelegliptin and Insulin Glargine.



APIs are the raw materials that give drugs the intended therapeutic effect.

The government released the revised list of National List of Essential Medicines (NLEM), in which it has added 39 drugs, removed 16 drugs.

Most of the new drugs added to the list were anti-cancer like Azacitidine and Fludarabine antiretroviral such as Dolutegravir, Darunavir+Ritonavir, new generation TB medications such as Bedaquiline and Delamanid, anti-allergy Montelukast, anti diabetes drugs like Tenelegliptin and Insulin Glargine, and tobacco cessation and addiction treatment drugs like nicotine replacement therapy (NRT), Buprenorphine (opioid antagonists), Buprenorphine+Naloxone.

The 39 new drugs included Amikacin (antibiotic), Azacitidine (anti-cancer), Bedaquiline (anti-TB), Bendamustine Hydrochloride (anti-cancer), Buprenorphine (opioid antagonists), Buprenorphine+Naloxone (opioid antagonists), Cefuroxime (antibiotic), Dabigatran (anticoagulant), Daclatasvir (antiviral), Darunavir+Ritonavir (antiretroviral), Delamanid (anti-TB), Dolutegravir (antiretroviral), Fludarabine (anti-cancer), Fludrocortisone (corticosteroid), Fulvestrant (anti-cancer), Insulin Glargine (anti-diabetes), Irinotecan HCL Trihydrate (anti-cancer), Itraconazole (antifungal), Ivermectin (anti-parasitic), Lamivudine (antiretroviral), Latanoprost (treat ocular hypertension), Lenalidomide (anti-cancer),

Montelukast (anti-allergy), Mupirocin (topical antibiotic), Nicotine replacement therapy, Nitazoxanide (antibiotic), Ormeloxifene (oral contraceptive), Phenoxymethyl penicillin (antibiotic), Procaine Benzylpenicillin (antibiotic), Rotavirus vaccine, Secnidazole (anti-microbial), Tenelegliptin (anti-diabetes), Tenofovir+Lamivudine+Dolutegravir (antiretroviral), Tenofovir+Alafenamide Fumarate (TAF) (antiretroviral), Terbinafine (antifungal), and Valganciclovir (antiviral).

The deleted drugs are Alteplase (clot buster), Atenolol (anti-hypertension), Bleaching Powder, Cetrimide (antiseptic), Erythromycin (antibiotic), Ethinylestradiol+Norethisterone (birth control), Ganciclovir (antiviral), Lamivudine+Nevirapine+Stavudine (antiretroviral), Leflunomide (antirheumatic), Nicotinamide (Vitamin-B), Pegylated interferon alfa 2a, Pegylated interferon alfa 2b (antiviral), Pentamidine (antifungal), Pilocaine+Lignocaine (anesthetic), Rifabutin (antibiotic), Stavudine+Lamivudine (antiretroviral), and Sucralfate (anti-ulcer).

NLEM list is revised and the ceiling prices are fixed every five years. NLEM 2015, which was implemented from 2016 has ended in March 2021

The Health Ministry prepares a list of drugs eligible for price regulation, following which the Department of Pharmaceuticals, which comes under the Ministry of Chemicals and Fertilizers, incorporates them into Schedule 1 of DPCO. The Standing Committee on Affordable Medicines and Health Products (SCAMHP) will advise the drug price regulator the National Pharmaceutical Pricing Authority (NPPA) on vetting the list. The NPPA then fixes the prices of drugs in this Schedule.

At present, around 374 medicines are part of NLEM which are subject to price controls. About 18 percent of the drugs sold in India are under price controls.

Source: Money Control, 03.09.2021



Release of New NLEM List - reg.



New NLEM List being handed over to Hon'ble Health & Family Welfare Minister by vice chairman-SNCM (The Standing National Committee on Medicines). Hence based on past experiences, let's get in readiness for some supply chain challenges in it's roll out on ground level in coming months !!



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Celebrating the National Pharmacovigilance Week from 17th -23rd September 2021

Theme: Pharmacovigilance: A Step Towards Patient Safety

National Coordination Centre, Indian Pharmacopoeia Commission, is pleased to announce the official celebration of "National Pharmacovigilance Week" from 17th-23rd September to be celebrated every year on this day which will go a long way in reaching common masses about the importance of reporting Adverse Drug Reaction.

Healthcare professionals including Physicians, Nurses, Pharmacist and Others are the backbone of the healthcare system who contributes for patient safety. Hence, Indian Pharmacopoeia Commission has decided to celebrate "National Pharmacovigilance Week" on the

occasion of Patient safety day in order to make the public and healthcare professionals aware about the importance of ADR reporting to improve patient safety.

NCC-PvPI on behalf of the Ministry of Health & Family Welfare, Govt of India, urges all the Healthcare Professionals/Marketing Authorization Holders/ Professional Bodies/ Academic Institutions and other stakeholders to celebrate it by organizing activities like Conferences/Debates/Poster-Oral Presentations/Quiz Contests/Essay Writing Competitions etc. in the area of Pharmacovigilance at your respective organizations.

The banner is divided into several sections. At the top, it features the Indian Pharmacopoeia Commission logo and name, along with its address: National Coordination Centre, Pharmacovigilance Programme of India, Ministry of Health & Family Welfare, Govt. of India, Sector-23, Raj Nagar, Ghaziabad - 201002. Below this, a blue section describes the Pharmacovigilance Programme of India (PvPI) and its mission. A central diagram shows 'Pharmacovigilance for Patient Safety' surrounded by six key areas: Benefit-Risk Assessment, Signal Detection, Rational use of Medical Products, AE/ADR Reporting, Capacity Building, and Benefit-Risk Assessment. The theme 'Pharmacovigilance: A Step Towards Patient Safety' is prominently displayed. The middle section features a green banner for 'National Pharmacovigilance Week 17th-23rd September, 2021'. The bottom section encourages participation with the hashtag #NationalPharmacovigilanceWeek and lists various activities: e-Poster, Essay, Sensitization Programme, Quiz, and Fun & Games. Social media icons for Facebook (ipcgzb), YouTube (Indian Pharmacopoeia Commission), LinkedIn (NCC-PvPI IPC), and Twitter (@IPC_Ghaziabad) are provided. Contact information for more details is listed at the bottom.

Indian Pharmacopoeia Commission
National Coordination Centre, Pharmacovigilance Programme of India
Ministry of Health & Family Welfare, Govt. of India
Sector-23, Raj Nagar, Ghaziabad - 201002

Pharmacovigilance Programme of India (PvPI)
PvPI monitors the safety profile of medical products used in India. In line with its mission to safeguard health of Indian population, we are beginning to celebrate National Pharmacovigilance Week from this year, which will serve as a platform for communication & knowledge enrichment to the various stakeholders in the field of safety of medical products for ultimate benefit of patient.

Theme:
Pharmacovigilance:
A Step Towards Patient Safety

National Pharmacovigilance Week
17th-23rd September, 2021

Let's All Celebrate!!!
National Pharmacovigilance Week
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IIMPACT HEALTH 2021

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Simultaneously, the start-up landscape in India has matured significantly as well. Several Indian start-ups across sectors have managed to scale successfully, with more start-ups joining the vaulted Unicorn club in 2020 alone.

Indian healthcare start-ups, have now started to see the scale of success, it, has been a great year for Indian healthtech, with Pharmeasy -becoming India's first healthtech unicorn, and Krsnaa Diagnostics - a teleradiology player, getting a successful IPO

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To understand opportunities in Healthcare, IIMPACT 2021 is an event you cannot afford to miss!



The poster features a light blue background with a grid of squares. At the top left is the TIE Mumbai logo with the tagline 'FOSTERING ENTREPRENEURSHIP'. In the center is the IIMPACT HEALTH logo with the tagline 'DEFINING THE FUTURE' and a stylized graphic of three overlapping curved shapes in yellow, pink, and blue. At the top right is the IIMA Ahmedabad Healthcare SIG logo. The main title is 'GLOBAL SHIFTS, DISRUPTIONS & THE AGE OF UNICORNS - SCALING HEALTHCARE INNOVATION IN INDIA'. Below the title is a pink and yellow bar followed by the text 'A marquee healthtech conclave that brings together the best minds in global healthcare'. The event dates are 'BLOCK YOUR DATES SEPTEMBER 16-17, 2021' and the time is '5.30 PM - 8.30 PM (IST)'. A 'LIVE VIRTUAL EVENT' icon is in the bottom right. At the bottom, it says 'For more details visit <https://bit.ly/IIMPACT2021>'.

Hetero gets DCGI nod to launch biosimilar version of Tocilizumab

The Hyderabad-based company said on Monday the drug would be available in the country by the end of September under the brand name Tocira.



Hetero's Tocilizumab 400mg/20ml is the biosimilar version of Roche's Actemra/RoActemra drug. Tocilizumab is distributed by Cipla in India under licence from Roche. (Representational image)

The Drug Controller General of India (DCGI) has granted Emergency Use Authorization (EUA) to Hetero for launching a biosimilar version of Tocilizumab, a Covid-19 drug for hospitalised adults. The Hyderabad-based company said on Monday the drug would be available in the country by the end of September under the brand name Tocira. Hetero's Tocilizumab 400mg/20ml is the biosimilar version of Roche's Actemra/RoActemra drug. Tocilizumab is distributed by Cipla in India under licence from Roche. It has been used for treatment of critical Covid patients to reduce fatalities. The drug was in short supply in the country during the second wave. There is also a global shortage of this drug.

B Partha Saradhi Reddy, chairman of Hetero Group, said the approval was extremely crucial for supply security in India, considering there is a global shortage of Tocilizumab. "This demonstrates our technical capabilities and commitment to bringing important therapeutics relevant to Covid care," Reddy said. Hetero Biopharma, a Hetero group company, will be manufacturing the drug in Hyderabad. Hetero said the drug would be used for treating Covid-19 in adults who receive systemic corticosteroids and even those who require supplementary oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation.

Hetero had earlier launched Covid-19 drugs Covifor (generic for Remdesivir) and Favivir (generic for Favipiravir). Hetero has a licensing agreement with MSD for the manufacturing and distribution of investigational oral therapeutic antiviral drug Molnupiravir for the treatment of Covid-19. Hetero also has inked a manufacturing partnership with the Russian Direct Investment Fund for manufacturing 100 million doses of the Sputnik V Covid-19 vaccine.

Source: Financial Express, 06.09.2021



CRAMS segment boosts Indian pharma cos amid pricing pressure

Challenged by pricing pressure within the US, the world's largest pharmaceutical market, Indian corporations have taken succour from contract analysis and manufacturing providers (CRAMS) for development.



With generic medication going through pricing pressure, corporations are engaged on creating and launching speciality merchandise similar to biosimilars and different advanced generics to assist development. Nonetheless, the 2 companies within the CRAMS area that profit most embody Divi's Laboratories Ltd and Gland Prescribed drugs Ltd. No marvel that shares of Gland Pharma and Divi's Labs have surged greater than 70% and 35% year-to-date, respectively. This compares with the 22% achieve within the Nifty Healthcare index throughout the interval.

Gland Pharma owns the mental property (IP) rights of its merchandise. With accredited merchandise being provided to a number of companions by means of non-exclusive partnerships, it additionally advantages from economies of scale. Deriving a share of revenue from a

number of companions, the corporate can command good valuations in comparison with plain contract producers, stated analysts.

For Divi's Laboratories, the advantages accrue from its power in chemistry. The corporate records data and produces area of interest generic substances, which aren't produced by many. Within the CRAMS enterprise, the corporate has a powerful relationship and stays a most well-liked accomplice for a minimum of six of the highest 10 massive pharma corporations, added analysts.

The outcomes are seen of their earnings efficiency, too. Divi's clocked 13.3% year-on-year income development throughout Q1, pushed by a powerful 38.2% development in customized synthesis or CRAMS. The sturdy positioning of Divi's will assist in monetizing the expansion alternative within the API and CRAMS area given its stellar execution observe report and being one of many most well-liked suppliers, stated analysts at ICICI securities Ltd in a notice.

Gland Pharma reported 31% income development, helped by a strong present throughout geographies. The corporate has additionally benefited from covid-19 vaccine manufacturing orders, which have improved its earnings outlook additional.

Analysts at Motilal Oswal Monetary Providers Ltd count on Divi's and Gland to proceed to outperform different contract manufacturing corporations. In addition they stay optimistic on Laurus Labs, which has ventured into biologics/fermentation contract manufacturing by means of the acquisition of Richore Lifesciences within the US.

The scope for development within the CRAMS segment is additional strengthened by the truth that worldwide pharma corporations need to reduce prices by outsourcing analysis and manufacturing actions, and Indian corporations have develop into most well-liked manufacturing companions.

Source : Financial News India, 7.09.2021

Zydus Cadila gets USFDA nod for diabetes medication

Drug firm Zydus Cadila on Monday said it has received approval from the US health regulator to market Sitagliptin, a medicine indicated to treat diabetes. The company said its subsidiary has received tentative approval from the United States Food and Drug Administration (FDA) for its

new drug application for Sitagliptin base 25, 50 and 100 mg tablets.

On October 31, 2020, Zydus had filed a new drug application (NDA) with the USFDA seeking approval to market Sitagliptin base 25, 50 and 100 mg tablets.

The NDA received tentative approval upon completion of the first review cycle on September 2, 2021, Zydus Cadila stated.

Zydus Cadila discovers, develops, manufactures, and markets a broad range of healthcare therapies including small molecule drugs, biologic therapeutics, and vaccines.

The group employs around 23,000 people worldwide.

Source : The Free Press Journal, 06.09.2021

Lupin, TB Alliance join hands for new therapy for drug-resistant Tuberculosis

Lupin intends to commercialise the medicine in around 140 countries and territories, including many of the highest TB burden nations around the world

New Delhi: Drugmaker Lupin on Monday said that non-profit drug developer TB Alliance has granted it a non-exclusive licence to manufacture anti-TB drug pretomanid as part of the three-drug BPaL regimen. The Mumbai-based company said it intends to commercialise the medicine in around 140 countries and territories, including many of the highest TB burden nations around the world.

"As a global leader in anti-TB medicines, Lupin is committed to enhancing access to bridge unmet needs in countries where it is needed the most. This collaboration with TB Alliance leverages our strength and expertise to contribute to better global health,"

Lupin MD, Nilesh Gupta said in a statement. TB Alliance President and CEO Mel Spigelman said that partnering with Lupin a well-established manufacturer with experience delivering high-quality TB therapies will help further enable widespread access to the novel regimen while promoting a competitive market to drive affordability.

TB is one of humanity's oldest, deadliest, and most persistent diseases. The BPaL regimen offers the TB community the first all-oral, six-month treatment for

highly resistant forms of drug resistant-TB. Lupin is the largest supplier of first-line anti-TB drugs in the world, the drugmaker stated.

Source : Hans India Bizz Buzz, 06.09.2021



Union Health Minister Mansukh Mandaviya meets Health Ministers of UK, Brazil, Italy

NEW DELHI: Union health minister Mansukh Mandaviya on Sunday said he had an interaction with his Italian counterpart Roberto Speranza on giving priority in travel to vaccinated Indian students enrolled in educational institutions in Italy and on enhancing bilateral cooperation in the field of health and medicine. Mandaviya is in Rome, Italy, for the G20 health ministers' meeting.

In a series of tweets, he said, "Had an interaction with Mr Roberto Speranza, Health Minister, Italy to enhance the bilateral cooperation between the two nations in the field of health and medicine."



Mansukh Mandaviya meets health Ministers of UK, Brazil, Italy. credits: Twitter)

"Discussed giving priority in travel to Indian vaccinated students enrolled in Italian educational institutions. Also, invited Italian pharmaceutical companies to invest and expand their business in India," he added.

In another tweet, the minister said he invited UK Secretary of State for Health and Social Care Sajid Javid to visit India and discussed with him a roadmap for a new health dialogue between the two countries.

"UK appreciated India's management of Covid and congratulated on administering first #Covid-19 vaccine dose to more than half the population," he stated.



"Our discussions included ways to promote digital health & enhancing access to new models of telemedicine," Mandaviya said of his meeting with Javid, adding that he highlighted various areas of cooperation in the field of healthcare. Mandaviya also met his Brazilian counterpart.

"Had an excellent discussion with Mr Marcelo Queiroga, Minister of Health for Brazil, for better cooperation in healthcare. We spoke about One Health & the introduction of Nano-Urea for better results. Also, offered India's full support to aid Brazil's fight against TB," he tweeted.

Source : Times of India, 05.09.2021



India is the most digital friendly and proficient (GRP)-driven regulatory : DCGI

The regulator has taken various steps including the GRP to grow in tandem with the changes, rather than remaining a mute spectator or a weak regulator



India as one of the best, easiest, digital friendly and most proficient Good Regulatory Practices (GRP)-driven regulatory systems in place and is striving towards a better ecosystem by reducing the compliance burden or redundant procedures, informed Dr V G Somani, Drug Controller General (India).

Speaking at the medical technology industry representatives in a plenary session on demand generation, triggering the growth of med tech industry, organised by Confederation of Indian Industry (CII) in its 13th Global MedTech Summit, Somani said the demand for med tech is always there and the regulatory ecosystem is also good.

He added that the government is trying to reduce the compliance burden or the redundant procedures to increase India's ranking on the ease of doing business, and these measures are being taken as part of that.

“As for the medical devices industry, the regulators will keep on increasing its barriers in a predictable manner over a period of time so that there are no knee jerk reactions, no unpredictability. If we have to move fast at the pace which is required, we have to work shoulder to shoulder. That is what we are doing and we are having one of the best, easiest, most digital friendly and most competent and Good Regulatory Practices-driven regulatory systems,” he said.

The GRP starts with making the customer satisfied, he noted that the customer includes patients, doctors, industry and NGOs, government everybody. Pointed out that consensus building on how the regulators can frame the regulation is important.

“We can frame the best of best regulation, but if they are not compilable, it has no meaning. People may start cutting corners,” he noted.

As for the challenges during the current pandemic, the country is reinventing itself, identifying the gaps and filling them with the strengths. The regulator has taken various steps including the GRP to grow in tandem with the changes, rather than remaining a mute spectator or a weak regulator.

Informing that in order to match the global standards, the drug regulator has adopted the medical device rule, which is at par with the IMDRF (International Medical Device Regulators Forum) or in line with the global regulatory requirement of the IMDRF.

“CDSCO adopted it and started moving in a short time and we are on the path of implementing it. With all industry and government partnering, it has created a roadmap which is ranging for 42 months and the office will move slowly towards the regime. First we know each other, with a voluntary registry system, and then giving advantage of that voluntary registry system to those who have come in our network by putting the registration number on your product. After 30 months for A & B and 42 months for C & D class of medical devices, you have a compulsory licensure system where you go through all pre-registration conformity assessment and post registration surveillance and others. In order to make this ecosystem well poised to be a real quality and affordable medical technology provider for the Indian patient and global patient, we have made all these through the Good Regulatory Practices,” he added.

With these efforts in place, many countries are now taking guidance from CDSCO. In pharmaceuticals, they have been asking India’s guidance for many years. But

now they are asking in the medical technology sector also. CDSCO is starting these regulatory measures on medical devices.

Patients need to access the product regardless where it is coming from. If it can be made in India, it is further welcome. Being a country, India has a right to encourage the local supplies so that the affordability increases and if it is competitive in quality along with affordability it is certainly welcome.

Source : ET-Healthworld News, 07.09.2021



Biomedical waste: Notices sent to 50 labs, private clinics in Gurugram

GURUGRAM: As many as 50 healthcare facilities, including diagnostic laboratories and private clinics, in the city have been sent show-cause notices as they have failed to obtain the statutory authorisation for handling biomedical waste from Haryana State Pollution Control Board (HSPCB), officials said. An HSPCB official said the board recently issued final notices to 50 healthcare facilities in the city and told them to comply with the Biomedical Waste Management Rules, 2016, within a week, else strict action would be initiated against them.



As per the biomedical waste management rules, all healthcare units are to establish a bar-code system for bags or containers containing biomedical waste for disposal. Image used for representational purpose only

“We have sent show-cause notices to the healthcare units which are yet to get no objection certificate (NOC) for handling biomedical waste management rules. We have asked them to reply within seven days failing which we will take necessary

action against them,” an official said. According to the HSPCB data, the city has 583 health units. Biomedical waste is the waste generated in the diagnosis, treatment or immunisation of human beings or animals, in research or in the production or testing of biological products, including all categories of infected and toxic waste that is a potential threat to human beings and the environment.

Human and animal anatomical waste, solid waste, expired medicines, mercury thermometers, chemical waste, body fluid, blades, contaminated waste like plastic bags, bottle, pipe and used needles and syringes all come under bio-medical waste. According to Biotic, the MCG's concessioner for biomedical waste management in the city, Gurgaon generates around 7 tonnes of hazardous biomedical waste daily, including 1.5 tonnes of Covid-19 waste, said Vishesh Gaur, director, Biotic.

As per rules, all healthcare facilities, irrespective of the method of treatment and the quantity of biomedical waste, have to seek authorisation from HSPCB. "Yes, there are many healthcare facilities which do not have authorisation to handle biomedical waste in the city yet," he added.

As per the biomedical waste management rules, all healthcare units are to establish a bar-code system for bags or containers containing biomedical waste for disposal. In fact, all units are also supposed to maintain four colour-coded dustbins (green, red, blue and black) for scientific disposal of such biomedical waste through segregation, collection and treatment to minimise the adverse impact on health workers and environment.

The 'yellow' bin collects anatomical waste, the 'blue' bin collects surgical tools and needles, while the 'red' bin is for plastics, such as syringes and IV packs and 'black' bin for chemical waste. "If health facilities are found to be violating the norms, action will be taken. Improper disposal of waste increases the risk of infection to the garbage collector," said Dr Virender Yadav, chief medical officer.

Source: Ipsita Pati, TNN , 07.09.2021



WHO, UNDP, UNEP & UNICEF develop action-led compendium to save lives from climate change

The repository presents actions and recommendations to address a comprehensive range of environmental risk factors to health.

Geneva: WHO has partnered with UNDP, UNEP and UNICEF to create a new compendium of 500 actions aimed at reducing death and diseases driven by environmental risk factors. This is the first such resource repository to unite this expertise from bodies across the UN system.

Informing that 24 percent of all deaths around the world are caused due to the environmental risks and climate change, WHO in a statement, said, "This toll could be substantially reduced - even eliminated - through bold preventive measures at national, regional, local and sector-specific levels to improve the environmental condition we thrive in."

The Compendium of WHO and other UN guidance on health and environment can be accessed for practitioners to scale up efforts to create a healthy environment that reduces environment-related diseases and increases life expectancy. It is designed for policymakers, staff in government ministries, local government, in-country UN personnel and other decision makers.

The repository presents actions and recommendations to address a comprehensive range of environmental risk factors to health, such as air pollution, unsafe water, sanitation, and hygiene, climate and ecosystem change, chemicals, radiation and occupational risks, among others.

Giving startling facts, WHO stated that air pollution alone leads to 7 million deaths each year, while climate change is expected to have a negative impact on health, both directly and indirectly through effects on biodiversity.

Talking about the action-led compendium, Dr Maria Neira, Director, Department of Environment, Climate Change and Health, at WHO said "Implementing the actions in the compendium should be part of a healthy and green recovery from the Covid pandemic and beyond, and is essential to attaining the Sustainable Development Goals (SDGs). The UN is uniting its health and environment expertise to support countries in this endeavour."

The compendium can also play an important role in achieving health equity, as low- and middle-income countries bear the greatest brunt of environmental changes.

The compendium calls for a scaling up of actions in countries by ministries of health and others at national, regional, local levels, with each of the outlined interventions classified according to principally involved sectors, level of implementation and necessary instruments, such as regulation, taxes and subsidies, infrastructure, education, communication, and others.

Source: ETHealthworld News, 06.09.2021



India administering 1.25 crore COVID-19 vaccines daily: PM Modi

Narendra Modi said Himachal Pradesh has become a champion by being the first state to administer the first dose of Covid vaccine to all eligible people despite logistic difficulties.

Prime Minister Narendra Modi on September 6 said India is administering 1.25 crore COVID-19 vaccines daily which is higher than the population of several countries.

Modi said Himachal Pradesh has become a champion by being the first state to administer the first dose of Covid vaccine to all eligible people despite logistic difficulties.

Sikkim and Dadra and Nagar Haveli too have achieved this target, he said.

Earlier, Modi interacted with healthcare workers and beneficiaries of the Covid vaccination programme in the state through video conference.

Interacting with Dr Rahul, posted at the DodraK war Civil Hospital in Shimla district, Modi said 10 percent of the expenditure can be saved if all 11 shots in a single vial are used while administering Covid vaccines.

Source : Money Control News, 06.09.2021



Vice President calls for improving doctor-population ratio

The Vice President called for focusing on improving healthcare infrastructure in the rural areas, noting that the Covid-19 pandemic has “reminded us of our responsibilities in this regard”.

Hyderabad, Vice President M. Venkaiah Naidu on Sunday called for improving the doctor-population ratio in the country.

He also underlined the need to improve the healthcare infrastructure and increase the number of medical colleges in the country.

Addressing the 11th Annual Medical Teachers Day Awards of the Association of National Board Accredited Institutions (ANBAI) in Hyderabad, Naidu noted that in India, there is one doctor for every 1,456 people, while as per the recommendations of the World Health Organisation (WHO), the doctor-population ratio should be 1:1,000.

The Vice President called for focusing on improving healthcare infrastructure in the rural areas, noting that the Covid-19 pandemic has “reminded us of our responsibilities in this regard”.

He also called for increasing the number of medical colleges. He said to improve this ratio, the government is making efforts to establish at least one medical college in every district headquarter.

He suggested that all stakeholders in medical education also play their role in this regard, highlighting the fact that a large number of doctors prefer to render their services in the urban areas as compared to the rural areas.

Naidu said both medical education and healthcare should become affordable for the common man, and everyone connected with this sector has a responsibility to ensure this.

Referring to the technological advancements across the world, he said the latest technologies should be adopted and state-of-the-art equipment be made available for diagnosis and treatment. He stated that the Covid pandemic has taught a lesson to all including doctors and scientists.

Stating that medicine is one of the noblest professions, he said it should be the endeavour of every physician to play his role to uphold the values and sacredness of the profession. Young doctors and medical students should imbibe the ethics and high values of the profession and implement them in their day-to-day life, he added.

Appreciating the yeoman service rendered by doctors during Covid pandemic, he said that they not only treated the patients but also gave counselling, confidence, and solace to them.

Naidu was all praise for the ANBAI for its efforts to provide education based on highest standards. He said it was commendable that leading hospitals and medical institutions of the country came together to impart graduation in medical education through the ANBAI. The Vice President paid tributes to former President, Sarvepalli Radhakrishnan on his birth anniversary which is celebrated as Teachers’ Day. He called Radhakrishnan a great teacher and philosopher. Naidu said teachers shape the lives and careers of the students and especially in medical education, students have to be groomed to become great doctors.

Source: ETHealthworld News, 06.09.2021



Indian exporters allege global shipping companies are forming cartels

Ask govt to regulate them, bat for a larger Indian shipping company

A crisis is staring exporters in the face with high freight rates and few ships and containers. These two factors are expected to spoil the upcoming Christmas season.

Alleging that shipping companies are forming cartels, various industry players have approached the government, seeking its intervention and the setting up of a large shipping company under its guidance to break the international monopoly.

A major point the exporters are raising as proof of this is the performance of the top 10 shipping companies in the world in the past one year.

For these top 10 companies (no Indian companies on the list), the average operating profit increased 12-fold, revenue 66 per cent, the margin 27 per cent, and net profit 19,754 per cent in 2021, against 2020. This was on account of a low base, rise in volumes, and increase in freight rates. This is likely to go up this financial year.

In a meeting with the Ministry of Shipping last week, representatives of the spices exports sector had highlighted that at least six of the top 10 shipping lines posted a net profit of over 30-fold in the past one year.

“The top shipping lines seem to have formed a cartel and are controlling freight rates as they know this shortage and crisis will continue until the first quarter of 2023. We want the government to form a big shipping company or scale up the Shipping Corporation of India, or maybe even join hands with private sector players like Essar and Great Eastern Shipping. T

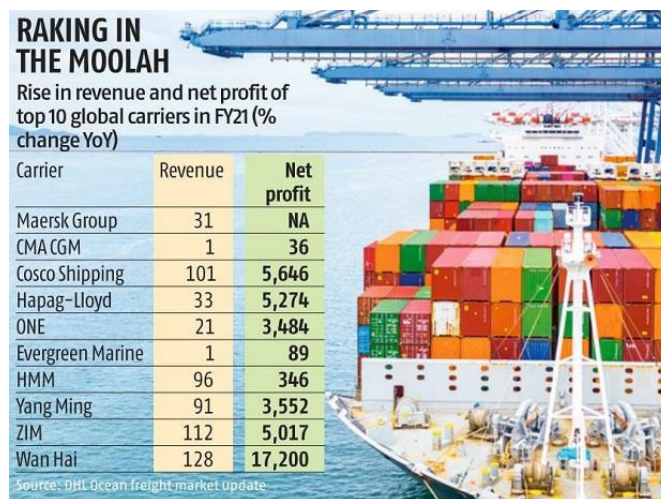
his will ensure ship availability for India,” Hitesh Gutka, president of the Indian Spices and Foodstuff Exporters’ Association, told Business Standard.

Exporters are saying the shipping companies not accepting the call by ports and skipping calls are leading to blank sailing and also an increase in transit time between various ports.

For example, the transit time to Vancouver, which used to be about 35 days, is now 80 days. Even ships that call the ports are not accepting cargo, leading to exportable

stuff getting stuck at Indian ports, causing demurrages and contract cancellations many a time, exporters have indicated.

“The winter orders, focused on the Christmas season, are going to be crucial because it is the most profitable time for exporters from our country. In addition to the container shortage, blank sailing, and transit delay that we are witnessing, higher rates are likely to impact our business for a longer term as we fear these consumers shifting to other countries,” said K Venkatachalam, advisor to the Tamil Nadu Spinning Mills Association (Tasma).



Exporters are expecting blank sailings of the weekly Europe vessel on August 24, September 1, and October 12 from Chennai and Cochin and are seeking government regulation on international shipping lines operating in India.

The spices body said freight rates from Cochin to cities like Melbourne increased even 10-fold in the past one year, while for several routes like Hamburg-Mundra also rates increased over eight-fold.

Shipping lines up defence

According to the Container Shipping Lines Association (CSLA), the only body that represents such firms in India, all efforts have been made by the lines to meet the demand, which has helped Indian exports to grow.

“This has helped India achieve growth in export volumes during the first half of 2021 over 2019 by 12 per cent and over 2020 by 29 per cent. It must also be noted that any increases in freight rates have happened due to

increased cost not just in the case of India but in the case of other countries too. It happened more so in the case of China and Southeast Asia,” said Sunil Vaswani, executive director of CSLA.

The shipping lines have placed orders for about 600 new vessels, which will start hitting the waters from the second quarter of 2022. This should help further ease the pressure on space and equipment, he said.

Source : Shine Jacob, Business Standard, 07.09.2021



India works on multi-variant vax

India is working to develop an umbrella Covid-19 vaccine, just like the multi-variant flu shots in the market.

Government institutions, along with the pharmaceutical industry, are examining if a 'cocktail' approach to making a multi-variant Covid-19 vaccine works against multiple strains of the ever-mutating virus, a senior government official told Business Standard.

While the official did not divulge details about the institutions involved in the project, he said the government was partnering with the industry. “The product is not ready yet; it is under development. This will take some time. Once the product is ready, it will go for clinical trials,” the official said.

He said basic science institutions, the pharma industry, and industry-academia collaborations were working to develop the new-generation Covid vaccine. “This is a scientific effort, and ongoing,” the person said.

According to sources in the industry, there are two approaches to this – one is developing vaccines using a strain different from the Wuhan one, for example, the Delta variant; and second, to mix two strains and see whether that gives a better coverage and has better neutralising capacities.

Ahmedabad-based Zydus Cadila, for example, is trying to develop a Delta variant vaccine for its already-approved DNA-plasmid Covid vaccine. It is also testing whether a multi-variant vaccine can be developed in the laboratory.

Speaking to Business Standard, Sharvil Patel, managing director of Zydus Cadila, said, “We are making a Delta variant construct, and we will test that variant to

see whether it works to neutralise the Delta variant better, and potentially other variants also.” He added that if the Delta variant construct proves to neutralise several variants better than the current Wuhan strain, then in the future the vaccine can be upgraded with the genetic sequence from the Delta variant.

ALL-ROUND DEFENC

- Multi-variant Covid-19 vaccine will have two or more strains of the Sars-CoV-2 virus
- Such a vaccine will give better coverage against mutating viruses
- Currently, all Covid vaccines are based on the original Wuhan strain that started the pandemic
- The mixed vaccine approach may carry one Delta strain and at least one more strain
- Zydus is already working on a Delta variant of its DNA vaccine
- Govt institutions, too, are working on similar approach

Patel said that apart from this, there was a second approach. “We put two variants in one vaccine – a mixture of the Delta and one more variant. This is like the flu vaccine shots where three or four flu strains are part of the same vaccine. However, all this research is still very preliminary, and I do not think that we have anything in sight anytime soon. To have something practically would take at least five to six more months,” he said.

Theoretically, each vaccine platform can be changed, but for some vaccine platforms, like recombinant ones (mRNA and DNA platforms), the change is relatively easier. One is only changing the genetic sequence (of the virus strain), and not changing anything else that is part of the construct.

Also, the mixing of sequences is not possible for all platforms, pointed out one industry source. It is possible to develop multi-variant vaccines on the inactivated virus vaccine platform like Bharat Biotech’s Covaxin. However, research is needed to see how things work out.

“Every time we change, we are inactivating a live virus, and every inactivation is different. The way one inactivates

the Wuhan strain may not be the same as one inactivates a different strain,” the source explained.

For recombinant vaccines like mRNA or DNA, the process is relatively simpler. Here, one changes the genetic sequence of the Wuhan strain with whichever strain one wants to. For virus-like particle technology vaccines (Novavax or Biological E) also, this is possible.

There is no data today on whether mixing two strains in the same vaccine gives better results. Industry sources said US majors Pfizer and Moderna might be working on this approach already.

Source: Sohini Das, Business Standard, 07.09.2021



INTERNATIONAL NEWS

There is still no vaccine for kids under 12 | Here's why

Clinical trials are underway in hopes of developing a vaccine that is safe and effective for young children.

Why is there still no vaccine for children under 12?

ATLANTA — COVID-19 cases among young children are climbing as parents wonder when pharmaceutical companies will release a vaccine for kids under the age of 12.

It's a bit like Goldilocks testing bowls of porridge. Scientists are in the process of developing a COVID-19 vaccine for children that is just right.

Months after adults started rolling up their sleeves, parents are wondering when their school-age kids will get a shot in the arm.

“It's very complex,” Dr. Grace Gowda, of the University of Georgia's College of Pharmacy, said.

Before FDA Approval or even an Emergency Use Authorization, vaccines are tested in clinical trials. In this case, manufacturers had to find healthy children willing to take the vaccine in order to test the effectiveness and safety.

“It's very hard to recruit patients,” Dr.Gowda said. “How many of us will volunteer our children to be in trials?”

Pfizer and Moderna began their pediatric clinical trials over the spring and summer, roughly a year after similar trials in older patients. Dr.Gowda said manufactures used that year to evaluate data on safety and effectiveness to decide how many doses to give children during the pediatric trials.

“It's a standard practice,” Dr.Gowda said. “In children we want to be a little bit more cautious because they're developing rather than fully developed human beings.”

Because children are growing and changing, one age group may require more doses than another.

Manufacturers may take as much as six months to evaluate the results of current clinical trials.

“It will give us an indication if there are nuances in safety that need to be considered before we give it to children,” Dr.Gowda said.

According to the CDC, at the end of July only 32% of the eligible adolescents were fully vaccinated. Less than half of the nation's 12- to- 7-year-olds had received a single dose.

Source : Jerry Carnes, Alive, 06.09.2021



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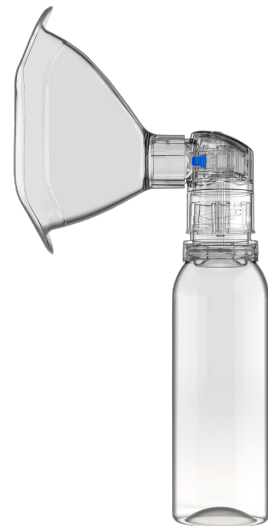


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