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IDMA BULLETIN

VOL. NO. 52 | ISSUE NO. 38 (PAGES: 52) | 08 TO 14 OCTOBER 2021 | ISSN 0970-6054 | WEEKLY PUBLICATION

Indian APIs & Formulations for Global Healthcare

INDIAN DRUG MANUFACTURERS' ASSOCIATION

IDMA 60TH YEAR CELEBRATIONS 2022

Friday, 7th & Saturday, 8th January 2022, Hotel Sahara Star, Mumbai

(Details on Page: 4)

HIGHLIGHTS

A Publication of
Indian Drug Manufacturers' Association
102-B, 'A-Wing', Poonam Chambers,
Dr. A.B. Road, Worli, Mumbai - 400 018
Tel : 022-2494 4624 / 2497 4308 **Fax:** 022-2495 0723
e-mail: publications@idmaindia.com/
actadm@idmaindia.com/ website: www.idma-assn.org

Published on 7th, 14th, 21st and 30th of every month

Annual Subscription
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₹ 2000/- *(for Government Research/Educational Institutions)*
₹ 4000/- *(for non-members)* **US$ 400** *(Overseas)*
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IDMA BULLETIN

Vol. No. 52 **Issue No. 38** **08 to 14 October 2021**

IDMA ACTIVITIES:

CONGRATULATIONS:

MoEF&CC MATTERS:

DoPT MATTERS:

PARLIAMENT NEWS:

NATIONAL NEWS:

IPR MATTERS:

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

102, Poonam Chambers, A Wing, 1st Floor, Dr. Annie Besant Road, Worli,
Mumbai - 400 018. Maharashtra, India.
Tel: +91-22-24974308 / 24944624 E-mail: actadm@idmaindia.com / Website: www.idma-assn.org

Dear Member,

IDMA 60TH YEAR CELEBRATIONS 2022

Friday, 7th & Saturday, 8th January 2022
Hotel Sahara Star, Mumbai

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

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

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

As part of the Celebrations, the winners of the:

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

would be announced and the Awards would be presented.

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

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

IDMA 60th ANNUAL PUBLICATION 2022

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

AN OFFER NOT TO BE MISSED

Advertisers can, through this single medium, reach their target audience such as Bulk Drug Manufacturers, Formulators, Researchers, Analysts, Traders, Scientists, Students, Consultants, various Government Officials etc and leave an enduring impression on everyone connected with the Industry.

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We invite sponsors for our 60th Year Celebrations as below:

PLATINUM SPONSOR : Rs.25 Lakh

DIAMOND SPONSOR : Rs.15 Lakh

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SILVER SPONSOR : Rs.5 Lakh

Sponsors will be provided special benefits & privileges: For details please contact IDMA Secretariat.

REGISTRATION FEES:

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

Reception Committee Member	Rs.7,500/- plus GST @ 18%
Delegate	Rs.6,000/- plus GST @ 18%
(For more than 4 registrations from one Company, the 5th registration will be complimentary)	

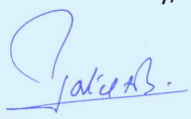
Mr. Melvin	**Ms. Geeta**	**Ms. Batul**
9821868758	9820161419	9920045226
actadm@idmaindia.com	publications@idmaindia.com	technical@idmaindia.com

Your active participation & interaction with the cream of the Pharmaceutical Industry as well as Ministry Officials and Bureaucrats, from the Centre as well as States, will not only add value to your business but also ensure that the flag of our Association continues to fly higher in the Global Pharmaceutical Industry.

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

Thanking you,

Yours faithfully,



Daara B Patel
Secretary–General

IDMA Gujarat State Board Team Meets New Gujarat Chief Minister Shri Bhupendra Patel And Health Minister Shri Rushikesh Patel

IDMA Gujarat State Board Team congratulating and welcoming the New Gujarat Chief Minister Shri Bhupendra Patel

IDMA Gujarat State Board Team also met Health Minister Shri Rushikesh Patel. Took up the burning issues of the Pharma sector

A Win-Win Solution For Mutual Benefit And Prosperity

Dr Gopakumar G Nair, *Editor, Indian Drugs*

Dear Reader,

Nobel Laureate Prof. Amartya Sen cites a story of three children, Anne, Bob and Carla. Prof. Sen quotes Aristotle and Bentham too while narrating the story, I heard from Prof (Dr.) James Nedumpara at his recent live lecture at Jindal Global Law School. This story fascinated me and it goes like this. Clara worked hard to successfully build a flute. Anne knows to play the flute, but Clara does not know to play the flute. Bob, the third child, does NOT have any toys to play with, so he wants the flute. All the children are claimants to the flute. Prof. Sen and many legal luminaries quote many legal theories such as Libertarianism, Utilitarianism, Egalitarian and also try to distinguish between "Niti and Nyaya" to resolve this problem, as to who merits (deserts and deserve) to keep the flute. The debate and deliberations go on and pens go dry, of the reviewers, commentators and lecturers in UPSC and higher legal studies. Here is where and when it dawned on me that I have the right formula to resolve this dispute or dilemma. I draw on my little bit of experience in Intellectual Property, especially Patents and pharmaceutical industry to extend this story and find a resolution. Let me replant these characters into my story as follows;

Extended to Industry scenario, Carla is a Research Scientist in Academic or Research Institute, who has come up with a breakthrough innovation which has high potential to be utilised or commercialised. She patents the invention. However, she does not have a manufacturing facility and does not know how to scale up to commercial levels. Bob has manufacturing facility but does not have the finances or working capital as well as technically qualified professionals to scale up Carla's invention and take it to the market place. Anne is an experienced pharmacist with extra-ordinary expertise in scaling-up and making the product and taking it to the market as a block-buster. Once Anne, Bob and Carla come under the venture-based start-up umbrella, the dispute is resolved. Carla licenses it to Anne who gets it manufactured with Bob. All are happy in a win-win end of the story.

***Dr. Gopakumar G. Nair** is a Ph.D in Organic Chemistry (1966) from National Chemical Laboratory, Pune (Pune University). He was a Post-Doctoral fellow at IIT Bombay, Powai (1967) before joining the Pharma Industry. He was Director of Bombay Drug House P. Ltd., later Chairman of BDH Industries Ltd. as well as CMD of Bombay Drugs & Pharma Ltd., which was merged with Strides Arcolab Ltd. in 2001. Dr. Nair served IDMA as office bearer for many years from 1972 onwards and was Chairman of various Committees for nearly 4 decades. He was the President of IDMA in 1999/2000. Currently, Dr. Nair is the Chairman of the IPR Committee in IDMA.*

Having moved into the Intellectual Property field, he was the Dean of IIPS (Institute of Intellectual Property Studies) at Hyderabad in 2001/2002. Later, he set up his own boutique IP firm, Gopakumar Nair Associates, as well as Gnanlex Hermeneutics Pvt. Ltd., having done his L. L. B. from Mumbai University. He is also CEO of Patent Gurukul and President of Bharat Education Society, Kurla, Mumbai, managing many educational institutions in and around Mumbai.

The Indian Pharmaceutical Industry is already on a win-win route, having commenced working on this model of partnerships. Research institutes and Universities such as ICT (Institute of Chemical Technology, Mumbai), Indian Institute of Chemical Technology (IICT), Hyderabad, IITs and their innovation hubs, NCL (National Chemical Laboratory, Pune) and their Venture Center, renowned universities and colleges such as JSS Ooty/Mysuru, SRM, Amity, Manipal, Punjab, Andhra and others. It is heartening to note that more and more Corporates are working closely with research entities in Academic environs. The breakthroughs achieved by CIPLA by working with CSIR Laboratories such as NCL (Pune); CDRI, Lucknow; IIM (Indian Institute of Integrative Medicine), Jammu and others are being replicated by many leading pharmaceutical and

biological corporate leaders Biocon, Zydus, Alembic, Aurobindo, FDC, Mankind and many more. In this context, I am happy to recall the Guest Editorial by Dr. Madhu Dikshit in the April, 2019 issue of Indian Drugs. There is a huge data bank of research professional who have retired from active and vibrant centres in public research laboratories, who can be productively made to associate with public-private research initiatives. Indian Drugs and IDMA will be happy to contribute in an organized platform for making such tie-ups and alliances fruitful and innovatively successful.

It is heartening to note that the Government of India is fully aware of the potential role and contribution from educational institutions and universities which are valuable in generation of new technologies and patentable innovations. Keeping this aspect in mind, Department for Promotion of Industry and Internal Trade under Ministry of Commerce has come out with a Patents (Amendment) Rules, 2021 extending the 80% reduction in patent filing and prosecution fees to all recognized educational institutions (whether or not financed or owned or controlled by the Government) along with Natural person, Start-up and Small entities.

Much more needs to be done and achieved. Instead of having success stories to quote, it should become a day-to-day habit and routine for all of industry including MSME to partner with academic, researchers and industry professionals. There are no dearth of mentors and gurus. They need to be approachable to make them part of the projects and make the deals and tie-ups, part of supply chain management. Every organization, research industry or consultancies and professional must get interconnected and be ready to take off, anytime and every time. Let us make it happen, the win-win-win story of Anne, Bob and Carla.

Courtesy: Indian Drugs, Editorial, 58(07), July 2021

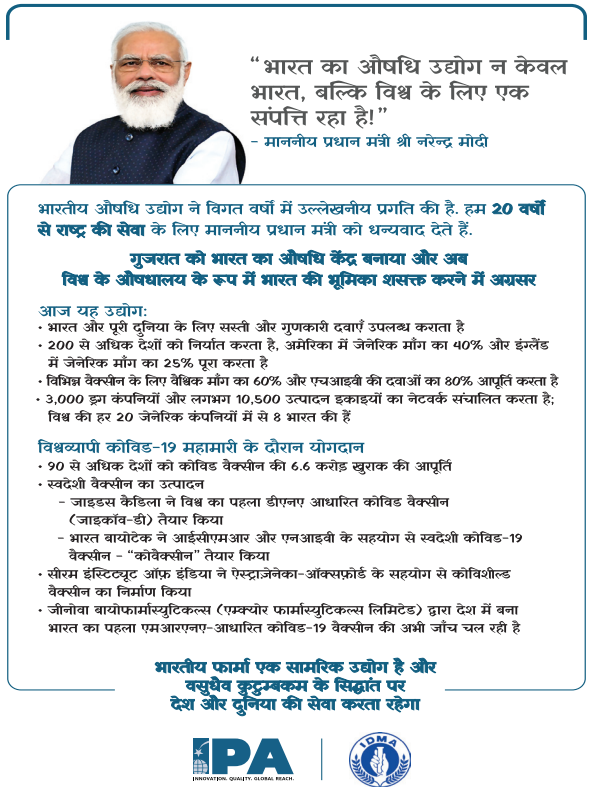
IPA & IDMA thank our Honourable Prime Minister Shri Narendra Modi

Dear Member,

We are pleased to inform you that our Honourable Prime Minister Shri Narendra Modi has completed 20 years of Service to the Nation.

On this occasion, IPA & IDMA took the opportunity to thank our Honourable Prime Minister Shri Narendra Modi for such a great achievement.

Our gratitude and appreciation, in the form of an advertisement has appeared in Economic Times (Page 13), Times of India (Page 9) dated 8th October 2021 and Dainik Jagran (Copy attached).



Granting of Environment Clearance (EC) with EC identification number for Category A and B project proposals—reg.

Office Memorandum dated 06th October, 2021

To,
1. The Chairman, Central Pollution Control Board
2. All ADGs of Integrated Regional Office; MoEF&CC
3. All Chairman and Member Secretaries of SEIAA/SEAC;
4. Sr. Technical Director, NIC, MOEF&CC
5. Guard file

Ministry in August 2018 launched PARIVESH (Pro-Active Responsive facilitation by Interactive and Virtuous Environmental Single-window Hub), a single window portal for the Environmental, Forests, Wildlife and Coastal Regulation Zone (CRZ) Clearances. The main objective of the PARIVESH was to enhance the efficiency, transparency, and accountability in Environmental, Forest, Wildlife and CRZ clearance processes.

2. With a view to bring efficiencies and transparency in the issuance of ECs and to encourage issuance of ECs in online mode, a new feature has been added on PARIVESH portal that generates 16 digit EC identification number alongwith e-sign and other required credentials.

3. All the Member Secretaries in the Ministry and State Environment Impact Assessment Authority (SEIAA) are therefore directed to issue system generated EC letter. Aforesaid functionality in the PARIVESH shall be made mandatory w.e.f 10.10.2021 at Central level and 20.10.2021 at SEIAAs. Thereafter, any new EC issued on or after aforesaid dates without EC identification number & e-siqn shall be treated as invalid.

4. Detailed User Manual delineating steps for generation of the EC letter is annexed for information. Further, Project Proponents are advised to meticulously fill required credentials in the Form 2 for generation of EC letter, to avoid undue delay in granting EC.

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

No. 1A3-19/95/2021-1A-111

(Sharath Kumar Pallerla)
Scientist 'F'/Director
Ministry of Environment, Forest & Climate Change
(IA. III Division)
Government of India
Indira Paryavaran Bhawan
Aliganj, Jor Bagh Road
New Delhi-110 003 E-mail: sharath.kr@gov.in

Copy for information:

1. PPS to Secretary, EF&CC/PSO to AS(RA)/Sr. PPS to JS(SKB);
2. All Member Secretaries, IA division
3. Addl. Director, IA-Monitoring

Pro Active Responsive facilitation by Interactive and Virtuous Environmental Single Window Hub *https://parivesh.nic.in/*

User Manual

Online Generation of EC Cover Page and EC Identification Number for Environmental Clearance (EC) Letter (Cat-A/B1/B2 Projects)

Table of Contents

Overview

The new project proposed to introduce the system generated EC cover letter while granting the environmental clearance as a first step. While uploading EC letter on the PARIVESH portal by the Member Secretary, it is proposed to add EC cover page generated by the system alongwith 16 digit EC identification number to bring efficiencies and transparency in the issuance of ECs and to encourage issuance of ECs in online mode. The newly generated online EC Identification cover page will be added as a first page with the EC letter. The environmental clearance letter is appended alongwith from page 2 to Page… of the letter.

Objective

This User manual is meant for User Agencies who are supposed to do the operations and activities that are required to generate the EC Identification number and Cover page of the EC letter having the gist of the EC-approved proposal. Earlier there was no provision for online generation of EC cover page and identification number. To bring efficiencies and transparency in the issuance of ECs and to encourage issuance of ECs in online mode, a system generated page having the gist of the EC-approved Proposal is added. The details required for the generation of page are fetched from the different places of application.

Scope

The purpose of this user manual document is to provide an interface between the user and "**PARIVESH**". (**P**ro-**A**ctive **R**esponsive facilitation by **I**nteractive and **V**irtuous **E**nvironmental **S**ingle-window **H**ub). The process of generating the EC Cover page having gist of the approved proposal as a first page of EC, will help the user in generating the cover page with a 16 digit EC identification number, generated by the system Online. The newly generated online EC cover page will be added as a First page of the EC letter. The environmental clearance letter is appended along with from page 2 to Page… of the letter.

Authorship

This manual has been prepared by Ministry of Environment, Forests and Climate Change, Government of India, New Delhi-110003.

Copyright

Contact Information

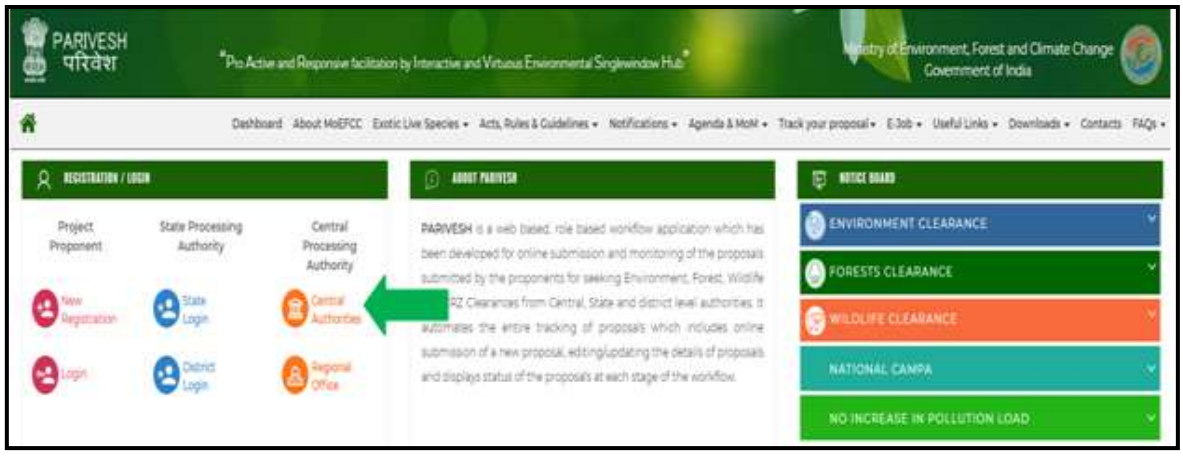
Environment, Forests and Climate Change Informatics Division (EFCCID)
Ministry of Environment, Forests and Climate Change
Jor bagh, Lodhi Colony
New Delhi-110003

Website: https://parivesh.nic.in Email: monitoring-ec@nic.in;

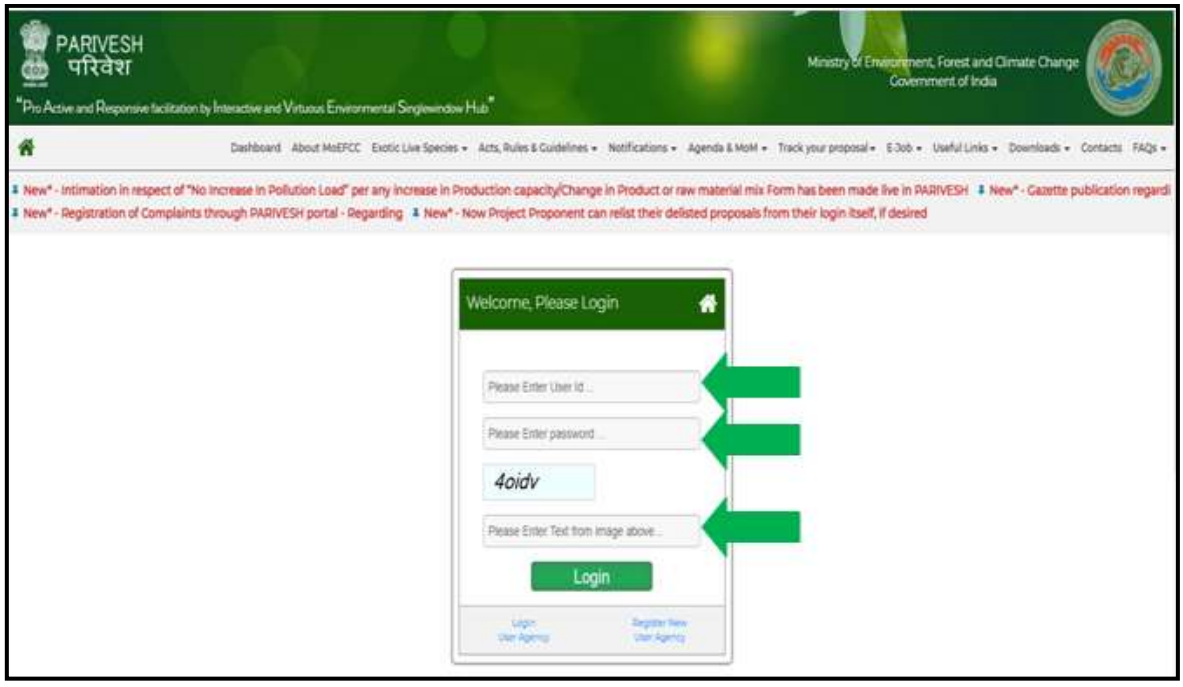
The Detailed Process for Generation of EC Cover Page and EC Identification Number

- This Provision is only for the project/Activity granted EC under EIA-Notification -2006
- Generation of cover letter for EC approval letter is available in MS login.

Step-1 MS click on Central Authorities for login in PARIVESH



Step-2 Login with user ID and Password and enter the randomly generated text in text box.

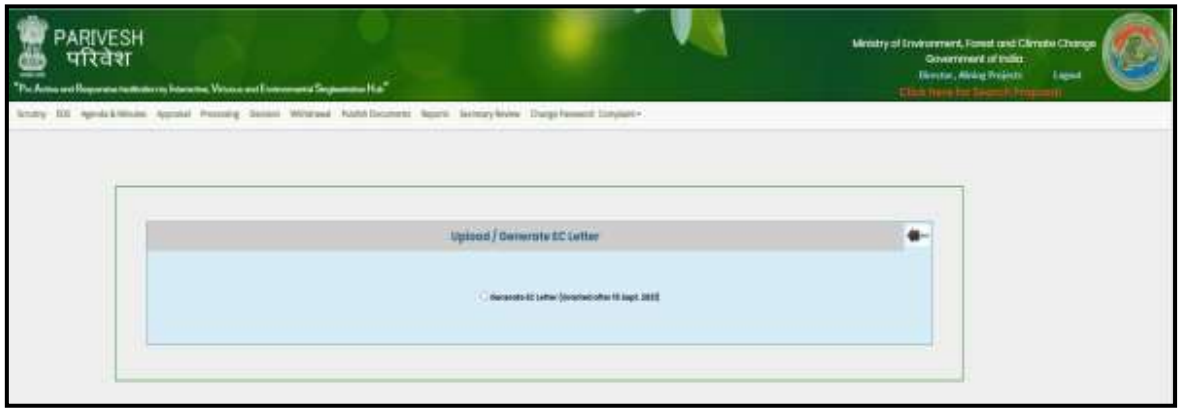


Click on Login

Step-3 Click on Decision

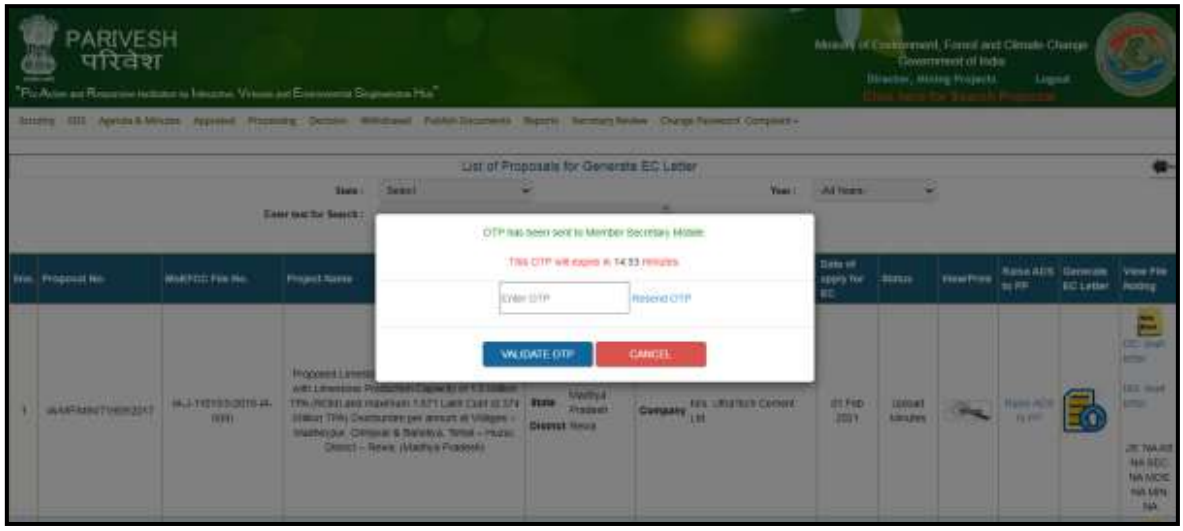
Step-4 Click on Upload/ Generate Letter For EC

Step-5. A page open showing the option of Upload EC letter (Granted before XX Oct. 2021 and Generate EC letter (granted after XX Oct. 2021)

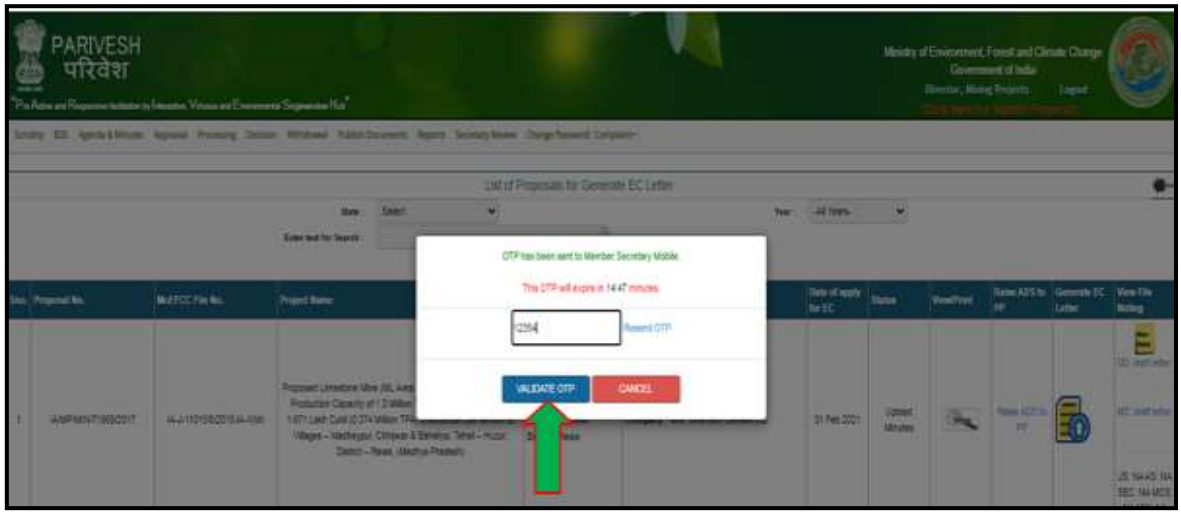


Step-6 Select **Generate EC letter** (granted after XX Oct 2021)

Step-7 For security reasons an OTP is sent to MS registered mobile associated with their credential.

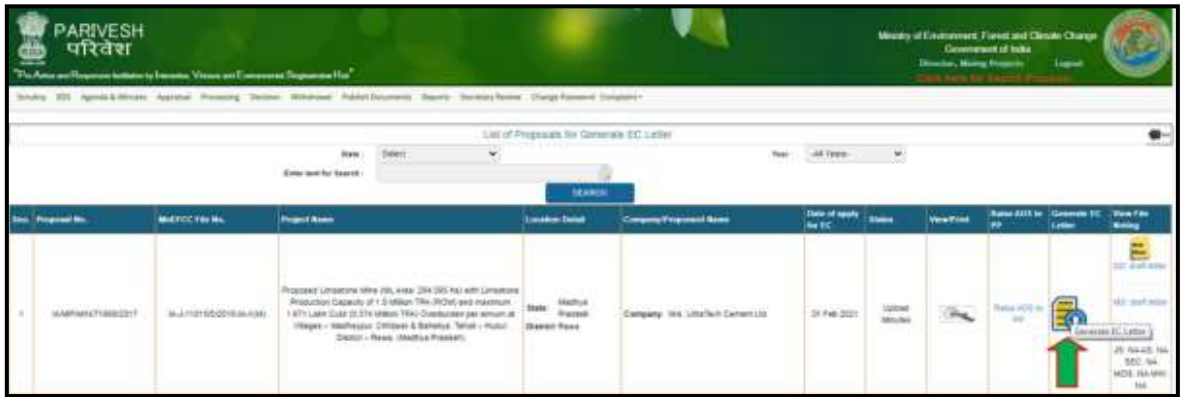


Step-8 MS enter the OTP received on their mobile and click on "**VALIDATE OTP**"



Step-9 A page will open showing details of EC selected to generate EC letter having details like Proposal No., File No., Project Name, and Project type.

Step-10 Click on **"Generate EC letter"**

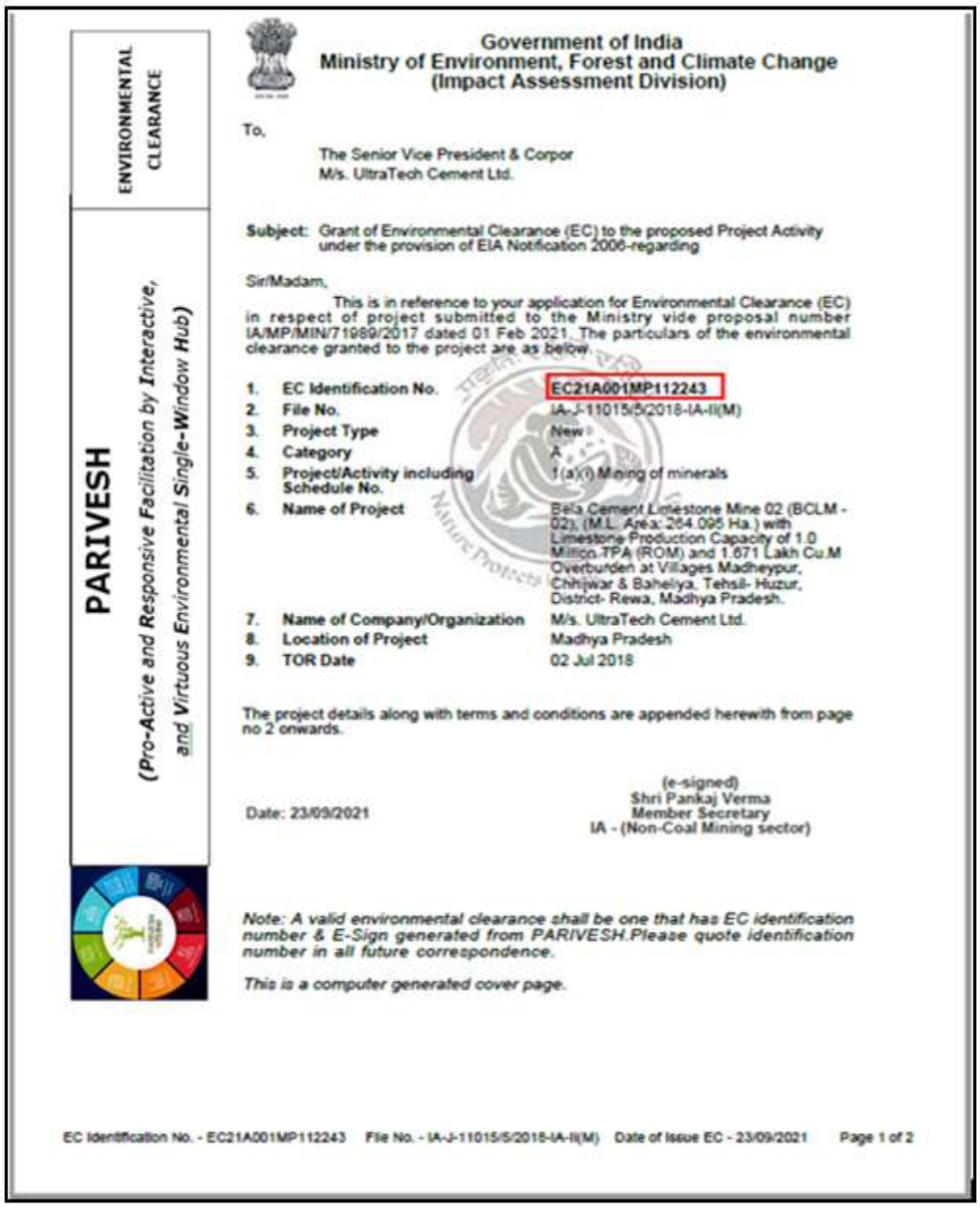


Step-11 Upload Approved EC document in PDF format (Max-20 MB)

Step-12 Click on "**GENERATE EC COVER PAGE & PREVIEW EC**"

Step-13 Preview of EC letter with cover page having EC identification number is generated and open as preview. It can be downloaded or print.

- Sample EC Cover Page for CAT A Project to be issued at Central level



ENVIRONMENTAL CLEARANCE

PARIVESH

(Pro-Active and Responsive Facilitation by Interactive, and Virtuous Environmental Single-Window Hub)

Government of India
Ministry of Environment, Forest and Climate Change
(Impact Assessment Division)

To,

The Senior Vice President & Corpor
M/s. UltraTech Cement Ltd.

Subject: Grant of Environmental Clearance (EC) to the proposed Project Activity under the provision of EIA Notification 2006-regarding

Sir/Madam,

This is in reference to your application for Environmental Clearance (EC) in respect of project submitted to the Ministry vide proposal number IA/MP/MIN/71989/2017 dated 01 Feb 2021. The particulars of the environmental clearance granted to the project are as below:

1.	EC Identification No.	EC21A001MP112243
2.	File No.	IA-J-11015/5/2018-IA-II(M)
3.	Project Type	New
4.	Category	A
5.	Project/Activity including Schedule No.	1 (a)(i) Mining of minerals
6.	Name of Project	Bela Cement Limestone Mine 02 (BCLM - 02), (M.L. Area: 264.095 Ha.) with Limestone Production Capacity of 1.0 Million TPA (ROM) and 1.671 Lakh Cu.M Overburden at Villages Madheypur, Chhijwar & Baheliya, Tehsil- Huzur, District- Rewa, Madhya Pradesh.
7.	Name of Company/Organization	M/s. UltraTech Cement Ltd.
8.	Location of Project	Madhya Pradesh
9.	TOR Date	02 Jul 2018

The project details along with terms and conditions are appended herewith from page no 2 onwards.

Date: 23/09/2021

(e-signed)
Shri Pankaj Verma
Member Secretary
IA - (Non-Coal Mining sector)

Note: A valid environmental clearance shall be one that has EC identification number & E-Sign generated from PARIVESH.Please quote identification number in all future correspondence.

This is a computer generated cover page.

EC Identification No. - EC21A001MP112243 File No. - IA-J-11015/5/2018-IA-II(M) Date of Issue EC - 23/09/2021 Page 1 of 2

- Sample EC Cover Page for Cat-B Project to be issued by SEIAA

State Environment Impact Assessment Authority (SEIAA) is an authority that grants environmental clearance for Category B projects. Procedure to generate EC cover page for Category B projects is exactly similar to that of Category A projects, as explained in the preceding pages. 5th character of the EC identification number will define the Category of the project and therefore, the project can be easily identified as Cat A or B.

Further, a valid environmental clearance shall be one that has EC identification number & E-Sign generated from PARIVESH.

SAMPLE

ENVIRONMENTAL CLEARANCE

PARIVESH
(Pro-Active and Responsive Facilitation by Interactive, and Virtuous Environmental Single-Window Hub)

Government of India
Ministry of Environment, Forest and Climate Change
(Issued by the State Environment Impact Assessment Authority (SEIAA), Rajasthan)

To,

The Partner
R.R.C. MINES AND MINERALS
Near Ashapura Mandir, Outside Nathusar Gate, Bikaner -334001

Subject: Grant of Environmental Clearance (EC) to the proposed Project Activity under the provision of EIA Notification 2006-regarding.

Sir/Madam,

This is in reference to your application for an Environmental Clearance (EC) in respect of the project submitted to SEIAA vide proposal number SIA/RJ/MIN/23211/1900 dated 15 Jun 2019. The particulars of the environmental clearance granted to the project are as below

1.	**EC Identification No.**	**EC21B001RJ191110**
2.	**File No.**	14110
3.	**Proposal type:**	New
4.	**Category**	B2
5.	**Project/Activity including Schedule no.**	1(a)(i) Mining of minerals
6.	**Name of the Project**	Ball Clay, Gravel, Murrum, Silica Sand & Bajri Mining Project
7.	**Name of Company/ Organization**	R.R.C. MINES AND MINERALS
8.	**Location of Project:**	Rajasthan
9.	**ToR date:**	02 Jan 2019

The project details along with terms and conditions are appended herewith from page 2 onwards.

(e-Signed)
#Name of Member Secretary
(SEIAA , Rajasthan)

Date: 04/10/2021

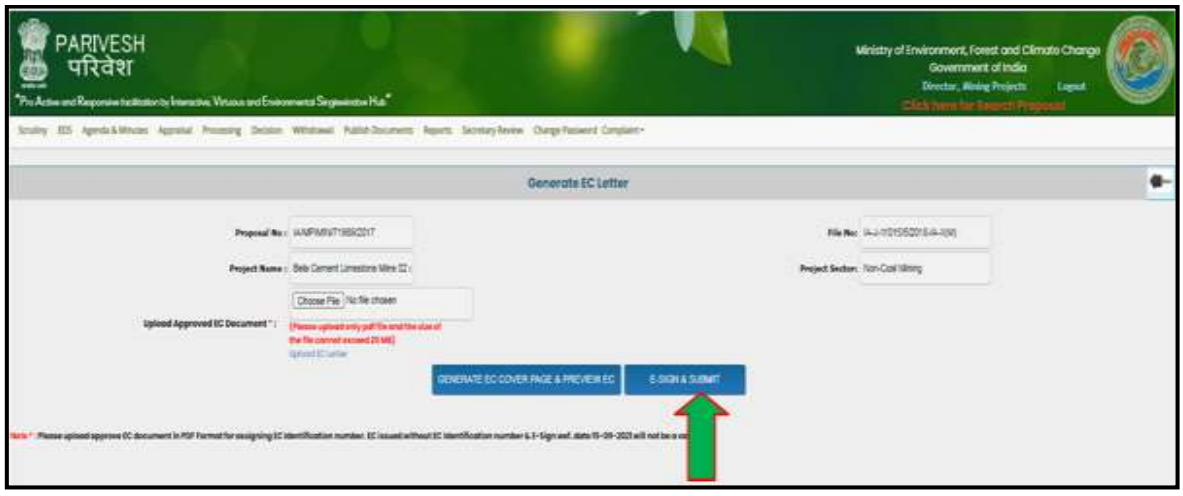
Note: A valid environment clearance shall be one that has EC identification & E-Sign number generated from PARIVESH. Please quote identification number in all future correspondence

This is Computer generated Cover Page

EC Identification No: EC21B001RJ191110 File No:14111 Date of EC issue:04/10/2021 Page 1 of 3

Step-14 After preview, E-Sign and Submit button is visible.

Step-15 Now click on "**E-Sign & Submit**"



Step-16 A page open for e-Sign Service of Aadhaar Based e-Authentication

Step-17 Enter AADHAAR number and click on "**GET OTP**"

Step-18 Enter OTP received on mobile registered with Aadhaar, and accept the consent

Step-19 A message appears showing message “Successfully E-Verified through Aadhaar and EC letter uploaded on PARIVESH.

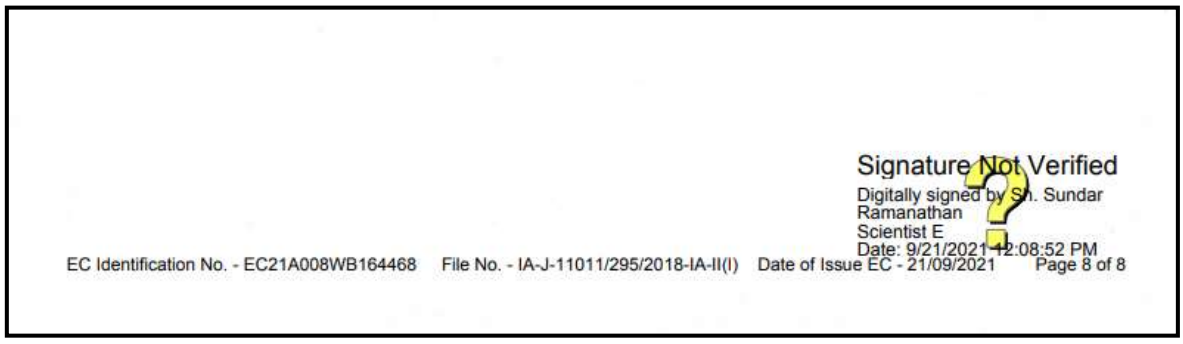
Step-20 Click on Ok, a Popup message appear showing message

Step-21 After successful generation of EC letter with EC cover page the screen appear as

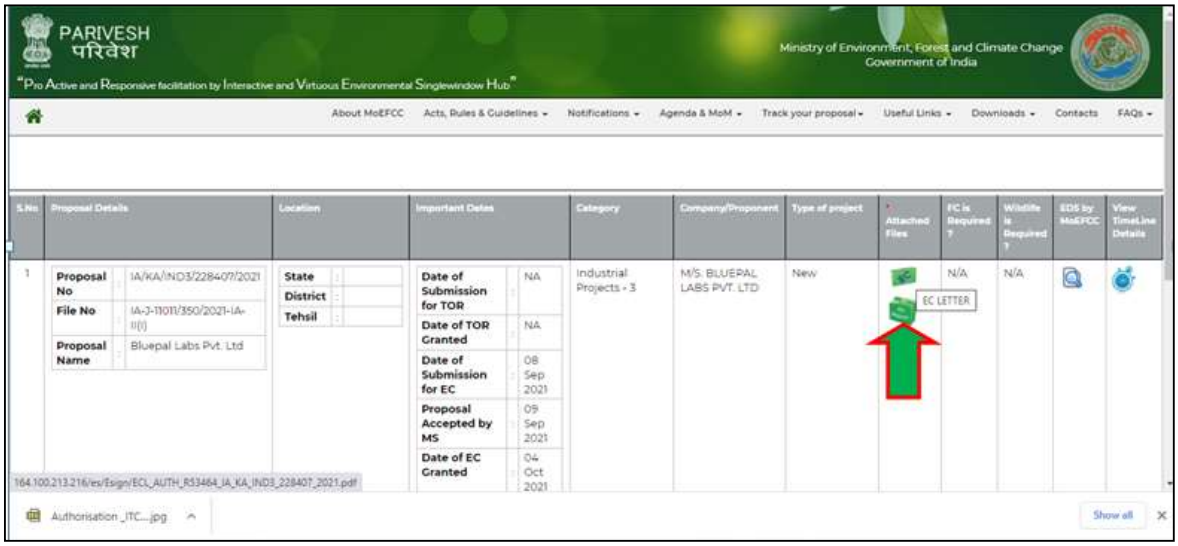
Step-22 Click on print EC Letter to Print EC letter

E-Sign signature validation in PDF:

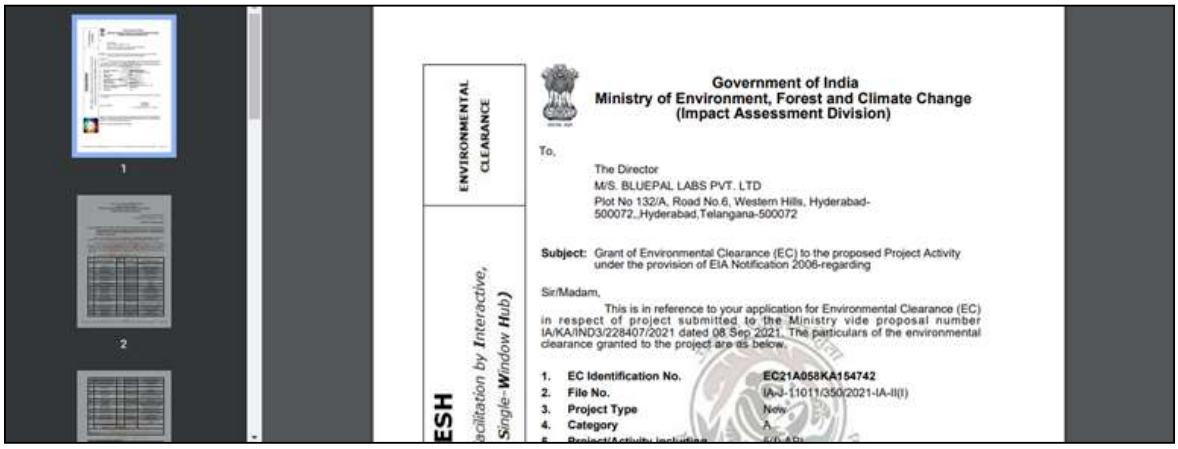
In case digitally signed signature on EC letter appear as Not verified, same needs to be validated as per the following steps



Step 1: Download EC letter

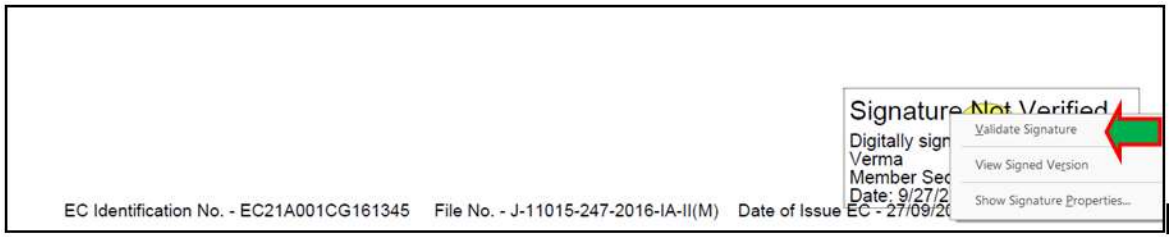


Step 2: Open EC letter with PDF (Make sue the PDF is pre installed on the System)

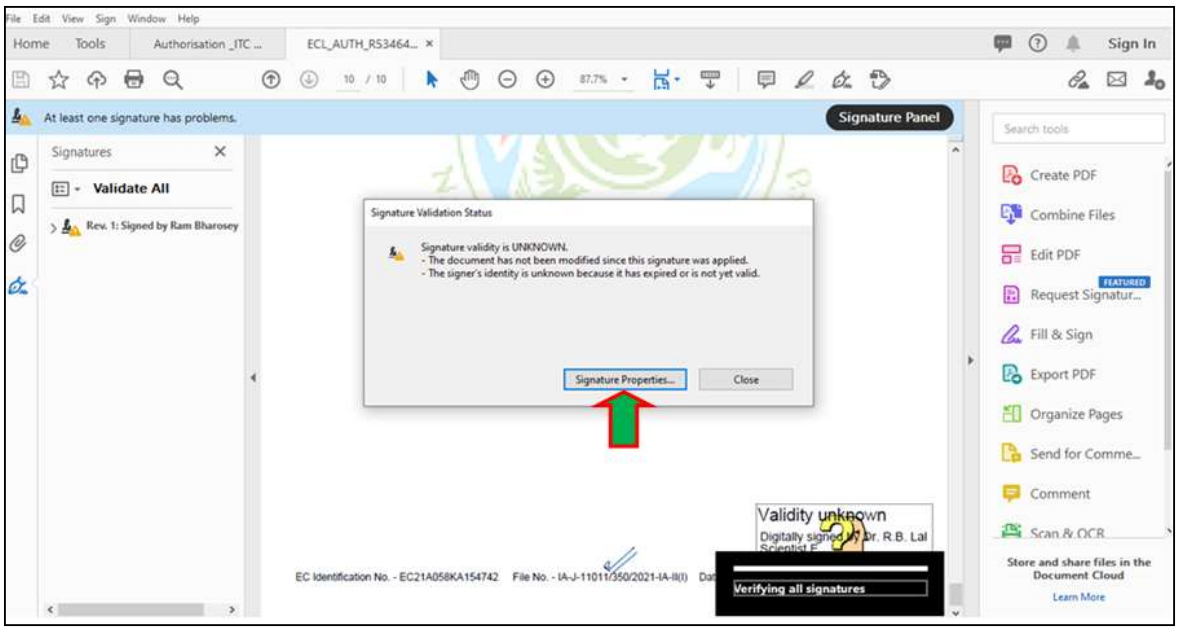


Step3: Right click on Signature not Verified

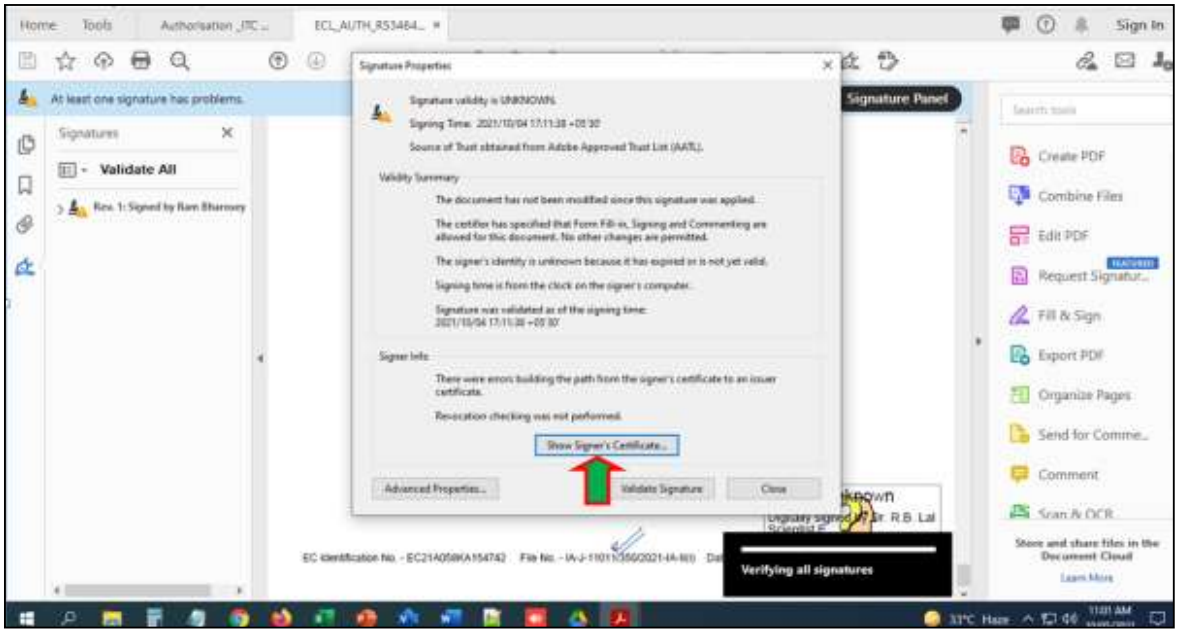
Step 4: Click on Validate Signature



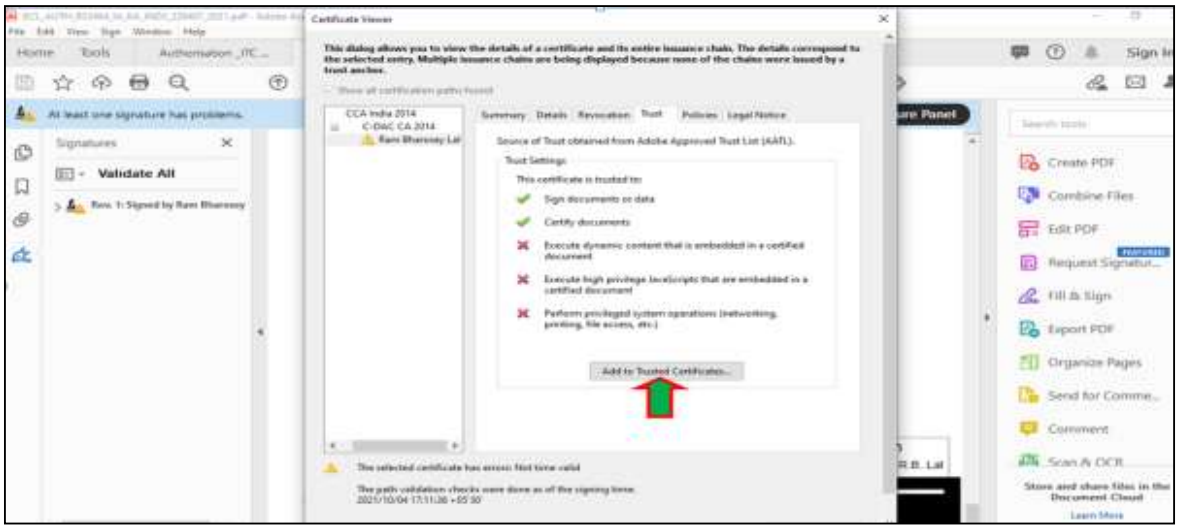
Step 5: Click on Signature Properties



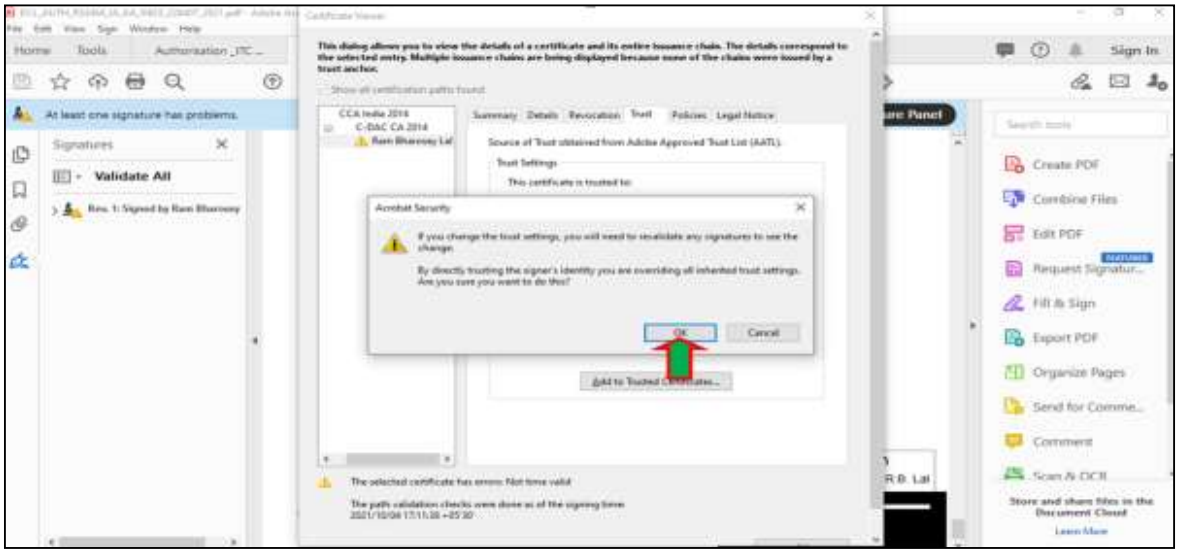
Step 6: Click on Show Signer's Certificate



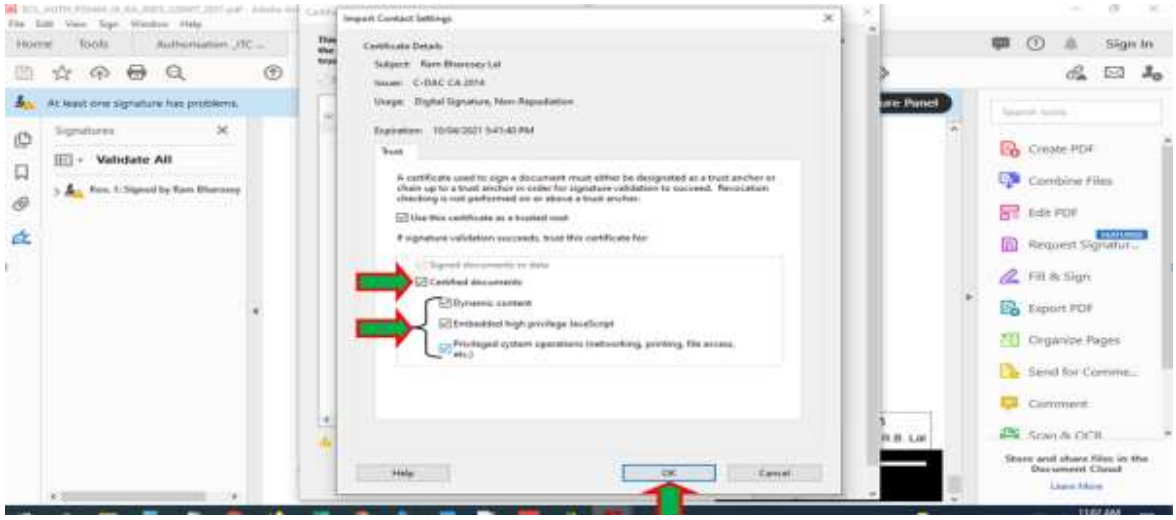
Step 7: Click on Add to trusted Certificate



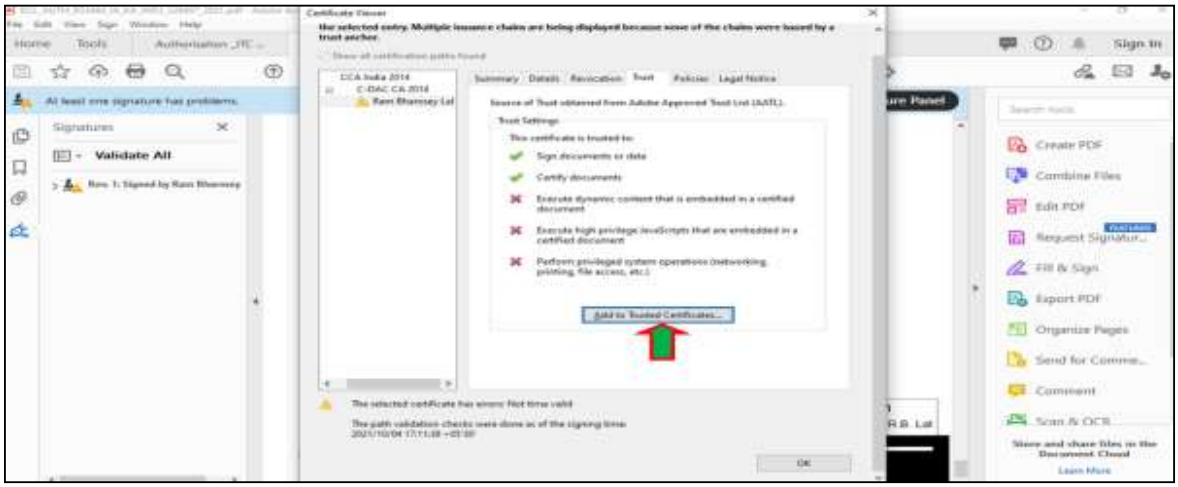
Step 8: Click on OK



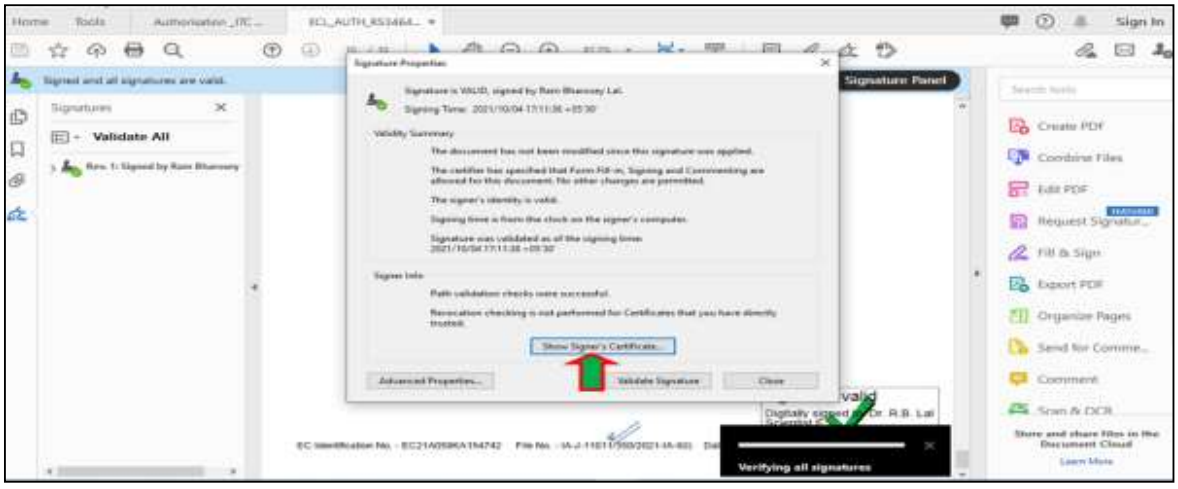
Step 9: Check Certified document and click on OK



Step 10: Click on Add to Trusted Certificates

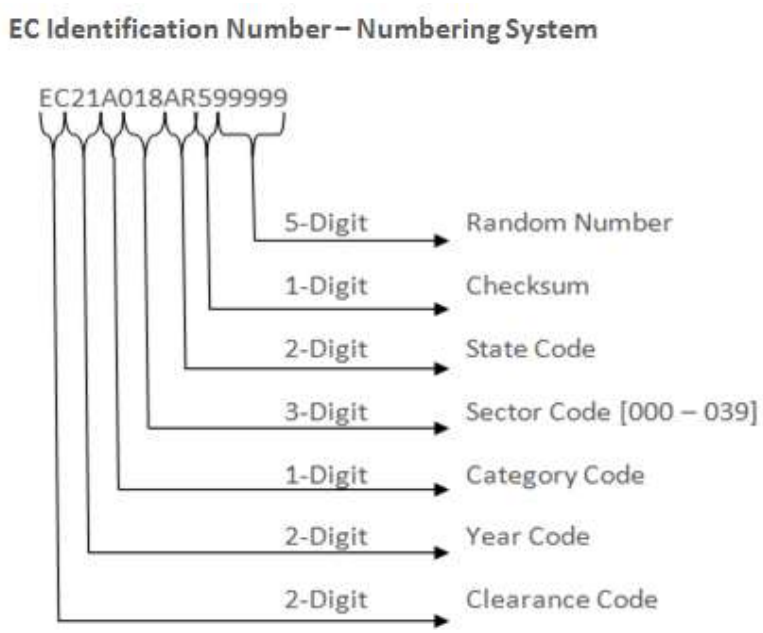


Step 11: Click on show Signer Certificate



Step 12 Signature validate successfully

EC Identification numbering logic

EC Identification No.	EC21A018AR599999 

Example:

EC Identification Number		**EC21A018AR599999**
First two Digit	EC	Clearance code (Environmental Clearance)
3rd & 4th Digit	21	Year Code (2021)
5th Digit	A	Category Code (CAT A)
6th to 8th Digit	018	Sector Code (5(c) Petro-chemical complexes (industries based on processing of petroleum fractions & natural gas and/or reforming to aromatics)
9th & 10th Digit	AR	State Code (Arunanchal Pradesh)
11th Digit	5	Checksum
12th to 16th Digit	99999	Random Number

Activity ID	Activity Name	Sector
1	1(a)(i) Mining of minerals	MIN
2	1(b) Offshore and onshore oil and gas exploration, development & production	IND2
3	1(c)(i) River Valley projects	RIV
4	1(d) Thermal Power Plants	THE
6	2(a) Coal washeries	CMIN
7	2(b) Mineral beneficiation	IND
8	3(a) Metallurgical industries (ferrous & non ferrous)	IND
9	3(b) Cement plants	IND
10	4(a) Petroleum refining industry	IND2
11	4(b)(i) Coke oven plants	IND
12	4(c) Asbestos milling and asbestos based products	IND
13	4(d) Chlor-alkali industry	IND3
14	4(e) Soda ash Industry	IND3
15	4(f) Skin/hide processing including tanning industry	IND
16	5(a) Chemical fertilizers	IND3
17	5(b) Pesticides industry and pesticide specific intermediates (excluding formulations)	IND3
18	5(c) Petro-chemical complexes (industries based on processing of petroleum fractions & natural gas and/or reforming to aromatics)	IND2
19	5(d) Manmade fibers manufacturing	IND2
20	5(e) Petroleum products and petrochemical based processing such as production of carbon black and electrode grade graphite (processes other than cracking & reformation and not covered under the complexes)	IND2
21	5(f) Synthetic organic chemicals industry (dyes & dye intermediates; bulk drugs and intermediates excluding drug formulations, synthetic rubbers, basic organic chemicals, other synthetic organic chemicals and chemical intermediates)	IND3
22	5(g) Distilleries	IND2
23	5(h) Integrated paint industry	IND3
24	5(i) Pulp & paper industry	IND
25	5(j) Sugar Industry	IND2
27	6(a) Oil & gas transportation pipe line (crude and refinery/ petrochemical products), passing through national parks /sanctuaries/coral reefs /ecologically sensitive areas including LNG Terminal	IND2
29	7(a) Air ports	MIS
30	7(b) All ship breaking yards including ship breaking units	NCP
31	7(c) Industrial estates/ parks/ complexes/ areas, export processing Zones (EPZs), Special Economic Zones (SEZs), Biotech Parks, Leather Complexes.	NCP
32	7(d) Common hazardous waste treatment, storage and disposal facilities (TSDFs)	MIS
33	7(e) Ports, harbors, break waters, dredging	NCP
34	7(f) Highways	NCP
35	7(g) Aerial ropeways	MIS
36	7(h) Common Effluent Treatment Plants (CETPs)	MIS

37	7(i) Common Municipal Solid Waste Management Facility (CMSWMF)	MIS
38	8(a) Building and Construction projects	MIS
39	8(b) Townships and Area Development projects.	MIS
42	1 (a) Mining of minerals	CMIN
43	2(b) Mineral beneficiation	MIN
57	7(d)(a)Common Bio-Medical Waste Treatment Facility	MIS
58	5(f) API	IND3
59	4(b)(ii) Coal Tar Processing Units	IND2
60	5g(a) Grain Based distilleries for Ethanol Blended Petrol	IND2
61	1(a)(ii)Slurry pipelines (coal, lignite and other ores) passing through national parks / sanctuaries / coral reefs, ecologically sensitive areas.	MIN
62	1(c)(ii) Irrigation projects	RIV

Note: *System will generate the first page of the EC document only. Rest pages of the EC document i.e page 2 and onwards should be manually prepared and saved in the PC in pdf format*

Note: *Page 2 and onwards of the EC letter should be prepared using Times New Roman font (Size 12) without header, footer and page number. Water mark of Ministry logo should be used at the center of page 2 and onwards. Last page of the EC letter should have the sufficient space to accommodate the Aadhaar based digital signature.*

EC generated at the Central level having the proposal number IA/WB/IND/78705/2018 may be referred for the structure of EC letter.

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Appointment of Shri Amit Khare, IAS (Retd.) as Advisor to the Prime Minister in Prime Minister's Office- reg.

DoPT order dated 12th October 2021

The Appointments Committee of the Cabinet has approved the appointment of **Shri Amit Khare, IAS (Retd.) (JH:1985) as Advisor to the Prime Minister in Prime Minister's Office,** in the rank and scale of Secretary to Government of India, on contract basis, as per other usual terms and conditions as are applicable in the case of reemployed officers of Secretary level in Government of India, initially for a period of two years or until further orders, whichever is earlier.

No. 36/01/2021-EO(5M-I)

Deepti Umashankar
Secretary
Appointments Committee of the Cabinet
& Establishment Officer
Government of India
Secretariat of the
Appointments Committee of the Cabinet
Ministry of Personnel, Public Grievances and Pensions
Department of Personnel and Training
New Delhi,

● ● ●

Appointments of officers at Joint Secretary/Joint Secretary equivalent level - reg.

DoPT order Dated 12.10.2021

The Appointments Committee of the Cabinet has approved the following appointments of officers at Joint Secretary/Joint Secretary equivalent level with pay at Level 14 (₹ 1,44 200 - 2,18,200/-) of the Pay Matrix:

(1) Appointment of Shri Vipul Bansal, IAS (KN:2005) as Joint Secretary, Department of Commerce, for an overall tenure of five years upto 18/01/2022 from the date of assumption of the charge of the post or until further orders, whichever is earlier, which is further extendable for two additional years on availability of cadre clearance from the State Government, vice Shri Keshav Chandra, IAS(UT:1995):

(2) Appointment of Shri Pawan Kumar Sain, IAS (UT:2005), as Joint Secretary, Economic Advisory Councii to PiW, NITi Aayog, for a combined tenure of seven years upto 24/07/2022 from the date of assumption of the charge of the post or until further orders, whichever is earlier vice Ms. Sumita Misra, IAS (HY:1990);

(3) Appointment of Shri N. Yuvaraj, IAS (AP:2005), as Joint Secretary, Department of Pharmaceuticals, for a combined tenure upto 04/11/2023 from the date of assumption of the charge of the post or until further orders, whichever is earlier vice Shri Navdeep Rinwa, IAS (UP:1999):

(4) Appointment of Ms. Meera Mohanty, IAS (HP:2005), as Joint Secretary, Prime Minister's Office, for a combined tenure upto 01/05/2022 from the date of assumption of the charge of the post or until further orders, whichever is earlier by temporarily upgrading the post of Director held by the officer.

No.33/05/2021-EO(SM-I)

Deepti Umashankar
Secretary
Appointments Committee of the Cabinet
& Establishment Officer
Government of India
Secretariat of the
Appointments Committee of the Cabinet
Ministry of Personnel, Public Grievances and Pensions
Department of Personnel and Training
New Delhi,

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In Rajya Sabha and In Lok Sabha

RAJYA SABHA

Protection of MSMEs in the country

Unstarred Question No. 2430
Shri T.G. Venkatesh:

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

(a) whether the MSME industry in the country is reeling under doldrums due to prolonged COVID – 19 situation along with 2nd wave and imminent 3rd wave warnings in the country;

(b) if so, the details thereof;

(c) whether the rehabilitation package announced by Government is not at all sufficient to revitalise the industry;

(d) whether Government has any plan of providing further sops and subsidies and financial assistance to the industry to overcome the situation keeping in view of the problems of the MSME industry, if so, the details thereof; and

(e) steps being taken by Government to protect the MSME industry in the country?

Answered On: 10.08.2021

(a) & (b): Assessments made by the National Small Industries Corporation and Khadi Village Industries Commission indicate that MSMEs units faced issues relating to liquidity, fresh orders, labour, logistics and availability of raw materials during the pandemic.

(c) to (e): As a consequence of the assessments made of the difficulties faced by MSMEs, Government of India and the Reserve Bank of India have launched a series of significant measures as part of Atmanirbhar Bharat, Budget for 2020-21 and recent package announced in June 2021 to support MSMEs. Details are provided at **Annex 1**. Government of India has also signed Micro, Small and Medium Enterprises Emergency Response Project for a World Bank loan of USD 750 million on July 06, 2020 as budgetary support to Government of India in order to support MSMEs under Atmanirbhar Bharat. This loan has been fully disbursed. Further, Raising and Accelerating Micro, Small and Medium Enterprise Performance (RAMP) loan has been approved by World Bank on June 04, 2021 for an amount of USD 500 million to support the Government of India"s nationwide initiative to revitalize the MSME sector, which has been heavily impacted by the COVID-19 crisis.

Minister of State In the Ministry of Finance (Shri Pankaj Chaudhary)

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 to be released in 45 days. 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** and they are allowed to be registered on UDYAM registration portal. 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 re-cyclers, 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

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 below. 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).

1. As credit facilities to MSME borrowers, extended under the emergency credit line guarantee scheme of GoI guaranteed by national credit guarantee trustee company (NCGTC), are backed by an unconditional and irrevocable guarantee provided by the GoI, 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. To meet the funding requirements of small industries including MSMEs and to kick start the investment cycle with additional focus on smaller MSMEs and businesses including those in credit deficient and

aspirational districts, the Reserve Bank extended to **SIDBI** refinance facilities of ₹15,000 crore in April 2020, ₹15,000 crore in April 2021 and ₹16,000 crore in June 2021 at the repo rate.

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.

GST On Covid-19 Essential Medical Products

Unstarred Question No-2466
Shri Neeraj Dangi:Dr. Amee Yajnik:

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

(a) whether Government imposed GST on essential medical products like oxygen, ventilators, vaccines and medicines during the COVID-19 pandemic; (b) the percentage of GST on such items; (c) the reasons for imposition of GST on life saving medicines and equipments; (d) whether Government intends to remove GST from all life saving medicines and equipments that are being used to fight the pandemic; and

(e) if not, the reasons therefor?

Answered On: 10.08.2021

(a) to (e): GST rates on supply of goods or services are prescribed on the recommendation of the GST Council which consists of Union Finance Minister and nominated Ministers of all State Governments. On Covid relief items like Oxygen, Ventilators, Oxygen Concentrators, specified medicines, testing kits etc., the GST rates have been substantially reduced on the recommendation of the Council, for the period upto 30th September, 2021. List of these items, with applicable GST rates, is at annexure

The Minister of State In The Ministry Of Finance (Shri Pankaj Chaudhary)

ANNEXURE

Covid Relief Goods on which GST rate has been reduced

S.No.	Description	From	To
A. Medicines			
1.	Tocilizumab	5%	Nil
2.	Amphotericin B	5%	Nil
3.	Anti-Coagulants like Heparin	12%	5%
4.	Remdesivir	12%	5%
B. Oxygen, Oxygen generation equipment and related medical devices			
1.	Medical Grade Oxygen	12%	5%
2.	Oxygen Concentrator/ Generator, including personal imports thereof	12%	5%
3.	Ventilators	12%	5%
4.	Ventilator masks / canula / helmet	12%	5%
5.	BiPAP Machine	12%	5%
6.	High flow nasal canula (HFNC) device	12%	5%
C. Testing Kits and Machines			
1.	Covid Testing Kits	12%	5%
2.	Specified Inflammatory Diagnostic Kits, namely D- Dimer, IL-6, Ferritin and LDH	12%	5%
D. Other Covid-19 related relief material			
1.	Pulse Oximeters, including personal imports thereof	12%	5%
2.	Hand Sanitizer	18%	5%
3.	Temperature check equipment	18%	5%
4.	Gas/Electric/other furnaces for crematorium, including their installation, etc.	18%	5%
5.	Ambulances	28%	12%

The above stated concessions are effective upto and inclusive of 30th September, 2021.

Wrong pricing and export cases unearthed by ED

Unstarred Question No.2472
Shri Shaktisinh Gohil:

Q. Will the Minister of Finance be pleased to State:

(a) the number of cases of wrong pricing and exports done through malafide means from Special Economic Zones (SEZ) that have been unearthed by the Enforcement Department (ED), Customs or other

departments of Government during the last three years and the details thereof; and

(b) the plan of Government to take steps to stop these illegal activities?

Answered On: Tuesday, August 10, 2021
Sravana 19, 1943 (Saka)

(a) Directorate of Revenue Intelligence has booked four such cases. These cases involve ₹5441 crore in which 12 persons have been arrested and ₹17 crore has been recovered. In addition, Ministry of Commerce has referred two cases of mis-declaration of value of goods being exported to DRI.

(b) Officers under CBIC maintain necessary vigil on the matter and stand committed to safeguard government revenue. Sample inspection of consignments are being resorted to.

Minister of State In The Ministry of Finance (Shri Pankaj Chaudhary)

National Portal For Persons Living With Rare Diseases

Unstarred Q.No. 2477
Smt. Priyanka Chaturvedi:

Q. Will the Minister of **Health and Family Welfare** be pleased to state:

(a) whether a national crowdfunding portal is being set up for persons living with rare diseases to crowdsource funds for their healthcare, as suggested in the National Policy for Rare Diseases 2021, and the recent Delhi High Court order; and

(b) whether there are entities being incentivised under the Production Linked Incentives scheme to innovate and manufacture orphan drugs, as suggested in the National Policy for Rare Diseases 2021?

Answered On: 10th August, 2021

(a) The Department of Health and Family Welfare has launched a Digital Portal for Crowdfunding & Voluntary Donations for the treatment of patients of Rare Diseases in accordance with the mandate of the National Policy for Rare Diseases 2021. The Digital Portal may be accessed through https://rarediseases.nhp.gov.in/

(b) The Department of Pharmaceuticals has initiated the implementation of Production Linked Incentive Scheme for Pharmaceuticals. The Scheme provides for financial incentives to manufacturers selected under the scheme for domestic manufacturing of various product categories, which also include Orphan drugs. The guidelines for the Scheme are available on the website of the Department of Pharmaceuticals under the tab 'Schemes'.

The Minister of State In The Ministry of Health And Family Welfare (Dr. Bharati Pravin Pawar)

Deaths Due To Lack Of Oxygen

Unstarred Q. No 2487
Shri Rajmani Patel:
Shri Akhilesh Prasad Singh:

Q. Will the Minister of **Health and Family Welfare** be pleased to state:

a) whether Government has maintained a record of deaths caused due to lack of oxygen in India;

b) if so, the number of deaths caused by lack of oxygen between March 1, 2021, till date; and

c) if not, the reasons for the same, including the reasons whether or not Government intends to build such a database?

Answered On: 10th August 2021

(a) to (c) Health is a state subject. Government of India has provided the required technical support and has also supported the states through logistic and financial support to further strengthen the existing health infrastructure to tackle COVID-19 pandemic.

Some of the ongoing initiatives to further strengthen healthcare infrastructure include:

- With the intent to reduce the risk of cross infection to non-COVID patients as well as to maintain continuity of non-COVID essential health services in the country, a three-tier arrangement of dedicated COVID-19 health facilities [(i) COVID Care Center (CCC); (ii) Dedicated COVID Health Centre (DCHC) and (iii) Dedicated COVID Hospital (DCH)] has been implemented in the country.
- Government of India, to supplement the hospital facilities has roped in tertiary care hospitals under ESIC, Defence, Railways, paramilitary forces, Steel Ministry etc. Further, many large temporary treatment facilities were established by DRDO to manage surge in COVID-19 cases

in the country.

- isolation bed capacity and ICU bed capacity which was only 10,180 and 2,168 before the first lockdown (as on 23rd March 2020) in being enhanced continuously and is currently at 18,03,266 isolation beds and 1,24,598 ICU beds (as on 5th August 2021).
- The daily liquid medical oxygen (LMO) supply, which was about 1292 MTs per day in February 2021 increased to 8593 MTs in April 2021. On 28th May 2021, a total of 10,250 MTs of LMO was allocated to the states. This was done by enhancement of LMO production in steel plants as well as in other LMO plants. Restrictions were imposed on industrial use of oxygen.
- A dynamic and transparent framework for allocation of medical oxygen in consultation with States/UTs and all the stakeholders such as relevant Ministries, manufacturers/suppliers of liquid oxygen etc. was prepared.
- Online digital solutions viz. Oxygen Demand Aggregation system (ODAS) and Oxygen Digital Tracking System (ODTS) have been developed to ascertain the demand for medical oxygen from all medical facilities and to track their transportation.
- To avoid wastage of medical oxygen, guidelines on rational use of oxygen were issued on 25th September 2020, and further revised and disseminated to States on 25th April 2021.
- 1,02,400 oxygen cylinders were procured in April and May of 2020 and distributed to States. Further orders for additional 1,27,000 cylinders have been placed on 21.04.2021 (54,000 jumbo cylinders (D type) and 73,000 regular cylinders (B type). Deliveries of the same have started and 73,352 (56,108 B-type and 14,244 D-type) cylinders have been delivered as on 3rd August 2021.
- To generate oxygen at the health facility level, PSA plants are being established in each district hospitals, especially in far flung areas enabling the hospitals to become self-sufficient in generation of oxygen for their needs and thereby, reduce the burden on the medical oxygen supply grid across the country.
- Further, to fast-track the availability of Medical Oxygen in rural and peri-urban areas, more than 39,000 oxygen concentrators have been allocated to various States.
- Ministry of Health & Family Welfare continues to provide technical guidance for managing various aspects of COVID-19. So far more than 150 guidelines/advisories/SoPs/plans have been provided to States/UTs. Taking note of ingress of COVID-19 pandemic in peri-urban and rural areas, Ministry of Health & Family Welfare on 16th May 2021 issued an SOP on COVID-19 Containment & Management in Peri-urban, Rural & Tribal areas.
- Further COVID-19 treatment protocols and advisories both for adults as well as pediatric age groups were issued and widely disseminated to promote rational use of drugs and oxygen.
- During the F.Y. 2019-20. funds to the tune of Rs.1113.21 crore was released to the States/ UTs under NHM towards management and containment of COVID-19 pandemic.
- In September 2020, the Union Government further allowed use of SDRF by the States for oxygen generation and storage plants in hospitals; strengthening ambulance services for transport of patients; and setting up containment zones, COVID-19 care centres. States were allowed to spend maximum 35% of annual allocation of funds under SDRF for the financial year 2019-20. The ceiling was further enhanced to 50% during the financial years 2020-21 and 2021-22 for containment measures of COVID-19.
- During the FY 2020-21, funds to the tune of Rs.8257.88 crore has been released to the States/ UTs towards the India COVID-19 Emergency Response and Health System Preparedness Package.
- In addition, 'India COVID-19 Emergency Response & Health System Preparedness Package: Phase-II' has also been approved by the Cabinet with Rs 23,123 crores (with Rs. 15,000 Cr as Central Component & Rs 8,123 Cr as State component) and is to be implemented from 1st July 2021 to 31st March 2022. So far Rs. 1827.78 crore has been released to States/UTs in 2021-22 under ECRP Phase-II in FY 2021-22.

  It includes support to State/UT level for ramping up Health Infrastructure including those in

rural, tribal and peri-urban areas closer to the community, providing support for procurement of drugs and diagnostics to enhance service delivery at district and sub district levels for management of COVID-19 cases (including pediatric care) and for maintaining a buffer of drugs, support for IT Interventions such as implementation of Hospital Management Information System and expanding access to tele-consultations in all districts, and support for capacity building and training for all aspects of management of COVID-19.

- Further, under the National COVID Vaccination Program, Government of India is procuring vaccines and providing them free of cost to States and UTs. As on 6th August 2021, a total of about 51.38 crore doses have been supplied to States/ UTs from all sources i.e. Government of India's Covid vaccine supply free of cost to all States/ UTs, State/UTs and Private Hospitals procured Covid vaccine.

Although health is a state subject, detailed guidelines for reporting of deaths have been issued by Union Health Ministry to all States/UTs. Accordingly, all States/UTs report cases and deaths to Union Health Ministry on a regular basis.

ICMR on 10th May 2020 issued 'Guidance for appropriate recording of COVID-19 related deaths in India'

(Available at: https://www.icmr.gov.in/pdf/covid/techdoc/Guidance_appropriate_recording_of_related_deaths_India.pdf). This was widely disseminated among States/UTs.

MoHFW vide letter dated 9th October 2020 has conveyed to States/UTs, WHO and ICMR guidelines on correct recording of COVID-19 related deaths in accordance with globally accepted ICD-10 classification and also urged states to undertake periodic death audits with the aim to improve quality of healthcare services by suitable corrective measures. States/UTs were also provided with a proforma for undertaking death audits in this regard.

The COVID-19 management toolkit for District Collectors shared by Ministry of Health & Family Welfare on 2nd April 2021 with states, also highlighted the need for deaths audits and follow up action as one of the key monitoring parameters.

168 Central teams deployed to 33 states/UTs have also reiterated need for correct recording of deaths and undertake periodic death audits.

The data of deaths are obtained from states/UTs. All states have also been advised that while reconciling the data, the details of deaths shall be indicated date wise & district wise to get a correct picture of the pandemic. As on 5th August 2021, a total of 4,26,290 deaths due to COVID-19 have been reported by States/UTs.

The Minister of State In The Ministry of Health And Family Welfare (Dr. Bharati Pravin Pawar)

"Dissolution of The Ministry of Health And Family Welfare"

Unstarred Question No. 2505
Ch. Sukhram Singh Yadav:
Smt. Chhaya Verma:

Q. Will the Minister of **HEALTH AND FAMILY WELFARE** be pleased to state:

(a) Whether health is a State subject;

(b) If so, the rationale and reasons for running jumbo Union Ministry of Health and Family Welfare along with the Ministers and huge expenditure of public money thereon;

(c) Whether Hon'ble Minister would propose to Cabinet Secretariat /PMO to dissolve the Union Ministry of Health and Family Welfare as health is a State subject and to reduce the unnecessary burden on public exchequer;

(d) If so, the details thereof; and

(e) If not, the rationale and reasons therefor;

Answered On: 10th August, 2021

(a) to (e): The subjects of public health, sanitation, hospitals and dispensaries figure in State List under Seventh Schedule of the Constitution of India. But port quarantine, including hospitals connected therewith are under the Union List; and medical education, medical profession and prevention of the extension from one State to another of infectious or contagious diseases or pests affecting men, animals or plants are under the Concurrent List.

Further, under the Government of India (Allocation of Business) Rules, 1961 (as amended from time to time) Ministry of Health and Family Welfare has been allocated Union Business concerning all matters

relating to Union agencies and institutes of research or for the promotion of special studies in medicine, central government hospitals, central government health scheme, laboratories relating to food and standardization thereof, port and airport health organization, international health relations and matters relating to epidemics – problems connected with supply of medicines, effects of malnutrition and shortage of drinking water leading to various diseases as a result of natural calamities. Also, matters relating to Business for Legislative and Executive purpose in respect of Union Territories are allocated to Ministry of Health and Family Welfare.

In respect of businesses with which the Central Government deal in a legislative capacity only for the Union and both the Legislative and Executive Capacities for Union Territories, all matters relating to medical/dental/nursing profession and education, pharmacists and pharmacy education, drugs standards, prevention of adulteration of foodstuffs and drugs are allocated to the Ministry. Ministry of Health and Family Welfare continues to perform the work assigned to it as per these Rules.

Further, health cannot be seen within a narrow ambit of medical treatment and disease control only, but has to be seen in the larger context of the well-being of all individuals. Ministry of Health and Family Welfare's work and responsibilities have to be seen in this larger context. Under the National Health Mission financial and technical support is provided by the Ministry to States/UTs to strengthen their health care systems including setting up/ upgrading public health facilities and augmenting health human resources. Through number of other Centrally Sponsored Schemes being implemented by the Ministry of Health and Family Welfare, it supports State Governments and Union Territories in managing disease control programmes, routine immunization, building new public health infrastructure, providing health insurance to deprived and poor families and improving the health of mother and child. Thus, Union Ministry of Health and Family Welfare, plays a critical role in the well being of all Indians.

The Minister of State In The Ministry of Health And Family Welfare (Dr. Bharati Pravin Pawar)

Acute Shortage Of Covid-19 Vaccine

Unstarred Question No. 2525 Dr. Narendra Jadhav:

Q. Will the Minister of **HEALTH AND FAMILY WELFARE** be pleased to state:

(a) Whether the nation is facing the acute shortage of COVID-19 vaccines, as there have been reports of vaccination centres shutting down, and gradual decrease in the number of people being administered vaccines, if so, the details thereof, State-wise; and

(b) Whether the prisoners lodged in various jails are being administered vaccines, if so, the details thereof?

Answered On: 10th August, 2021

(a) and (b) The Government of India has made all arrangements to secure COVID-19 vaccines for the eligible beneficiaries as per production and the availability of COVID-19 vaccines in the country. Government of India has been providing free supply of Covid vaccines in enough quantity to States/UTs for administration to prioritized beneficiaries as recommended by NEGVAC. Government of India is also providing 15 days' advance visibility of vaccine availability to States/ UTs with an advice to prepare and publicize in advance District-wise & CVC-wise plan for acceleration of Covid vaccination coverage while being cognizant of the total availability of Covid vaccines.

The pace of COVID vaccination has improved significantly from an average of 2.35 lakh doses administered per day in the month of January 2021 to an average of 43.41 lakh doses per day in the month of July 2021.

Government of India has issued detailed Standard Operating Procedures (SOPs) to facilitate vaccination of People Without Identity cards, including Prisoners. As on 4th August 2021 about 1.87 lakh Covid vaccine doses have been administered to the prisoners across the country.

The Minister of State In The Ministry of Health And Family Welfare (Dr. Bharati Pravin Pawar)

Side Effects Of Covid-19 Vaccination

Unstarred Question No.2530 Shri M.V. Shreyams Kumar:

Q.Will the Minister of **HEALTH AND FAMILY WELFARE** be pleased to state:

(a) whether the vaccines for COVID-19 do not provide any guarantee on their side effects;

(b) if so, the details thereof including reasons; and

(c) the steps taken or being taken by Government to ensure that people who develop side effects after vaccination are suitably compensated?

Answered On: 10th August, 2021

(a) & (b): Central Drugs Standard Control Organization (CDSCO) has granted permission to five COVID-19 vaccines for active immunization of individuals of ≥18 years old for the prevention of COVID-19.

Like any drugs, the administration of vaccine may result in side effects which are usually mild and self-limiting. Vary rarely serious adverse effects are noted. Common side effects may include headache, rash, chills, myalgia, fatigue, fever, dizziness, swelling or redness at the site of injection, pyrexia etc. However, the benefits of the current Covid-19 vaccines approved in the country, outweighs any risk associated with their vaccines.

New Drugs including Vaccines are approved under the provisions of New Drugs and Clinical Trials Rules, 2019 based on safety & efficacy profiles of product.

(c): For COVID-19 vaccination, measures have been put in place like availability of anaphylaxis kits at each vaccination site, immediate referral to Adverse Event Following Immunization (AEFI) management center and observation of vaccine recipients for 30 minutes at session site for any adverse events so as to take timely corrective measure. Also, the AEFI management of such cases are provided free of cost treatment in Public Health Facilities.

The Minister of State In the Ministry of Health And Family Welfare (Dr. Bharati Pravin Pawar)

Amendment To CSR Policy For Covid-19 Crisis

Unstarred Question No. 2415 Dr. Banda Prakash:

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

(a) whether Government has amended coverage of CSR policy to include-research and development of new vaccine, drugs and medical devices undertaken in normal course of business and research and development activity related to COVID-19. if so, details thereof;

(b) whether it is compulsory for such research activity to be carried out in collaboration with Central or State Government or specified public institutes, if so, details thereof;

(c) whether Government has received the data regarding CSR compliance during ongoing financial year; and

(d) if so, the details thereof including total amount spent under CSR funds to combat the pandemic?

Answered On: 10th August, 2021

(a) & (b): Yes, Sir. As per proviso to Rule 2(1) (d) of the Companies (CSR Policy) Rules, 2014, such research and development activities shall be carried out in collaboration with any of the institutes or organisations mentioned in item (ix) of Schedule VII of the Companies Act, 2013 ('Act').

(c) & (d): As per the Act, companies are required to hold Annual General Meeting (AGM) within six months from the end of financial year. Thereafter, financial statements and board report containing disclosure about CSR, are to be filed in MCA21 within 30 days of the AGM. Thus, filings for the ongoing financial year 2021-22 are required to be made only after the end of ongoing financial year.

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]

Lok Sabha

Price Control Of Drugs

Unstarred Question No. †3512
Shri Arun Sao: Shri Vijay Baghel: Shri Sunil Kumar Soni:

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

(a) the details about the criteria/guidelines fixed by the Government/National Pharmaceutical Pricing Authority (NPPA) for the pricing of essential medicines including the medicines used for the treatment of cancer, diabetes and HIV as well as heart and kidney diseases;

(b) whether the price of essential medicines and other medicines has been decreased and if so, the details thereof;

(c) the steps taken by the Government to control/ reduce the price of medicines during each of the last three years and the current year and the extent to which success has been achieved so far; and

(d) the details of total Jan Aushadhi Kendras set up so far including Chhattisgarh to provide inexpensive generic medicines through Pradhan Mantri Jan Aushadhi Yojana, State-wise?

Answered On: 10th August, 2021

(a) & (b): National Pharmaceuticals Pricing Policy (NPPP), 2012 prescribes the guidelines for regulation of prices of drugs. The key principles of price regulation are (i) essentiality of drugs (ii) control of prices of formulations and (iii) Market Based Pricing. Based on NPPP, 2012 and subsequent Drugs (Prices Control) Order, 2013 (DPCO, 2013), National Pharmaceutical Pricing Authority (NPPA) under the Department of Pharmaceuticals fixes the ceiling price of scheduled drugs specified in the first schedule of the DPCO, 2013 and monitors the prices of non-scheduled drugs.

NPPA has fixed the ceiling prices of scheduled drugs, including the essential medicines used for treatment of cancer, diabetes and HIV as well as heart and kidney diseases. Further, NPPA has put a cap on Trade Margin of 42 select non-scheduled anti-cancer medicines under 'Trade Margin Rationalization (TMR)' Approach resulting in reduction up to 90% of Maximum Retail Price (MRP) of 526 brands of these medicines.

NPPA has also brought 106 non-scheduled anti-diabetic and cardio vascular drugs under price control by invoking extra ordinary powers in public interest. The total annual savings on account of revision of ceiling prices of medicines under National List of Essential Medicines (NLEM), price control of anti-diabetic & cardiovascular, fixation of ceiling price of stents, knee implants and capping of TMR on anti-cancer are estimated to the tune of Rs. 12,500 crore.

(c): NPPA monitors the ceiling price of the scheduled formulations to ensure that the MRP of such formulations are within the range of ceiling price and monitors non-scheduled formulations to ensure that their MRP does not increase by more than 10% during the preceding twelve months. The details of retail/ceiling prices fixed/revised by NPPA are available on NPPA's website www.nppaindia.nic.in.

The details of the formulations for which price have been fixed by NPPA in the last 3 years are as follows:

S. No	Type	2018-19	2019-20	2020-21	2021-22 (till 31st July 2021)
1.	Ceiling Price	5	7	12	1
2.	Retail Price	329	256	321	84
3.	Ceiling price for Pharmaceutical Purchase Policy (Recommendation)	-	105	57	-
4.	TMR	42 (Anti Cancer drugs)	-	-	6 (Medical Devices)

(d): Under the Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP), till 04.08.2021, about 8,004 Pradhan Mantri Bhartiya Janaushadhi Kendras (PMBJKs) are open across the country to provide generic medicines at cheaper rates to the citizens. Till 04.08.2021, about 236 PMBJKs are open in the State of Chhattisgarh. State/UT wise list of PMBJKs is enclosed as **Annexure**.

Minister In the Ministry of Chemicals And Fertilizers (Shri Mansukh Mandaviya)

Annexure

State/UT wise list of PMBJK's functioning across the country as on 04.08.2021		
Sl. No.	**Name of the State/ UT**	**No. of PMBJK functional**
1	Andaman & Nicobar	2
2	Andhra Pradesh	180
3	Arunachal Pradesh	28
4	Assam	83
5	Bihar	244
6	Chandigarh	7
7	Chhattisgarh	236
8	Delhi	333
9	Goa	9
10	Gujarat	533
11	Haryana	215
12	Himachal Pradesh	61
13	Jammu And Kashmir	100
14	Jharkhand	73
15	Karnataka	916
16	Kerala	825
17	Ladakh	3
18	Lakshadeep *	0
19	Madhya Pradesh	223
20	Maharashtra	592
21	Manipur	32
22	Meghalaya	14
23	Mizoram	22
24	Nagaland	16
25	Odisha	302
26	Puducherry	16
27	Punjab	285
28	Rajasthan	125
29	Sikkim	3
30	Tamil Nadu	822
31	Telangana	153
32	DNH & D&D	35
33	Tripura	24
34	Uttar Pradesh	1114
35	Uttarakhand	205
36	West Bengal	173
Grand Total		**8004**

* Medicines are directly supplied to the administration of UT of Lakshwadeep

Medical Device Park

Unstarred Question No. 3567
Shri B.Y. Raghavendra:

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

(a) whether the Government is planning to take any steps to set up Medical Devices Park in the State of Karnataka;

(b) if so, the details thereof, district wise; and

(c) if not, by when it will be considered along with the criteria to implement the above said scheme?

Answered On: 10th August, 2021

(a), (b) & (c): The Government is implementing the scheme "Promotion of Medical Devices Parks" which provides for one-time grant-in-aid of maximum Rs. 100 crore per park for creation of common infrastructure facilities in 04(four) selected Medical Devices Parks which are to be developed by the State Governments. The total financial outlay of the scheme is Rs. 400 crore. The Department had invited proposals under the scheme from all the States and Union Territories and has received proposals from 16 States/Union Territories including a proposal from the Government of Karnataka for setting up a Medical Device Park at Kochanahalli Industrial Area in district Mysuru. The appraisal of the proposals received under the scheme has been initiated.

Minister In The Ministry Of Chemicals & Fertilizers (Shri Mansukh Mandaviya)

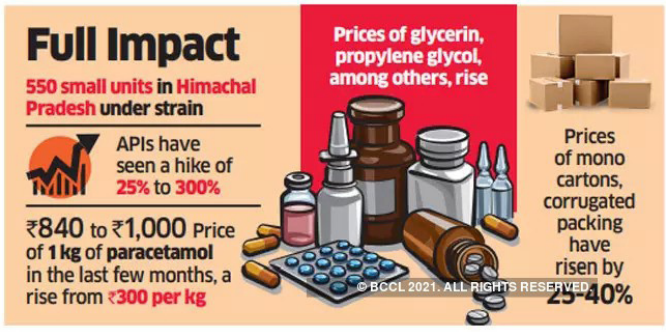
As input costs soar, small drug units reach out to Centre for help

A steep rise in raw material prices has begun to pinch the country's drug manufacturers to the extent that some have sought government intervention to tame the prices and a top drug maker said it may be forced to pass on the cost increase to consumers.

The prices of active pharmaceutical ingredients (APIs), excipients, glass vials and packaging material, among other inputs, have escalated over the last three months.

Executives of some leading pharmaceutical companies told ET that the situation is in large part due to factory shutdowns and production cuts in **China**, the main source of APIs and key starting materials for Indian companies. APIs are required to manufacture finished formulations.

Yasir Rawjee, chief executive of **Glenmark** Life Sciences (GLS), the maker of high-value APIs that target the chronic illness segments, said the company has so far been absorbing the increase in cost of inputs. "Now we will have to talk to our customers about passing on the input costs," he said.



The price rise has particularly hit the micro, medium and small **pharma** companies. In Himachal Pradesh's pharma hub, the 550-odd drug manufacturing units are facing a stiff challenge with raw material prices having trebled.

Rajesh Gupta, president of the Himachal Drug Manufacturers Association (HDMA), told ET that the prices of all APIs have risen by 25% to 300% over the last few months. For instance, paracetamol prices have risen to be in the Rs 840-1,000 per kg range, up from around Rs 300 per kg before the Covid-19 outbreak.

In this regard, HDMA has written to the prime minister, urging him to set up a task force on pharmaceutical inputs and packaging material to protect the industry and to prevent shortage of medicines in the country.

The association has also expressed concern over the increase in prices of excipients and solvents, including propylene glycol and glycerin. Glenmark Life's Rawjee, who is also the company managing director, said prices of widely used solvents like methanol has also gone up, rising by 59% in the last six months. The cost of tetrahydrofuran (THF), another solvent, has risen by 150% in the same period.

The **pharma industry** uses 10-15 solvents, mainly for extraction and purification in the drug manufacturing process.

Packaging material, another key material for the pharma industry, has become expensive, too.

According to HDMA's letter, prices of packaging material like aluminium and printed alu foils have risen by 25-30% over the last three months and are expected to increase further. The association's letter said that prices of mono cartons and corrugated packing have risen by 25-40% and continue to increase. Even the PVC for blistering of tablets and oral liquid PET bottles are showing 25-30% jump in prices.

Source: Teena Thacker and Vishwanath Pilla, ET Bureau, 12.10.2021

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AstraZeneca antibody cocktail study shows success treating COVID-19

Summary

- Shortly after infection, drug cuts risk of deterioration
- Astra sees shot's main use in preventative setting
- Faces competition from other antibodies, Merck tablet

AstraZeneca's (AZN.L) antibody cocktail against COVID-19, which has proven to work as a preventative shot in the non-infected, was also shown to save lives and prevent severe disease when given as treatment within a week of first symptoms.

The drug, a combination of two antibodies called AZD7442, reduced the risk of severe COVID-19 or death by 50% in non-

hospitalised patients who have had symptoms for seven days or less, the Anglo-Swedish drugmaker said on Monday.

The risk reduction was even better in patients who started therapy within just five days of initial symptoms, but AstraZeneca joins an already crowded field of medicines that were shown to prevent deterioration in patients with mild disease when given soon after diagnosis.

AstraZeneca executive Mene Pangalos said in a media call that the treatment results would mainly underscore the potential future use as a non-vaccine prevention. FWN2R716N

"If and when this is approved it will be used in the treatment setting as well. But the real differentiator for this antibody is going to be in the prophylactic setting," he said.

Similar therapies made with a class of drugs called monoclonal antibodies are being developed by Regeneron (REGN.O), Eli Lilly (LLY.N) and GlaxoSmithKline (GSK.L) with partner Vir (VIR.O). These therapies are approved for emergency use in the United States for treating mild-to-moderate COVID-19.

Regeneron's therapy showed 72% protection against symptomatic infection in the first week, and 93% after that.

GSK-Vir's showed a 79% reduction in the risk of hospitalisation or death due to any cause, while Eli Lilly's therapy showed a 70% reduction in viral load at day seven compared to a placebo.

Merck & Co Inc (MRK.N), in turn, is emphasising the convenience of use of its anti-COVID-19 tablet, which cut the risk of having to got to hospital or of dying by 50% in a trial of early-stage patients who had at least one risk factor.

Merck, collaborating with Ridgeback Biotherapeutics, on Monday applied for U.S. emergency clearance for the oral drug.

AstraZeneca, whose COVID-19 vaccine has been widely used across the globe, asked U.S. regulators last week to grant emergency use authorisation for AZD7442 as a preventative shot.

As such, it is designed to protect people who do not have a strong enough immune response to vaccines, primarily those who have received organ transplants or who are in cancer care.

If full market clearance is obtained after any emergency approval the market could widen, for instance, to include crew and passengers of a cruise ship, said Pangalos.

"You can say the same for people who don't want to be vaccinated but want an antibody," he added.

AstraZeneca said it is submitting the new treatment data on AZD7442 to global health regulators.

The trial took place across 13 countries and involved more than 900 adult participants, 90% of whom suffered from conditions that made the particularly vulnerable to COVID-19, such as cancer and diabetes. One half receiving AZD7442 and the rest a placebo.

Full trial results will be submitted for publication in a peer-reviewed journal, AstraZeneca said.

AZD7442 contains laboratory-made antibodies designed to linger in the body for months to contain the virus in case of an infection. A vaccine, in contrast, relies on an intact immune system to develop targeted antibodies and infection-fighting cells.

While Monday's results cover the use of AZD7442 in non-hospitalised patients, a separate trial is also studying its use as a treatment for hospitalised COVID-19 patients.

Source: Ludwig Burger, Yadarisa Shabong; Saumyadeb Chakrabarty, Kirsten Donovan and Alexander Smith, Reuters, 11.10.2021

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India rules out reducing gap between Covishield doses

Synopsis

Government officials say that the programme will continue to have the current dose interval. "The data is always under review and changes will be made only if required," said a senior government official. However, with the vaccine availability increasing by the day, experts say that the gap should be shortened for the elderly, immunosuppressed and persons over 45 with comorbidities.

The government has ruled out reducing the gap between the doses of **Covishield** in a bid to speed up administering both jabs to more people even when vaccine production and availability are increasing. Public health experts have raised concerns over the government's rule, pointing out that

relaxation should be given at least to immunosuppressed people, people with comorbidities.

Amar Jesani, editor of Indian Journal of Medical Ethics, feels that independent experts should review the government stand.

"Let them go through the data, and if they find that the lengthening of the period was not justified, let the government admit their mistake," he said. The government had in May this year decided to increase the gap between the two doses of Covishield, the Covid-19 vaccine by the **Serum** Institute to 12-16 weeks from the existing 6-8 weeks after the government's advisory body recommended it amid acute shortage of **vaccines**.

However, with the vaccine availability increasing by the day, experts say that the gap should be shortened for the elderly, immunosuppressed and persons over 45 with comorbidities. Serum Institute of India (**SII**) is gearing up to supply 200 million doses of Covishield this month as vaccination drive gains pace in the face of a possible third wave.

Government officials say that the programme will continue to have the current dose interval. "The data is always under review and changes will be made only if required," said a senior government official.

Sandeep Budhiraja, the group medical director at Max Healthcare, said that reducing the gap should be considered for those who must travel. "With the travel opening up and the mandatory requirement to show a full vaccine certificate is becoming an issue for those who have to travel. The government should think of shortening the time gap," he added.

Some experts have a different point of view though.

CMC Vellore microbiology professor Gagandeep Kang said there is no need to shorten the gap.

Source : *Teena Thacker, ET Bureau, 13.10.2021*

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Bharat Biotech's Covaxin gets expert panel's nod for children above 2 years

First Covid-19 vaccine in the world for children this young

Bharat Biotech's Covaxin will become the world's first Covid-19 vaccine approved for use in children as young as 2 years. The expert panel advising India's drug regulator on Tuesday recommended granting emergency use authorisation to the vaccine for children in the 2-18 years age group.

The Hyderabad-based company has been asked to submit data on any adverse event following vaccination every 15 days for the next two months. It has also been told to update the package inserts, fact sheet, and summary of product characteristics for its vaccine pack.

Bharat Biotech said it was awaiting further regulatory approval from the Central Drugs Standard Control Organisation (CDSCO) before the company could launch the product for children. The Subject Expert Committee (SEC) has submitted its recommendation to the drug regulator, and a formal approval from the Drugs Controller General of India (DCGI) is expected after he examines the data and the recommendation.

"Bharat Biotech has submitted data from clinical trials in the 2-18 years' age group for Covaxin (BBV152) to the CDSCO. The data has been thoroughly reviewed by the CDSCO and SEC, and they have provided their positive recommendations," the company said. The firm had submitted data from its paediatric trials to the regulator last week.

The gap between the two doses of Covaxin will be 28 days, as in the case of adults, the company said. Sources in the company confirmed that the vaccine for children was the same drug substance as Covaxin.

"This represents one of the first approvals worldwide for Covid-19 vaccines for the 2-18 age groups," the company said.

The SEC has asked Bharat Biotech to continue the study according to the whole-virion inactivated coronavirus vaccine-approved clinical trial protocol. The company has also been asked to submit safety data, including data on adverse events following immunisation (AEFI) and adverse event of special interest (AESI) every 15 days for the first two months, and thereafter on a monthly basis. The firm should submit a risk management plan according to the New Drugs & Clinical Trials Rules, 2019.

A Mumbai-based analyst said, "It is estimated that 350-400 million people in India are below the age of 18 years. A two-dose Covid vaccine regimen would translate into 700-800 million doses of potential demand."

Bharat Biotech has struggled to keep pace with demand for its Covid-19 shots. The company has indicated it would make 55 million doses in October and is aiming to touch 80 million doses a month by December.

As of now, the other vaccines approved for children so far are for use in three years and above.

Serum Institute of India is conducting trials on children aged 7 years and above for US major Novavax's Covid-19 vaccine (Covovax) here. The next leg of Covovax trials will include children aged 2 years and above. The permission from the regulator is coming in phases. Zydus Cadila's DNA vaccine has been approved for adolescents 12 years and above. The three-dose product is yet to be made available in the market. This would make Covaxin the first paediatric product available in India.

Clinicians felt that vaccine hesitancy would not be a problem for the paediatric vaccine. "The vaccine efficacy has been found to be similar to what was observed in adults. More importantly, the vaccine is extremely safe. With the WHO's approval expected in a week, which will also be a welcome progress, we could see the beginning of the last leg of the fight against Covid-19," said Dr Trupti Gilada, infectious disease specialist at Masina Hospital, Mumbai. She added that vaccine hesitancy observed during the initial phases was something that shouldn't be observed for children because India has had a very successful children immunisation tradition.

Globally, Sinovac had said its vaccine was safe for use in children aged 3 years and above. In September, Chile approved it for children aged 6 years and older. The Pfizer and Moderna mRNA vaccines have been used for adolescents.

Around June 2021, some cases of myocarditis (inflammation of heart walls) were reported in the US after taking the Pfizer-BioNTech vaccine, primarily among young males after they got the second shot. The US Centers for Disease Control and Prevention's advisory committee on immunisation practices reviewed available data and concluded that the benefits of Covid-19 vaccination to individual persons and the population outweigh the risks for myocarditis and recommended continued use of the vaccine in persons aged 12 years and above.

Source: Sohini Das, Business Standard, 13.10.2021

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India working with Indo-Pacific countries for recognition of vaccination certificates

Synopsis

Earlier, Hungary and Serbia agreed for mutual recognition of India's COVID-19 vaccination certificate. This move will help people move across countries for education, business, tourism and other things in the post-pandemic world.

The government is working closely with **Indo-Pacific** countries **Australia**, **Vietnam**, **Japan** and New Zealand on reciprocal recognition of **vaccination certificates**, according to people aware of the development, as it moves closer to reopening its doors to foreign tourists.

Top officials of the external affairs ministry have been in close touch with authorities in these four countries over this matter and the initiative has received positive response, ET has learnt. Vietnam, **India**'s key strategic partner in SE Asia, may soon announce its decision on mutual recognition of vaccination certificates, the people cited earlier said.

The response from Japan, too, has been positive, given the fact that it has a stricter Covid-19 protocol, one of the persons quoted earlier said. Japan is a top investor in India and a key economic partner and, therefore, mobility is a priority for the Indian government.

Recently, Hungary and India's traditional partner in Central Europe, Serbia, agreed on mutual recognition of India's vaccination certificate. This decision will facilitate mobility for education, business, tourism and employment. Serbia, which allows 30 visa-free entries for Indians, already recognises the Oxford/AstraZeneca Covid-19 vaccine Covishield for travel by Indians.

Last week, the home ministry announced that it will begin granting tourist visas to foreigners wanting to come to India on chartered flights with effect from October 15. Those travelling to India on flights other than chartered aircraft would be able to do so from November 15. ET had reported last week that India is reaching out to countries with a proposal to mutually recognise each other's vaccination certificates.

The heads of India's diplomatic missions across the globe have been directed to seek mutual recognition of vaccination certificates from their hosts, as India is geared up to relaunch tourist visas from the end of this week, ET has learnt.

The acceptance for India's indigenously developed Covid-19 vaccine Covaxin will be wider once the WHO approval comes through. The government may also relax quarantine norms for those countries recognising Indian vaccination certificates.

Source: *Dipanjan Roy Chaudhury, , ET Bureau, 11.10.2021*

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Speeding Up With Gatishakti

Amitabh Kant

Infrastructure has often been the back on which countries have transformed themselves. The New Deal, ushered in by President Roosevelt in USA, lifted the country off its feet after the Great Depression. Japan post World War II, where transit oriented development was crucial. Between 1960-1990, South Korea grew at an average rate of 10% per annum. China between 1980-2010 set a similar pace. The result was a socio-economic transformation within a generation in these countries. A critical enabler in the success of these countries was a multi-modal transport network, that significantly reduced the cost of logistics, boosting export competitiveness. As India seeks to usher in a similar economic transformation, exports will be key. However, our infrastructure has often been cited as a binding constraint in raising the potential growth rate of our country.

Why does infrastructure matter? In economics parlance, multiplier effects accrue to the economy through infrastructure spending. This means that not only does the project contribute immediately through increased demand for labour, construction materials, but also through the second order effects improved connectivity brings. Goods & people will move faster between destinations. The cost of logistics comes down. Studies by the Reserve Bank of India and the National Institute of Public Finance and Policy have estimated the multiplier to be between 2.5-3.5x. This means, for every rupee spent by the government in creating infrastructure, GDP gains worth Rs. 2.5-3.5 accrue. Furthermore, in times of economic contractions, this multiplier is larger than the one during times of economic expansion. This could imply that public investment if timed and targeted right, can actually 'crowd-in' private investment, rather than 'crowd-out'. To realise these benefits, raising our capital expenditure as a % of GDP will be crucial, at both the Central & State level.

At the same time, the infrastructure plan of a country must seamlessly & efficiently move goods & people across various modes of transport. However, this requires a coordinated approach. For instance, roads would feed into railway lines which in turn would feed into ports, efficiently moving goods from the hinterlands to the ports. This would enable the development of multiple urban, industrial centres across India. These urban centres in turn, would enable balanced regional development, as multiple industrial clusters could sprout up across India. Both Central and state government revenues would be bolstered, enabling higher spending on social sectors. This would have the spillover effect of easing pressure on existing urban agglomerations, leading to a higher quality of life across the board.

However, while India has tried to achieve the same, an end-to-end seamless, multi-modal transportation network is some way away. For instance, roads dominate the share of traffic. 64% of the freight in India is moved through roads. As diesel drives road transport, any spike in oil prices raise prices across the board, through higher transport costs and also because fuel is not part of GST, which means input tax credit is not available. Even post GST, FastTag and other initiatives, it is desirable to aspire for a higher share of railway in modal share as it remains a more efficient method. Furthermore, while many economic zones, industrial parks, logistics hubs and ports were planned, they often suffered owing to inefficient multi-modal connectivity, and also due to their small size. The fragmented nature of decision making, with each department working in silos meant that a disjointed industrial network was created. While several pieces of the puzzle were in place, many remained unconnected as well. A lack of scale in manufacturing and an inefficient logistics network hampered our global competitiveness.

However, achieving an efficient, seamless multi-modal transport network is no easy task. It requires independent government departments to work in close coordination and collaboration, guided by an overarching master plan. The Prime Minister during his Independence Day speech of 2021 had emphasised that the National Master Plan, GatiShakti would help realize the dreams of crores of our countrymen. The GatiShakti programme marks a paradigm shift in decision making to break the silos of departmentalism. In the proposed Plan, all the existing and proposed economic zones have been mapped along with the multimodal connectivity infrastructure in a single

platform. Individual projects of different line Ministries would be examined and sanctioned in future within the parameters of the overall Plan, leading to synchronisation of efforts. GatiShakti will bring synergy to create a world class, seamless multi-modal transport network in India. The National Master Plan will employ modern technology and the latest IT tools for coordinated planning of infrastructure. A GIS-based Enterprise Resource Planning system with 200+ layers for evidence-based decision-making is one example. The use of satellite imagery for monitoring is another. Digitisation will play a big role in ensuring timely clearances and flagging potential issues, and in project monitoring as well.

An efficient logistics network is one necessary condition. Another one is achieving economies of scale in manufacturing. Industrial parks and logistics parks need to grow in size to be globally competitive. The National Industrial Corridor Development Corporation (NICDC), formerly DMIDC will work in close coordination with state governments to develop these industrial corridors. State governments must take the lead in identifying parcels of land for industrialisation in consonance with the national plan to reap the maximum benefits of jobs and growth.

At the same time we must ensure these initiatives towards dedicated industrial corridors keep in mind the current realities. Climate change is upon is and all projects must incorporate adaptation and mitigation strategies. Indian Railways has made substantial commitments in greening railways, by committing towards becoming a net-zero carbon emitter before 2030. Railway electrification has been given a big thrust and has grown by 10x since 2014. The targets set for electrification must be regularly monitored.

Much has been achieved in ensuring India can transform into a manufacturing powerhouse. A continuous easing of the business environment, coupled with economic reforms will boost formality & productivity. Cleaning up of bank balance sheets will raise availability of credit. Availability of large tracts of land, can help achieve scale in manufacturing. Public investments in infrastructure will reduce the cost of logistics, through creating a seamless multi-modal infrastructure network. However, this would require synchronisation across various government levels and departments to execute. This is what the GatiShakti plan aims to achieve - synchronous decision making to create a world-class, seamless multi-modal transport network, on the back of which India will be transformed.

** The author is Chief Executive Officer, NITI Aayog. Views are personal.*

Source: Economic Times, 14.10.2021

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How Gennova is developing India's first indigenous mRNA Covid-19 shot

Where Gennova scores is that it has achieved to crack the stringent sub-zero temperature requirements

Speaking at the 76th session of the UN General Assembly last month, Prime Minister Narendra Modi said: "India has developed the world's first DNA vaccine. An m-RNA vaccine is in the final stages of development."

The announcement in the lofty halls of the UNGA in New York refers to a 15-year-old Pune-based pharmaceutical company, Gennova Biopharmaceuticals, the biotech subsidiary of the Rs 6,056-crore Emcure Group, which is developing the country's first indigenous mRNA Covid-19 vaccine, HGCO19, that is now under advanced human trials.

The firm now aims to leverage this platform for developing vaccines for Zika, Zoster and even TB. New-generation vaccines for Sars-CoV-2 are on the anvil, too – the company is working on different strains of the virus (like the variants of concern). It has administered at least the first dose to volunteers in its phase 2 trials. Phase 3 trials will be held soon in 22-27 sites across India.

Where Gennova scores is that it has achieved to crack the stringent sub-zero temperature requirements.

Unlike its global peers, its product, HGCO19, will be a lyophilized vaccine that can remain stable at 2 to 8 degrees Celsius. This would be a major advantage when it comes to distributing the vaccine within India as well as sub-Saharan Africa and other low- and medium-income countries. A lyophilized vaccine is based on freeze-drying and will come in powder form and be mixed with diluents before administration. US major Pfizer has started phase 3 clinical trials on a lyophilized version of its mRNA vaccine, and expects results this year.

Gennova's tryst with a Covid-19 vaccine based on an mRNA platform began last February but it has been working on the platform for the past three years.

As Samit Mehta, president and chief operating officer, Gennova, recollected: "We started off with biosimilars like erythropoietin (a hormone made by the kidneys and liver). We were importing the finished products and just marketing

it. Then we brought in Dr Sanjay Singh who was a tenured scientist at the National Institute of Health (NIH), US where he was heading the antigen research section."

IN THE MIX

- Gennova received **₹25 crore** funding from Dept of Biotechnology for HGC019
- Invested **₹125 crore** for clinical trials and other development of HGC019
- Was working on mRNA tech for a personalised therapeutic cancer vaccine
- Phase 2/3 trials are on in India
- GoI was eyeing **60 million** doses of HGC019 by December
- Vaccine to be in the market in 2022

Samit Mehta, who is the son of Emcure group founder Satish Mehta, said that after Singh joined the group, the biotech started to focus on establishing entire value chains from start to finish.

"Singh did not just focus on products, but on creating entire product technologies. That's how we launched tenecteplase (used in cardiac events), the world's first biosimilar for Boehringer Ingelheim's Metalyse," he added.

Gradually, Gennova added different technology platforms for biologic products to its repertoire – mammalian cell line tech, E-Coli or microbial tech, yeast-based platforms and so on. One thing led to the other and Gennova inaugurated its vaccine formulation plant in 2010.

In 2019, Gennova collaborated with well-known microbiologist and immunologist Steve Reed, who was at that time setting up his own company, HDT Bio, in Seattle. This is when Gennova started working on the mRNA platform.

"The original idea was to develop a personalised therapeutic vaccine for cancer, initially for HPV (human papillomavirus) and cervical cancer. This involves getting the gene sequence from the patient, and then within 45-60 days turning it into a personalised therapeutic vaccine," Mehta said. Gennova eventually wanted to move on to other cancers. (A therapeutic vaccine is one which is administered after a disease or infection has already occurred and works by activating the immune system of a patient to fight an infection.)

When the gene sequence of the Sars-CoV-2 was released in February last year, Gennova's leadership thought it was time to try their hands at developing a Covid-19 vaccine using mRNA technology.

The question, of course, is how Gennova's vaccine will fare against the competition. For one, Gennova is conducting phase 2 and 3 trials only now, so it will be some time before it hits the market. Meanwhile, Hyderabad-based Biological E has partnered with Canadian firm Providence Therapeutics for its mRNA Covid-19 vaccine and aims to make 600 million doses in 2022. US majors Pfizer and Moderna are waiting in the wings to enter the Indian market. Serum Institute of India and Biocon have recently said they are collaborating for working on this tech platform.

Emcure Group promoter and CEO Satish Mehta is optimistic. The latest research says there would be a need for booster doses of Covid-19 vaccines and he sees an opportunity here. "The best available vaccine would have demand," he said.

There are, however, entry barriers. As Samit Mehta explains: "There are few global suppliers for enzymes and speciality chemicals that go into making the mRNA vaccines. No one had anticipated such huge demand, and big pharma players have either bought these small firms or have long-term contracts with them. So the supply chain is a challenge."

As many as 43 different raw materials are required in the manufacturing process and Gennova and Emcure Group are working on backward integration for some of these products. Mehta senior feels that having succeeded in making a 2-8-degree product, Gennova has a game-changer. "Emerging markets would not opt for a sub-zero cold chain product. We would see demand there. Moreover, there would be demand for booster doses that people will eventually take in the long run," he said.

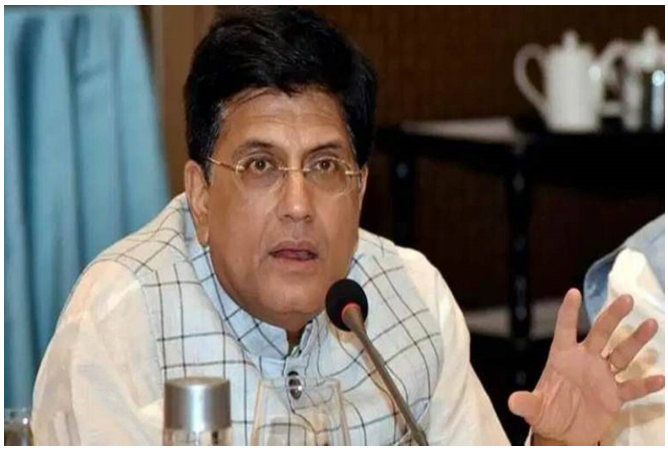
The founder of Emcure Group says that when he started his journey into branded generic drugs from a contract manufacturing company in the mid-1990s everyone had advised him against it. "We had a turnover of Rs 2-3 crore annually then, and all my friends had advised me against entering a fragmented pharma market," he recalled.

Emcure now ranks 12th in the domestic pharma market. The real growth is expected from Gennova. As he said, "The exponential growth will come from cutting-edge technology that Gennova is working on. The mRNA platform opens up lots of opportunities for us – it's a fourth generation technology – and we are excited about our early entry advantage."

Source: Sohini Das, Business Standard, 13.10.2021

India calls for IPR waiver in WTO, dismantling trade barriers in global fight against pandemic

It is a multilateral agreement on intellectual property (IP) rights such as copyright, industrial designs, patents and protection of undisclosed information or trade secrets.



In May this year, a revised proposal was submitted by 62 co-sponsors, including India, South Africa, and Indonesia.

Commerce and Industry Minister Piyush Goyal on Tuesday called for waiver of Intellectual Property Rights (IPR) in World Trade Organisation (WTO) and dismantling new trade barriers in the global fight against the COVID-19 pandemic.

In October 2020, India and South Africa had submitted the first proposal, suggesting a waiver for all WTO members on the implementation of certain provisions of the Trade-Related Aspects of Intellectual Property Rights (TRIPs) Agreement in relation to the prevention, containment or treatment of COVID-19.

In May this year, a revised proposal was submitted by 62 co-sponsors, including India, South Africa, and Indonesia.

The agreement on TRIP came into effect in January 1995. It is a multilateral agreement on intellectual property (IP) rights such as copyright, industrial designs, patents and protection of undisclosed information or trade secrets.

"Our response to the pandemic needs to ensure equitable access to vaccines and other COVID-19 related health products by ensuring quick resolution of the supply side constraints. One of the ways to demonstrate this is by accepting the TRIPS waiver proposal," Goyal said, in his address to the G20 Trade and Investment Ministerial Meeting in Naples, Italy.

He also pitched for actively resolving new trade barriers like vaccine differentiations or COVID passports, which impose mobility restrictions and impede the movement of personnel needed for delivering critical services.

"COVID-19 crisis is a powerful reminder of our inter-connectedness, and the need for a coordinated global strategy to overcome such an unprecedented public health situation," he said.

The minister also said that besides focusing on facilitating free flow of goods, G20 countries should make health services accessible and more affordable by the citizens of the world by enabling free flow of health services.

Commenting on the ongoing talks in WTO about fisheries subsidies, Goyal said countries engaged in distant water fishing should stop subsidizing their fishing in high seas and gradually reduce their fishing capacities, particularly, for overfished stocks.

"To achieve balanced outcomes in fisheries subsidies, policy space for the future is a must, not only to protect the livelihoods of poor and marginal fishermen and address the food security concerns but also to diversify, modernise and develop the fisheries sector, " he said.

Further he urged the G20 members to fulfil their commitments regarding Transfer Of Technology and climate finance, which are far from being fulfilled by the developed countries.

"India has consistently maintained that environmental/ sustainability measures need careful assessment to ensure that they do not become new trade barriers and the right forum for them is the dedicated Multilateral Environmental Agreements," he said.

On the sidelines of the G20 Trade Ministers Meeting, the minister held bilateral meetings with the Director General of the WTO, US, UK, EU, Brazil, China, Australia, South Africa, Indonesia, Canada, South Korea and Mexico.

"Historical wrongs against developing countries must be corrected rather than being carried over," he said.

In his meetings with the Canadian minister, he discussed steps to take forward the free trade agreement negotiations with the newly elected government while he called upon his South Korean and EU counterparts to accelerate review of the FTA.

Source: PTI , 12.10.2021

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LICENCE NO. MR/Tech/WPP-337/West/2021-23
RNI REGN. NO. 18921/1970, REGN.NO.MCW/95/2021-23
Published and Posted on 7th, 14th, 21st and 30th of every month
This issue posted at Mumbai Patrika Channel Sorting Office on 14.10.2021

Edited, Printed and Published by **Dr.Gopakumar G. Nair** on behalf of **Indian Drug Manufacturers' Association**, Printed at **Ebenezer Printing House**, Unit No. 5 & 11, 2nd Floor, Hind Services Industries, Veer Savarkar Marg, Dadar (West), Mumbai 400 028 and Published from 102-B, Poonam Chambers, "A" Wing, 1st Floor, Dr. A. B. Road, Worli, Mumbai 400 018. Editor: **Dr.Gopakumar G. Nair.**