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Indian APIs & Formulations for Global Healthcare

INDIAN DRUG MANUFACTURERS' ASSOCIATION

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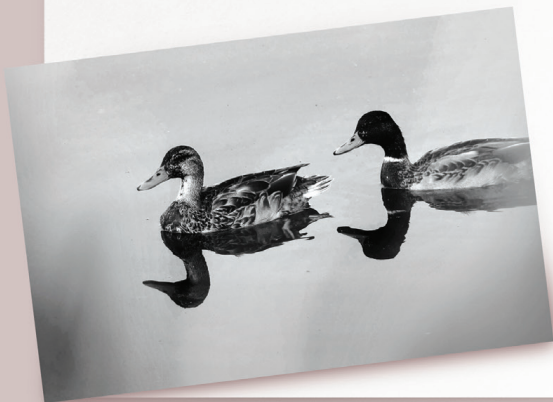
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102-B, 'A-Wing', Poonam Chambers,
Dr. A.B. Road, Worli, Mumbai - 400 018

Tel : 022-2494 4624 / 2497 4308 Fax: 022-2495 0723
e-mail: mail_idma@idmaindia.com/
actadm@idmaindia.com/ Website: www.idma-assn.org

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IDMA BULLETIN

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Address by Special Guest of Honour, Mr. Daara B Patel Secretary - General of IDMA at Pharma Leadership Summit held on 29-30 April 2021

Good Morning Ladies and Gentleman

Greetings from Indian Drug Manufacturers' Association (IDMA)

It gives me great pleasure and honour to address the august gathering & deliver my Special Guest of Honour address at the Pharma Leadership Summit today wherein the focus is on the theme '**Embracing Digitization in Pharma - Adopting the New Normal**' which delves into understanding future challenges and opportunities for the Pharma sector.

During Covid-19 Pandemic last year, there was a complete lockdown throughout India and production suffered as many migrants left their work place and returned to their native place. Even the Police and other Government Authorities were not able to handle the situation due to the lack of understanding of the covid-19 virus effects and were not in a position to decide which manufacturing comes under essential items and which doesn't. The authorities knew that Pharma Manufacturing comes under essential but weren't sure about the ancillary productions like raw materials, packing materials, transport, loaders, etc. Thus affecting the production of medicines.

IDMA Secretariat along with the State Boards has played an important role in facilitating uninterrupted supply of quality medicines by coordinating between the Industry, Government and Regulators. With regular interactions with the then Secretary, DoP, Dr P D Vaghela, Shri Navdeep Rinwa, Jt. Secretary, Dept. of Pharmaceuticals, the Chairperson NPPA, Madam Shubhra Singh IAS & her officers and various State FDA Officials & State Governments, the DCG(I) Dr. V G Somani & his dedicated team, the CDSCO, the Police Department, officials of AIOCD and the rest, we achieved a great feat – the capacity utilization in our factories rose from a meagre 25-30% during March / April 2020 to 60-80% during May / June 2020. Infact some companies touched 100% capacity. We managed this by increasing

the availability of raw materials, packing materials & requisite manpower not to forget the supply chain & distribution channels.

This was possible as the pharma companies provided extra facilities to the workers / staff like transportation, food and specially lodging facilities. All covid-19 protocols were strictly followed. Thus keeping their workers safe and secured while ensuring their manufacturing activities continue.

Today, the pharma industry business is normal and is progressing very well. There is an increase in demand of medicines.

This was possibly the first time in the history of our Association and the Pharma Industry that we have worked closely and shoulder to shoulder with our Parent Ministry, i.e. Ministry of Chemicals & Fertilizers, Department of Pharmaceuticals, DCG(I) as well as the other concerned Ministries along with the local authorities, Police, etc. We have proved to the Nation that by close and regular co-ordination between Industry Associations and the Ministries – the impossible could be achieved.

The New Normal has taught us to change as follows:

- **Work From Office**
- **Work From Home**
- **Work From Anywhere**

Nowadays there are Webinars, Virtual Meetings, Training Programs, AGMs, Shareholder Meetings, Job Interviews, Panel Discussions, Television Interviews on virtual platform.

Even the Doctor visits/calls are virtual. Infact Doctors prefer Virtual Calls. Digital Payments are being preferred and Paytm, Google Pay, etc. are mostly used.

Digital is an idea whose time has come. Despite these trying times, the pharmaceutical industry has triumphed and now we have learned to live with the New Normal that we all have experienced during this Covid-19

Pandemic throughout the year. Most of the Healthcare & Pharma Companies have learnt to adapt to this New Normal. The companies who have not adapted to the New Normal, Digitalization will have to catch up with the rest of the pharma companies or will have to lag behind in their development.

IDMA has all its Executive Committee Meetings, Special / Issue based Meetings, AGM, etc. virtually. We have helped several pharma and non-pharma seminar and training programs virtually.

It is a very simple rule to understand – earlier the rule was Perform or Perish now it is Digitize or Diminish.

The covid-19 crisis has led us to improvise through Digitalization and I will cover the important issues in brief:

1. Virtualized Healthcare Practitioners Marketing
2. Virtual Peer to Peer Sessions

3. Medical Webinars Multi – Customer Video Conferences on Treatment Protocols
4. Remote Patient Support – Remote Prescribing due to Social Distancing.
5. Clinical Trials are a big challenge – Monitoring the Participants, hosting them at Labs / facilities
6. Digital Technology / A.I

Most importantly nowadays even the Government Applications, Government approvals are being done virtually.

Thank you for the opportunity given to me to share my thoughts on the New Normal and Digitization. I wish the organizers and participants fruitful deliberations.

Best of Luck!

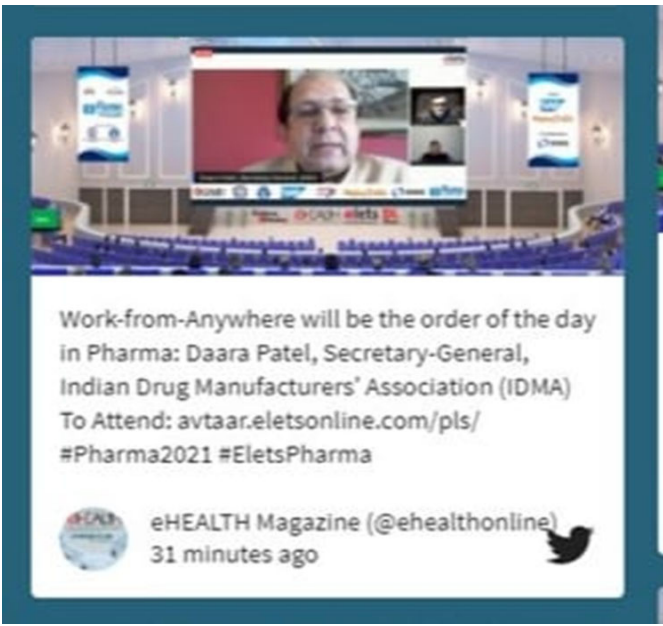
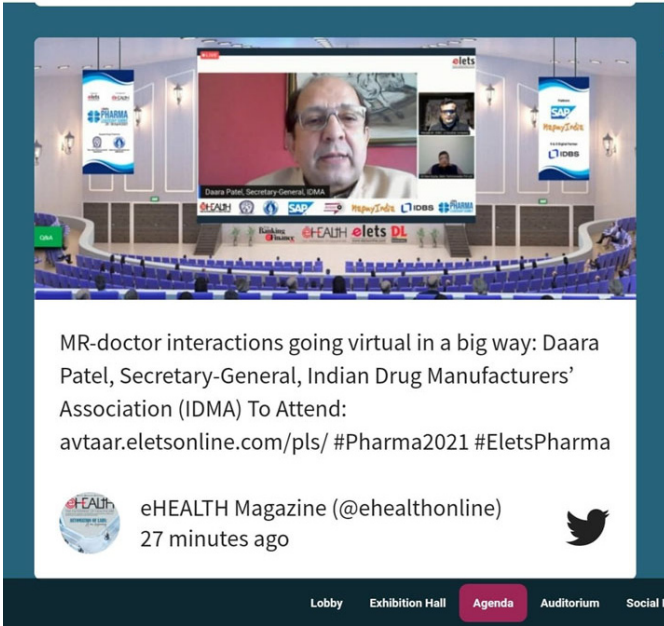
Stay Safe, Stay Well and Stay Connected.

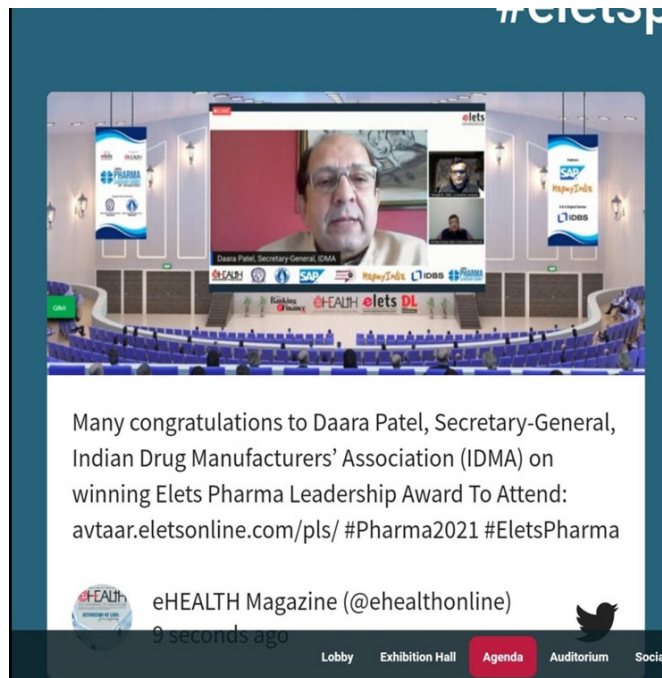
Glimpses - Pharma Leadership Summit





Mr. Daara B Patel's quotes on Social Media





Request for help for restoration of Sichuan Airlines Cargo Services: IDMA representation to Hon'ble External Affairs Minister

The Association has submitted the following representation on 29th April 2021 to Hon'ble Dr. S. Jaishankar, External Affairs Minister, Ministry of External Affairs for restoration of Sichuan Airline Cargo Services:

We wish to extend our sincere thanks for the tremendous support extended by the Government to the pharmaceutical industry and taking several measures to mitigate the adverse impacts on the economy.

All our members are working hard to continue their research & manufacturing operations for the availability of essential medicines for the nation's as well as global population during the tough times.

You will appreciate the fact that Indian pharma exports have recorded outbound growth of 18% in the current financial year despite all odds and reached \$ 24.4 billion mark.

Sir, our country is sourcing almost 60 to 70% of our requirement of drug intermediates/ Key Starting Materials (KSM)/ Active Pharmaceutical Ingredients (API) from China and most importantly 45-50% of all APIs imported feature in the National List of Essential Medicines (NLEM). Though the Product Linked Incentive (PLI) Scheme for API manufacturing is rolled out by the Government, it is going to take some time to reduce our dependence on import of KSMs.

While the Pharma industry is struggling hard to meet the global commitments even during this hard phase of Covid second wave in the country, the decision of Chinese state-owned Sichuan Airlines suspending its cargo services to India for 15 days is worrisome in addition to the enormous increase of freight and shortage of containers. It is likely to disrupt frantic efforts by Indian pharma industry to import medical supplies including oxygen concentrators as well as the KSMs/APIs required to manufacture Finished Formulations and the Industry

is fearing of cascading effects on its entire supply chain leading to shortage of the essential medicines for the nation's population as well as severe impact on exports.

We sincerely request the Government to kindly intervene and help initiate necessary measures to restore the cargo services of Sichuan Airlines.

Yours Sincerely,

Mahesh H Doshi
National President

As advised by National President following mail request sent to Hon'ble External Affairs Minister. We have also sent similar letters to the following:

1. Mr. D. V. Sadananda Gowda ji, Minister of Chemicals & Fertilizers
2. Mr. Mansukh L Mandaviya ji MoS, Chemicals & Fertilizers
3. Mr. Piyush Goyal, Minister of Commerce & Industry
4. Dr. Harsh Vardhan, Minister for Health & Family Welfare
5. Dr. Anup Wadhawan, Commerce Secretary
6. Ms. S, Aparna Secretary, DoP and
7. Mr. Shyamail Misra, Joint Secretary (Commerce)



Restoration of Medical Supplies from China to India – Update

Dear Ma'am / Sir

Reference is invited to the above-mentioned subject. In this regard, I am directed to inform that Sichuan Airlines is restarting its operations from Chengdu to Chennai from 12th May, and from Chengdu to Bengaluru on 9th May 2021.

In addition, there are multiple other cargo operations available from China to India including charter flights. The contact details for some of the cargo operators is also attached herewith.

भवदीय/ yours Faithfully

वेंकट हरिहरन आशा / VENKAT HARIHARAN ASHA

उप- निदेशक / DEPUTY DIRECTOR

औषध विभाग/ DEPARTMENT OF PHARMACEUTICALS

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टेलीफोन 011-23071162 / TEL. NO.: 011-23071162

मोबाइल: 9082507094 / MOBILE NO.: 9082507094

SL. NO.	Airlines/ Charterers	CONTACT PERSON	CONTACT NUMBER	CONTACT EMAIL ID
1	Spicejet	Winie Yang Megacap (China)	(+86)18344555156	
2	Air India	Rajesh Singh Sushil Gigu (India)	(+91)-9819986630 (+91)-9811304879	rajesh.singh@spicejet.com sushil.gigo@airindia.in
3	Indigo	Prakash Chand Mr. Vipin Mohla	(+86)-13818391404 (+91)9811157330	fmgr@airindia-china.com vipin.mohla1@goindigo.in
4	Sichuan Airline	Mr. Edward Zhou	86-28-6539241586-13880431269	edward.zhou@sichuanair.com, edward.zjr@foxmail.com
5	Emirates	Emirates only can be contacted by Freight Forwarder.	1. M/s. CIM Mover Contact point: Ms. Harriet Liu, Managing Director Mob: +86 13801015647 Email: rates@cimmover.com 2.M/s. Alpha Express(zhejiang) Ltd. Contact point: Mr. Tony Tong, Sales Manager Head office:RM2009,tower 8,United Plaza,58 Qianjiang RD.,Hangzhou,P.R.China,310008 Airprot office:Rm 218,Hangzhou Airport Customs Building Tel:86-571-85819436 Fax:86-571-85819437 Mob:15381098758 E-mail:tony@dtinker.com 3. M/s. Air Sea Worldwide Contact point: Mr. Dell Du Liaoning Air Sea Worldwide Logistics Ltd. - Beijing Branch Rm 1012, Building A, International Negotiate Garden, Courtyard 3, Jinguan North 2nd St, Shunyi District, Beijing, China Tel : +86 10 61429356, Fax : +86 10 6458 9939 Wechat: +86 132 6416 9406 / Skype: delldu / QQ: 2106474218 Email: dell.du@asw-beijing.com.cn 4. M/s. Panda Global Beijing	
6	Shunfeng Express	Chen Sihua, Core customer Headquarters, SF Shanghai	+86 13651888273	sergio@sfmail.sf-express.com
6	Shunfeng Express	Mr Sun Chao (Sam)	(+86)-15210583978	chao.sun3@sf-express.com
7	YTO	Ms Alice Yan	(+86)-028-85293050 / (+86)-13635363770	alice.yao@ckg.on-time-express.com
8	Fedex			
9	Air Asia			
10	UPS			
14	Ethiopian Airlines	Mr. Eshetu Fikadu	Manager, Shanghai Pudong Airport Tel +86 10 5651 0318 Fax +86 10 5651 0366 Mob +86 186 1821 9018 Web www.aircharterchina.cn Mobile: +86 13636504597	EshetuF@ethiopianairlines.com
15	Air Charter Service (ACS)	Gary Guo	Sino Global Logistics Co. Limited Room 1010, Kerry Everbright City Tower 1, 218 Tian Mu West Road, Jingan District, Shanghai 200070	gary.guo@flyacs.cn
16	Sino Global Logistics	Siddharth Sinha		siddharth@sinogloballogistics.com
17	Qatar Airways	Mr Li, Shanghai Office	+86 17521231608	
16	Air India Hong Kong	Mr. Amiya Das, Air port Manager, +852 5309 8065	GSA Megacap S.A. Limited 9/F, Chung Nam Building 1 Lockhart Road, Wanchai, Hong Kong Contact person : Mr. Allan CEO Tel: 852-2253 1519 Fax: 852-2983 8784 E-mail: saleshkg1@groupmcl.com Sales Line : (852) 2796 6311 Website: https://www.skycargo.com	hkgmgrai@flyairindia.com.hk
17	Emirates - Hong Kong			skycargohkg@emirates.com
	Ethiopian Airlines - Hong Kong	Mr. Kebebew B. Air port Manager HK +852-63377438 KebebewB@ethiopianairlines.com Ethiopian Airlines largely take bookings through logistics agents. One of the agents in Hong Kong is SMT Global. Contact person: M Sajith (+852-98254930)	Tel: 852 2117 0233/3968 9035 Website: hkgres@Ethiopian Airlines.com	CargoSales@ethiopianairlines.com hkgres@Ethiopian Airlines.com hkgcto@Ethiopian Airlines.com
11	Cathay Pacific Cargo	Mr. William Lo (Hong Kong) Assistant Manager, Cargo Sales, T: +852- 2747 7284 M: + 852- 9707 7222	Sales Line: +852 - 27477222 https://www.cathaypacificcargo.com	William_lo@cathaypacific.com
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13	SpiceXpress / Spicejet	Mr. Ismail Ali (India), Cargo Regional Manager (West) +91- 9784429786 GSA in Hong Kong: Zeling Aviation Contact person: Roland (+ 852- 61110814)	033-25112852 Website: https://www.spicexpress.com/	roland@zelingaviation.com ali@spicejet.com

Processing of Export/Import permits –Public Notice – 05/2020 dated 04.08.2020 and Route change : IDMA Representation to the Narcotics Commissioner

The Association has submitted the following representation on 27th April 2021 to Shri. Rajesh Dhabre, IRS, Narcotics Commissioner, Central Bureau of Narcotics with a copies to Mr. Tarun Bajaj, IAS, Secretary; Mr. Ritvik R Pandey, IAS, Joint Secretary (Revenue) and Mr. Dinesh Bouddh, Director (Narcotics), Department of Revenue, Ministry of Finance on Processing of Export/Import permits –Public Notice – 05/2020 dated 04.08.2020 and Route change:

Greetings from Indian Drug Manufacturers' Association.

Due to the Central Government invoking the Disaster Management Act, 2005 and imposition of Lockdown since March 22nd' 2020, IDMA had made representations to your office, with copies to the Department of Revenue, Ministry of Finance to accept scanned copies of applications for export authorization/import licence/NOC, import and export permits, and issuance of export authorization/import licence/NOCs by email or uploading the same on Customs portal and permit route change by prior intimation to CBN, at least 48 hours prior to a shipment.

With reference to the representations, your office issued three Public Notices, dated April 1st, 2020, on July 7th, 2020 and another on August 4th, 2020 (attached herewith) permitting submission of scanned copy of the application along with self authenticated copies of all documents (including the import certificate), issuance of export authorization/import licence/NOC by email to the registered email of the importer/exporter or uploading the same on the window system of Customs in case of firms whose IEC is available with CBN and are registered on the e-SANCHIT website and permitting route change with 48 hours prior intimation.

Sir, the above had functioned smoothly and resulted in speedier issuance of export authorization/import licence/NOC, thereby, facilitating Industry to export/import critical medicines to/from the World.

The facilitations allowed in the said Public Notices were temporary measures applicable only till August 30th, 2020.

As you are aware, the second surge of COVID-19 is raging across different regions in India. Several states have issued lockdown orders, offices are not functional, several International airlines have suspended services and even domestic couriers are not functional in different parts of the country. Considering the practical difficulties, submission of Original import permits to CBN, is becoming a challenge. However, wherever possible, Companies are submitting the Original permits to CBN and would continue to do so.

We therefore request your URGENT consideration to issue a Public Notice with the following considerations -

- 1) CBN accept scanned application form, including import permit, relevant documents from registered email ids of Companies, who have a track record of exports with CBN. Hard copy of Original Import permits and other relevant documents would be submitted by the Companies, within 90 days from the date of application by email.
- 2) CBN issues the export / import permit after due verification and scanned copies of the same are sent to the registered mail id of the Companies and also to the respective Customs department (Sea/Airport) from CBN registered mail id.
- 3) The Customs department be notified to accept the scanned copies of the same by email and permit exports of Narcotic and Psychotropic substances or CBN may upload the permits at Custom Online Portal ie., WWW.ICEGATE.GOV.IN.
- 4) To make the procedure, as stipulated in the April 1st, 2020 Public Notice on route change, permanent.

The above is an URGENT need of the hour, considering the extraordinary situation and we humbly request a speedy consideration and disposal of the same by your office.

Your consideration of the above request would ensure smooth conduct of exports/imports during these challenging times for Industry and Trade. Thanking you,

Mahesh Doshi
National President

Encl:

1. Copy of Public Notice F. No. XVI/13/53/T/P/2020 dated 01.04.2020.
2. Copy of Public Notice F. No. XVI/13/53/T/P/2020 dated 07.07.2020.
3. Copy of Public Notice F. No. XVI/13/53/T/P/2020 dated 04.08.2020. (as reproduced below)

Change in modality for submission of applications of export authorization/Import Licences/NOCs for export/import of Narcotic Drugs/Psychotropic Substances/Controlled Substances during the Lockdown period

F. No. XVI/13/53/T/P/2020, dated 04th August 2020

Public notice on the above cited subject was issued on 01st April 2020 and 7th July, 2020, in view of non-functioning of the postal/Courier services during the lockdown period. Since, now the lockdown norms have been relaxed and the courier services and postal services are operational, therefore in supersession of the public notice dated 01st April, 2020 and 7th July, 2020 on the above cited subject, following changes in submission of application for import/export of narcotic drugs/Psychotropic Substances/controlled substances are being brought to the notice of all concerned: -

- (i) The exporter/importer of Narcotic Drugs/Psychotropic Substances/ Controlled Substances is now required to submit hard copies of their application along with the requisite documents, wherever possible.
- (ii) The importer/exporter situated in the area or city where the courier/postal services are not operational or partial lockdown is in place by local authorities or offices are not functional due to containment Zone declared by a local authority, they may continue to submit the application by email on the email-id given below: -

Sr. No.	Application for	Email-id on which application is to be submitted
1.	Import and export of Narcotic Drugs	Suptd-narco@cbn.nic.in
2.	Import and export of Psychotropic Substances	Supdt-tech@cbn.nic.in
3.	Export of precursor chemicals	onkarmishra@cbn.nic.in
4.	Import of precursor chemicals	skverma@cbn.nic.in

- Application received on any other email-id will not be entertained-
- (iii) The application and the requisite documents shall be uploaded as single pdf file. The application shall be submitted only once, if the applications are forwarded multiple times, then the said application will not be entertained.
 - (iv) The importer/exporter submitting the application by email is required to submit declaration as mentioned in Annexure 'A' of this public notice.
 - (v) In case of application submitted by email, licence fee/ application fee, is to be paid online through NTRP (Non-Tax Receipt Portal) of <https://bharatkosh.gov.in/> only and self attested copy of Challan is required to be submitted along with the application.
 - (vi) The exporter submitting application by email and in possession of the original import permit, is required to submit declaration in para 3 of the Annexure 'A' of this public notice to the effect that they are in possession of original import certificate and the same would be sent to this office as soon as the applicant's office resumes or postal/courier services resume in their area.
 - (vii) The exporter who is not in possession of original Import Certificate will have to submit a declaration by the importer that their offices are closed due to the lockdown/ being in containment zone declared by a local authority or that the postal / courier service in their country is not operational. Further the exporter will have to submit the declaration in Annexure 'B' of this public notice that within a period of 30 days of the lockdown/containment of the importer's offices

being lifted or resuming of postal /courier services in the importing country, the import certificate shall be sent to this office.

(viii) The copy of the export authorization/import licence/ NOC of the firms whose IEC is available with us

and are registered on the esanchit website will also be uploaded on the single window system of customs.

This public notice will be valid only till 31/08/2020.

Change in modality for submission of applications of export authorization/Import Licences/NOCs for export/ import of Narcotic Drugs/Psychotropic Substances/ Controlled Substances during the Lockdown period.

F. No. XVI/13/53/T/P/2020, dated 07th July 2020

Public notice on the above cited subject was issued on 01st April 2020, in view of non-functioning of the postal/ Courier services during the lockdown period. Since, now the lockdown norms have been relaxed and the courier services and postal services are operational, therefore in supersession of the public notice dated 01st April, 2020 on the above cited subject, following changes in submission of application for import/export of narcotic drugs/Psychotropic Substances/controlled substances are being brought to the notice of all concerned:

- (i) The exporter/importer of Narcotic Drugs/Psychotropic Substances/ Controlled Substances is now required to submit hard copies of their application along with the requisite documents, wherever possible.
- (ii) The importer/exporter situated in the area or city where the courier/postal services are not operational or partial lockdown is in place by local authorities or offices are not functional due to containment Zone declared by a local authority, they may continue to submit the application by email on the email-id given below: -

Sr. No.	Application for	Email-id on which application is to be submitted
1.	Import and export of Narcotic Drugs	Suptd-narco@cbn.nic.in
2.	Import and export of Psychotropic Substances	Supdt-tech@cbn.nic.in
3.	Export of precursor chemicals	onkarmishra@cbn.nic.in
4.	Import of precursor chemicals	skverma@cbn.nic.in

Application received on any other email-id will not be entertained-

- (iii) The application and the requisite documents shall be uploaded as single pdf file. The application shall be submitted only once, if the applications are forwarded multiple times, then the said application will not be entertained.
- (iv) The importer/exporter submitting the application by email is required to submit declaration as mentioned in Annexure 'A' of this public notice.
- (v) In case of application submitted by email, licence fee/ application fee, is to be paid online through NTRP (Non-Tax Receipt Portal) of <https://bharatkosh.gov.in/> only and self attested copy of Challan is required to be submitted along with the application.
- (vi) The exporter submitting application by email and in possession of the original import permit, is required to submit declaration in para 3 of the Annexure 'A' of this public notice to the effect that they are in possession of original import certificate and the same would be sent to this office as soon as the applicant's office resumes or postal/courier services resume in their area.
- (vii) The exporter who is not in possession of original Import Certificate will have to submit a declaration by the importer that their offices are closed due to the lockdown/ being in containment zone declared by a local authority or that the postal / courier service in their country is not operational. Further the exporter will have to submit the declaration in Annexure 'B' of this public notice that within a period of 30 days of the lockdown/containment of the importer's offices

being lifted or resuming of postal /courier services in the importing country, the import certificate shall be sent to this office.

(viii) The copy of the export authorization/import licence/ NOC of the firms whose IEC is available with us

and are registered on the esanchit website will also be uploaded on the single window system of customs.

This public notice will be valid only till 31/07/2020.

Route change for export consignments – During lock down period declared by the Central Government

F.No. XVI/13/53/T/P/2020, dated the 01st April, 2020

It is in the notice of the department that due to outbreak of COVID-19 Epidemic there is worldwide lockdown and cancellation of scheduled international airlines and there are only a few cargo freighters operating in and out of India. Therefore, the exporters of Narcotic Drugs, Psychotropic Substances and Controlled Substances are facing difficulty in adhering to the routing for which export authorization/ NOC has been issued.

Therefore, in order to facilitate the trade, it has been decided that till the time scheduled international airlines

starts operating smoothly, the exporters in case of change in route (than that mentioned in the export authorization/ NOC issued by CBN) shall intimate CBN (on email id - narcommr@cbn.nic.in), from their registered email ids, about the exact routing, at least 48 hours PRIOR to the shipment of a consignment of Narcotic, Psychotropic or Controlled substance and can proceed to export the shipment with changed route without waiting for formal approval of CBN.

Change in modality for submission of applications of export authorization/Import Licences/NOCs for export/import of Narcotic Drugs/Psychotropic Substances/ Controlled Substances during the Lockdown period

F.No. XVI/13/53/T/P/2020, dated the 01st April, 2020

Due to outbreak of COVID-19 Epidemic, the Central Government has invoked the Disaster Management Act, 2005 and has imposed Lockdown with exceptions of Essential Commodities. Pharmaceutical APIs and Dosage forms fall under the Essential commodities as these are medicines required to maintain healthcare of human beings.

It has been brought to the notice of the department that during the lockdown period, due to non-functioning of courier companies or speed post or expected substantial delays in deliveries the exporter/ importer of Narcotic Drugs/Psychotropic Substances/Controlled Substances

are facing difficulty. Therefore, in order to facilitate the trade it has been decided that during the lock down period: -

- (i) The exporter/importer of Narcotic Drugs/ Psychotropic Substances/ Controlled Substances can submit the scanned copy of the application along with self authenticated copies of all the documents (including the import certificate) on the email id suptd-narco@cbn.nic.in/suptdttech@cbn.nic.in/onkarmishra@cbn.nic.in respectively for Narcotic Drugs/ Psychotropic Substances/ Controlled Substances from their registered email id.

- (ii) Once the lock down is lifted by the Central Government, the exporter/importer shall submit the hard copies of the original import certificate within the period of 15 days of uplifting of the lock down. Non submission of the import permit within the period specified above will make the company liable for suitable action under the provisions of NDPS Act along with withholding all the future application of the firm.
- (iii) The firm shall forward the scanned copy of the demand draft of Rs. 1000/- in favour of DDO, CBN, Gwalior along with the application. Once the lock down is lifted, the company shall submit the original demand draft with in 15 days of lifting the lock down. Non-submission of this demand draft will lead to future withholding of the application of the firm along with suitable legal action against the firm.
- (iv) The CBN will issue the export authorization/import licence/ NOC after following the due procedure and scanned copy of the said export authorization/import licence/ NOC will be sent to the registered mail id of the Company.
- (v) The copy of the export authorization/import licence/ NOC of the firms whose IEC is available with us and are registered on the esanchit website will be uploaded on the single window system of customs. For rest of the firms the scanned copy of the export authorization/import licence/ NOC will be sent to customs on their registered email-id. The Department of Revenue vide OM No. N-99014/06/2018-NC-II dated 31st March, 2020 has already requested the Customs to accept the copies of export authorization/ import licence/ NOC forwarded on their email id and on single window system.

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IDMA communication on CPCB directive dated February 2nd, 2017 – reg.

The Association has made the following communication on 27th April 2021 to Dr. P. Anbalagan, IAS, CEO, MIDC on CPCB directive dated February 2nd, 2017 :

It was indeed a pleasure interacting with you on April 23rd, and understanding your initiatives and your prompt response to the Industry's problems.

Accordingly plz find attached the Feb 2nd' 2017 directive from CPCB to all SPCBs - that Consent To Establish (CTE) is not required if EC is there (para iv).

We humbly request MIDC to issue a circular to all MIDCs for not insisting on CTE to start construction activity.

Thanking you once again,

Sincerely

Daara B Patel, Secretary - General

(CPCB Directive reproduced as below)

Grant of Consents under the Water (Prevention *and* Control of Pollution) Act, 1974 and Air (Prevention and Control of Pollution) Act, 1981, and charging Consent fees thereon

F.No.B- 29012/ESS/CPA/2016-17, dated 02nd February 2017

To,
The Member Secretary,
All the State Pollution Control Boards / Pollution Control Committees (As per List Attached)

This has reference to the subject matter relating to streamlining the modalities of consent mechanism which

has been discussed with SPCBs /PCCs in earlier meetings and conferences.

The matter was also deliberated at the 175th Meeting of the Board of CPCB held on 21st December, 2016 and it has been decided that the following modified mechanism

for granting of consent to various categories of industries / projects may henceforth be followed :

- i. For White category of industries, there is no need to obtain Consents. Information to concerned SPCB is sufficient.
- ii. Combined Consent for Establishment & Operation can be issued to Green category of industries irrespective of their sizes i.e. large/ medium/ small. In such cases, the industry shall submit an undertaking regarding expected date of start-up of production and intimate the SPCB/ PCC atleast 15 days in advance before start-up of commercial production.
- iii. There should not be any need to obtain Consent to Establish for Building / Construction Projects / Area Development Projects and Township Projects, which are mentioned at serial no. 8(a) and 8(b) of Schedule of Projects in EIA Notification, 2006. For such projects, Environment Clearance shall suffice subject to the condition that there should a permanent

member from SPCB in the State Level EIA Authority to represent the views of SPCB.

- iv. Further, all the projects requiring Environmental Clearance either from State Level EIA Authority or MoEFCC may be exempted from obtaining the Consent to Establish. Such projects may be directly granted CTO subject to EC and installation of pollution control devices.
- v. It has brought to the knowledge of CPCB that SPCBs/PCCs have adopted different definitions for MSMEs and have different consent fee structure. It is requested that definition of MSME given under the MSME Act, 2006 be adopted and accordingly consent fee structure be rationalized.

All the SPCBs / PCCs are requested to initiate action in the matter accordingly.

A B Akolkar, Member Secretary, Central Pollution Control Board, Ministry of Environment, Forest & Climate Change, India

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MINISTRY OF CORPORATE AFFAIRS

Clarification on spending of CSR funds for ‘creating health infrastructure for COVID care’, ‘establishment of medical oxygen generation and storage plants’ etc - reg.

General Circular No.09/2021, dated 05th May 2021

To,
All Stakeholders.

1. In continuation to this Ministry's General Circular No. 10/2020 dated 23.03.2020, wherein it was clarified that spending of CSR funds for COVID-19 is an eligible CSR activity, it is further clarified that spending of CSR funds for ‘creating health infrastructure for COVID care’, ‘establishment of medical oxygen generation and storage plants’, ‘manufacturing and supply of Oxygen concentrators, ventilators, cylinders and other medical equipment for countering COVID-19’ or similar such activities are eligible CSR activities under item nos. (i) and (xii) of Schedule VII of the Companies Act, 2013 relating to promotion of health care, including preventive health care, and, disaster management respectively.
2. Reference is also drawn to item no. (ix) of Schedule VII of the Companies Act, 2013 which permits contribution to specified research and development projects as

well as contribution to public funded universities and certain Organisations engaged in conducting research in science, technology, engineering, and medicine as eligible CSR activities.

3. The companies including Government companies may undertake the activities or projects or programmes using CSR funds, directly by themselves or in collaboration as shared responsibility with other companies, subject to fulfillment of Companies (CSR Policy) Rules, 2014 and the guidelines issued by this Ministry from time to time.
4. This issues with the approval of competent authority.

E-file no.CSR-01/5/2021-CSR-MCA

Shobhit Srivastava, Deputy Director (CSR Cell), Ministry of Corporate Affairs, 5th Floor, ‘A’ Wing, Shastri Bhawan, Dr R. P. Marg, New Delhi.

Mandatory Updation of Importer-Exporter Code (IEC) Details before 01.07.2021

JT. DGFT Mumbai Trade Notice No.01/2021-22, dated 29th April 2021

To,
All Exporters/Members of Trade,
All Export Promotion Councils/Commodity Boards.

1. All Members of the Trade Community is directed to please take due cognizance of the following instructions on priority.
2. It is submitted that DGFT has mandated all IEC holders to update their Importer-Exporter Code (IEC) yearly between April to June. The IEC not updated within this prescribed period would be deactivated. DGFT has created the following video with simple and easy to understand steps for updation of IEC. This video is also available in Hindi on the DGFT channel. You may please refer to video at the given link - <https://youtu.be/B5zrx5k8QC4>.
3. Due care has been taken to not increase any specific compliance burden because of this updation exercise. The given process is automatic and no fee is charged for such updations. The online process can be completed within 5-10 minutes if all IEC details are correct or within 30 minutes otherwise. Objective of the given exercise is to prune out inactive IECs and incorrect IEC details. The support of all active IEC holders for this limited updation is kindly solicited.
4. IECs not updated within this prescribed period would be de-activated (post June). Subsequently, the firms that wish to re-activate their IEC (post de-activation for non-compliance), would be required to update the IEC. IEC shall be auto re-activated on updation after June.
5. There are various queries received in regard to the authentication process for linking and updating the IEC. In this regard, you may please note that any of the following authentication options may be used on the DGFT Websitei.
 - i. Aadhaar e-sign - Any of the proprietors/partners/directors can use their Aadhaar given that their

name and PAN are correctly mentioned under the IEC.

- ii. Individual Digital Signature Certificate (DSC) Token - DSC in the name of the proprietors/partners/directors can be used given that their name and PAN are correctly mentioned under the IEC.
- iii. Organization-based DSC - DSC in the name of the organization can use given that the firm name of the IEC matches the firm name on the DSC.
- iv. IEC-based DSC – DSC with the IEC number embedded in it would also work for linking and updation of IEC.

A Class-II or Class-III DSC used with any other organization such as MCA/Customs/CBDT/GSTN et al. would also work on the DGFT e-Platform.

6. In case you wish to use the Aadhaar e-sign but your name on PAN does not match your Aadhaar, please refer to the following instructions for any suitable corrections- <https://uidai.gov.in/292-faqs/youaadhaar/panaadhaar/195-my-name-is-different-in-pan-and-aadhaar-it-is-not-allowing-me-to-link-both-what-to-do.html>
7. In case of any further issues or requirement for any guidance, please reach out the DGFT Help-desk using the toll-free helpline number or the DGFT Support Email (dgftedi@nic.in) or the Help-desk ticketing system.
8. You are once again directed to ensure that the IEC is duly updated within the prescribed time.

This issues with the approval of the competent Authority.

Ramesh Holeyachi, Joint Director General of Foreign Trade, Ministry of Commerce, Office of The Additional Director General of Foreign Trade, Mumbai.



Amendment in Para 2.25 of Foreign Trade Policy, 2015-20

Notification No.4/2015-2020 S.O.(E), dated 30th April, 2021

In exercise of powers conferred by Section 3 and Section 5 of the FT(D&R) Act, 1992, read with paragraph 1.02 and 2.01 of the Foreign Trade Policy, 2015-2020, as amended from time to time, the Central Government hereby amends Para 2.25 of Foreign Trade Policy (FTP), 2015-2020 as under:

Existing Para 2.25 of FTP, 2015-2020	Revised Para 2.25 of FTP, 2015-2020
<p><i>Import of goods, including those purchased from e-commerce portals, through post or courier, where Customs clearance is sought as gifts, is prohibited except for life saving drugs / medicines and Rakhi (but not gifts related to Rakhi).</i></p> <p><i>Explanation:</i></p> <ol style="list-style-type: none"><i>Rakhi (but not gifts related to Rakhi) will be covered under Section 25(6) of Customs Act. 1962 that reads " no duty shall be collected if the amount of duty leviable is equal to or less than Rs. 100/-"</i><i>Import of goods as gifts with payment of full applicable duties is allowed</i>	<p><i>Import of goods, including those purchased from e-commerce portals, through post or courier, where Customs clearance is sought as gifts, is prohibited except for life saving drugs / medicines/ oxygen concentrators and Rakhi (but not gifts related to Rakhi).</i></p> <p><i>The exemption for oxygen concentrators is allowed only for a period till 31 July 2021 for personal use.</i></p> <p><i>Explanation:</i></p> <ol style="list-style-type: none"><i>Rakhi (but not gifts related to Rakhi) will be covered under Section 25(6) of Customs Act. 1962 that reads " no duty shall be collected if the amount of duty leviable is equal to or less than Rs.100/-"</i><i>Import of goods as gifts with payment of full applicable duties is allowed</i>

Effect of the Notification: Para 2.25 of Foreign Trade Policy, 2015-20 is revised to include import of oxygen concentrators for personal use through post, courier or e-commerce portals in the list of exempted categories, where Customs clearance is sought as "gifts", till 31 July 2021.

This issues with the approval of Minister of Commerce & Industry.

F.No. 01/93/180/16/AM-16/PC-II(B)/E-I 713)

Amit Yadav, Director General of Foreign Trade & Ex- officio Addl. Secretary, Directorate General of Foreign Trade, Ministry of Commerce & Industry, Department of Commerce, New Delhi.



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Ad hoc Exemption from IGST on imports of specified COVID-19 relief material donated from abroad – reg.

Customs Instructions No.09/2021, dated 3rd May 2021

To

All Principal Chief Commissioners/Chief Commissioners of Customs/Customs (Preventive),

All Principal Chief Commissioners/Chief Commissioners of Customs & Central tax,

All Principal Commissioners/Commissioners of Customs/Customs (Preventive),

All Principal Commissioners/Commissioners of Customs & Central tax,

All Principal Director Generals/Director Generals under CBIC.

1. Kind attention is drawn to the Ad hoc Exemption Order No.4/2021-Customs, dated 3rd May, 2021 wherein exemption from IGST has been granted, in circumstances of exceptional nature, to goods specified in the following Customs notifications:

- i. 27/2021-Customs dated 20.04.21 (as amended by notification No.29/2021-Customs dated 30.4.21)
- ii. 28/2021-Customs dated 24.04.21, when received free of cost for free distribution anywhere in India for COVID relief.

2. This exemption shall be subject to the following conditions specified therein:

- (i) State Government shall appoint a nodal authority in the State for the purpose of this exemption. As per section 2 (103) of the Central Goods and Services Tax Act, 2017, state include a Union territory with Legislature.
- (ii) The Nodal authority so appointed shall authorise any entity, relief agency or statutory body, for free distribution of such Covid-relief material.
- (iii) The said goods can be imported free of cost by a State Government or, any entity/relief agency/statutory body, authorized in this regard for free distribution anywhere in India.
- (iv) The importer shall before clearance of goods from Customs produce a certificate from the said nodal authorities that goods are meant for free distribution for Covid relief.
- (v) After imports, the importer shall produce, to the Deputy or Assistant Commissioner of Customs

at the port within a period of six months from the date of importation or within such extended period not exceeding nine months, a simple statement containing details of goods imported and distributed free of cost. This statement shall be certified by the said nodal authority of the State Government.

3. Field formations may take special note that the exemption order shall apply to all the such consignments pending clearance from Customs as on date of issue of order, i.e., the 3rd May, 2021.
4. Revenue Secretary has also written to all the Chief Secretaries for creation of a State/Union Territory Nodal Agency for taking immediate action for the purpose of imports of such relief material. The State Governments, importers, relief agencies, may approach the customs formation in case they face any difficulty. Chief Commissioners may suitably sensitize the Nodal officers already appointed in their formation for facilitating the expeditious clearance of COVID relief material so that they are aware of this exemption and deal pro-actively with issues, if any, in their smooth clearance.
5. A large number of such consignments are anticipated to arrive in the coming days and certain consignments may be pending for clearance as on date. The customs formation, may proactively, take action for speedy clearance of such consignments. It is requested that necessary instructions be issued to the assessing officers to clear all such Covid-19 relief material expeditiously. Also, field formation make every possible effort to work in close coordination with the State Authorities.
6. In case of any difficulty, in implementing the order, the field formations may approach the Joint Secretary (TRU-1) or other officers on email gd.lohani@nic.in, gaurav.singh80@nic.in, or swasif.haider@gov.in.

F.No.CBIC-190354/2/2021-TO (TRU-I)-CBEC

Gaurav Singh, Deputy Secretary (TRU-I), Central Board of Indirect Taxes and Customs, Tax Research Unit, Ministry of Finance, Department of Revenue, New Delhi.

Seeks to reduce IGST on Oxygen Concentrators when imported for personal use

Notification No.30/2021-Customs, dated 1st May, 2021

1. In exercise of the powers conferred by sub-section (1) of section 25 of the Customs Act, 1962 (52 of 1962), the Central Government, on being satisfied that it is necessary in the public interest so to do, hereby exempts the goods of the description specified in column (3) of the Table below, falling within the Chapter, heading, sub-heading or tariff item of the First Schedule to the Customs Tariff Act, 1975 (51 of 1975) specified in column (2) of the said Table, when imported into India, from so much of the integrated tax leviable thereon under sub-section (7) of section 3 of the said Customs Tariff Act, read with section 5 of the Integrated Goods and Services Tax Act, 2017 (13 of 2017), as is in excess of the amount calculated at the rate specified in the corresponding entry in column (4) of the said Table, namely-

Table

Sr. No.	Chapter, heading, sub-heading or tariff item	Description	IGST rate
(1)	(2)	(3)	(4)
1.	9804	Oxygen concentrator, imported for personal use	12%

2. This notification shall remain in force upto and inclusive of the 30th June, 2021.

F.No.CBIC-190354/1/2021-TO(TRU-I)-CBEC

Gaurav Singh, Deputy Secretary, Ministry of Finance Department of Revenue, New Delhi.



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NPPA fixes the Ceiling price of Levothyroxine Scheduled Formulation under the Drugs (Price control) order, 2013 - reg.

NPPA Notification No.S.O.1725(E), dated 30th April 2021

In exercise of the powers conferred by paragraphs 4, 6, 10, 11, 14, 16, 17 and 18 of the Drugs (Prices Control) Order, 2013, read with S.O.1394(E) dated the 30th May, 2013 and S.O.701(E) dated 10th March, 2016 issued by the Government of India in the Ministry of Chemicals and Fertilizers, the National Pharmaceutical Pricing Authority (hereinafter referred as NPPA) hereby fixes the price as specified in column (5) of the table herein below as ceiling price exclusive of goods and services tax applicable, if any, in respect of the Scheduled formulation specified in the corresponding entry in column (2) of the said Table with the dosage form & strength and unit specified respectively in the corresponding entries in columns (3) and (4) thereof:

TABLE

Sr. No.	Name of the Scheduled Formulation	Dosage form & Strength	Unit	Ceiling Price (Rs.)
(1)	(2)	(3)	(4)	(5)
1.	Levothyroxine	Tablet 37.50mcg	1 tablet	1.18

Note:

- (a) All manufacturers of scheduled formulation, selling the branded or generic or both the versions of scheduled formulations at a price higher than the ceiling price (plus Goods and Services Tax as applicable) so fixed and notified by the Government, shall revise the prices of all such formulations downward not exceeding the ceiling price specified in column (5) in the above table plus goods and services tax as applicable, if any.
- (b) All the existing manufacturers of above mentioned scheduled formulations having MRP lower than the ceiling price specified in column (5) in the above table plus goods and services tax as applicable, if any, shall continue to maintain the existing MRP in accordance with paragraph 13 (2) of the DPCO, 2013.
- (c) The manufacturers may add goods and services tax only if they have paid actually or if it is payable to the Government on the ceiling price mentioned in column (5) of the above said table.
- (d) The ceiling price for a pack of the scheduled formulation shall be arrived at by the concerned manufacturer in accordance with the ceiling price specified in column (5) of the above table as per provisions contained in paragraph 11 of the Drugs (Prices Control) Order, 2013. The manufacturer shall issue a price list in Form-V from date of Notification as per paragraph 24 of the DPCO, 2013 to NPPA through IPDMS and submit a copy to State Drug Controller and dealers.
- (e) As per para 24(4) of DPCO 2013, every retailer and dealer shall display price list and the supplementary price list, if any, as furnished by the manufacturer, on a conspicuous part of the premises where he carries on business in a manner so as to be easily accessible to any person wishing to consult the same.
- (f) Where an existing manufacturer of scheduled formulation with dosage or strength or both as specified in the above table launches a new drug as per paragraph 2 (u) of the DPCO, 2013 such existing manufacturer shall apply for prior price approval of such new drug to the NPPA in Form I as specified under Schedule-II of the DPCO, 2013.
- (g) The manufacturers of above said scheduled formulations shall furnish quarterly return to the NPPA, in respect of production/ import and sale of scheduled formulations in Form-III of Schedule-II of the DPCO, 2013 through IPDMS. Any manufacturer intending to discontinue production of above said scheduled formulation shall furnish information to the NPPA, in respect of discontinuation of production and/or import of scheduled formulation in Form-IV of Schedule-II of the DPCO, 2013 at least six months prior to the intended date of discontinuation.
- (h) The manufacturers not complying with the ceiling price and notes specified hereinabove shall be liable to deposit the overcharged amount along with interest thereon under the provisions of the Drugs (Prices Control) Order, 2013 read with Essential Commodities Act, 1955.

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

PN/218/86/2021/F/

F.No.8(86)/2021/D.P./NPPA-Div.-II

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



GOVERNMENT NOTIFICATIONS

Implementation of containment measures for COVID -19

Home Affairs Order No.40-3/2020-DM-I(A), dated 29th April 2021

To:

1. *The Secretaries of Ministries/Departments of Government of India*
2. *The Chief Secretaries/Administrators of States/Union Territories (As per list attached)*

Whereas, an Order of even number dated 23.03.2021 was issued for effective control of COVID-19 in the country, for a period upto 30.04.2021;

And whereas, considering the unprecedented surge in COVID-19 cases across the country, Ministry of Health & Family Welfare (MoHFW) vide DO No.Z.28015/85/2021-DM Cell dated 25th April 2021, has issued an advisory to all States and Union Territories (UTs), for implementing intensive, local and focused containment framework, in specific districts/cities/areas, identified based on a prescribed criterion;

Whereas, in exercise of the powers under section 6(2)(i) of the Disaster Management Act, 2005, National Disaster Management Authority (NDMA) has directed the undersigned to issue an order, for ensuring compliance on the focused containment measures, as mentioned in the aforesaid MoHFW letter dated 25.04.2021, for containment of COVID-19 in the country;

Now, therefore, in exercise of the powers, conferred under Section 10(2)(1) of the Disaster Management

Act 2005, the undersigned, hereby directs the State/ Union Territory Governments and State/Union Territory Authorities to consider the containment measures for COVID-19, as conveyed vide aforesaid MoHFW advisory dated 25.04.2021, as per Annexure-I, for immediate implementation in their State/UT, based on the assessment of the situation, until 31.05.2021. States/UTs, will take the necessary containment measures, under the relevant provisions of the Disaster Management Act 2005. It is further directed that:

- (i) The National Directives for COVID-19 Management, as specified in Annexure-II, shall continue to be strictly followed throughout the country.
- (ii) All the District Magistrates shall strictly enforce the containment measures taken by States/ UTs and the National Directives.
- (iii) Any person violating these measures will be liable to be proceeded against as per the provisions of Section 51 to 60 of the Disaster Management Act, 2005, besides legal action under Section 188 of the IPC, and other legal provisions as applicable.

F.No.40-3/2020-DM-I(A)

Union Home Secretary and, Chairman, National Executive Committee (NEC), Ministry of Home Affairs, New Delhi.



Government notifies Relief measures for taxpayers from compliances under GST Law in view of COVID-19 - reg.

GST Press Release dated 02nd May, 2021

In view of the challenges faced by taxpayers in meeting the statutory and regulatory compliances under GST law due to the outbreak of the second wave of COVID-19, the Government has issued notifications, all dated 1st May, 2021, providing various relief measures for taxpayers. These measures are explained below:

1. Reduction in rate of interest:

Concessional rates of interest in lieu of the normal rate of interest of 18% per annum for delayed tax payments have been prescribed in the following cases.

- a. **For registered persons having aggregate turnover above Rs. 5 Crore:** A lower rate of interest of 9 per cent for the first 15 days from the due date of payment of tax and 18 per cent thereafter, for the tax payable for tax periods March 2021 and April 2021, payable in April 2021 and May 2021 respectively, has been notified.
- b. **For registered persons having aggregate turnover upto Rs. 5 Crore:** Nil rate of interest for the first 15 days from the due date of payment of tax, 9 per cent for the next 15 days, and 18 per cent thereafter, for both normal taxpayers and those under QRMP scheme, for the tax payable for the periods March 2021 and April 2021, payable in April 2021 and May 2021 respectively, has been notified.
- c. **For registered persons who have opted to pay tax under the Composition scheme:** NIL rate of interest for first 15 days from the due date of payment of tax and 9 per cent for the next 15 days, and 18 per cent thereafter has been notified for the tax payable for the quarter ending 31st March, 2021, payable in April 2021.

2. Waiver of late fee

- a. **For registered persons having aggregate turnover above Rs. 5 Crore:** Late fee waived for 15 days in respect of returns in FORM GSTR-

3B furnished beyond the due date for tax periods March, 2021 and April, 2021, due in the April 2021 and May 2021 respectively

- b. **For registered persons having aggregate turnover upto Rs. 5 Crore:** Late fee waived for 30 days in respect of the returns in FORM GSTR-3B furnished beyond the due date for tax periods March, 2021 and April, 2021 (for taxpayers filing monthly returns) due in April 2021 and May 2021 respectively/and for period Jan-March, 2021 (for taxpayers filing quarterly returns under QRMP scheme) due in April 2021.

3. Extension of due date of filing GSTR-1, IFF, GSTR-4 and ITC-04

- a. Due date of filing FORM GSTR-1 and IFF for the month of April (due in May) has been extended by 15 days.
- b. Due date of filing FORM GSTR-4 for FY 2020-21 has been extended from 30th April, 2021 to 31st May, 2021.
- c. Due date of furnishing FORM ITC-04 for Jan-March, 2021 quarter has been extended from 25th April, 2021 to 31st May, 2021.

4. Certain amendments in CGST Rules:

- a. Relaxation in availment of ITC: Rule 36(4) i.e. 105% cap on availment of ITC in FORM GSTR-3B to be applicable on cumulative basis for period April and May 2021, to be applied in the return for tax period May 2021. Otherwise, rule 36(4) is applicable for each tax period.
- b. The filing of GSTR-3B and GSTR-1/IFF by companies using electronic verification code has already been enabled for the period from the 27.04.2021 to 31.05.2021.

5. Extension in statutory time limits under section 168A of the CGST Act: Time limit for completion of various actions, by any authority or by any person, under the

GST Act, which falls during the period from 15th April, 2021 to 30th May, 2021, has been extended upto **31st May, 2021**, subject to some exceptions as specified in the notification.

Central Board of Indirect Taxes & Customs,
Ministry of Finance,
Department of Revenue,
New Delhi.



CBIC provides relief by lowering of interest rate for the month of March and April, 2021 - reg.

GST Central Tax Notification No.08/2021, dated 01st May, 2021

1. In exercise of the powers conferred by sub-section (1) of section 50 of the Central Goods and Services Tax Act, 2017 (12 of 2017) read with section 148 of the said Act, the Government, on the recommendations of the Council, hereby makes the following further amendments in notification of the Government of India in the Ministry of Finance (Department of Revenue), No.13/2017–Central Tax, dated the 28th June, 2017, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i) vide number G.S.R.661(E), dated the 28th June, 2017, namely:–
- (i) In the said notification, in the first paragraph, in the first proviso, in the Table after S.No.3, the following shall be inserted, namely:–

(1)	(2)	(3)	(4)
4.	Taxpayers having an aggregate turnover of more than rupees 5 crores in the preceding financial year	9 per cent for the first 15 days from the due date and 18 per cent thereafter	March, 2021, April, 2021
5.	Taxpayers having an aggregate turnover of up to rupees 5 crores in the preceding financial year who are liable to furnish the return as specified under sub-section (1) of section 39	Nil for the first 15 days from the due date, 9 per cent for the next 15 days, and 18 per cent thereafter	March, 2021, April, 2021
6.	Taxpayers having an aggregate turnover of up to rupees 5 crores in the preceding financial year who are liable to furnish the return as specified under proviso to sub-section (1) of section 39	Nil for the first 15 days from the due date, 9 per cent for the next 15 days, and 18 per cent thereafter	March, 2021, April, 2021
7.	Taxpayers who are liable to furnish the return as specified under sub-section (2) of section 39	Nil for the first 15 days from the due date, 9 per cent for the next 15 days, and 18 per cent thereafter	Quarter ending March, 2021.”.

2. This notification shall be deemed to have come into force **with effect from the 18th day of April, 2021.**

F.No.CBEC-20/06/08/2020-GST

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

Note: The Principal Notification Number 13/2017–Central Tax, dated the 28th June, 2017, was published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i) vide number G.S.R.661(E), dated the 28th June, 2017 and was last amended vide Notification Number 51/2020–Central Tax, dated the 24th June, 2020, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i) vide number G.S.R.404(E), dated the 24th June, 2020.



CBIC amends Notification No.76/2018-Central Tax in order to provide waiver of late fees for specified taxpayers and specified tax periods - reg.

GST Central Tax Notification No.09/2021 dated 01st May, 2021

1. In exercise of the powers conferred by section 128 of the Central Goods and Services Tax Act, 2017 (12 of 2017), the Government, on the recommendations of the Council, hereby makes the following further amendments in the notification of the Government of India in the Ministry of Finance (Department of Revenue), No.76/2018–Central Tax, dated the 31st December, 2018, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i) vide number G.S.R.1253(E), dated the 31st December, 2018, namely:–

In the said notification, after the seventh proviso, the following proviso shall be inserted, namely:–

“Provided also that the amount of late fee payable under section 47 shall stand waived for the period as specified in column (4) of the Table given below, for the tax period as specified in the corresponding entry in column (3) of the said Table, for the class of registered persons mentioned in the corresponding entry in column (2) of the said Table, who fail to furnish the returns in **FORM GSTR-3B** by the due date, namely:–

Table

Sr. No. (1)	Class of registered persons (2)	Tax period (3)	Period for which late fee waived (4)
1.	Taxpayers having an aggregate turnover of more than rupees 5 crores in the preceding financial year	March, 2021 and April, 2021	Fifteen days due from the date of return furnishing
2.	Taxpayers having an aggregate turnover of up to rupees 5 crores in the preceding financial year who are liable to furnish the return as specified under sub-section (1) of section 39	March, 2021 and April, 2021	Thirty days due from the date of return furnishing
3.	Taxpayers having an aggregate turnover of up to rupees 5 crores in the preceding financial year who are liable to furnish the return as specified under proviso to sub-section (1) of section 39	January-March, 2021	Thirty days due from the date of return.”.

2. This notification shall be deemed to have come into force **with effect from 20th day of April, 2021.**

F.No.CBEC-20/06/08/2020-GST

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

Note: The Principal Notification No.76/2018-Central Tax, dated 31st December, 2018 was published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i) vide number G.S.R.1253(E), dated the 31st December, 2018 and was last amended vide notification number 57/2020–Central Tax, dated the 30th June, 2020, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i) vide number G.S.R.424(E), dated the 30th June, 2020.



CBIC extends the due date for filing FORM GSTR-4 for financial year 2020-21 to 31.05.2021 - reg.

GST Central Tax Notification No.10/2021 dated 01st May, 2021

- In exercise of the powers conferred by section 148 of the Central Goods and Services Tax Act, 2017 (12 of 2017), the Government, on the recommendations of the Council, hereby makes the following further amendments in the notification of the Government of India in the Ministry of Finance (Department of Revenue), No.21/2019-Central Tax, dated the 23rd April, 2019, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i) vide number G.S.R.322(E), dated the 23rd April, 2019, namely:–
In the said notification, in the third paragraph, after the first proviso, the following proviso shall be inserted, namely:–
“Provided further that the said persons shall furnish the return in **FORM GSTR-4** of the Central Goods and Services Tax Rules, 2017, for the financial year ending 31st March, 2021, upto the 31st day of May, 2021.”.
- This notification shall be deemed to have come into force **with effect from the 30th day of April, 2021.**

F.No.CBEC-20/06/08/2020-GST

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

Note: The Principal Notification No.21/2019-Central Tax, dated the 23rd April, 2019, was published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i) vide number G.S.R.322(E), dated the 23rd April, 2019 and was last amended by Notification No.64/2020-Central Tax, dated the 31st August, 2020, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i) vide number G.S.R.539(E), dated the 31st August, 2020.



CBIC extends the due date for furnishing of FORM ITC-04 for the period Jan-March, 2021 till 31st May, 2021 - reg.

GST Central Tax Notification No.11/2021 dated 01st May, 2021

- In exercise of the powers conferred by section 168 of the Central Goods and Services Tax Act, 2017 (12 of 2017) and sub-rule (3) of rule 45 of the Central Goods and Services Tax Rules, 2017, the Commissioner, with the approval of the Board, hereby extends the time period upto the 31st day of May, 2021, for furnishing the declaration in **FORM GST ITC-04**, in respect of goods dispatched to a job worker or received from a job worker, during the period from 1st January, 2021 to 31st March, 2021.
- This notification shall be deemed to have come into force **with effect from the 25th day of April, 2021.**

F.No.CBEC-20/06/08/2020-GST

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



CBIC extends the due date of furnishing FORM GSTR-1 for April, 2021 - reg.

GST Central Tax Notification No.12/2021 dated 01st May, 2021

- In exercise of the powers conferred by the second proviso to sub-section (1) of section 37 read with section 168 of the Central Goods and Services Tax Act, 2017 (12 of 2017), the Commissioner, on the recommendations of

the Council, hereby makes the following amendment in the notification of the Government of India in the Ministry of Finance (Department of Revenue), No.83/2020–Central Tax, dated the 10th November, 2020, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i) vide number G.S.R.699(E), dated the 10th November, 2020, namely:–

In the said notification, after the proviso, the following proviso shall be inserted, namely:–

“Provided further that the time limit for furnishing the details of outward supplies in **FORM GSTR-1** of the said rules for the registered persons required to furnish return under sub-section (1) of section 39 of the said

Act, for the tax period April, 2021, shall be extended till the twenty-sixth day of the month succeeding the said tax period.”.

F.No.CBEC-20/06/08/2020-GST

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

Note: The Principal Notification Number 83/2020–Central Tax, dated the 10th November, 2020, was published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i) vide number G.S.R.699(E), dated the 10th November, 2020.



Seeks to make third amendment (2021) to CGST Rules

GST Central Tax Notification No.13/2021 dated 01st May 2021

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

1. Short title and commencement:

- (1) These rules may be called the **Central Goods and Services Tax (Third Amendment) Rules, 2021**.
- (2) These rules shall come into force on the date of their publication in the Official Gazette.

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

- (i) in sub-rule (4) of rule 36, after the first proviso, the following proviso shall be inserted, namely:–
“Provided further that such condition shall apply cumulatively for the period April and May, 2021 and the return in FORM GSTR-3B for the tax period May, 2021 shall be furnished with the cumulative adjustment of input tax credit for the

said months in accordance with the condition above.”;

- (ii) in sub-rule (2) of rule 59, the following proviso shall be inserted, namely:–

“Provided that a registered person may furnish such details, for the month of April, 2021, using IFF from the 1st day of May, 2021 till the 28th day of May, 2021.”.

F.No.CBEC-20/06/08/2020-GST

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

Note: The Principal Rules were published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i) vide Notification No. 3/2017-Central Tax, dated the 19th June, 2017, published vide Number G.S.R.610(E), dated the 19th June, 2017 and last amended vide Notification No.07/2021-Central Tax, dated the 27th April, 2021 published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i) vide number G.S.R.292(E), dated the 27th April, 2021.



CBIC extends specified compliances falling between 15.04.2021 to 30.05.2021 till 31.05.2021 in exercise of powers under section 168A of CGST Act - reg.

GST Central Tax Notification No.14/2021 dated 01st May, 2021

1. In exercise of the powers conferred by section 168A of the Central Goods and Services Tax Act, 2017 (12 of 2017) (hereafter in this notification referred to as the said Act), read with section 20 of the Integrated Goods and Services Tax Act, 2017 (13 of 2017), and section 21 of Union Territory Goods and Services Tax Act, 2017 (14 of 2017), in view of the spread of pandemic COVID-19 across many parts of India, the Government, on the recommendations of the Council, hereby notifies, as under,-

(i) where, any time limit for completion or compliance of any action, by any authority or by any person, has been specified in, or prescribed or notified under the said Act, which falls during the period from the 15th day of April, 2021 to the 30th day of May, 2021, and where completion or compliance of such action has not been made within such time, then, the time limit for completion or compliance of such action, shall be extended upto the 31st day of May, 2021, including for the purposes of-

- (a) completion of any proceeding or passing of any order or issuance of any notice, intimation, notification, sanction or approval or such other action, by whatever name called, by any authority, commission or tribunal, by whatever name called, under the provisions of the Acts stated above; or
- (b) filing of any appeal, reply or application or furnishing of any report, document, return, statement or such other record, by whatever name called, under the provisions of the Acts stated above;

but, such extension of time shall not be applicable for the compliances of the following provisions of the said Act, namely:-

- (a) Chapter IV;
- (b) sub-section (3) of section 10, sections 25, 27, 31, 37, 47, 50, 69, 90, 122, 129;

- (c) section 39, except sub-section (3), (4) and (5);
- (d) section 68, in so far as e-way bill is concerned; and
- (e) rules made under the provisions specified at clause (a) to (d) above:

Provided that where, any time limit for completion of any action, by any authority or by any person, specified in, or prescribed or notified under rule 9 of the Central Goods and Services Tax Rules, 2017, falls during the period from the 1st day of May, 2021 to the 31st day of May, 2021, and where completion of such action has not been made within such time, then, the time limit for completion of such action, shall be extended upto the 15th day of June, 2021;

(ii) in cases where a notice has been issued for rejection of refund claim, in full or in part and where the time limit for issuance of order in terms of the provisions of sub-section (5), read with sub-section (7) of section 54 of the said Act falls during the period from the 15th day of April, 2021 to the 30th day of May, 2021, in such cases the time limit for issuance of the said order shall be extended to fifteen days after the receipt of reply to the notice from the registered person or the 31st day of May, 2021, whichever is later.

2. This notification shall come into force **with effect from the 15th day of April, 2021.**

F.No.CBEC-20/06/08/2020-GST

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



COVID -19 supplies received from the Global Community have been Effectively Allocated to States and UTs by Government of India

1764 Oxygen Concentrators; 1760 Oxygen Cylinders; 07 Oxygen Generation Plants; 450 ventilators; more than 1.35 L Remdesivir vials delivered so far

There has been an unprecedented surge in the number of COVID19 cases in the country since the past few weeks. The health infrastructure of several States and UTs has been overwhelmed by the very high number of daily cases and increased mortality. The Government of India is at the forefront of the fight against the COVID19 pandemic in collaboration with the States and UTs. The aim is to extend all support and assistance through various means and measures to strengthen their efforts during this critical phase.

Following the spirit of Vasudhaiva Kutumbakam, the global community has extended a helping hand in supporting efforts of Government of India in this collective fight against the global COVID19 pandemic.

Government of India has been receiving international donations of Covid-19 relief medical supplies and equipment since 27 April 2021 from different countries including United Kingdom, Ireland, Romania, Russia, UAE, USA, Taiwan, Kuwait, France, Thailand, Germany, Uzbekistan, Belgium, Italy, etc.

Cumulatively delivered from 27th April 2021 to 04th May 2021 - 1764 Oxygen Concentrators; 1760 Oxygen Cylinders; 07 Oxygen Generation Plants; 450 ventilators; more than 1.35 L Remdesivir vials; 1.20 L Favipiravir strips

Major items received on 4 May 2021 include:

- Oxygen Concentrators (1274),
- Ventilators (101),
- Oxygen Cylinders (587),
- Oxygen generation units /Plants (2),
- Remdesivir (1,53,708),

- Medical Cabinet (33), and others.

All items received up to 4th May 2021 are allocated to the states/institutions and substantial part of it stands delivered. This is an ongoing exercise.

A streamlined and systematic mechanism for allocation of the support supplies received by India has been put into place by Government of India for effective distribution of the medical and other relief and support material. A Standard Operating Procedure has been framed and implemented by the Health Ministry since 2nd May, 2021. A dedicated Coordination Cell has been created in the Health Ministry to coordinate the receipt and allocation of foreign COVID relief material as grants, aid and donations. This Cell started functioning from 26th April 2021.

All these relief medical supplies and equipment are being allocated by the Ministry of Health and Family Welfare in a timely manner to the 38 tertiary care institutions and 31 States, so far in the first tranche. This is done considering certain criteria like number of active cases, case fatality rate, positivity rate, need, etc. This will help to supplement the medical infrastructure of these Institutions and 31 States/UTs, and strengthen their clinical management capacities for prompt and effective clinical management of the hospitalised COVID19 patients.

The cargo clearance and deliveries are facilitated without delay in coordination with agencies concerned. The deliveries and further installations, if required, are also being monitored by the Health Ministry on a regular basis.

Source: Posted On: 05 May 2021 2:52PM by PIB Delhi



Union Minister of Chemicals & Fertilisers reviews the availability of drugs for covid treatment and other essential drugs

Increased capacity of Remdesvir will augment the domestic availability of injection - Shri Sadananda Gowda

16.5 lakh vials of Remdesivir allocated between May 3 and May 9

Union Minister of Chemicals & Fertilisers Shri D.V Sadananda Gowda chaired a meeting to review availability of drugs for covid treatment and other essential drugs. The Meeting was attended by Ms. S. Aparna, Secretary (Pharma), Dr. V. G. Somani, DCGI, Smt. Shubhra Singh, Chairperson, NPPA, Dr Mandeep Kumar Bhandari, Joint Secretary (Health and Family Welfare), Shri Navdeep Rinwa, Joint Secretary (Pharma), Smt. Vinod Kotwal, Member Secretary, NPPA and other senior officers.

Shri Gowda during the meeting appreciated the efforts of all seven manufacturers of Remdesivir for increasing the production capacity to 1.03 crore vials per month, up from 38 lakh vials per month a month ago. This increased capacity will augment domestic availability of the injection. He added that allocation of 16.5 lakh vials of Remdesivir has been made to all States for period between May 3 and May 9. Since April 21, a total allocation of 34.5 lakh vials has been made so far. Allocation to States is a dynamic process and efforts will be made to further enhance supply in the coming weeks.

During the meeting availability of other essentials drugs was also discussed. Shri Gowda stressed the need to continuously monitor availability of other essential medicines and to check instances of black marketing and hoarding. Dr. Somani, DCGI informed that already a survey is being undertaken to ascertain availability of various medicines in the market. Preliminary findings suggest that

at present, there is adequate availability of medicines in the market and Department of Pharma, NPPA and CDSCO will continue to closely monitor their availability. Regarding black marketing and hoarding, he conveyed that State Drug Controllers have been instructed to make teams at State level for field inspections. Strict Action is being taken against hoarding and black-marketing of drugs. A number of preventive and enforcement actions have been taken by DCGI/SDCs to stop hoarding/ black marketing/ overcharging of Covid management drugs like Remdesivir, Tocilizumab, Favipiravir, etc. By 1.5.2021, as many as 78 actions have been taken all over India, in coordination with SDCs, local police, FDA etc. for hoarding, overcharging, black marketing, and arrests were made/ cases were registered. Seizures of drugs, vehicles, empty vials (meant probably for making spurious drugs) and cash were made. In one case in Chandigarh, Remdesivir vials to the tune of 3000 units were recovered.

Shri Gowda lauded pharma companies and officers of Department of Pharma, NPPA, Ministry of Health & Family Welfare and CDSCO for their coordinated efforts and close cooperation in ramping up availability of drugs for covid treatment and other essential drugs within shortest possible time. Such close collaboration between Government and private sector is need of the hour.

Source: Posted On: 05 MAY 2021 2:52PM by PIB Delhi



PM Modi reviews public health response to Covid-19

PM reviews state-wise and district wise covid situation

PM directs help & guidance to the states about leading indicators to ramp up healthcare infrastructure

PM reviews availability of medicines

PM reviews India's vaccine drive

Need to sensitise states that the speed of vaccination doesn't come down: PM

PM Modi today undertook a comprehensive review of the Covid-19 related situation in the country. He was given a detailed picture on the Covid outbreak in various states and districts. He was informed about the 12 states which have more than 1 lakh active cases. PM was also apprised about the districts with high disease burden.

PM was briefed about the ramping up of healthcare infrastructure by the states. PM directed that states should be given help & guidance about leading indicators to ramp up healthcare infrastructure.

The need to ensure quick & holistic containment measures were also discussed. PM noted that an advisory was sent to the states to identify districts of concern where Case positivity is 10% or more & Bed occupancy is more than 60% on either oxygen supported or ICU beds.

PM also reviewed the availability of medicines. He was briefed about the rapid augmenting of production of medicines including Remdesivir.

PM reviewed the progress on vaccination & the roadmap for scaling up production on vaccines in the next few months. He was informed that around 17.7 crore vaccines have been supplied to the states. PM also reviewed the state wise trends on vaccine wastage. PM was briefed that around 31% of eligible population over the age of 45 has been given atleast one dose. PM spoke about the need to sensitise states that the speed of vaccination doesn't come down. Citizens should be facilitated for vaccination despite lockdowns and healthcare workers involved in vaccination must not be diverted for other duties.

Rajnath Singh, Amit Shah, Nirmala Sitharaman, Dr Harsh Vardhan, Piyush Goyal, Mansukh Mandaviya other ministers and top officials were present in the meeting.

Source: Posted On: 06 MAY 2021 2:51PM by PIB Delhi



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Pharma sector under pressure over price rise, shortage of raw materials

Chandigarh The pharma sector is facing shooting prices and shortage of raw materials, known as active pharmaceutical ingredients (APIs), as 85 per cent of them come from China, Assocham said on Tuesday. It sought government's intervention in clearing the bottleneck in the import. "Such practices are not acceptable during these challenging times when the whole country is fighting a battle against the pandemic. We urge an immediate intervention from authorities to take necessary action against this practice," Assocham Chairman of Northern Region Development Council A.S. Mittal said in a statement.

The drugs for which the raw material cost has gone up multifold include paracetamol (price from Rs 350 to Rs 790 per kg), propylene glycol (from Rs 140 to Rs 400 per kg) ivermectin (from Rs 18,000 to Rs 52,000 per kg) doxycycline (from Rs 6,000 to Rs 12,000 per kg) and azithromycin (from Rs 8,000 to Rs 12,000 per kg). Jitender Sodhi, Assocham Chairman of Himachal Pradesh State Development Council, said, "The economic impact of the Covid-19 second wave has started taking a toll on pharma sector as well. Pharma grade raw materials should be supplied to manufacturers uninterrupted through provision of special passes and green passes can help in curbing the problem of shortage of raw material."

Call on action for mandatory fixing of base prices on per km basis for transportation vehicles and ambulances indulged in the services of Covid-19 should be taken by the government, which can help in cost cutting of raw material, he added.

Source: Bizz Buzz, 04.05.2021



Key Covid-19 bulk drugs see 180% price increase over four months

However, there is no shortage expected at the retail level anytime soon

Prices of key bulk drugs that go into making medicines actively used to treat Covid patients and relatives have surged in the range of 25-180 per cent in the past few months owing to two factors — a sudden surge in demand and slower supplies from China.

No shortage, however, is expected at the retail level anytime soon as big firms carry a few months of inventory.

Prices of the active pharmaceutical ingredient (API) of paracetamol, azithromycin, doxycycline, ivermectin etc have gone up. These are either antibiotics or analgesics and other drugs used to treat Covid-19.

Sample this: the API of paracetamol, a fever and pain medication has grown 25 per cent from Rs 450-480 per kg in December 2020 to Rs 580-600 per kg in April. When compared to the pre-Covid prices of December 2019, the surge is much steeper – around 140 per cent, said Sudarshan Jain, secretary general of the Indian Pharmaceutical Alliance (IPA), the umbrella organisation of big pharma players in India. IPA members account for 60 per cent of the domestic market and about 80 per cent of India's exports of pharmaceutical products.

On the other hand, a relatively lesser prescribed drug ivermectin, which is now given to Covid patients and also their relatives, has seen a 188 per cent jump — from Rs 18,000 per kg a few months back to Rs 52,000 per kg now.

Jain said there was a surge in demand with the caseload increasing in recent months. "Supplies from China are coming, but it has been slow intermittently. We have taken this up with the Indian embassy in China to ensure the logistics are smooth," he explained.

The Pharmaceutical Exports Promotion Council (Pharmexcil), too, had written to the Indian embassy in Beijing after Chinese state-owned Sichuan Airlines had suspended cargo services to India for 15 days, a decision which the airline soon retracted.

Shortage of containers and high freight rates are adding to the woes, Pharmexcil noted. Smaller [pharma](#) firms are the ones more hit as they carry less inventory compared to big [pharma](#). Chirag Doshi, former chairman of the Indian Drugs Manufacturers Association (IDMA) Gujarat state board, said a large consignment is expected to reach India in a week or ten days through the sea route. "It has already left China, and apart from key bulk drugs, it would also have intermediates. That would ease the situation for some drugs like paracetamol for which we have manufacturing capacity here, but need intermediates from China," Doshi said.

He said smaller players are finding it difficult to buy at high prices and some have also cut down on production as a result. "Some suppliers are even quoting Rs 850 per kg for paracetamol," Doshi claimed.

While the prices of bulk drugs go up, the MRP of these drugs are under price control, hence, the input cost rise cannot be passed on to the consumer, he said. Larger players are more comfortable. Alembic Pharmaceuticals, the market leader in azithromycin, a common antibiotic, with a 30 per cent market share, has bulk drug stock till August. RK Baheti, director of finance of Alembic Pharma, said they continue to buy and if need be, give the spot prices to suppliers. "For most of our products, we have stock till August. But purchasing is also a continuous process. So, we buy if need be."

Kedar Upadhye, global CFO of Cipla, said inventory covers are adequate, but one needs to keep a watch at all times. Once the fresh case additions go down, the demand would also taper. In the past month or so there has been a huge surge — ivermectin, for example, has seen a 67 per cent jump in volume sales in March compared to February, according to the data from AIOCD AWACS.

The data for April has not been compiled yet, but industry insiders expect the demand has risen more sharply last month.

Source: Sohini Das, Mumbai, 05.05.2021



Import bottlenecks send API prices soaring

The unprecedented price hike has resulted in a huge demand and supply gap for Covid drugs — manik batra assocham chairman, J &K Development council

The pharma sector is facing shooting prices and shortage of raw materials, known as active pharmaceutical ingredients (APIs), as 85 per cent of them come from China, Assocham said on Tuesday. It sought government's intervention in clearing the bottleneck in the import.

"Such practices are not acceptable during these challenging times when the whole country is fighting a battle against the pandemic. We urge an immediate intervention from authorities to take necessary action against this practice," Assocham Chairman of Northern Region Development Council AS Mittal said in a statement.

The drugs for which the raw material cost has gone up multifold include paracetamol (price from Rs 350 to Rs 790 per kg), propylene glycol (from Rs 140 to Rs 400 per kg) ivermectin (from Rs 18,000 to Rs 52,000 per kg) doxycycline (from Rs 6,000 to Rs 12,000 per kg) and azithromycin (from Rs 8,000 to Rs 12,000 per kg).

Jitender Sodhi, Assocham Chairman of Himachal Pradesh State Development Council, said, "The economic impact of the Covid-19 second wave has started taking a toll on pharma sector as well. Pharma grade raw materials should be supplied to manufacturers uninterrupted through provision of special passes and green passes can help in curbing the problem of shortage of raw material."

Call on action for mandatory fixing of base prices on per km basis for transportation vehicles and ambulances indulged in the services of Covid-19 should be taken by the government, which can help in cost cutting of raw material, he added.

Asia's biggest pharmaceutical hub — Baddi-Barotiwala-Nalagarh (BBN) in Himachal Pradesh, producing several primary life-saving, anti-inflammatory, anti-viral, and Covid-19 drugs, is facing problem in procuring active pharmaceutical ingredients. "This industrial belt is the backbone of India in the current Covid war. The unprecedented price hike and shortage of raw material due to various reasons has resulted in a huge demand and supply gap for these drugs. The government should intervene to streamline the availability and the transportation of raw material as most of the active pharmaceutical ingredients are imported from outside India," said Manik Batra, Assocham Chairman, J&K Development Council.

The Chinese state-owned Sichuan Airlines has also suspended its cargo services to India for 15 days following the second wave of Covid-19. This, many industrial units in the BBN, fear will add to the problems.

Source: IANS, 05.05.2021



Govt triples Remdesivir production to 1.05 crore in just few days, says Fertilizer Minister Mandaviya

Number of plants producing the drug has also gone up from 20 as on April 12 to 57

To meet the growing demand, the government has increased the production of Remdesivir drugs three times

in just a few days, Chemicals and Fertilizers Minister Mansukh Mandaviya has said in a tweet.

The production of Remdesivir has gone up from 37 lakh on April 12 to 1.05 crore on May 4. The number of plants producing the drug has also gone up from 20 as on April 12 to 57 on May 4, 2021, he further said.

According to the government data, 2,000 pieces of Remdesivir were received on May 1 from Uzbekistan and the Indian Community Association in Uzbekistan. India received 9,000 vials of the drug from Belgium and 1,25,000 vials from the US on May 2.

Source: Our Bureau, 04.05.2021



API supply concerns from China fuel Alembic Pharma's global prospects

Company's segment revenues surge 35% during the year

The Covid-led supply disruptions of Active Pharmaceutical Ingredients (API) from China last year has proved to be a blessing in disguise for Alembic Pharma.

The API revenues of the Indian drug major during fiscal 2020-21 jumped by 35 per cent following international buyers' preference for 'China-plus-one' strategy to secure key medical inputs.

API shortage after Chinese supply disruptions early in 2020 had triggered concerns across the markets for a possible shortage of the raw materials.

Speaking to *BusinessLine*, Pranav Amin, MD, Alembic Pharmaceuticals Ltd, said, "This (API supply disruptions from China) gave an impetus to our API business globally. After second half of the year, Chinese were back in the market and there was competition again. (But) we had secured some markets with existing customers, who adopted a China-plus-one strategy to reduce their dependence on China. They were looking for pharmaceuticals suppliers from India."

For the fourth quarter of fiscal 2020-21, Alembic's API business grew by 38 per cent to ₹214 crore, while for the full year, it was reported at ₹955 crore, up 35 per cent from previous year. API is a key raw material for drug manufacturing.

Amin expects to maintain the momentum in the current fiscal, too. "We'd like to compete with better pricing and for more FDA approved facilities. There is still opportunity

for good Indian suppliers in the global market," Amin said.

Even as Alembic opened a parallel front to China, the company isn't worried about what may prompt to become a 'price-war.' "We don't have any load on pricing. We realised that compliance and supply is equally important. Buyers want quality and right documentation," he added.

During the fiscal, the company's international formulations business grew by 19 per cent to ₹2,942 crore, while US generics business grew by 9 per cent to ₹2,163 crore. But the company saw a sharp surge in the non-US International Formulations business in Australia, Canada and Europe besides some parts of Brazil, by growing 57 per cent to ₹779 crore during the fiscal.

R&D aimed at the US

Alembic will continue to focus on its R&D for new product development with its eyes on US market. "About 80 per cent of our R&D spend is targeted to the US market. And within that we have all products including ophthalmic, oncology, oral solids, injectibles, etc. We need to have a large-enough portfolio to tap new opportunities," he added.

Alembic spent ₹670 crore or about 12 per cent of its annual revenues of ₹5,393 crore for fiscal 2020-21.

Financial results

The consolidated net profit for the quarter ended March, stood at ₹251 crore (₹225 crore). Quarterly revenues grew by 6 per cent on year at ₹1,280 crore for the period under review.

On annual basis, the company's consolidated net profit stood at ₹1,178 crore (₹829 crore). Revenues for the year stood at ₹5,393 crore (₹4,606 crore).

Source: Rutam Vora, Business Line, 04.05.2021



Zydus may seek job nod soon

Drugmaker Zydus Cadila is expecting the first set of its interim efficacy data for its covid-19 vaccine this month, following which the company will immediately apply for an emergency use authorization with the Indian regulator, managing director Sharvil Patel said.

"Now we are in the phase where we believe we have to get an event number. We believe this can be achieved

this month. Once that outcome is achieved, we can submit the information (to the regulator) in the same month and eventually seek approval if the data is good,” Patel said in an email interview.

The Ahmedabad-based drugmaker had started the 28,000-participant phase 3 trial of its DNA plasmid vaccine in February. Unlike the Covishield, Covaxin and Sputnik V vaccines, which require two doses, Zydus Cadila’s vaccine requires three doses, with the subsequent shots administered one month after the previous dose.

This meant that the vaccine required an extra month before the counting of covid-19 cases across the placebo and vaccine arms was started. Zydus is waiting to get 158 cases across the two arms before the trial is unblinded to determine the interim efficacy.

Apart from the regimen of three doses, it is also testing a two-dose regimen, the trial for which is also expected to be completed in May, Patel said. “If the data is equally good, we will look at it; but currently, we believe the three-dose regimen is more suitable for our vaccine and will give a better immune response and longer antibody response, which we have seen in our data,” Patel said.

After it secures authorization, Zydus plans to manufacture the vaccine at the rate of 10 million doses per month to start with and subsequently scale it up to 20 million doses. If the data is good and the company is able to secure an emergency authorization from Drugs Controller General of India V.G. Somani, Zydus Cadila’s vaccine is likely to be the fourth in India and the second indigenously developed jab to get clearance.

Bharat Biotech International’s Covaxin is also indigenously developed, while Serum Institute of India’s Covishield is a version of the vaccine developed by the University of Oxford and AstraZeneca Plc. Russia’s Sputnik V on 12 April became the third vaccine to get an emergency authorization in India.

Source : HT Mint, 05.05. 2021



US Pricing pressure impacts margins of pharma firms

Lack of new launches due to inspection delays, intensifying competition key headwinds

The margins of Indian generic drug makers could be under pressure given rising instance price erosion in the US market. Further, the drop in new launches given the

lack of inspection and approvals by the US Food and Drug Administration (USFDA) amid intensifying competition is adding to the margin worries. The National Average Drug Acquisition Cost or NADAC data, which captures the price pharmacies in the US pay for medications indicates that 73 per cent of generic drugs during February to March 2021 have seen some degree of price erosion as compared to 47 per cent of drugs in this category in the same period last year. This highlights that a record number of drugs have experienced price erosion.

Not adjusting for fresh launches, the price erosion in the generics portfolio for April is pegged at 10 per cent as compared to 6-8 per cent in the March quarter. An analyst at a domestic brokerage says that the competitive intensity in the US generics industry has increased and there are signs of deflation, especially in the legacy portfolio. This may worsen in the next few months in the absence of fresh product launches, he adds. This can not only impact the margin profile of the companies in the March quarter but also in the current quarter.

IIFL Research believes the demand environment will be weak in the March quarter due to the lower intensity of the flu season and the fact that elective surgeries in the US are still down 20 per cent as compared to pre-Covid levels.

Some of these trends are visible in the recent March quarter results of companies, such as Biocon. Brokerages have cut the company’s FY22 earnings estimates by 10 per cent due to delays in approvals for biosimilars, as well as higher competition in its legacy drug portfolio.

The pressure is expected to ease once the impact of the pandemic wanes and new products are launched in the second half of FY22. The impact on Indian pharma companies will be a mixed bag, according to Tushar Manudhane of Motilal Oswal Institutional Equities. Companies with limited competition the complex generics portfolio and those with compliant manufacturing facilities can show better growth and profitability, while delays in approvals for niche drugs due to Covid will cap overall growth prospects. Among the listed players, Aurobindo gets the biggest proportion of revenues from the US market, followed by Cadila, Dr Reddy’s, Lupin, and Sun Pharma. Given the near-term pressure, investors should wait for a meaningful improvement in volumes and market share gains in the US market before considering the stocks.

Source : Ram Prasad Sahu, Business Standard, 05.05.2021



Natco Pharma gets emergency nod for Baricitinib tablets to treat Covid-19

Natco Pharma Limited has received Emergency Use approval for Baricitinib tablets from Central Drugs Standard Control Organization (CDSCO) in India.

Baricitinib in combination with Remdesivir, is used for treatment of Covid-19 positive patients.

Hyderabad-based Natco will be requesting a Compulsory License based on emergency use and in light of the grave and serious public health emergency across India due to the Pandemic.

Product Launch

The company is ready to launch the product this week, so as to make it available to suffering patients across India, the release added.

Source : Business Line , 04.05.2021



Hyderabad: Remdesivir not a lifesaver, but Dexamethasone best

Blackmarketing of Remdesivir is at peak. It is not a lifesaver remedy for corona virus, it's just an antiviral drug that is still under trial. It has not yet been proved that it saves lives of Covid patients who are in critical condition. But still, it is been sold in black market while dexamethasone is more effective than Remdesivir; and it costs just Rs 15.

The demand for the Remdesivir injection has led to blackmarketing prompting the police to arrest those who are selling it at high price illegally. The actual price of this injection is Rs. 5,400 while it is being sold between Rs. 35,000 to one lakh to the needy. Why is Remdesivir being sold so costly? Why is it in demand? Is it so effective that it can be bought at exorbitant prices? Is it the lifesaver for a Corona patient? The answer is absolutely no. According to experts, Remdesivir is not an effective drug to eradicate corona.

If it cannot cure a Covid-19 patient then why is this vaccine in so much demand during a global pandemic and why are people buying it at any cost? Let us know for which disease this medicine was made. According to reports, Remdesivir was developed to treat hepatitis C, MARS, SARC and Ebola but it could not be proved it is efficient in treating those viruses.

The drug has halted for a long time and was not used in any treatment until the corona virus outbreak. As this was meant to treat the viruses similar to Covid-19 and there was no remedy to cure the Novel CoronaVirus this drug was the only ray of hope. Many trials of Remdesivir were conducted in America and China but it proved not an effective option. The Food and Drug Association (FDA) has approved it and allowed the use of Remdesivir under conditional emergency use of authenticity.

State health officials repeatedly requested people that Remdesivir is not a lifesaver and it is an antiviral drug and still under trial people should not prefer it over medicines being provided by the State government. Despite the requests and warnings, people are paying a hefty amount for it.

Dr Sanjeev Kumar, a Pulmonologist, has revealed that "the Remdesivir is not at all lifesaver it could not treat the patient even with mild symptoms." He said that after failing in the purpose for which the drug was made, how can the drug cure such a strong virus. The doctor said that after the outbreak of corona virus, several experiments were performed on it and it found be of no effect, yet the FDA conditionally approved its sale, recommending that it be used only in the Emergency Use Authenticity".

He added that there are three categories of medicines. A medicine that falls under the first stage is said to be effective, medicine which stands second in a category will not be effective can be used rarely, while the medicine in the third stage is harmful and can not be used and Remdesivir stands in the second category", the Doctor said.

Speaking about the best alternative of Remdesivir, Dr Sanjeev Kumar said that Dexamethasone has been found very effective, with very good results and it is a lifesaver compared to Remdesivir. Dexamethasone has developed for asthma patients but it is found that it is working on high-risk patients. Though the use of the drug raises blood sugar levels, diabetics suggested using it with a doctor's advice. It is available in the form of injections and tablets and costs very less. Dexamethasone injection costs Rs 15 and the tablet cost is Rs 2 Maximum and it is available very easily in the market. The public should be encouraged to use it and the black market of remediation should be stopped, Dr Sanjeev said.

Source : Mohsin Ali, Hans India,04.05.2021



Glenmark launches nasal spray for allergic rhinitis in India

Pharma major Glenmark Pharmaceuticals Limited on Monday announced the launch of Ryaltris-AZ nasal spray for the treatment of moderate to severe allergic rhinitis, in India. Glenmark has been the first to launch the branded generic version for the treatment of allergic rhinitis in India. According to a study, around 20-30 per cent of the Indian population suffers from allergic rhinitis, Glenmark said.

Glenmark has priced the nasal spray Ryaltris-AZ at Rs 175 per pack of 75 metered doses (MD). The average cost of therapy of top 10 existing brands of the similar drug category is Rs 365, the company said. According to Glenmark, it is the first company in the world to launch Ryaltris-AZ, as a novel fixed dose combination of Mometasone furoate 50 mcg + Azelastine 140 mcg. Developed by Glenmark, Ryaltris-AZ is a novel fixed-dose combination nasal spray of an anti-histamine and a steroid, indicated for treatment of symptoms associated with allergic rhinitis (AR) in patients over 12 years of age. It relieves symptoms of allergic rhinitis, including stuffy nose, runny nose, nasal itching, sneezing, as well as itchy, red and watery eyes, Glenmark said.

Source : IANS, 03.05.2021



Mankind Pharma to donate ₹100 cr to families of deceased COVID warriors

Drug firm Mankind Pharma on Monday said it will donate ₹100 crore for the families of deceased doctors, police officers, pharmacists, and other healthcare workers who have lost their lives fighting the pandemic.

The company plans to start releasing the money with immediate effect and hopes to complete it within three months, Mankind Pharma said in a statement.

As the country continues to grapple with the second wave of coronavirus pandemic, healthcare and frontline workers are racing against time to contain its spread. Many dedicated heroes have lost their lives in the process, it added. "As a responsible organisation, Mankind Pharma is standing alongside the families of these heroes and will donate ₹100 crore to support them," the company said.

On the initiative, Mankind Pharma MD and Vice Chairman Rajeev Juneja said, being the first line of defence they are highly exposed to this deadly disease. Many have

lost their lives fighting the pandemic and protecting us.

"As a homage to them, we have pledged a fund of 100 crore to support and care for the families of these lost warriors. This is not our duty, but a debt we owe them. Because they are truly our hope," he added.

The company knows it can never do enough to replace their void but it can at least try to help them ride through these trying times, Juneja said.

Source : Mint, 29.04.2021



No room for vaccine nationalism

***Developed countries need to share technology:
Sitharaman***

Finance Minister says one critical point in ramping up the production (of coronavirus vaccine) capacity is access to critical raw materials

New Delhi: Cautioning the global community against vaccine nationalism at this hour of the COVID pandemic, India on Monday asked the developed nations to share technology and allow free movement of critical components and raw material needed for production of vaccines.

Speaking at the annual meet of the Asian Development Bank (ADB), Finance Minister Nirmala Sitharaman also underlined the need for a re-look at the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement in the context of the coronavirus pandemic.

"Countries will have to be open about sharing vaccine-based technologies. The TRIPS agreement will have to be looked at in the context of the pandemic. There cannot be any more vaccine nationalism, countries will have to be flexible about it," she said.

The TRIPS agreement is a legal pact between all the member nations of the World Trade Organization (WTO). It establishes minimum standards for regulation by national governments of different forms of intellectual property as applied to nationals of other WTO member nations. The agreement has been in force from January 1995.

Participating in a virtual Governors' seminar, Sitharaman said there is a need to have a global multilateral approach to deal with the COVID pandemic. One critical point in ramping up the production (of COVID vaccine) capacity is access to critical raw materials, she said.

“Although we speak about global value chain and the need for countries to open up trade and also facilitate free movement of raw materials, critical components, critical APIs and so on, we find that the movement of critical raw materials for production of vaccines is finding certain hiccups. We would love that to be sorted out at the earliest so that India can produce,” she said.

It is important that critical raw materials are available and made to flow freely, she said, adding, two more vaccines, including a nasal spray are in the offing to treat COVID. Indian vaccine manufacturers, including Serum Institute of India (SII), faced problems in production last month as Europe and the US banned export of critical raw materials.

Tagging the Twitter handle of the President of the United States, SII CEO Adar Poonawalla had tweeted, “Respected @POTUS, if we are to truly unite in beating this virus, on behalf of the vaccine industry outside the U.S., I humbly request you to lift the embargo of raw material exports out of the U.S. so that vaccine production can ramp up. Your administration has the details.”

Ban was lifted post Prime Minister Narendra Modi and the US President Joe Biden discussions on issues related to COVID crisis in India last week.

Modi had also discussed India’s initiative at the WTO for a relaxation in the norms of the agreement on TRIPS to ensure quick and affordable access to vaccines and medicines for developing countries.

Noting that India being a pharmaceutical hub, Sitharaman on Monday said, “we have readily and generously extended help for the global community earlier this year and we can see that gesture being returned as a favour now.”

She thanked the global community for expressing solidarity with India at this time, when the country is in the grip of the second COVID wave.

Praising the efforts of two vaccine manufacturers including Bharat Biotech, she said they have definitely worked together with the government and kept their profit considerations aside. They have given vaccines at an affordable price for the government to distribute it freely for all citizens, she added.

Post pandemic, she said, “the future as I said, will have to be based on principles of openness, transparency, fairness, sustainability and inclusiveness”. If you’re actually aiming at resilient and sustainable growth

particularly coming out of the pandemic, she said, “I think, regional cooperation we have to focus on and multilateral institutions working towards building digital assets, creation of digital assets, and above all, giving education and health digitisation for all.”

As regards global climate action, she said, India is committed to all the Paris agreement-based commitments and it is well on a course to fulfill all those commitments.

About efforts of the government to keep the wheels of economy running during the pandemic, Sitharaman said the government extended financial assistance to various sectors.

Observing that MSMEs are the backbone of the economy, she said the government has extended financial assistance in terms of Rs 3 lakh crore loan guarantee to help them amid the pandemic.

Source : Millennium Post , 04.05.2021



Indigenous pharma cos need support to make raw materials

There is no dearth of human resources and industry is ready to take up the challenge in the global competition. But what is needed is policy support from the governments like strengthen the much-needed ecosystem to handle the crisis like Covid-19, Dr C Linga Reddy, Chairman and Managing Director of Bio-Vin Research Laboratories said in an exclusive interview with VRC Phaniharan of The Hans India.

Govt shall provide incentives to the industries engaging in the manufacturing basic raw material

Given the fallout of the current Covid-19 situation, is our pharmaceutical industry in a position to compete and what are the key issues the industry is facing? Most of the time, the basic raw material is being sourced from China. Now, the supplies of the same are not reliable. So there is a need to encourage the indigenous industries to focus on manufacturing the basic raw material. Earlier, the industries in the country did not evince much interest in indigenous raw material as the imported one was 30 times cheaper. Governments should take the initiative to encourage indigenous institutions.

Where does Telangana stand in this whole picture? Particularly, when it is intending to come up with pharma city?

Encouraging industries based on the basic raw materials available within the State would benefit Telangana. Many major manufacturing industries and research labs in pharmaceuticals are located in and around Hyderabad. If they can get basic raw material locally, it would benefit the State.

What kind of eco-system is needed in the short-term and long-term to give a fillip to the industry to make it globally competitive?

Governments can do a lot of things in this direction. In China, they provide loans to the manufacturers and give advance for the exports which are recovered from the industry. A similar system also exists in the USA. We should emulate such systems and policies and come up with policy backups providing incentives for the industries to come and proactively engage in the manufacturing.

Do you face any issues in terms of human capital supply for making the pharma industry globally competitive?

No. There is no dearth of skilled human capital in the country. We have credible resources on this front to tap and compete at the global level.

What is the time scale we can expect that the pharmaceutical industry can play in a situation like the current crisis?

First thing that we need to focus on is to get rid of the Covid-19. Then, the Centre might come up with certain steps in this direction, as they have already taken some initiatives in this direction.

In a post-Covid scenario, we can expect many things to happen in this direction.

For the past several months the top engineering institutions like IITs and engineering colleges have been coming up with several interventions and innovations along with the industry in the country's fight against Covid-19. Why was it that we could not witness the same earlier?

So far, IT sector had impacted the people from going to science as that sector provides good salaries and other facilities. However, now, it is coming back, and more and more people are taking science seriously. I am optimistic that it is going to improve a lot more in the future.

In a nutshell, what should be the driver of any likely policy that might help the industry?

To fulfill the existing deficiencies, the government should encourage the private sector as it happens in countries like USA.

This would help in strengthening not only a competitive global value product manufacturing but also to achieve self-reliance if encouragement was given to the indigenous industry.

Source : HI BIZZ BUZZ, 04.05.2021



Reliance takes steps to expand its pharma biz

Mukesh Ambani-led Reliance Industries Ltd (RIL) is expanding its presence in the pharma sector and has operationalized 114 pharmacies. It is engaging customers through outreach initiatives, an RIL official said, adding that the company has started a pilot for hyperlocal delivery in Bengaluru.

“Pharma is a business which we are in the process of establishing. We’re activating Netmeds, which we acquired in September last year, and a whole round of impactful activation and campaigns which have gone behind it,” said Dinesh Thapar, group chief financial officer, Reliance Retail, after the company’s fourth-quarter earnings announcement on 30 April.

RIL had acquired a 60% stake in online pharmacy Netmeds for ₹620 crore not only to strengthen its e-commerce play but also to beef up its healthcare portfolio using the Jio platform. Netmeds has been integrated with Reliance Retail’s online grocery platform, JioMart.

RIL is holding camps, society interactions and door-to-door marketing to further its reach. The pan-India brand campaign for Netmeds has also helped the traffic on its website rise by over 25% quarter-on-quarter, the company said. “We continue to grow the catalogue. We are testing hyperlocal delivery. So, we are looking at a route to being able to service Netmeds orders via stores. It’s a pilot which is underway and is poised to scale up, as the rest of the store network comes online,” added Thapar.

RIL made a series of acquisitions, such as Karexper and C-Square, to build its healthcare portfolio. It plans to integrate its brick-and-mortar network through its digital arm Jio Platforms Ltd to offer a bouquet of services that

can be monetized through transaction-based services, delivery and subscriptions. “RIL has been building a healthcare portfolio for a few years now and through a web of health services ranging from lab testing to medicines to hospitalization, it plans to be a formidable player in the segment. Its digital business Jio Platforms and 426 million Jio subscribers will aid the pharma segment’s growth,” said an analyst from a domestic brokerage, seeking anonymity.

RIL’s pharmacy business is embedded with its Smart Points stores—the last-mile hub for delivering all digital orders.

Reliance Life Sciences or RLS, the biotechnology company from the promoter group of RIL, which started the largest testing facility for covid-19 last May, is performing over 3,500 tests per day. RLS is also in the

process of starting pathology labs across India through partnerships with local entrepreneurs. The Jio Health Hub app, which was launched in January 2017, will integrate the offline initiatives. The app offers lab tests and health checkups, including home collection of samples, and delivers reports on the phone. It also offers doctor consultations online.

Services offered by Karexpert, which connects healthcare providers with patients using cloud-based technologies, have already been integrated with Jio Health Hub. C-Square, which sold an 82% stake to RIL and provides software solutions for distribution, retail, e-commerce and automation with a focus on the pharma sector, will allow the company to expand into the pharma e-tailing business.

Source: HT Mint, 04.05.2021



INTERNATIONAL NEWS

US FDA to authorise Pfizer jabs for 12 to 15-year-old by next week

Vaccinating adolescents may also be key to boost immunity levels in the general population

The US Food and Drug Administration (FDA) is planning to open Pfizer-BioNTech coronavirus vaccine for adolescents aged 12 to 15 years by early next week, according to federal officials, the media reported.

The FDA authorisation would be a welcome news to parents anxious to protect their children, The New York Times reported.

Earlier in March, results of a clinical trial led by the companies showed that the Pfizer-BioNTech coronavirus vaccine is extremely effective in young adolescents, even more than in adults. The children produced strong antibody responses and experienced no serious side effects.

Vaccinating adolescents may also be key to boost immunity levels in the general population and thus reduce the number of hospitalisation and death, the report said.

“We can assure the public that we are working to review this request as quickly and transparently as possible,” Stephanie Caccamo, a spokeswoman for the FDA, was quoted as saying by the NYT.

Caccamo, however, said she could not comment on the timing of the agency’s decision.

The FDA authorisation is also likely to ease concern among middle school and high school administrators planning for opening schools by later this year. If students are able to be vaccinated by then, that could allow more normal gatherings and let administrators plan further ahead in the academic year, the report said.

The Pfizer and Moderna vaccines both require two doses. Pfizer is authorised for ages 16 and up, while Moderna is authorised for ages 18 and up.

Moderna is also expected to announce results from its own clinical trial involving adolescents ages 12 to 17, followed by results for children 6 months to 12 years old later this year, the report said.

Source: IANS, Washington, 04.05.2021





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