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# IDMA BULLETIN

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## Indian APIs & Formulations for Global Healthcare

INDIAN DRUG MANUFACTURERS' ASSOCIATION

## HIGHLIGHTS

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# IDMA BULLETIN

**Vol. No. 51** **Issue No. 18** **08 to 14 May 2020**

# Digitalization of process of issuance of Export/Import permits and route change - IDMA Representation to DoR, Ministry of Finance

***The Association has made the following representation on 8th May 2020 to Mr Anil Kumar Jha, IAS, Additional Secretary (Revenue), Department of Revenue, Ministry of Finance with copies to Mr Ritwik R Pandey, IAS, Joint Secretary (Revenue), Department of Revenue, Ministry of Finance, Mr Dinesh Bouddh, Director (Narcotics), Department of Revenue, Ministry of Finance, Mr Rakesh Asthana, IPS, DG, Narcotics Control Bureau, and Mr R N Srivastava, IRS, DDG (Operations), Narcotics Control Bureau, New Delhi on the above subject:***

**"Greetings from Indian Drug Manufacturers' Association.**

IDMA member companies have been working overtime to ensure availability of all critical medicines for the Indian citizens. It is pertinent to note that India is also a key generic producer of medicines for the World and 30% of the medicines (in terms of Volume) in the World are manufactured and exported from India.

Due to the Central Government invoking the Disaster Management Act, 2005 and imposition of Lockdown since 22nd March 2020, IDMA had made representations to the Narcotics Commissioner 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 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, the Narcotics Commissioner issued two Public Notices *(reproduced on page no.6)*, dated 1st April, 2020 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 has been functioning smoothly and resulted in speedier issuance of export authorization/ import licence/NOC, thereby, facilitating Industry to export/ import critical medicines to/from the World. IDMA would like to place on record, its deep appreciation to the Narcotics Commissioner and CBN, in enabling digitalization of the process of issuance of export authorization/import licence/ NOC and speedier issuance of the same.

The facilitations allowed in the said Public Notices are temporary measures applicable only during the lock down period. The Public Notices also make it mandatory for the importer/exporter to submit the original import certificate along with Demand Draft of Rs. 1000/- within 15 days of the lifting of lock down. Hence, keeping in mind the increasing trends towards digitalization and the intent of the Government departments to minimize, reduce or completely eliminate physical interface between regulatory agencies and the trade, it is our humble request that the current process is formalized, even beyond the Lockdown period, to facilitate "Ease of doing business", reduce paperwork, eliminate delays and increase in trade of Pharmaceutical APIs and Dosage forms from India.

The following is proposed for your URGENT consideration for streamlining the procedure of application, processing and issuance of export authorization/import licence/NOC and route change:

**ISSUANCE OF EXPORT AUTHORIZATION/IMPORT LICENCE/NOC:**

1) CBN accept scanned application form for export authorization/import licence/NOC, including import permit and other relevant documents from registered email ids of Companies (importer/exporter). CBN can use the PEN Online system to verify the authenticity of Import Permit for Controlled substances under the RCS Order, 2013.

It is therefore requested that Rule 55 (2) and 58 (2) of the NDPS Rules 1985, Form J of the RCS Order, 2013 be amended to eliminate the need for submission of original or authenticated copy of the excise permit or ORIGINAL import permit.

(a) The proposed sub-rule (2) to Rule 55 of the NDPS Rules, 1985 is as under:

*"(2) The importer applying for an import certificate under sub-rule (1) in relation to narcotic drug shall submit in such manner as may be specified by the Narcotic Commissioner an application for import certificate along with self-authenticated copy of the excise permit issued by the concerned State Government."*

(b) The proposed sub-rule (2) to Rule 58 of the NDPS Rules, 1985 is as under:

*"(2) The exporter applying for an export authorisation under sub-rule (1) shall submit in such manner as may be specified by the Narcotic Commissioner:*

*(a) where the export authorisation relates to narcotic drug, along with his application the self-authenticated copy of excise permit issued by the concerned State Government; and*

*(b) the self-authenticated copy of import certificate issued by the Government of the importing country certifying the official approval of the concerned Government."*

(c) Amendment to Form J of the RCS Order, 2013:

*"In Form J, in LIST OF DOCUMENTS TO BE SUBMITTED ALONG WITH APPLICATION FORM, for clause (iii), the following shall be substituted:-*

*"(iii) self-authenticated import certificate issued by the competent authority of the importing country (wherever applicable)"*

2) CBN accepts the payment of fee for export authorization/import licence by way of NEFT/RTGS from the importer/exporter in specified account of the Central Government.

3) CBN issues the export authorization/import licence/ NOC after due verification and scanned copies of the same are sent to the registered mail id of the importer/exporter and also to the respective Customs department (Sea/Airport) from CBN registered mail id.

Or

4) CBN upload the export authorization/import licence/ NOC on e-SANCHIT at ICES (Indian Customs EDI System) in terms of Circular No. 13/2019-Customs dated 03.06.2019 issued by CBIC New Delhi, wherein CBN was brought on board the e-SANCHIT platform, to facilitate uploading of digitally signed Licenses/Permits/Certificates/Other Authorizations (LPCOs) by Participating Government Agencies (PGAs) (copy of Circular attached)**.

**ROUTE CHANGE:**

Currently, as per RCS Order, 2013, an exporter of Schedule B substances, has to apply in Form J mentioning therein the **routing of an export consignment**. Based on the application in Form J, No Objection Certificate is issued by CBN mentioning the routing of the consignment.

Under NDPS Rules exporter of Narcotic Drugs or Psychotropic Substances also have to apply in Form EXP-1 giving therein the routing of the export consignment. Based on the application in Form EXP-1, Export Authorisation in Form 5 is issued by CBN.

Neither the RCS Order 2013, nor Rule 58 or Form 5 stipulates the requirement of routing of an export consignment of Narcotic Drugs, Psychotropic Substances or Controlled Substances. However, the Form J and Form EXP-1 require the details of the routing of a consignment to be provided, while making an application for export. We would also like to draw your attention that there is no requirement of routing being specified in any of the International Conventions on Narcotics, Pscyhotropic & Precursors.

Since most of the NDPS products including Controlled Substances are exported by Air and freight charges are dependent on availability of space at the time of export, it is not possible to pre-determine the cost effective routing, at the time of application for NOC or Export Authorisation. As the routing is frozen 4-8 weeks before export of any consignment, Airlines charge a premium of 3-5 times the normal freight charges, as Companies have no option to choose an alternate route of export. This in turn makes exports uncompetitive for Indian companies.

We therefore humbly request that the requirement of routing in the application for exports be eliminated. If required, Companies be allowed to intimate CBN, 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, for which NOC or Export Authorisation has been issued by CBN.

The above is an URGENT need of the hour and we humbly request a speedy consideration and amendment of the NDPS Rules/RCS Order, 2013 to facilitate "Ease of doing business" and digitalization of the process."

(***Not reproduced here*)

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

**CBN Public Notice Ref. F.No. XVI/13/53/T/P/2020, dated 1st 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.

*By Order of Narcotics Commissioner, Narcotics Commissioner of India, Central Bureau of Narcotics, Government of India, Ministry of Finance, Morar, Gwalior (M.P.).*

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## 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.

**CBN Public Notice Ref. F.No. XVI/13/53/T/P/2020, dated 1st 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:

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/supdttech@cbn.nic.in/onkarmishra@cbn.nic.in** respectively for Narcotic Drugs/Psychotropic Substances/Controlled Substances from their registered email id.

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.

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 within 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.

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.

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.

*By Order of Narcotics Commissioner, (Narcotics Commissioner of India), Central Bureau of Narcotics, Government of India, Ministry of Finance, Morar, Gwalior (M.P.).*

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# IDMA representation for directions to Shipping Companies not to charge Penal charges

***The Association has made the following representation on 3rd May 2020 to Hon'ble Shri Mansukh L Mandaviya, Minister of State (Independent Charge) for Ministry of Shipping & Minister of State in the Ministry of Chemicals & Fertilizers with copy to Dr P D Vaghela, Secretary, Department of Pharmaceuticals, New Delhi on the above subject:***

**"Greetings from Indian Drug Manufacturers' Association.**

At the outset we wish to thank you for advising the port authorities vide letters dated 31.03.2020 and 21.04.2020 for the exemptions and remission of charges for ease of doing business.

Office of the DG, Shipping had also issued advisories through DGS order 7 of 2020 dated 29.03.2020, 8 of 2020 dated 31.03.2020 and 11 of 2020 dated 22.04.2020 to shipping lines and shippers not to charge detention or other penal charges from the trade due to their inability to lift containers and other cargo from the ports.

Despite the fact that directions have been issued by your esteemed office to the Shipping companies not to charge detention or other penal charges; shipping companies are not paying heed to the advice. Leaving the initial few days, they have started levying penal charges US$ 100/150 per day.

We request your kind intervention and direction to Shipping companies not to levy such penal charges which are against the advice rendered by your esteemed office."

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# Initiatives taken by Central Drugs Standard Control Organization in light of COVID-19 situation - reg.

**CDSCO Press Release dated 7th May 2020**

CDSCO has taken several Initiatives for fast track approval of COVID-19 related proposals, ease of import / release of drugs, vaccines, critical *in vitro* diagnostics and blood products into the market, streamlining the challenges for conduct of clinical trials, etc. Details are as under:

**i. Fast Track approval process for new drugs including vaccines, r-DNA derived product, etc for COVID-19.**

- In order to process applications for clinical trial or approval of new drugs including vaccines, r-DNA derived products etc. CDSCO has issued a Notice on 19.03.2020 for the stakeholders indicating modalities & pathway for **fast track approval** of such product for COVID-19.
- All such COVID-19 related proposals for approval of clinical trial or new drugs are examined in consultation with the Subject Expert Committee and decision is taken for approval or otherwise in an expedited manner.
- Meetings of the expert committee are held frequently to dispose of such applications mostly within 2-5 working days.

**ii. Fast track approval of diagnostic kits for COVID-19.**

So far, CDSCO has approved total 161 diagnostic kits for COVID -19 on fast track basis which includes 66 RT PCR kits and 95 Rapid antibody kits.

**iii. Acceptance of self-attested document instead of notarized/ apostilled documents from overseas Indian embassy for Import and Registration of drugs and medical devices in light of Covid-19.**

CDSCO has published a notice on 23.04.2020 to address the difficulties in submission of notary, apostilled and embassy attestation of regulatory documents such as Power of Attorney, Manufacturing Licence, GMP Certificate, COPP certificate etc., allowing such application to be processed, if found satisfactory and import registration may be issued based on self-attested documents and an undertaking with certain condition.

**iv. Revised modalities for lot release of human vaccine for smooth supply due to COVID-19 pandemic situation.**

CDSCO issued a circular on 03.04.2020, easing out the lot release for Human vaccines with condition that the manufacturer shall send the samples as per usual procedures to CDL, Kasauli for evaluation when logistics are restored. Till such time, CDL, Kasauli may carry out lot release activity for Human vaccines manufactured domestically by review of summary lot protocol on case by case basis.

**v. Revised modalities for permittingthe import of drug with residual shelf life less than 60% to ensure availability of drugs in light of Covid-19 situation.**

CDSCO issued a circular on 17.04.2020, allowing the import of drug having residual shelf life less than 60%, after taking undertaking from the importer that the drug will be utilised/ consumed before expiry date and no part of drug will be available for sale and distribution after its expiry.

**vi. Extension of validity of WHO GMP/CoPP certificate in light of Covid-19 situation.**

CDSCO published a notice on 01.05.2020 extending the validity of WHO GMP/CoPP which are expiring from March to August 2020 by another 6 months from the date of expiry of the certificate.

**vii. Extension of validity of BA/BE study centres in light of Covid- 19 situation.**

CDSCO issued a circular on 30.04.2020 extending the validity of BA/BE study centres who has already applied or will apply for renewal of the registration within 90 days prior to the date of expiry of its existing registration along with requisites fees and necessary documents till further order.

**viii. Revised modalities to address challenges arises during conduct of Clinical Trial in the wake of outbreak COVID-19.**

CDSCO published a notice on 30.03.2020, by giving modalities (protocol amendment/ deviation/ modification in the approved procedures) to address challenges arises during conduct of clinical trial in the wake of outbreak COVID-19 in the country and difficulties to maintain complete adherence to the approved protocol, regulatory provisions / procedures and applicable guidelines in respect of various activities involved in conduct of clinical trial.

**ix. Facilitation for import of consignments of vaccines, critical *in vitro* diagnostics and blood products for ensuring early accessibility in situation arisen by Covid-19 outbreak.**

CDSCO has directed to all its port offices on 25.03.2020 that the consignments of vaccines, critical *in vitro* diagnostics and blood products (Which are usually sampled 100% for testing) may be released based on the review of the documents, protocol, certificate of release of batch by the manufacturer and satisfactory history of the product subject to certain conditions.

**x. Fast-track approvals of Hand Sanitizer manufacturing license in wake of Covid-19 pandemic situation.**

CDSCO has written a letter to all State & UT Drugs Controllers on 18.03.2020 requesting them to process the manufacturing applications for Hand Sanitizer products within 3 working days for grant of manufacturing license.

**xi. Allowing the manufacturer of industrial oxygen to manufacture the oxygen for medical use within 24 hours in light of Covid-19 situation.**

To ensure the availability and supply of oxygen for medical use in light of Covid-19 situation, CDSCO has written a letter to all State & UT Drugs Controllers on 07.04.2020, requesting that the premises which are having facility to manufacture industrial oxygen should be granted manufacturing license to manufacture oxygen for medical use within 24 hours of receiving the application.

**xii. Monitoring on availability of critical drugs required in the management of COVID-19.**

CDSCO is involved in collection and compilation of data of various critical drugs required in the management of COVID-19 from the State/ UT Drugs Controllers to ensure their availability.

**xiii. Daily monitoring of hydroxychloroquine API and formulation.**

CDSCO is actively involved in collection, compilation of data in respect of hydroxychloroquine API and formulation on daily basis to ensure their availability in light of COVID-19 situation.

**xiv. Regular survey on availability of formulations Azithromycin, Paracetamol and Hydroxychloroquine.**

CDSCO is also actively involved in conducting regular survey on availability of formulations Azithromycin, Paracetamol and Hydroxychloroquinein the Pharmacies in various parts of the country to ensure their availability.

**xv. Monitoring of working status of Pharma industry.**

In order to ensure availability of drugs in the country, CDSCO is actively involved in co-ordination with the State Drugs Controllers to monitor their working capacity and production in light of COVID-19 situation.

*Source: CDSCO website, 07.05.2020*

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PRESS RELEASE

# India supplies medicines to African Countries

1. In response to the pandemic, India has readily come to the assistance of inter alia, various African countries affected by COVID-19. This is in keeping with India's traditionally strong bonds of friendship and solidarity with Africa, which has reached new heights in the last few years.

2. India is dispatching packages of medicines to more than 25 countries in Africa. This package of medicines includes Hydroxychloroquine, Paracetamol and other drugs which are immediately required to fight the pandemic. These medicines are expected to complement the national efforts of the various countries in Africa to combat the pandemic.

3. Prime Minister Narendra Modi had telephonic conversation on April 17, 2020 with President Ramaphosa of South Africa, who is also the current Chairperson of the African Union. Prime Minister, in his conversation, conveyed India's full support for the joint African effort against the virus. PM had a telephone conversation on April 9, 2020 with H.E. President Yoweri Kaguta Museveni of the Republc of Uganda. PM also spoke to the Prime Minister of Ethiopia Abiy Ahmed on May 6, 2020.

4. Earlier during the month April 2020, External Affairs Minister had also spoken to his counterparts in several African countries to reiterate India's solidarity with African people in the fight against COVID-19 and offered them all assistance. His offer was deeply appreciated by these countries.

5. The e-ITEC course for healthcare workers and others on "COVID-19 Pandemic: Prevention and Management Guidelines for healthcare professional" organised by the Ministry of External Affairs along with its partner AIIMS Raipur is also now been extended to all healthcare workers of Africa. This initiative of the Ministry has been widely welcomed. It is worth mentioning that more than 40% of all the training and capacity building slots under ITEC programme has traditionally been earmarked for African countries.

*Source/Courtesy: MEA Press Release, 08.05.2020*

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# Formal launch of the inter-disciplinary studies involving AYUSH interventions for COVID-19 situation

**Ministry of Ayush Press Release dated 06th May 2020**

AYUSH Minister Shri Shripad Yesso Naik and Health Minister Shri Harsh Vardhan will jointly launch three AYUSH based studies related to COVID-19 situation at New Delhi.

Ministry of AYUSH has taken initiatives to address the COVID-19 pandemic problem in the country through clinical studies (prophylactic and add-on interventions) of AYUSH systems. The ministry is also studying the impacts of AYUSH based prophylactic interventions in high risk population and AYUSH advocacies and AYUSH measures for prevention of COVID-19.

Ministry of AYUSH has setup an *Interdisciplinary Ayush R&D Task Force* with a group of experts under the Chairmanship of Dr Bhushan Patvardhan, Vice Chairman, University Grant Commission (UGC) to formulate and develop strategies for this initiative.

Formal launch of the following studies will take place on 07th May, 2020:

**1. Clinical research studies on Ayurveda interventions as prophylaxis and as an add-on to standard care to COVID-19:**

Collaborative clinical studies as a joint initiative of Ministry of AYUSH, Ministry of Health and Family Welfare (MoHFW) and the Ministry of Science & Technology through Council of Scientific & Industrial Research (CSIR) with technical support of ICMR.

The *Interdisciplinary Ayush R&D Task Force* has formulated and designed clinical research protocols for prophylactic studies and add-on interventions in COVID-19 positive cases through thorough review and consultative process of experts of high repute from different organisations across the country for studying four different interventions viz. *Ashwagandha, Yashtimadhu, Guduchi +Pippali* and a poly herbal formulation (AYUSH-64)

1.a. Ashwagandha for the Prophylaxes Against SARS-COV-2 in subjects with increased risk during the COVID-19 Pandemic: A comparison with Hydroxychloroquine in the health care providers and

1.b. Effectiveness of Ayurveda Formulation as an adjunct to 'Standard of Care' for the Treatment of Mild to Moderate COVID-19: A Randomized, Open Label, Parallel Efficacy, Active Control, Multi-Centre Exploratory Drug Trial.

**2. Population based interventional studies on impact of AYUSH based prophylactic interventions:**

The Ministry of AYUSH is initiating population based studies to study the impact of Ayurvedic Interventions in prevention of COVID-19 infection in high risk population. The core objectives comprise of, assessment of preventive potential of AYUSH interventions for COVID-19 and also to assess the improvement in Quality of Life in high risk population. The study will be carried out through four Research Councils under Ministry of AYUSH and National Institutes in 25 states across the country and several State Governments covering approximately 5 lakhs population.

The outcome of the study would certainly pave a new horizon in understanding the preventive potential of AYUSH interventions during pandemics like COVID-19 through scientific evidence.

3. **Ayush Sanjivani application based study for impact assessment of acceptance and usage of AYUSH advisories in its role in prevention of COVID-19:**

The Ministry of AYUSH has developed Ayush Sanjivani mobile app, for generating data of large population with a target of 5 million people. The core expected outcomes includes to generate data on acceptance and usage of AYUSH advocacies and measures among the population and its impact in prevention of COVID-19.

*Source: Ministry for Ayush, 06.05.2020*

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DGFT MATTERS

# Amendment in Export Policy of Sanitizers - reg.

**DGFT Notification No.04/2015-2020, dated 06th May, 2020**

**1.** In exercise of powers conferred by Section 3 of the Foreign Trade (Development & Regulation) Act, 1992 (No.22 of 1992), as amended, read with Para 1.02 and 2.01 of the Foreign Trade Policy, 2015-20, the Central Government hereby makes the following amendments to the Notification No.53 dated 24.03.2020 related to the export policy of Sanitizers, with immediate effect:

| Sr. No. | ITC HS Codes | Description | Present Policy |
|---|---|---|---|
| 207 D | ex3004<br>ex3401<br>ex3402<br>380894 | Alcohol Based Hand Sanitizers | Prohibited |

**2.** **Effect of this Notification:** The Notification No.53 dated 24.03.2020 is a mended to the extent that only "Alcohol based Hand Sanitizers" falling under any ITCHS Code including the HS Codes mentioned above, are prohibited for export. All other items falling under the above HS Codes are freely exportable.

**File No.01/91/180/21/AM20/EC/Part-III**

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

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# MCA allows Companies to hold Annual General Meetings (AGMs) through VC or OAVM - reg.

**Corporate Affairs Press Release dated 05th May 2020**

The Ministry of Corporate Affairs (MCA) vide its General Circular No.18/2020, dated 21.04.2020 has already allowed the companies whose financial year ended on 31st December, 2019, to hold their AGM by 30th September, 2020.

However on account of need for continuous adherence to the social distancing norms and restrictions placed on movement of persons, it has become necessary and hence it has been decided to allow companies to hold their Annual General Meeting (AGM) by Video Conferencing (VC) or Other Audio Visual Means (OAVM) during the calendar year 2020. Accordingly, the General Circular No: 20/2020 has been issued today for this purpose.

The framework provided in the earlier Circulars for holding of extraordinary general meeting (EGM) would be applicable *mutatis mutandis* for conduct of AGMs during 2020, based on the classification of companies which are required to: (i) provide the facility of e-voting or have opted for the same, and (ii) those companies which are not required to provide such a facility.

Owing to the difficulties in sending physical copies of the financial statements, the Circular allows the companies to send the financial statements, along with Board's reports, Auditor's reports and other documents required to be attached therewith, only through email. The companies are also required to provide a window to the shareholders for registering their mandate for transferring dividends electronically to them through the Electronic Clearing Service (ECS) or any other means.

The measure has been taken to facilitate Companies to conduct their ordinary & special business through AGMs conducted by leveraging the Digital India platforms. The circular is available at http://www.mca.gov.in/Ministry/pdf/Circular20_05052020.pdf

*Source: Press Release, Ministry of Corporate Affairs, 05.05.2020*

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# Central Goods and Services Tax (Fifth Amendment) Rules, 2020: GSTR-3B - reg.

**Notification No.38/2020-Central Tax, dated 5th May, 2020**

In exercise of the powers conferred by section 164 of the Central Goods and Services Tax Act, 2017 (12 of 2017), the Central 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.** (1) These rules may be called the **Central Goods and Services Tax (Fifth Amendment) Rules, 2020.**

(2) Save as otherwise provided, they shall come into force on the date of their publication in the Official Gazette.

**2.** In the Central Goods and Services Tax Rules, 2017 (hereinafter referred to as the said rules), with effect from the 21st April, 2020, in rule 26 in sub-rule (1), after the proviso, following proviso shall be inserted, namely:-

"Provided further that a registered person registered under the provisions of the Companies Act, 2013 (18 of 2013) shall, during the period from the 21st day of April, 2020 to the 30th day of June, 2020, also be allowed to furnish the return under section 39 in **FORM GSTR-3B** verified through electronic verification code (EVC).".

**3.** In the said rules, after rule 67, with effect from a date to be notified later, the following rule shall be inserted, namely:-

**"67A. Manner of furnishing of return by short messaging service facility** - Notwithstanding anything contained in this Chapter, for a registered person who is required to furnish a Nil return under section 39 in **FORM GSTR-3B** for a tax period, any reference to electronic furnishing shall include furnishing of the said return through a short messaging service using the registered mobile number and the said return shall be verified by a registered mobile number based One Time Password facility.

Explanation.- For the purpose of this rule, a Nil return shall mean a return under section 39 for a tax period that has nil or no entry in all the Tables in **FORM GSTR-3B.".**

**F.No.CBEC-20/06/04/2020-GST**

*Pramod Kumar, Director, Central Board of Indirect Taxes and Customs, Ministry of Finance, Department of Revenue, New Delhi.*

***Note:*** *The Principal Rules were published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i) vide notification No. 3/2017-Central Tax, dated the 19th June, 2017, published vide Number G.S.R.610(E), dated the 19th June, 2017 and last amended vide Notification No.30/2020-Central Tax, dated the 3rd April, 2020, published vide number G.S.R.230(E), dated the 3rd April, 2020.*

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# Clarification *re.* certain challenges faced by the registered persons in implementation of provisions of GST Laws - reg.

**Circular No.138/08/2020-GST, dated 6th May, 2020**

*To*
*The Principal Chief Commissioners /Chief Commissioners/*
*Principal Commissioners/Commissioners of Central Tax (All)*
*The Principal Director Generals/Director Generals (All).*

**1.** Circular No.136/06/2020-GST, dated 03.04.2020 and Circular No.137/07/2020-GST, dated 13.04.2020 had been issued to clarify doubts regarding relief measures taken by the Government for facilitating taxpayers in meeting the

compliance requirements under various provisions of the Central Goods and Services Tax Act, 2017 (hereinafter referred to as the "CGST Act") on account of the measures taken to prevent the spread of Novel Corona Virus (COVID-19). Post issuance of the said clarifications, certain challenges being faced by taxpayers in adhering to the compliance requirements under various other provisions of the CGST Act were brought to the notice of the Board, and need to be clarified.

**2.** The issues raised have been examined and in order to ensure uniformity in the implementation of the provisions of the law across the field formations, the Board, in exercise of its powers conferred under section 168(1) of the CGST Act hereby clarifies as under:

| Sr. No. | Issue | Clarification |
|---|---|---|
| | **Issues related to Insolvency and Bankruptcy Code, 2016** | |
| 1. | Notification No.11/2020–Central Tax dated 21.03.2020, issued under section 148 of the CGST Act provided that an IRP/CIRP is required to take a separate registration within 30 days of the issuance of the notification. It has been represented that **the IRP/RP are facing difficulty in obtaining registrations during the period of the lockdown and have requested to increase the time for obtaining registration from the present 30 days limit.** | Vide Notification No.39/2020-Central Tax, dated 05.05.2020, the time limit required for obtaining registration by the IRP/RP in terms of special procedure prescribed vide notification No.11/2020–Central Tax dated 21.03.2020 has been extended. Accordingly, IRP/RP shall now be required to obtain registration **within thirty days of the appointment of the IRP/RP or by 30th June, 2020, whichever is later.** |
| 2. | The Notification No.11/2020–Central Tax dated 21.03.2020 specifies that the IRP/RP, in respect of a corporate debtor, has to take a new registration with effect from the date of appointment. **Clarification has been sought whether IRP would be required to take a fresh registration even when they are complying with all the provisions of the GST Law under the registration of Corporate Debtor** (earlier GSTIN) i.e. all the GSTR-3Bs have been filed by the Corporate debtor/IRP prior to the period of appointment of IRPs and they have not been defaulted in return filing. | i. The Notification No.11/2020–Central Tax dated 21.03.2020 was issued to devise a special procedure to overcome the requirement of sequential filing of **FORM GSTR-3B** under GST and to align it with the provisions of the IBC Act, 2016. The said notification has been amended vide notification No.39/2020-Central Tax, dated 05.05.2020 so as to specifically provide that corporate debtors who have not defaulted in furnishing the return under GST would not be required to obtain a separate registration with effect from the date of appointment of IRP/RP.<br>ii. Accordingly, it is clarified that IRP/RP would <u>not be required to take a fresh registration</u> in those cases where statements in FORM GSTR-1 under section 37 and returns in **FORM GSTR-3B** under section 39 of the CGST Act, for all the tax periods prior to the appointment of IRP/RP, have been furnished under the registration of Corporate Debtor (earlier GSTIN). |
| 3. | Another doubt has been raised that the present notification has used the terms IRP and RP interchangeably, and in cases **where an appointed IRP is not ratified and a separate RP is appointed, whether the same new GSTIN shall be transferred from the IRP to RP,** or both will need to take fresh registration. | i. In cases where the RP is not the same as IRP, or in cases where a different IRP/RP is appointed midway during the insolvency process, the change in the GST system may be carried out by an amendment in the registration form. Changing the authorized signatory is a non-core amendment and does not require approval of tax officer. However, if the previous authorized signatory does not share the credentials with his successor, then the newly appointed person can get his details added through the Jurisdictional authority as Primary authorized signatory. |

| | | |
|---|---|---|
| | | ii. The new registration by IRP/RP shall be required only once, and in case of any change in IRP/RP after initial appointment under IBC, it would be deemed to be change of authorized signatory and it would not be considered as a distinct person on every such change after initial appointment. Accordingly, it is clarified that such a change would need only change of authorized signatory which can be done by the authorized signatory of the Company who can add IRP/RP as new authorized signatory or failing that it can be added by the concerned jurisdictional officer on request by IRP/RP. |
| **Other COVID-19 related representations.** | | |
| 4. | As per Notification no.40/2017-Central Tax (Rate) dated 23.10.2017, a registered supplier is allowed to supply the goods to a registered recipient (merchant exporter) at 0.1% provided, inter-alia, that the merchant exporter exports the goods within a period of ninety days from the date of issue of a tax invoice by the registered supplier. Request has been made to clarify the provision vis-à-vis the exemption provided vide notification no.35/2020-Central Tax dated 03.04.2020 | i. Vide Notification No.35/2020-Central Tax dated 03.04.2020, time limit for compliance of any action by any person which falls during the period from 20.03.2020 to 29.06.2020 has been extended up to 30.06.2020, where completion or compliance of such action has not been made within such time.<br>ii. Notification no.40/2017-Central Tax (Rate) dated 23.10.2017 was issued under powers conferred by section 11 of the CGST Act, 2017. The exemption provided in notification No.35/2020-Central Tax dated 03.04.2020 is applicable for section 11 as well.<br>iii. Accordingly, it is clarified that the said requirement of exporting the goods by the merchant exporter within 90 days from the date of issue of tax invoice by the registered supplier gets extended to 30th June, 2020, provided the completion of such 90 days period falls within 20.03.2020 to 29.06.2020. |
| 5. | Sub-rule (3) of that rule 45 of CGST Rules requires furnishing of **FORM GST ITC-04** in respect of goods dispatched to a job worker or received from a job worker during a quarter on or before the 25th day of the month succeeding that quarter. Accordingly, the due date of filing of **FORM GST ITC-04** for the quarter ending March, 2020 falls on 25.04.2020. Clarification has been sought as to whether the extension of time limit as provided in terms of notification No.35/2020-Central Tax dated 03.04.2020 also covers furnishing of **FORM GST ITC-04** for quarter ending March, 2020 | Time limit for compliance of any action by any person which falls during the period from 20.03.2020 to 29.06.2020 has been extended up to 30.06.2020 where completion or compliance of such action has not been made within such time. Accordingly, it is clarified that the due date of furnishing of **FORM GST ITC-04** for the quarter ending March, 2020 stands extended up to 30.06.2020. |

4. It is requested that suitable trade notices may be issued to publicize the contents of this circular.

5. Difficulty, if any, in the implementation of the above instructions may please be brought to the notice of the Board.

**CBEC-20/06/04-2020-GST**

*Yogendra Garg, Principal Commissioner, Central Board of Indirect Taxes and Customs, GST Policy Wing, Department of Revenue, Ministry of Finance, New Delhi*

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# Review of Circular on Measure to facilitate trade during the lockdown period – reg.

**Circular No.23/2020-Customs, dated 11th May, 2020**

*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.*

**1.** Kind attention is invited to Board's Circular No.17/2020 dated 03.04.2020 on 'Measure to facilitate trade during the lockdown period- section 143AA of the Customs Act, 1962' wherein relaxation was given, in the context of lockdown announced by the Government due to COVID-19 pandemic, to accept an undertaking in lieu of a bond required during customs clearance, subject to conditions as underlined in the circular. The facility was extended till 15.05.2020 vide Circular 21/2020 dated 21.04.2020.

**2.** In reference to MHA order 40-3/2020-DM-I(A) dated 01.05.2020, wherein the lockdown was further extended for two weeks with effect from 4th May, 2020, and taking into consideration that it might take sometime after the end of the lockdown for the situation to normalise, the Board has decided to further extend the facility of accepting undertaking in lieu of bond for the period till 30.05.2020. Consequently, the date for submission of proper bond in lieu of which the undertaking is being temporarily accepted is extended till 15.06.2020. This relaxation will be reviewed by the Board at the end of the lockdown period.

**3.** The conditions underlined in Circular No.17/2020 dated 03.04.2020 stand as they are.

**4.** Suitable Trade Notice/Standing Order may be issued to guide the trade and industry. Difficulty, if any, faced in implementation of this circular may be brought to the notice of Board immediately.

**F.No.473/02/2020-LC**

*Bullo Mamu,*
*OSD (LC),*
*Central Board of Indirect Taxes & Customs,*
*Ministry of Finance,*
*Department of Revenue,*
*New Delhi.*

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# CBIC notifies New Exchange Rates w.e.f. 07th May 2020 - reg.

**Notification No.41/2020-Customs (N.T.), dated 6th May, 2020**

In exercise of the powers conferred by section 14 of the Customs Act, 1962 (52 of 1962), and in supersession of the Notification No.39/2020-Customs (N.T.), dated 16th April, 2020 except as respects things done or omitted to be done before such supersession, the Central Board of Indirect Taxes and Customs hereby determines that the rate of exchange of conversion of each of the foreign currencies specified in column (2) of each of **Schedule I** and **Schedule II** annexed hereto, into Indian currency or *vice versa,* shall, **with effect from 7th May, 2020**, be the rate mentioned against it in the corresponding entry in column (3) thereof, for the purpose of the said section, relating to imported and export goods.

**SCHEDULE-I**

| Sr. No. | Foreign Currency | Rate of exchange of one unit of foreign currency equivalent to Indian rupees | |
|---|---|---|---|
| (1) | (2) | (3) | |
| | | (a) | (b) |
| | | (For Imported Goods) | (For Exported Goods) |
| 1. | Australian Dollar | 49.95 | 47.75 |
| 2. | Bahraini Dinar | 207.20 | 194.20 |
| 3. | Canadian Dollar | 54.90 | 53.05 |
| 4. | Chinese Yuan | 10.85 | 10.55 |
| 5. | Danish Kroner | 11.20 | 10.80 |
| 6. | EURO | 83.70 | 80.70 |
| 7. | Hong Kong Dollar | 9.95 | 9.60 |
| 8. | Kuwaiti Dinar | 253.55 | 237.75 |
| 9. | New Zealand Dollar | 47.20 | 45.05 |
| 10. | Norwegian Kroner | 7.50 | 7.25 |
| 11. | Pound Sterling | 95.95 | 92.65 |
| 12. | Qatari Riyal | 21.50 | 20.20 |
| 13. | Saudi Arabian Riyal | 20.85 | 19.55 |
| 14. | Singapore Dollar | 54.40 | 52.60 |
| 15. | South African Rand | 4.25 | 3.95 |
| 16. | Swedish Kroner | 7.85 | 7.60 |
| 17. | Swiss Franc | 79.50 | 76.50 |
| 18. | Turkish Lira | 11.00 | 10.35 |
| 19. | UAE Dirham | 21.30 | 20.00 |
| 20. | US Dollar | 76.70 | 75.00 |

**SCHEDULE-II**

| Sr. No. | Foreign Currency | Rate of exchange of 100 units of foreign currency equivalent to Indian rupees | |
|---|---|---|---|
| (1) | (2) | (3) | |
| | | (a) | (b) |
| | | (For Imported Goods) | (For Export Goods) |
| 1. | Japanese Yen | 72.65 | 70.00 |
| 2. | Korean Won | 6.40 | 6.00 |

**F.No.468/01/2020-Cus.V**

*Pramod Kumar, Director, Central Board of Indirect Taxes and Customs, Department of Revenue, Ministry of Finance, New Delhi.*

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# Furnishing of Return under section 39 in FORM GSTR-3B for the period 21 April 2020 to 30 June 2020 - reg.

**(No.38/2020 Central Tax) - Gazette Notification No.G.S.R.272(E), dated 5th May, 2020**

In exercise of the powers conferred by section 164 of the Central Goods and Services Tax Act, 2017 (12 of 2017), the Central 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.** (1) These rules may be called the **Central Goods and Services Tax (Fifth Amendment) Rules, 2020.**

(2) Save as otherwise provided, they shall come into force on the date of their publication in the Official Gazette.

**2.** In the Central Goods and Services Tax Rules, 2017 (hereinafter referred to as the said rules), with effect from the 21st April, 2020, in rule 26 in sub-rule (1), after the proviso, following proviso shall be inserted, namely: -

Provided further that a registered person registered under the provisions of the Companies Act, 2013 (18 of 2013) shall, during the period from the 21st day of April, 2020 to the 30th day of June, 2020, also be allowed to furnish the return under section 39 in **FORM GSTR-3B** verified through electronic verification code (EVC).

**3.** In the said rules, after rule 67, with effect from a date to be notified later, the following rule shall be inserted, namely: -

"**67A. Manner of furnishing of return by short messaging service facility**.- Notwithstanding anything contained in this Chapter, for a registered person who is required to furnish a Nil return under section 39 in **FORM GSTR-3B** for a tax period, any reference to electronic furnishing shall include furnishing of the said return through a short messaging service using the registered mobile number and the said return shall be verified by a registered mobile number based One Time Password facility.

Explanation - For the purpose of this rule, a Nil return shall mean a return under section 39 for a tax period that has nil or no entry in all the Tables in **FORM GSTR-3B.**

**F. No. CBEC-20/06/04/2020-GST**

*Pramod Kumar, Director, 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. 30/2020-Central Tax, dated the 3rd April, 2020, published vide Number G.S.R. 230(E), dated the 3rd April, 2020.*

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# Amendments to Special Procedure for Corporate Debtors undergoing the Corporate Insolvency Resolution process - reg.

**(No.39/2020 Central Tax) - Gazette Notification No.G.S.R.273(E), dated 5th May, 2020**

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 amendments in the notification of the Government of India in the Ministry of Finance (Department of Revenue), No.11/2020- Central Tax, dated the 21st March, 2020, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), vide number G.S.R. 194(E), dated the 21st March, 2020, namely:—

In the said notification

(i) in the first paragraph, the following proviso shall be inserted, namely: -

Provided that the said class of persons shall not include those corporate debtors who have furnished the statements under section 37 and the returns under section 39 of the said Act for all the tax periods prior to the appointment of IRP/RP.

(ii) for the paragraph 2, with effect from the 21st March, 2020, the following paragraph shall be substituted, namely: -

2. **Registration**: The said class of persons shall, with effect from the date of appointment of IRP/RP, be treated as a distinct person of the corporate debtor, and shall be liable to take a new registration (hereinafter referred to as the new registration) in each of the States or Union territories where the corporate debtor was registered earlier, within thirty days of the appointment of the IRP/RP or by 30th June, 2020, whichever is later.

**F. No. CBEC-20/06/04/2020-GST**

*Pramod Kumar, Director, Central Board of Indirect Taxes and Customs, Department of Revenue, Ministry of Finance, New Delhi.*

***Note :*** *The Principal Notification was published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i) vide Notification No. 11/2020-Central Tax, dated the 21st March, 2020, published vide Number G.S.R. 194(E), dated the 21st March, 2020.*

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# Extending validity of e-way bills till 31 May 2020 - reg.

**(No.40/2020 Central Tax) - Gazette Notification No.G.S.R.274(E), dated 5th May, 2020**

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), the Central Government, 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.35/2020- Central Tax, dated the 3rd April, 2020, published in the Gazette of India, Extraordinary, Part II, Section 3, Subsection (i), vide number G.S.R. 235(E), dated the 3rd April, 2020, namely:-

In the said notification, in the first paragraph, in clause (ii), the following proviso shall be inserted, namely: -

"Provided that where an e-way bill has been generated under rule 138 of the Central Goods and Services Tax Rules, 2017 on or before the 24th day of March, 2020 and its period of validity expires during the period 20th day of March, 2020 to the 15th day of April, 2020, the validity period of such e-way bill shall be deemed to have been extended till the 31st day of May, 2020.

**F. No. CBEC-20/06/04/2020-GST**

*Pramod Kumar, Director, Central Board of Indirect Taxes and Customs, Department of Revenue, Ministry of Finance, New Delhi.*

***Note :*** *The Principal Notification was published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i) vide Notification No. 35/2020-Central Tax, dated the 3rd April, 2020, published vide Number G.S.R. 235(E), dated the 3rd April, 2020.*

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# Due date for furnishing of FORM GSTR- 9/9C for FY 2018-19 extended till 30 September 2020 - reg.

**(No.41/2020 Central Tax) - Gazette Notification No.G.S.R.275(E), dated 5th May, 2020**

In exercise of the powers conferred by sub-section (1) of section 44 of the Central Goods and Services Tax Act, 2017 (12 of 2017) (hereafter in this notification referred to as the said Act), read with rule 80 of the Central Goods and Services Tax Rules, 2017 (hereafter in this notification referred to as the said rules), and in supersession of notification No. 15/2020-Central Tax, dated the 23rd March, 2020, published in the Gazette of India, Extraordinary,

Part II, Section 3, Sub-section (i), vide number G.S.R. 198(E), dated the 23rd March, 2020, except as respects things done or omitted to be done before such supersession, the Commissioner, on the recommendations of the Council, hereby extends the time limit for furnishing of the annual return specified under section 44 of the said Act read with rule 80 of the said rules, electronically through the common portal, for the financial year 2018-2019 till the 30th September, 2020.

**F. No. CBEC-20/06/04/2020-GST**

*Pramod Kumar, Director, Central Board of Indirect Taxes and Customs, Department of Revenue, Ministry of Finance, New Delhi.*

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# Due date for furnishing FORM GSTR-3B, January-March, 2020 Returns for taxpayers registered in Ladakh - reg.

**(No.42/2020 Central Tax) - Gazette Notification No.G.S.R.276(E), dated 5th May, 2020**

**1.** In exercise of the powers conferred by section 168 of the Central Goods and Services Tax Act, 2017 (12 of 2017) read with sub-rule (5) of rule 61 of the Central Goods and Services Tax Rules, 2017, the Commissioner, 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.44/2019 – Central Tax, dated the 9th October, 2019, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i) vide number G.S.R.767(E), dated the 9th October, 2019, namely:–

In the said notification, in the first paragraph, for the sixth proviso, the following provisos shall be substituted, namely: –

Provided also that the return in **FORM GSTR-3B** of the said rules for the months of November, 2019 to February, 2020 for registered persons whose principal place of business is in the Union territory of Jammu and Kashmir, shall be furnished electronically through the common portal, on or before the 24th March, 2020:

Provided also that the return in **FORM GSTR-3B** of the said rules for the months of November, 2019 to December, 2019 for registered persons whose principal place of business is in the Union territory of Ladakh, shall be furnished electronically through the common portal, on or before the 24th March, 2020:

Provided also that the return in **FORM GSTR-3B** of the said rules for the months of January, 2020 to March, 2020 for registered persons whose principal place of business is in the Union territory of Ladakh, shall be furnished electronically through the common portal, on or before the 20th May, 2020.

**2.** This Notification shall be deemed to come into force with effect from the 24th Day of March, 2020

**F. No. CBEC-20/06/04/2020-GST**

*Pramod Kumar, Director, Central Board of Indirect Taxes and Customs, Department of Revenue, Ministry of Finance, New Delhi.*

***Note:*** *The Principal Notification number 44/2019–Central Tax, dated the 09th October, 2019, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i) vide number G.S.R.767(E), dated the 09th October, 2019 and was last amended by Notification Number 25/2020–Central Tax, dated the 23rd March, 2020, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i) vide number G.S.R. 208(E), dated the 23rd March, 2020.*

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## Indian scientists lead battle against COVID-19

***'Unless we make our own testing kits, we will not get out of this disease faster'***


*IMAGE: The Sree Chitra Thirunal Institute of Medical Sciences and Technology in Thiruvanathapuram has decided to transfer technology developed by it free of cost to manufacturers in order to boost the production and combat the coronavirus pandemic. Photograph: ANI Photo*

"The earlier you identify the person, you can isolate him faster. So, it is not only good for the patient, but for the population also. When an asymptomatic patient walks around, s/he spreads the virus," ***Dr Anoop Thekkuveettil,*** Senior Scientist in the division of molecular medicine at the Sree Chitra Thirunal Institute of Medical Sciences and Technology in Thiruvanathapuram, tells Shobha Warrier/Rediff.com in the second segment of a three-part interview.

**You and your team developed the testing kit Chitra Gene Lamp-N first, and now Chitra Magna. What is the difference between the two?**

They are not two different things; just two parts of a kit. In COVID-19 detection, you need RNA isolation because this is an RNA virus. Only if you isolate the RNA can you convert it to the DNA. After that you need to amplify it either in a lab or in a PCR (polymerase chain reaction, which is a method widely used in molecular biology to make millions of copies of a specific DNA sample).

We do lab LAMP (*loop-mediated isothermal amplification*) reaction of the DNA, and that's why our testing kit is called Chitra Lamp-N.

Chitra Magna is mainly to isolate the RNA, and it is part of Chitra Lamp-N. Right now, all the RNA isolation kits, rather 99% of them, are coming from abroad. Because we do not have any good high-quality RNA isolation kit, we decided to develop it.

In fact, it is mainly for the LAMP reaction that we developed it.

Then we found that even those doing PCR also suffer from lack of RNA isolation kits. That's when we thought why can we not give Chitra Magna to them so that they can isolate the RNA through their PCR.

Though Chitra Magna is essential for our testing, PCR people also can use it. That's when we decided to split the testing into two; for us and also for PCR. Chitra LAMP reaction is a new kind of chemistry which is an alternate to RT- PCR. Reverse transcription polymerase chain reaction, or RT-PCR, is the current technology that is used by everyone to detect COVID-19.

But RT-PCR is a very expensive machine costing around Rs 50 lakhs to Rs 1 crore and operating the machine also requires very high expertise. That's why it is done only in medical colleges and research institutes. Moreover, there are only very few machines available in the country.

We felt we needed a smaller, simple system which can be used, for example, in a district hospital so that we can test faster and at a cheaper rate. And we get almost equivalent PCR results.

**How fast is your result?**

Usually in a PCR from the sample to result takes about 6 to 8 hours, but in our machine you get the results in less than 2 hours.

Chitra Lamp N, *left*, is faster and it is the size of a laptop only. So, you don't require a very high-end machine. And even normal technicians can run this machine.From the swab, we isolate the RNA using Chitra Magna and then test for the virus.

**Your hospital press release says Chitra Magna has an advantage in RNA extraction...**

The advantage Chitra Magna has in RNA extraction is, we can extract a very highly concentrated RNA. On the other hand, the other kits used currently give only a very diluted RNA.

When the RNA is fresh it works everywhere, but the problem in India is that the testing centres are far away. So, samples have to be transported to the testing centres. You are supposed to transport the samples in a very low temperature, which is -20 degree centigrade.

**What happens if the temperature rises?**

In high temperatures the RNA will get spoilt, and you will get a negative result even if the person is positive. This problem can only be solved by maintaining the cold chain, which is very difficult in India.

We thought if we could increase the amount of RNA, even if some of the RNAs get spoiled we would have a few good ones left. That's where Chitra Magna has an advantage as it extracts a very high concentrated RNA.

The second advantage is, it is very easy to do the extraction. You don't need any equipment; you only need a small magnet and can isolate the RNA.

The best kits are made in Germany, but they are not selling them now as they also need them. So, they will not sell us till the disease is over there. What India suffers from right now is lack of good testing kits. What we get are from China, Korea, etc.

**And the testing kits that came from China are said to be defective and ICMR is sending them back to China.**

Yes. We have no choice right now. Since we do not have any testing kits in our country, we have to buy from somewhere.As the good quality kits are bought by other countries, we are only left with these Chinese kits.

Unless we make our own testing kits, we will not get out of this disease faster.

**Will you be able to make it in bulk so that it is available all over the country?**

We plan to make the testing kit Chitra Lamp-N together with Chitra Magna, and also Chitra Magna alone, available in the market. We have given the technology to a company in Kochi and they are making it in bulk.

We also plan to give it to three more companies so that more kits are available in the market. We will be signing an MoU with one of the biggest companies in the country very soon.

*IMAGE: Dr Anoop Thekkuveettil, second from right, with his team at the Sree Chitra Thirunal Institute of Medical Sciences and Technology.*

**Is it because the genetic information specific to the coronavirus is in the RNA that the extraction of RNA is very important in detecting the virus?**

Yes. Only by testing the RNA can you recognise whether it is COVID-19 or not. That's because every virus has a particular signature gene. Is there any advantage for the patient in testing the RNA?

Yes, the advantage of testing the gene is that you can pick up the presence of the virus in the patient even on day one. The earlier you identify the person, you can isolate him faster.

So, it is not only good for the patient, but for the population also. When an asymptomatic patient walks around, s/he spreads the virus.

The problem with the antibodies test is that it takes 7 days to show the antibodies in the blood. By the time

s/he would have infected many people. That is why ICMR has now withdrawn many antibodies testing kits.

*Source: Shobha Warrier, Rediff.Com, 06.05.2020 (Excerpts)*

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## 2 arthritis drugs show different results in Covid-19 trials

With different approaches to treating Covid-19 patients being tried, varying results of two different arthritis drug trials on patients have further complicated the search for a cure.

While makers of the drug Kevzara (sarilumab) found that it proved to be less effective in treating "severe" respiratory illness caused by Covid-19 as compared to the "critical patients in trials conducted in the US", another drug Actemra (tocilizumab) showed benefit in treating seriously ill patients in a trial in France.

Announcing the preliminary results from the Phase 2 portion of an ongoing Phase 2/3 trial evaluating Kevzara, Sanofi and Regeneron Pharmaceuticals Inc said that Kevzara had no notable benefit on clinical outcomes when combining the "severe" and "critical" groups, versus placebo.

However, there were negative trends for most outcomes in the "severe" group, while there were positive trends for all outcomes in the "critical" group, the results showed.

Following a review by the Independent Data Monitoring Committee (IDMC) of all available Phase 2 and Phase 3 data, the trial will be immediately amended so that only "critical" patients continue to be enrolled to receive Kevzara 400 mg or placebo, Sanofi and Regeneron Pharmaceuticals said.

The randomised Phase 2 portion of the trial compared intravenously-administered Kevzara higher dose (400 mg), Kevzara lower dose (200 mg) and placebo.

It assessed 457 hospitalised patients, who were categorised at baseline as having either "severe" illness, "critical" illness or "multi-system organ dysfunction".

"Emerging evidence with Kevzara and other repurposed drugs in the Covid-19 crisis highlight the challenges of making decisions about existing medicines for new viral threats using small, uncontrolled studies," George D. Yancopoulos, Regeneron Co-Founder, President and Chief Scientific Officer, said in a statement. "We await results of the ongoing Phase 3 trial to learn more about Covid-19, and better understand whether some patients may benefit from Kevzara treatment," Yancopoulos said.

The trail of Roche Holding AGs Actemra by the Assistance Publique -- Hopitaux de Paris (AP-HP) -- showed that seriously ill patients due to complications from Covid-19 might benefit from the drug.

While the hospital revealed the results of the small study, the findings are yet to be published.

Further studies will be required to know if the drug can prove to be effective against the disease, according to researchers.

Interestingly, the Kevzara trial was designed after a small, single-arm study in China among mostly severe, febrile hospitalised Covid-19 patients, which found elevated IL-6 levels, and suggested that inhibiting this pathway with the IL-6 inhibitor tocilizumab rapidly reduced fever and improved oxygenation in severe patients, allowing for successful hospital discharge.

*Source: IANS, Outlook, 28.04.2020*

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## COVID-19 vaccine in 1 month? CSIR pins hope on Sepsivac

India's top Research and Development organization, the Council of Scientific & Industrial Research (CSIR), which is currently testing a "repurposed" vaccine against Covid-19 in a Phase 2 trial, is hoping to seek approval from the Drug Controller for its wider use against the pandemic in as early as 30 days from now, the scientist who is coordinating the effort said.

India's top Research and Development organization, the Council of Scientific & Industrial Research (CSIR), which is currently testing a "repurposed" vaccine against Covid-19 in a Phase 2 trial, is hoping to seek approval from the Drug Controller for its wider use against the pandemic in as early as 30 days from now, the scientist who is coordinating the effort said.

CSIR is currently testing Cadila Pharmaceuticals' "Sepsivac" against COVID-19. This treatment was developed as a result of a partnership between CSIR and Cadila Pharmaceuticals many years ago. This immunotherapy

treatment, which boosts "innate immunity", was initially approved by the Drug Controller General of India (DCGI) for gram negative sepsis which is a disease caused by bacteria.

But the scientists found that the pathological symptoms of this disease and Covid-19 were quite similar. And given the urgency of finding a solution to the rapidly rising Covid-19 cases across the world, the scientists thought of testing the treatment against the current pandemic caused by the SARS-CoV-2 virus.

CSIR got the approval to test "Sepsivac" against Covid-19 in a Phase 2 clinical trial about 10 days ago. The trial is being conducted on 50 patients at the All India Institute of Medical Sciences (AIIMS), New Delhi, AIIMS Bhopal, and Post Graduate Institute of Medical Education and Research (PGIMER), Chandigarh.

"We expect the results from this Phase 2 trial within 30-45 days from now. And if the results are encouraging, we will seek approval from the Drug Controller because of emergency and keep on continuing the Phase 3 trial. That's how it happens," Ram Vishwakarma, Director, Integrative Medicine (Council of Scientific & Industrial Research), Jammu, told.

Vishwakarma said that once it applies, the approval from the Drug Controller is expected to come fast as it is an emergency situation. So if the Phase 2 trial shows that "Sepsivac" is effective against Covid-19, the world may have a vaccine against the disease as early as one month from now, at least for emergency use.

Meanwhile, Vishwakarma informed that CSIR has also got approval for conducting Phase 3 clinical trial of "Sepsivac" against Covid-19.

"The Phase 3 trials will be done on 1,100 people 600 will be those who have tested positive but non-symptomatic, and 500 will be those who are out of hospital," Vishwakarma said.

**How does Sepsivac work?**

It contains heat-killed mycobacterium w (Mw), an immunomodulator, which is a non-pathogenic mycobacterium. "Normally when you develop a vaccine, you grow the organism and kill it. It is called heat killed. Here we heat killed the bacteria. It is a standard vaccine concept," Vishwakarma said, adding that the bacterium is produced by fermentation.

"The treatment we are testing against Covid-19 is designed to enhance innate immunity which is very critical. People who are weak in innate immunity will get the infection faster," he said.

Vishwakarma explained that it is a non-specific vaccine which could be used to both cure and protect people. He explained that there are generally three types of vaccines.

"There are therapeutic vaccines, where you give them as a drug for curing. There are prophylactic vaccines, which you give to people to protect them. And there are some which have both the properties, which are called immunomodulators.

"Sepsivac will be an immunomodulator, which will have protective effect and therapeutic effect both," he said.

Vishwakarma is hopeful that the Phase 2 clinical trials of the treatment will provide positive results. And because the drug is already in use for sepsis or septic shock treatment, "human safety is already assured," he said, adding that it will be applicable for all age groups.

"We are keeping our fingers crossed and hoping for the best," Vishwakarma said. As developing a vaccine against a new disease takes time, researchers the world over are rushing to repurpose existing drugs, vaccines against the disease.

*Source: IANS, IndiaTVNews, 02.05.2020*

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## Pharma exports fail to meet FY20 target due to curbs

India's Pharmaceutical exports have taken a hit by about $1.5 billion due to export restrictions on a few drugs and supply disruptions, resulting in $20.58 billion for FY20, against the estimated target of $22 billion. However, the industry reported a 7.57% growth as against $19.13 billion reported in the previous year, according to Pharmaceuticals Export Promotion Council of India (Pharmexcil) data.

"Combined with lockdown measures across the countries and export restrictions on some of the products, led to a downturn in export growth," Mr Ravi Udaya Bhaskar, Director-General, Pharmexcil, said. According to him, Pharma exports during February and March are usually quite brisk to an extent of 22-23%. "Having seen the good pace of export trend in first three quarters and price stabilisation in the US, it was estimated that FY20 exports would reach $22 billion. As the fourth quarter of FY20 brought in a negative growth, the overall exports fell to 7.57% from 11.5%."

Drug formulations and biologicals, which contribute to almost 72% of exports, have shown 9.5% growth in FY20. However, export of bulk drugs and drug intermediates posted negative growth (-0.73%), dragging down the overall performance. Vaccines and surgicals recorded 22% and 10.5% growth, respectively.

India has exported pharmaceuticals to 202 destinations during FY20 with North America as the largest exporting region with 34% share recording 15.11% growth. "About $6.7 billion worth of drugs was exported to the US with 15.8% growth. This has constituted almost 32.74% of our total exports followed by Africa with 17% share and Europe with 15% share. Our exports to China in FY19 was $230 million and this year, it is $228 million," he said, adding India is still dependent on China to an extent of 60-70% of its needs of bulk drugs and has faced disruption in the supply chain due to Covid-19.

Meanwhile, understanding the over-dependence of Indian Pharma Industry on China for bulk drugs, Key Starting Materials (KSM) and intermediates, Pharmexcil conducted a study with the support of Commerce Ministry on 'Strategies to reduce import dependence of APIs, KSMs and Intermediates' and gave a Detailed Project Report (DPR) to the Government in January 2020. The DPR has given inputs for framing the schemes for promotion of domestic manufacturing of critical KSMs, drug intermediates and APIs in the country.

The sanctioned schemes include promotion of bulk drug parks and production-linked incentive scheme. "The proposal is to develop three mega bulk drug parks in partnership with states. While the Government of India will give grants in aid to states with Rs 1,000 crore for each bulk drug park, a sum of Rs 3,000 crore is approved for this scheme for next five years. The scheme is expected to reduce manufacturing cost of bulk drugs in the country and dependency on other countries for bulk drugs," Mr Bhaskar said.

Further, a financial incentive is given for eligible manufacturers of 53 critical bulk drugs (26 fermentation-based and 27 chemical synthesis-based bulk drugs) on their incremental sales over base year 2019-20 for a period of six years. Towards this, a sum of Rs 6,940 crore has been approved for the next eight years. "This scheme intends to boost domestic manufacturing of critical KSMs, drug intermediates and APIs by attracting large investments in the sector to ensure sustainable domestic supply and thereby reduce India's import dependence on other countries," he said.

*Source: Financial Express, 09.05.2020*

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## Covid's vitamin D link: What data from 20 countries show?

A new study has found an association between low average levels of vitamin D and high numbers of Covid-19 cases and mortality rates across 20 European countries. The research, led by scientists from UK's Anglia Ruskin University (ARU) and Queen Elizabeth Hospital King's Lynn NHS Foundation Trust, is published in the journal Aging Clinical and Experimental Research.

Vitamin D is known to modulate the response of white blood cells, preventing them from releasing too many inflammatory cytokines (part of the body's immune response to fight infections). And the SARS-CoV2 virus is known to cause an excess of pro-inflammatory cytokines, called a cytokine storm.

The new study shows that Italy and Spain, both of which have experienced high Covid-19 mortality rates,

have lower average vitamin D levels than most northern European countries. This, the researchers said, is partly because people in southern Europe, particularly the elderly, avoid strong sun, while skin pigmentation also reduces natural vitamin D synthesis.

The highest average levels of vitamin D are found in northern Europe, due to the consumption of cod liver oil and vitamin D supplements, and possibly less sun avoidance. Scandinavian nations are among the countries with the lowest number of COVID-19 cases and mortality rates per head of population in Europe, ARU said in a statement on the new research.

"We found a significant crude relationship between average vitamin D levels and the number Covid-19 cases, and particularly Covid-19 mortality rates, per head of population across the 20 European countries," Dr Lee Smith of ARU said in the statement.

"Vitamin D has been shown to protect against acute respiratory infections, and older adults, the group most deficient in vitamin D, are also the ones most seriously affected by Covid-19. A previous study found that 75% of people in institutions, such as hospitals and care homes, were severely deficient in vitamin D. We suggest it would be advisable to perform dedicated studies looking at vitamin D levels in COVID-19 patients with different degrees of disease severity," Dr Lee said.

*Source: Anglia Ruskin University, Indian Express, 11.05.2020*

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## Finance Ministry set to extend anti-dumping duty on import of sodium citrate from China

The Union Finance Ministry is set to extend existing anti-dumping duty on import of Chinese sodium citrate used in pharmaceutical and food industry following Union Ministry of Commerce and Industry's insistence.

The Finance Ministry imposed anti-dumping duty on sodium citrate imported from China on May 20, 2015 for five years. The duty will expire on May 19, 2020.

The imposition of anti-dumping duty on import of Chinese chemical was recommended by Directorate General of Trade Remedies (DGTR), an investigative arm of Union Ministry of Commerce and Industry on February 26, 2015 after conducting a probe into it. The probe was initiated by DGTR on February 28, 2014.

The import of Chinese chemical declined over the last five years only due to the imposition of anti-dumping duty. However, they continue to remain significant despite the imposition of anti-dumping duty.

Landed price of imports is below the level of selling price of the domestic industry and price undercutting has remained positive over the last five years except briefly in 2017-18. Therefore, imports are likely to undercut prices of the domestic industry in the event of cessation of anti-dumping duty.

India has imported 841 metric tons of sodium citrate from China in FY 2015-16 followed by 1,159 metric tons of Chinese chemical in FY 2016-17, 772 metric tons in FY 2017-18, 1,014 metric tons in FY 2019-20 and 811 metric tons in FY 2020-21.

Before the expiry of the said duty, Posy Pharmachem Private Limited has filed an application before the DGTR for initiating sunset review investigation into imports of sodium citrate from China, alleging likelihood of recurrence of dumping and consequent injury to the domestic industry in case of cessation of existing anti-dumping duties.

Posy Pharmachem accounts for around 32% production of sodium citrate in India. Besides Posy, some of the major producers of sodium citrate in India are Adani Pharmachem, Sunil Chemicals, India Phosphate, Alpine Labs, Amijal Chemicals, Sujata Chemicals, Vasa Pharmachem, Devendra Kirti Pharmachem, Wang Pharaceuticals & Chemicals, Ishita Drugs & Industries Ltd.

The DGTR on the basis of the prima facie evidence initiated sunset review investigation on October 25, 2019 to examine whether the expiry of the anti-dumping duty on import of Chinese chemical is likely to lead to recurrence of dumping and injury to the domestic industry.

The directorate noted that the performance of the domestic industry has deteriorated considerably, and continued dumping of sodium citrate may adversely impact the ability of the domestic industry to raise capital investment.

It recommended to extend existing anti-dumping duty to protect domestic industry and suggested imposition of USD 152.78 per metric ton anti-dumping duty on import of sodium citrate from China. Sodium citrate is imported in India from several Chinese companies-- Qingdao Sonef Chemical Company Limited, Weifang Vot International

Business, Hai Hui Group, Foodchem International Corporation, Yixing Zhenfen Medical Chemical Co Ltd., Hainan Huarong Chemical Co Ltd, Lianyungang Dongtai Food Ingredients Co Ltd, Lianyugang Shuren Kechuang Food, Addivtive Co Ltd., COFCO, Laiwu Taihe Biochemistry Co, Ltd, Weifang Ensign Industry Co Ltd., Jiangsu Guoxin Union Energy Co Ltd etc.

Sodium citrate is a chemical compound that comes in the form of monosodium citrate, disodium citrate and tri-sodium citrate. It is sodium salt of citric acid and has a sour and salty taste. Sodium citrate is mainly used in pharma industries as an expectorant and urine alkanizer. It is also used as a pharmaceutical aid, food additive in dairy industries, laboratory reagent in water treatment, acidity regulator in drinks, an emulsifier for oils when making cheese and an antioxidant in food, etc.

Sodium citrate is also known as tri sodium citrate, tri sodium citrate dehydrate, sodium citrate dehydrate, tribasic sodium citrate, sodium citrate tribasic dehydrate, sodium citrate dibasic sesquihydrate, sodium citrate monobasic bioxtra.

Countries conduct anti-dumping investigation to determine whether their domestic industries have been suffered due to rise in cheap imports. To reduce the dumping of cheap imported product, they impose duties under the multilateral regime of the World Trade Organization.

The objective of the duty is to ensure fair trade practices and create a level-playing field for domestic manufacturers with regard to foreign producers and exporters.

*Source: Laxmi Yadav, Pharmabiz, 07.05.2020*

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## FPME hails proactive measures by Centre to assist trade & industry to tide over crisis induced by COVID-19 pandemic

The Federation of Pharmaceutical Merchant Exporters and Allied Products (FPME) has hailed several measures announced by the Union Finance Minister, Reserve Bank of India (RBI) and the Directorate General of Foreign Trade (DGFT) to help the trade and industry in the country which has been badly bit due to the COVID-19 pandemic in the world. In view of the disruption caused by the COVID-19 pandemic, the time period for realization and repatriation of export proceeds for exports made up to or on July 31, 2020 has been extended to 15 months from the date of export. "This measure will enable the exporters to realise their receipts, especially from COVID-19 affected countries within the extended period and also provide greater flexibility to the exporters to negotiate future export contracts with buyers abroad," says Ashish Shah, Secretary, FPME .

FPME also stated that DGFT extending implementation of track and trace till September 30, 2020, was also a big relief for merchant exporters. Earlier, FPME has also urged the Union Government to resolve track and trace issue being faced by the merchant exporters in the country.

"Giving relief in late returns and interest is a welcome move but government should consider waiving interest to everyone whatever the turnover. Currently, they have given full interest waiver to turnover below Rs. 5 crore and 9% interest is still applicable for turnover above Rs. 5 crore. The further extension to current foreign trade policy till March 2021 was a nice step by a year till March 31, 2021, which will again give relief to our members," Shah added.

The Union Government had recently issued a circular clarifying refund related issues. It is clarified that there is no bar in claiming refund by clubbing different month across successive financial years and accordingly restriction on clubbing of refund claims across financial years shall not apply. The merchant exporters are also facing some issues such as non-acceptance of Indian Pharmacopoeia (IP) drugs, FPME said.

Incorporated on March 30, 2019, FPME today has 130 members in a span of just six months and is planning to add 500 members this year. As per Pharmexcil data, there are approximately 2,000 merchant exporters in the country.

*Source: Yash Ved, Pharmabiz, 07.05.2020*

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## Pradhanmantri Jan Aushadhi Kendras achieve record sales of ₹52 crore in April 2020

Pradhanmantri Bhartiya Jan Aushadhi Kendras (PMBJAKs) achieved a record sales turnover of Rs 52 crore in the month of April 2020 during COVID-19 lockdown as compared to Rs. 42 crore in March 2020. It was Rs. 17 crore in April 2019.

This led to total savings of approximately Rs. 300 crore of common citizens as Jan Aushdhi Kendra's medicines are cheaper by 50 to 90 per cent of the average market price. Presently, more than 6,300 PMJAKs are functioning across the nation covering 726 districts of the country. They are playing a vital role in COVID-19 outbreak as around 10 lakh persons per day are visiting these centres to source quality medicines at affordable prices. These centres are also selling hydroxchloroquine (HCQ) tablets.

Indian Council of Medical Research (ICMR) has recommended the use of HCQ for treating healthcare workers handling suspected or confirmed COVID-19 cases and also the asymptomatic household contacts of the lab-confirmed cases.

Bureau of Pharma PSUs of India (BPPI) CEO Sachin Kumar Singh informed that BPPI has developed 'Jan Aushadhi Sugam Mobile App' to help people in a big way to locate their nearest Jan aushadhi Kendras and availability of affordable generic medicine with its price. Pradhan Mantri Bhartiya Jan Aushadhi Pariyojana (PMBJP) has been providing over 900 quality generic-medecines and 154 surgical equipments and consumable at affordable prices for every citizen of the nation.

Over 325,000 people are using 'Jan Aushadhi Sugam Mobile App'. They can avail a host of user-friendly options like direction guided through Google Map for location of the Janaushadhi Kendra, search Jan Aushadhi generic medicines, analyze product comparison of generic and branded medicine in form of MRP and overall savings with the help of this App. This App is available on both Android and I-phone platforms.

*Source: Shardul Nautiyal, Pharmabiz, 06.05.2020*

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## Ayurvedic drug Zingivir-H gets approval for clinical trial to treat COVID-19 patients

An ayurvedic medicine Zingivir-H tablet developed by Pankajakasthuri Herbal Research Foundation, an ayurvedic organisation from Kerala, has got approval from the Clinical Trial Registry of India (CTRI) for clinical trials on adults who have tested positive for COVID-19.

"This drug, which is effective against respiratory infections, viral fever, acute viral bronchitis has now been found to be effective against the respiratory syncytial virus and influenza virus in the scientific studies conducted", the company said.

*In vitro* experiments done at the Rajiv Gandhi Center for Biotechnology has proven that there are no side effects in the human cell.

The approval was received from the Institutional Ethics Committees (IEC), based on which the Central government's CTRI (an arm of the Indian Council of Medical Research), has provided approval to conduct a randomised single-blinded placebo-controlled prospective multicenter interventional clinical trial to various medical colleges across the country.

"The company will start the trial in around 120 patients, 15 patients have already been administered as part of the trial and end of May results will come out," Hareendran Nair, Managing Director of the company, said.

Currently, it is only being tested at the Mysore Medical College and Research Institute (MMCRI) with a sample size of 120 patients with 15 people already enrolled.

"Zingivir-H has seven ingredients including herbomineral and these have been prescribed in our scientific manuscript. It has been part of our clinical practice for so many years. I have been using this formula for nearly 15 years for viral fever, acute viral bronchitis and contagious fever and have got fantastic results," Nair added.

According to Hareendran Nair, the founder of the Pankajakasthuri Herbal Research Foundation in Kerala where the drug was developed, other medical colleges in Tamil Nadu, Karnataka, Maharashtra, Telangana and Delhi have also been approached.

This is the first known ayurvedic approach to cure COVID-19.

The drug developed by Pankajakasthuri, will now be tested as potential medicine for COVID-19 in medical college across the country.

*Source: Pharmabiz, 06.05.2020*

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## DCGI extends validity of registration of BA/BE study centres

The Central Drugs Standard Control Organisation (CDSCO) has clarified that registration of bioavailability-bioequivalence (BA-BE) study centres is valid if application for renewal has been made 90 days prior to expiry in

accordance with New Drugs and Clinical Trial (NDCT) Rules 2019.

The clarification comes in the wake of Drugs Controller General of India (DCGI) office having received representations from stakeholders requesting to extend validity of BA/BE study centres registrations whose validities are expiring between now and August 2020 in view of COVID-19 outbreak.

"Matter was examined by CDSCO committee in light of COVID-19 outbreak and it is therefore clarified that in accordance with NDCT Rules, 2019, if application for the renewal of registration of BA/BE study centre in Form CT-08 is received by CDSCO 90 days prior to the date of expiry, the registration shall continue to be in force until order passed by the said authority on the application," according to a CDSCO circular.

BA/BE centres have been mandated and registered under Rule 44 of NDCT Rules 2019 to conduct the BA/BE study of new drugs in human in the country. Before the implementation of NDCT Rules, 2019 on March 19, 2019, permissions were issued to the study centres to conduct BA/BE studies having validity of 3 years. All such centres permitted by CDSCO before implementation of the NDCT Rules, 2019 also need to be registered under the NDCT Rules.

In view of the above, BA/BE study centres which has already applied or will apply for renewal of the registration 90 days prior to the date of expiry of its existing registration in Form CT-08 along with requisite fees and documents, the registration of such centres will remain valid until any order is issued by CDSCO otherwise, the circular further stated. CDSCO had earlier urged the manufacturers to submit stability studies data as per NDCT Rules, 2019.

As per NDCT Rules, 2019, clinical trial in relation to a new drug or investigational new drug means any systematic study of such new drug or investigational new drug in human subjects to generate data for discovering or verifying its clinical or pharmacological including pharmacodynamics, pharmacokinetics or adverse effects with the objective of determining the safety, efficacy or tolerance of such new drug or investigational new drug.

As per the new rules, bio-equivalence study means a study to establish the absence of a statistically significant difference in the rate and extent of absorption of an active ingredient from a pharmaceutical formulation in comparison to the reference formulation having the same active ingredient when administered in the same molar dose under similar conditions.

*Source: Shardul Nautiyal, Pharmabiz, 05.05.2020*

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## DCGI directs state DCs to take stock of issues in procurement & prices of HCQ, azithromycin and paracetamol APIs

Amid concerns over increase in the procurement price of hydroxychloroquine (HCQ), azithromycin and paracetamol APIs and Key Starting Materials (KSMs), the Drugs Controller General of India (DCGI) has sought details from drugs controllers in states and Union Territories regarding procurement and pricing of these three APIs and KSMs so as to take further action.

On May 5, 2020 DCGI had written to state and UT drugs controllers seeking details in this regard following a direction from National Pharmaceutical Pricing Authority (NPPA).

The NPPA on April 30, 2020 had dashed a letter to Central Drugs Standard Control Organisation (CDSCO) intimating that member companies of the pharma associations, mostly belonging to small and medium sector, are facing financial crisis due to rise in the prices of paracetamol API and media reports pointed towards rise in prices of azithromycin and HCQ APIs/KSMs.

Earlier, the Federation of Pharma Entrepreneurs (FOPE) on April 28, 2020 had written to NPPA expressing concern over rising prices of paracetamol APIs over last three months. Currently market price of the same is about Rs. 425 per kg as against Rs. 250 a kg in January 2020.

"Our members who are mostly MSMEs are already in deep financial crisis and are facing difficulties to remain afloat due to lockdown, manufacturing of paracetamol tablets with the current price of API being Rs. 450 per kg and then selling the same at the present ceiling price as notified by NPPA under DPCO, 2013 is not viable and will result in huge losses to them," stated FOPE.

The Pharma body has urged NPPA to increase ceiling prices of paracetamol formulation for at least six months based on the exponential increase in the price of API by invoking the powers vested with it under paragraph 19 of DPCO, 2013.

Earlier NPPA had asked the manufacturers of paracetamol tablets to supply minimum quantity of paracetamol, but not less than their average supply of the past three months (January, February and March), in the domestic market.

On April 27, 2020 Chronicle Pharmabiz carried a report stating that the prices of azithromycin and HCQ APIs have increased two to ten times due to sharp rise in their demand to fight against COVID-19 pandemic. The prices of azithromycin have jumped to Rs. 16,000 a kg from Rs. 9,000 per kg earlier. The API is imported from China. Taking a cue from Indian traders, the Chinese exporters have also increased the prices of azithromycin to US$ 150 a kg from US$ 90 per kg earlier.

On the other hand, the prices of HCQ API, being touted as game changer in COVID-19 treatment, have gone up ten times to Rs. 70,000 a kg from Rs. 7,000 per kg earlier.

In this regard, CDSCO has been requested by NPPA to assess the procurement and price issue of HCQ, azithromycin and paracetamol APIs/KSMs and as to whether there are any constraints in the procurement of these APIs.

Taking serious note of this, DCGI has asked state drugs regulators to report any issue faced by them regarding procurement and pricing of HCQ, azithromycin and paracetamol APIs and KSMs.

*Source: Laxmi Yadav, Pharmabiz, 08.05.2020*

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## Indian Pharma & Machinery sector sees Smart Factory model to mitigate future challenges of COVID-19 like lockdowns

Indian pharma and machinery sector is keen to transit to a Smart Factory model to mitigate challenges of COVID-19 like lockdowns in the coming years. The machinery sector is the lifeline to the pharmaceutical industry. More so during the lockdown, the two sectors teamed-up to ensure uninterrupted medicine supply for patients battling the pandemic globally and in India.

Noting the importance of regular supply of drugs across the healthcare centres, Kaushik Desai, Advisor, Indian Pharma Machinery Manufacturers Association (IPMMA) said that COVID-19 has affected day-to-day subsistence of everyone around globe and India is no exception. As essential services, operations of pharma and machinery sectors did not come to a standstill.

However, this pandemic has brought out unique challenges to the fore which were never thought of. The machinery sector has undergone a radical change in its approach to work and support the pharma industry, Desai noted at a webinar on 'COVID-19: Pharma and Machinery sector joining hands to mitigate the issues'."In these particularly challenging times, flexibility and adaptability are vital. As we have always believed, challenging times present great opportunities, the positive side of this pandemic too is that both sectors are working as a cohesive team," said Desai.

The panel of experts at the webinar: Narsima Raju, site head, quality, Dr Reddys Laboratories; Ashis Banerjee, CMD, Gansons; Shankar Gupta, COO, ACG Engineering; R Ramanathan, COO & Director, Parle Global Technologies; Vishesh Parekh, Managing Partner, INCOME, and Shaunak Dave, CEO (Asia), Optel Group said that a Smart Factory concept is the next industrial revolution for the pharma and machinery sector.

Providing a perspective on the current situation, the panel noted that major issues at present included continuing manufacturing with minimum workforce, difficulty to access machinery spare parts and at the same time ensure employee safety.

There are some machines or critical spare parts under clearance by customs in India and other countries. Yet going by a pressing demand for hydroxychloroquine (HCQ) tablets for export and the domestic market supply, we had to buck up to ensure seamless production schedules and a strong supply chain, noted the experts. Queries from Desai, who was the moderator of the webinar, prompted the panel to respond to the kind of actions taken during the prevailing tough scenario. These experiences included moves to tackle trouble shooting, stocking adequate spares to thwart production loss. The experts observed that it was perseverance, adaptability and agility along with technology adoption that enabled efficiency in manufacture. Hence the future would see a surge in advanced and novel technology implementation with automation and digitisation.

Pharma is moving towards high volume generics, including biosimilars, biologics, orphan drugs and backward integration of APIs. Hence the effort is to sustain proactive approaches to lower costs and streamline operations as we see only a Smart Factory concept as the answer, they concluded.

*Source: Nandita Vijay, Pharmabiz, 08.05.2020*

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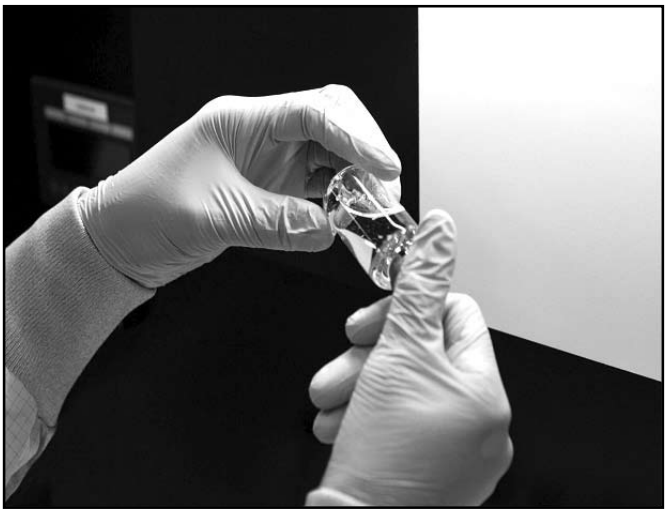
# Remdesivir – a Drug in Search of a Disease

***Samir Malhotra***



*A vial of pure remdesivir. Photo: Gilead Sciences Inc/Handout via Reuters.*

'Marketism' is the notion that markets are not a tool but an end in themselves. 'Peoplism' is the notion that welfare of masses is the end for which markets are a useful tool, but there can be other tools too.

When we conduct a Clinical Trial, we have a primary aim that we call an endpoint. For example, mortality reduction is an endpoint. Blood pressure is another type of endpoint because it's an indirect marker of mortality. A medicine is a tool to reduce blood pressure (if it's too high) and thus mortality.

We test new medicines so that they can get regulatory approval for marketing. During the testing, it is possible (and has happened) that a new medicine decreases BP in patients with high BP, but instead of decreasing mortality, increases it. What do we do in that case? We abandon that drug. In the same way, if markets fail in some situations, it would be irrational to keep sticking to that tool – as if achieving marketism was the goal and not peoples' lives.

**Remdesivir:**

According to some estimates, it could take up to $2 billion to bring one substance to market as a drug. Whatever be the figure, drug discovery/development is an expensive, time-consuming endeavour and most new drugs are brought to the market by companies. Remdesivir was developed by Gilead Sciences, an American pharmaceutical company, for Hepatitis C and respiratory syncytial viruses more than a decade ago but did not receive marketing approval.

It was later tested for Ebola, SARS, MERS and Marburg virus infections, and again didn't demonstrate sufficient efficacy to be approved. The COVID-19 pandemic has provided a new opportunity. It soon generated a lot of hype during the current pandemic and was even offered by the US President to the British Prime Minister in the first week of April when the latter developed COVID-19. Gilead wasn't claiming any efficacy at that time, only saying it was a promising medicine.

On 10th of April, the New England Journal of Medicine published data of an experiment in which researchers administered remdesivir to 61 hospitalised COVID-19 patients over 10 days. They found 68% improved while 13% died. Data for eight patients was not provided. It is difficult to say based on this as to how efficacious or inefficacious the drug was because there was no control group. Nonetheless, Gilead called the results "hopeful".

Soon, there was also a 'leaked' video in which an infectious disease specialist from the University of Chicago said, "The best news is that most of our patients have already been discharged, which is great. We've only had two patients perish." The university statement was more cautious: "Partial data from an ongoing clinical trial is by definition incomplete and should never be used to draw conclusions about the safety or efficacy of a potential treatment that is under investigation."

**No atheists in foxholes:**

On April 17, a Bret Stephens of the New York Times criticized "big-Pharma haters" and claimed "effective diagnostic tests, therapies and vaccines - typically emerge from profit-seeking companies operating in fiercely competitive and well-regulated marketplaces." He added, "One lesson from this pandemic is how dependent we are for our survival on an innovative and robust pharmaceutical industry. May be we should do more as a country to cultivate it than tear it down."

It was a twisted logic. For one thing, is it okay to hate Big Pharma outside of a pandemic? And is it okay for

a company to cling to profits at such a fraught time as this?

A few days later, articles in *The Guardian* and *Financial Times* reported a WHO report of results of a randomised, controlled clinical trial in China: 158 patients had received remdesivir and 79 received placebo. There was no difference in mortality (14% in remdesivir group v. 13% in placebo); adverse reactions to remdesivir led to its early stoppage in about 12% patients; no other details were provided. However, the results were quickly removed from the web because they had not been peer-reviewed, according to the WHO.

Gilead also has other ongoing trials of this drug. Recently, it changed its trial protocols at least in one instance, where it increased the sample size to 6,000, added more study groups and changed the primary outcome measure – a step that led to a jump in its shares even though such post hoc changes in outcome measures are not recommended, especially when they happen after looking at the now-unavailable results of a failed trial.

At the time when all these activities were going on, Gilead applied for and was granted "orphan drug" status for remdesivir by the US Food and Drug Administration, which allows greater marketing exclusivity to companies but is reserved for drugs meant to treat rare diseases. After facing criticism, Gilead asked the FDA to revoke the orphan drug status. There are atheists in foxholes.

**Blinding by ideology:**

Bret Stephens's ideological blindness is absolute. His article did not even once remind people that a lot of funding based on which new drugs are developed comes from the public sector. A recent study showed Government funding contributed to discovery and/or development of every one of the 210 new drugs approved by the FDA between 2010 and 2016.

Gilead drew heavy flak a few years ago for pricing its hepatitis C virus drug sofosbuvir at $1,000 per tablet, $84,000 for the full course (Rs 75,540 and Rs 63.4 lakh respectively). Other related medicines soon followed, with excellent cure rates for Hepatitis C. The company claimed that the price was justified because of the value it provides. The latter is true – but there is more to this story.

The original research that led to this fantastic medicine occurred in a publicly funded laboratory at Emory University in the 2000s, from where a start-up, named Pharmasset, emerged and was later acquired by Gilead for $11 billion in 2011 after Pharmasset demonstrated that early results with sofosbuvir were better than other drugs under development. Within three years, Gilead had earned more than three times what it spent to acquire Pharmasset, and 40-times the cost of developing these medicines.

In a tragic irony, Gilead sued the US government last week for patent infringement of its anti-HIV drug after 15 years of collaboration.

**It's not the scientists' fault:**

Often times such critiques of the pharmaceuticals industry and its apologists are twisted to make them sound like criticism of scientists. Let there be no confusion: several colleagues, friends and students are currently involved in high-quality, advanced research to bring new medicines to patients.

They are dedicated professionals and we should recognize and applaud them as well as the industry for a lot of good work they do. Markets are a wonderful tool. However, we often forget that they are only tools, and that peoplism should come before marketism or profitism. Stephens never tries to explore people's contribution to R&D, and presents a one-sided market view.

This has consequences for the future too. According to the WHO, on 31 December 2019, the Wuhan Municipal Commission reported a cluster of cases of unidentified pneumonia, and on 12 January 2020, the genetic sequence of the novel Coronavirus had already been shared with the world.

This publicly available information was used to market testing-kits and start development of vaccines. Now to say that it is the profit-making companies doing everything is grossly misleading. We must devise ways to ensure that the people gets their return on investment, too. Having shown in test tubes to be useful against many viruses, remdesivir is still searching for a disease it can cure.

*(Samir Malhotra works at the Post-Graduate Institution of Medical Education and Research, Chandigarh).*

*Source: Science The Wire, 09.05.2020*

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# Corona's sting: The key is to adapt to a changed world

***Amit Khanna***

For over a century the role of nations soft power has been overemphasised. From European colonialism, Pax Americana, Soviet military prowess, China's economic miracle, India's secularism and so on are all inventions of intellectual discourse. These self-serving shibboleths will and must yield to newer visions of the world. Political bickering never assuages wounds. Rhetoric hurts and not heals. Globalization will get new contours even as nationalism rises.

Rather than being bound by moribund restrictions of ancient treaties from Bretton Woods to WTO, trade and commerce needs to be reinvented. The role of the UN and its sundry offspring will need to be reworked too. One nation one vote may not be ideal to run pan global organisations anymore. Multi-lateralism needs a relook in the context of new realities. Calamities have in the past led to confrontation. However, this time, no one region or power has remained unscathed. Governments and leaders will be more responsive to their own people rather than building notional alliances.

As a wise man said, ***"Cost of living is cheap, the cost of lifestyle is experience."*** When lifestyle becomes the fountainhead of disease -- diabetes, hypertension, strokes *et al* -- it will surely evoke a reassessment if not large-scale rejection of the way we live. Luxury itself will get redefined and exclusivity will override ostentation. Wealth in itself, after a point, is just symbolic as is borne by these shambolic times.

Humans are gregarious and so they shall be but gatherings will become smaller, personal and meaningful. The family as a fundamental building block of communities will rise once again. Look for more joint families rather than nuclear families in future. Empty nesters would love to hang on to the brood longer. The much-abused video calling and social messaging hopefully will be more interpersonal and help contact and bonding with kith and kin. A lot of grown-up children may end up staying with their parents even when they can move out.

I see the rise of larger households with inbuilt privacy. Independence needs interdependent individuals and groups. Somewhere virtual relationships will have to connect with the real world. Expect more spiritualism.

Every government, especially in a country like India, is raising its expenditure in the health sector. We will see an immediate ramp up of hospital beds, even new hospitals -- tertiary, general and primary. Obviously, the number of trained health workers from ward boys, nursing staff, laboratory technicians, radiologists to doctors cannot increase overnight.

We will see better wage structure in the health sector attract more youngsters. Perhaps we need to train a much larger paramedic force to cope up with future emergencies. Pharmaceuticals, bulk drugs, even vaccines manufacturing needs a desperate leg up with suitable incentives. While Ayushman Bharat is a great model, immediate attention must be given to the rural touch points. India will have to, in the short term, double its expenditure on health. Crowded hospitals and a perennial shortage of trained health workers and equipment just won't work in future emergencies.

Fortunately, this crisis has highlighted the significance of telemedicine and remote diagnostics. We shall see a spurt in distant treatment all over the world. Newer mobile phones will incorporate more diagnostic functions in them. Online delivery of medicines, especially in smaller towns and villages, is another area of growth.

Personal protection equipment (PPEs), Hazmat suits, surgical masks and gloves, and controlled entry into hospitals will become par for the course. A number of other vaccines (pneumonia, flu, malaria and HIV) will be added to polio, BCG which are mandatory today.

One more sector which will change is education. Schools and colleges are traditionally places where children and youth congregate. Our classrooms and campuses are largely overcrowded. With poor infrastructure. Even basic toilets are either missing or are unhygienic.

It is impossible to upgrade facilities in the short term so it is the way we teach which will change. A lot of classes will have to move online. The stilted examination-oriented system, where students score an absurd 99 per cent marks, will be replaced by a graded evaluation system. Tele-learning, classrooms on mobile and, of course, online courses will be the new norm. Classes and lectures will be staggered.

As Poornima Luthra of TalentEd Consultancy says: "The COVID-19 pandemic has resulted in educational institutions across the world being compelled to suddenly harness and utilize the suite of available technological tools to create content for remote learning for students in all sectors. Educators across the world are experiencing new possibilities to do things differently and with greater flexibility, resulting in potential benefits in accessibility to education for students. These are new modes of instruction that have previously been largely untapped particularly in the kindergarten to Grade 12 arena." Remote learning and online education will be among the fastest growing sectors in the next 10 years. Reskilling for the New Age economy is a challenge and with millions of young unemployed, it will require gigantic effort and money. How quickly we are able to adapt existing schools, polytechnics and universities to the needs of tomorrow is the key.

*Source: IANS, Outlook, 03.05.2020*

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# Building on Corona

***P B Jayakumar***

Unusual misfortunes create unexpected business opportunities. R C Mansuhkani, Chairman of Man Industries - which makes special steel pipes for oil & gas and hydrocarbon sectors, is keen to restart his factory at Anjar in Kutch, Gujarat. So far, Corona has not reached Kutch. The 2,000-plus workforce, mostly migrant workers, is idling in dwellings provided by the company. This Rs 2,200 crore-plus company, the largest supplier of such specialised pipes, has a near Rs 2,000-crore order book, half of which is for exports. Raw material (steel) prices are cooling and supplies, even from China, Japan and South Korea, have not been hit so far. Crude oil prices are also falling and his clients like IOC, BPCL, ONGC and oil exploration and production companies abroad are unlikely to freeze refinery expansion or repair work. "There can be only two-three week delay in supplies. I don't see many issues for us in both near and long term, compared to many other sectors," says Mansuhkhani, who is worrying more about high working capital loan rates that can negate his competitiveness on a global level.

Mansuhkhani is raring to go post-lockdown and so are several of India's Healthcare, Pharmaceuticals, FMCG, Vaccine, Chemicals, Hospitality and IT companies, which are gearing up to turn the capabilities acquired during the Coronavirus crisis into new businesses in India and abroad.

The post-coronavirus future will be defined by greater localisation of supply chains, backward integration, faster policy decisions, increase in digital capabilities and investments in enabling technologies such as cloud, data and cyber security. Focus will be on cutting business costs, including fixed costs, increasing outsourcing, reducing manpower, bringing down non-core manufacturing and supply chain re-alignments, say experts.

There will be many gainers from this crisis, apart from the prime and obvious candidates like our healthcare and biomedical sector. Before exploring the opportunities in health, let's look at other sectors like FMCG, IT, petrochemical and textiles that are facing the brunt of this disruption but have been able to identify opportunities, too.

**E-tail and Manufacturing:**

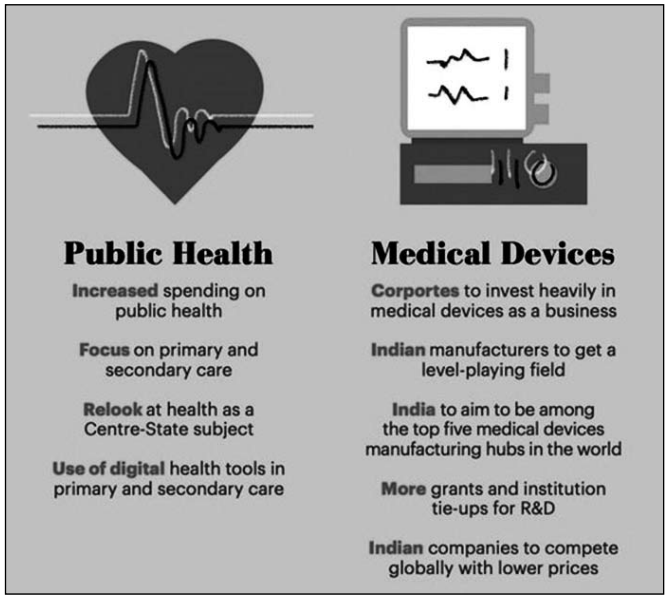
With supply chains broken during lockdown, FMCG majors Marico and Britannia teamed up with delivery platforms such as Swiggy, Zomato and Dunzo to distribute products being churned out by their plants. Flipkart and BigBasket partnered with cab aggregators such as Uber for delivery. Many retailers are also partnering with third-party supply chain companies like ShopX, Udaan, StoreKing and Jumbotail. "We are looking at third-party supply chain companies which have a strong digital backbone," says Unibic CEO Srini Vudayagiri.

These new relationships are unlikely to snap post lockdown. They have stood the test of a crisis and have proven their effectiveness. They are projected to evolve into new business partnerships when lockdown opens.

Market research firm Neilson says life after Covid-19 will be "a new normal" and FMCG companies and online retailers will be among the major gainers.

FMCG firms are re-inventing themselves for the future with new supply chain strategies and unconventional delivery models. This may be temporary for some but everybody agrees these models will gain prominence.

"E-commerce companies have to re-look at last-mile deliveries and reinvent current operating models and route to the customer, apart from how they buffer their stock. The entire operating model will change," says Easwaran P S., Lead, Supply Chain Solutions, Deloitte India. The companies will explore newer "direct to consumer" channels. The ability to predict and manage demand will be a game-changer.



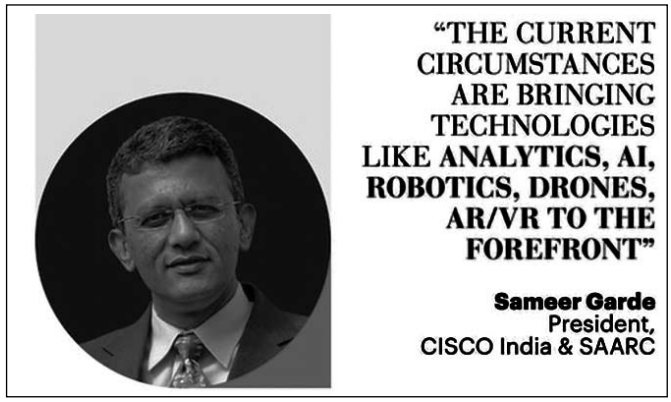

While Bata India CEO Sandeep Kataria says one can't really predict the future at this point, Arvind Mediratta, CEO, Metro Cash & Carry, says: "Digitisation earlier was a nice-to-do thing, but now it's becoming a must."

The e-commerce market in India is forecast to grow from about $64 billion in 2020 to about $200 billion by 2024. The post-coronavirus scenario and new business models can accelerate this growth.

**IT and Telemedicine:**

Sometimes, all it needs is a push and a shove for an industry to boom. Just as Paytm took off after the DeMo crisis, doctor consultations online may just become acceptable following the lockdown. So, healthcare aggregators like Ratan Tata-funded Lybrate and HealthAssure are leaving no stone unturned to make the most of this. They have launched new packages and innovations in the wake of the virus scare. Lockdown may have unravelled the true potential of "Telemedicine" as the number of people going to outpatient departments of hospitals will diminish.

"Every industry has to find ways to digitally engage with customers and employees," says Rob Thomas, General Manager, IBM Data & AI, which is helping numerous industries worldwide with its AI platforms for data analysis and communication. CISCO India & SAARC President Sameer Garde says many new technology-enabled businesses are emerging. These include telemedicine, online education and virtual conferences and meetings. "The current circumstances are bringing a lot of new technologies like analytics, AI, robotics, drones, AR/VR to the forefront. We can expect their adoption to accelerate," he says.




A McKinsey report says India could save up to $10 billion by 2025 if telemedicine replaces 30-40 percent of in-person outpatient consultations. Banking on opportunities in the medical tourism segment, Corporates like Apollo Hospitals are experimenting with business models combining telemedicine, hospitals and hospitality. A few days ago, Apollo Hospitals Group launched a partnership model to help quarantined patients stay at hotel rooms with telemedicine treatment support from Apollo. The partners are Hindustan Unilever, State Bank of India, Oyo Rooms, Lemon Tree, Ginger Hotels and Zomato. Already, private healthcare is popularising

the concept of key-hole surgeries and day-care surgical centres for minor procedures, so that they can improve their Average Revenue Per Occupied Bed.

There will be a host of changes in customer behaviour, too, say experts. Sanitation, self-hygiene, immunity, wellness and bio-waste disposal are some businesses that will indirectly get a fillip. A good number of people may avoid crowds and shop and order food online. "Fears related to social distancing are there to stay for some time, and we are looking at models like home delivery and e-tailing to improve sale of spirits," says Amrit Kiran Singh, Chairman of the International Spirits & Wines Association of India. India consumes about 350 million cases of spirits and 10 million cases of wine, but consumption out of bars and restaurants is only 25 percent. In the developed world, it is 50 percent.

**Bright for Petrochemicals:**

India is the sixth-largest chemical and petrochemical producer in the world. With crude oil prices falling, petrochemical prices are likely to remain low in the medium to long term. Given that China accounts for a third of global petrochemical capacity, many producers are expected to have large inventories, which will also drive down prices. "Most fundamental factors for growth and investments still hold in India - high population with increasing per capita demand for chemicals, shift to Asia as a manufacturing hub, increasing purchasing power and availability of labour. The only question mark is the timing of the recovery in economic activity," says a recent KPMG report on Covid-19 impact.

India's Pharmaceutical Sector, which supplies 20 percent medicines and one in every three tablets sold across the globe, is going to be a main gainer from this crisis. But a major worry is dependence on China for over 70-80 percent of the main Active Pharmaceutical Ingredients (APIs) and their intermediates. So, while the world is looking at India to supply Hydroxychloroquine, an old malaria medicine that can be effective in Covid-19 treatment, India has only two integrated manufacturers (Zydus Cadila and Ipca Laboratories) of this drug. "If I want to start an API plant in India, it requires at least one-and-a-half years, and getting environmental clearances is a big issue, whereas in China, you get all clearances quickly, apart from capital and other support infrastructure," says Arjun Juneja, Joint Managing Director, Mankind Pharma.


**Corona causes world to look at Indian Pharma for relief:**

Hydroxychloroquine (HCQ), an old pharmaceutical molecule, was invented by German multinational Bayer in the 1940s. Most multinationals stopped its production decades back as malaria is no longer prevalent in most developed nations.

India, however makes 80-85 percent of finished formulations of HCQ, including combination drugs. Majorities are exported to 70-80 countries. It is not a big market, though. India's exports of HCQ in FY19 were only $51 million and the whole current size of the US market is only $220 million. Zydus Cadila is the largest player in the US market with 32 percent market share by volume and the top 10 players include Dr Reddy's Lab (10%) and Sun Pharma (7%).

HCQ suddenly gained prominence as some studies found it has strong antiviral effects on the Coronavirus infection, which neither has a drug nor a vaccine. This prompted US President Donald Trump to direct the US Food and Drug Administration (FDA) to do away with rigid laws to ensure possible treatments for Covid-19.

Like Zydus, Mumbai-based Ipca Laboratories is a large integrated maker of HCQ and supplies across the world, except to the US. That was because its API unit at Ratlam in Madhya Pradesh and two formulation facilities were banned for almost five years by the US FDA citing sub-standard quality manufacturing. After Trump's Directive, the FDA has given temporary clearance for all these units to facilitate export to the US.

Another leading Indian respiratory drug maker Cipla was given fast-track permission this week by the US FDA to sell Albuterol Sulfate Inhalation Aerosol. Cipla's drug is first-generic of Merck Sharp & Dohme Corp's Proventil, used to treat severe chest congestion with asthma symptoms, which has a US market of $2.8 billion. Analysts were expecting approval for Cipla's product only by FY21 and

limited sales during the year. Now they estimate FY22 sales of $50-60 million from the product, an inhaler with the medicine. Another Indian drug maker Lupin also has a filing for Albuterol in the US and is expecting a similar fast-track approval.

But Coronavirus has triggered a small change for the better. The Government has announced development of three "Bulk Drug Parks" with financial investment of Rs 3,000 crore in the next five years and Rs 6,940 crore incentives for the next eight years for making critical Key Starting Material (KSM), intermediates and APIs in India. "About 8-10 drug intermediates and KSMs currently imported from China to the tune of 15,000 tonnes have been identified for use in Covid-19 treatment and we can work with the industry to indigenise them," says Ashwini Kumar Nangia, Director, CSIR-National Chemical Laboratory, Pune.

A related sector - technical textiles - is also going to gain, just like domestic manmade yarns and fabrics used in special application apparel like Personal Protection Equipment (PPE). For India's textile and apparel sector, which contributes 2 percent to GDP and employs 45 million, prices of imported manmade fibre-based high-value products are expected to rise at least 25-30 percent over the next two quarters due to slowdown in China. Besides, apparel production will shrink by 18-20 percent and yarn production by 12-15 percent during the next six months, says the KPMG report.

It also says that for the real estate sector, which is going to face a severe impact due to lack of demand and capital, demand for industrial (logistics and warehousing) construction and data centres is likely to lead to a strong recovery in future.

"If global manufacturing giants shift some capacity from China to India, aided by favourable Government policies, it could lead to some construction demand in the manufacturing sector. Long-term outlook for the commercial real estate sector also remains good," says Subodh C Dixit, Executive Director (Engineering and Construction), Shapoorji Pallonji.

**Make-in-India Future for Medical Devices:**

The crisis has given a lease of life to Indian medical device manufacturers, who are mostly in the MSME sector. "Many of these big companies that have partnered with medical device makers are going to stay back as partners as there is a business opportunity in future. They can not only bring capital to compete with multinationals but also create scale, big basket of products, technological expertise and quality standards for global competition," says Rajiv Nath, Forum Coordinator, Association of Indian Medical Device Industry; and Managing Director of Hindustan Syringes & Medical Devices.

A part of the Make-in-India initiative is focused on plans to catapult India to among the top five medical devices manufacturing hubs in the world. At present, 75-80 percent of the Rs 1,05,000-crore fragmented medical device industry in India is dominated by multinationals such as GE, J&J, Philips, Wipro, Abbott, Siemens, Baxtar and Fresenius.

There are just four domestic manufacturers - Trivitron, Transasia Biomedicals, Hindustan Syringes & Medical Devices and PolyMedicure - with over Rs 500 crore revenues a year.

**"ONE CAN'T REALLY PREDICT THE FUTURE AT THIS POINT"**

**Sandeep Kataria**
CEO, Bata India

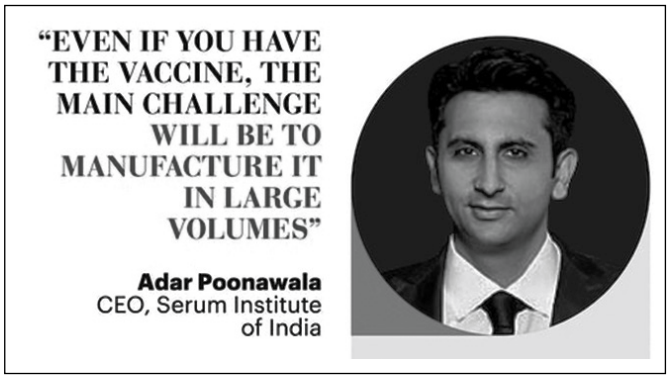
"Other than announcement of medical parks and small incentives, we never got a level-playing field. Almost all the policies or major tenders so far were in their favour and even big hospitals and procurers in India neglected the domestic manufacturers.

Those MNCs are not in a position to manufacture for India as they are busy managing crisis in their respective home countries," says G.S.K. Velu, Chairman and Managing Director, Trivitron - India's largest medical devices maker.

"Instead of a paltry Rs 1-2 crore grant, we require Rs 50-100 crore grants and incentives for research and also collaborations with institutions like IITs having precision engineering knowledge and talent," says Velu.

**Public Health and Biotechnology:**

Experts say the pandemic will lead to increased public pressure to invest more in health infrastructure, especially primary and secondary care. A Motilal Oswal research report says the Indian Government's health expenditure as percentage to GDP has remained at 1-1.5 percent, whereas the world average is 7.4 percent. Similarly, India has one of the least number of doctors per 1,000 population.




"India had, over decades, ignored fundamentals like strengthening primary healthcare, producing adequate doctors and setting up public sector hospitals and related infrastructure," says Muralidharan Nair, a Public Health Expert and Partner and Leader (Health) at EY India. "The old system of primary care and secondary care is broken and needs to be restored," says R B Smarta, Chairman and Managing Director, Interlink, which advises life science companies.

India also has an opportunity in the biotechnology sector, say experts. But lack of biotech infrastructure is a big issue. For example, Serum has been able to develop a vaccine candidate for Coronavirus, but is not sure if it can make that in India. "This (vaccine candidate) will have to be handled under BSL 3 (biosafety level) conditions, which is basically a very high containment level, and I don't know how many facilities in the world have high volume manufacturing in BSL 3. Even if you have the vaccine, the main challenge will be to manufacture it in large volumes," says Adar Poonawala, CEO, Serum Institute of India.

India will also have to develop a scientific community that can market its IPs, encourage entrepreneur-scientists and create infrastructure to make India a power house in the biomedical sector, Dr Kiran Majumdar Shah, Founder and Chairperson, Biocon, has written in a blog.

Muralidharan Nair says the Indian Pharma Industry should focus on developing new molecules rather than using chemistry skills to make copycat generic drugs for short-term profits.

"With bioengineering and advanced computing coming together, synthetic biology is going to have wide applications in infectious diseases, agriculture, water, air.

This is the time to be in biotech," says Ashok Trivedi, Founder and Trustee, Ashoka University; and Managing Partner of SWAT Capital, who will invest Rs 100 crore to launch Trivedi School of Biosciences with focus on synthetic biology, data science, biodiversity and ecology. The post-coronavirus phase might be a new dawn for several large chunks of India Inc, it seems.

*Source: Busines Today, 03.05.2020*

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