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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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Indian Drug Manufacturers' Association
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IDMA BULLETIN

Vol. No. 51 **Issue No. 23** **15 to 21 June 2020**

IDMA Comments on Draft Guidelines for dealing cases of discontinuation of Scheduled Formulations under Para 21 (2) of DPCO, 2013

The Association has submitted the following comments on 15th June 2020 to Shri Manjesh Purwal, Deputy Director (M&E), National Pharmaceuticals Pricing Authority (NPPA), New Delhi on Draft Guidelines for dealing cases of discontinuation of Scheduled Formulations under Para 21 (2) of DPCO, 2013.

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

We refer to the Draft Guidelines (F.No.31(67)/2016/ Div.III/NPPA) dated 01.06.2020 inviting comments & suggestions from stakeholders.

The above draft Guidelines are an extension of the Guidelines dated 17.09.2014 and 23.01.2016 (attached for reference)* regarding discontinuation of scheduled formulation with the addition of a few clauses. The Guidelines for discontinuation of scheduled formulation are specifically mentioned under para 21(2) of DPCO 2013, whereas para 3 of the Draft Guidelines dated 01.06.2020 has linked the discontinuation of scheduled formulation to para 3, para 19 and Form-I of DPCO 2013, which are not related.

While Para 21(2) of DPCO pertains to monitoring of the availability of the scheduled formulation in a normal scenario, para 3 and para 19 of DPCO are applicable only in circumstances of emergency or urgency or under extraordinary circumstances, which are not applicable in this case.

Also, the discontinuation of Scheduled Formulation under Form-IV has been linked to the processing of application of New Drugs under Form-I. Both these provisions are under separate paras of DPCO 2013 and serve different purposes. Form-I application includes details of Production/Import and Sale of a scheduled formulation, and is not connected to inadequate availability of scheduled formulations.

We reiterate that guidelines for discontinuation of scheduled formulation under para 21(2) should not be linked to any other Para of DPCO 2013, namely para 3 and para 19, nor to New Drug under Form-I.

Under para 2(s) of DPCO 2013, the Moving Annual Turnover (MAT) is defined only on the basis of Value. **Hence we request you to consider MAT (Moving Annual Turnover) Value and not Units for processing Form-IV applications under various slabs of market share for proposed discontinuation of a scheduled formulation.**

When the Government policy is to ensure '**Ease of doing Business'**, linking unrelated paras of DPCO 2013, creating more restrictions and slabs for discontinuation of Scheduled Formulations, defeats the purpose. The aim of providing Guidelines for discontinuation of Scheduled Formulations is to avoid shortages and the clauses and slabs should ensure gradual discontinuation and no shortages. **Hence clauses like public notice in two national dailies should be done away with for all categories as they are irrelevant in today's age of electronic media consumption. Instead, a list of scheduled formulations submitted for discontinuation under Form-IV should be displayed on the NPPA website for public information.**

We refer to the NPPA guidelines dated 17.09.2014 which are simpler, relevant in the current situation and much easier to implement. Under para 4.1 and 4.2 only the Form-IV application was mandatory, and the applicant company was allowed to discontinue the scheduled formulation if its market share was less than 1%, and gradually discontinue the scheduled formulation if its market share was between 1-3%, if the number of market players were ten or more. In both the cases issuance of Public Notice was not mandatory, which we propose should be extended for all slabs and categories in the discontinuation guidelines. We are providing our suggestions on the mechanism to deal with cases of discontinuation of scheduled formulations as under:

Sr. No.	Moving Annual Turnover (MAT) (Value) of Company *vis-a-vis* total MAT Value	Mechanism for discontinuation/ gradual discontinuation
1	Less than 1% applicant company MAT Value, of the total MAT Value, with 10 (ten) or more market players	Applicant company's Form-IV to be deemed approved within a period of thirty days of receipt by the NPPA.
2	1% or more, but less than 5% applicant company MAT Value, of the total MAT Value, with five (five) or more market players	Within sixty days of receipt of the Applicant company's Form-IV, the NPPA would direct the manufacturer to continue production/ import and sale of the scheduled formulation for a period of 3 (three) months, and ensuring no shortages during that period.
3	5% or more, but less than 10% applicant company MAT Value, of the total MAT Value	Within sixty days of receipt of the Applicant company's Form-IV, the NPPA will direct the manufacturer to continue production/import and sale of the scheduled formulation for a period of 6 (six) months, and ensuring no shortages during that period.
4	10% or more, but less than 25% applicant company MAT Value, of the total MAT Value	Within sixty days of receipt of the Applicant company's Form-IV, the NPPA will direct the manufacturer to continue production/import and sale of the scheduled formulation for a period of 9 (nine) months, and ensuring no shortages during that period.
5	Applicant company MAT Value, is more than 25% of the total MAT Value	Within sixty days of receipt of the Applicant company's Form-IV, the NPPA will direct the manufacturer to continue production/import and sale of the scheduled formulation for a period of 12 (twelve) months, and ensuring no shortages during that period.

We request you to kindly consider the above suggestions for inclusion in the final guidelines as this would ensure '**Ease of doing Business** and better compliance. Thanking You".

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Why Phytopharmaceutical Drug Discovery?

Prof S S Handa

Dear Reader,

"Phytopharmaceutical drug" includes a purified and standardised fraction with defined minimum fourbio-active or phyto-chemical compounds (qualitatively and quantitatively assessed) of an extract of a medicinal plant or its part, for internal or external use of human beings or animals for diagnosis, treatment, mitigation or prevention of any disease or disorder but does not include administration by parenteral route as specified in Rule 122 (eb) of the Drugs & Cosmetics (D&C) Govt. of India". The data requirements have been specified in the Appendix IB of Schedule Y & GMP manufacturing as per Schedule M (part VI) of D&C Rules. Clinical trials for phytopharmaceutical drugs is to be conducted as per applicable rules and guidelines for a new drug."

(DCGI promulgated new Phytopharmaceutical drug category notified in the Gazette notification (8th Amendment D&C Rules 2015), Ministry of Health & Family Welfare, Government of India on 30th November 2015).

Over 50% of all NCEs approved by the USFDA have its origin in natural phyto-constituents. A successful track record exists of NCEs discovered from medicinal plants over the last 100 years (eg. Quinine, Quinidine, Morphine, Codeine, Reserpine, Colchicine, Camptothecin, Vincristine, Paciltaxol, Artemisinin etc). under well-established regulatory pathways (US-FDA, EMA, DCGI). Presently the NCE pipeline of pharmaceutical MNCs is shrinking drastically. Introduction of the "phytopharmaceutical" category of new drugs opens new vistas for Multi Component Botanical Therapeutics (MCBT) discovery from the rich bio-resource of medicinal & aromatic plants which have been extensively studied up for pharmacological (in vitro & in vivo) activities. The identification and characterization of active fractions rather than single chemical constituents leading to bioactive leads in a multicomponent purified fraction of an extract of a medicinal plant has been reported in compilations of research done at various pharmaceutical academic and research institutes in India. An example is the "Reviews on Indian Medicinal Plants" published in 22 volumes covering 5400 Indian medicinal plant species from Alphabet A to Q (as per binomial nomenclature). This is a huge knowledge base available in the country to take forward for a translational approach for new drug discovery and development for a wide variety of therapeutic unmet needs such as Metabolic disorders (pre-diabetes / diabetic complications, osteoarthritis, osteoporosis bronchial asthma), Neurodegenerative disorders (stress, dementia, Alzheimer), Non-alcoholic hepatic fibrotic disorders and Antiviral drugs through phyto-pharmaceutical drug discovery & development.

Prof. S S Handa, a Pharmaceutical Scientist/ Academician, Ph.D., from London School of pharmacy, London (1972-75); postdoctoral (1979-82) at the Department of pharmacology & pharmacognosy, University of Illinois at the Medical Centre, Chicago, USA; served as Professor and Head/ Chairman of the University Institute of Pharmaceutical Sciences, Panjab University, Chandigarh (1969-1995) and as Director Indian Institute of Integrative Medicines (IIIM), CSIR (1995-2000). ICS-UNIDO (United Nations) Senior Specialist, "Sustainable Industrial Utilization of Medicinal and Aromatic plants" (March 2005 – December 2008) at the 'United Nations Industrial Development Organization' (UNIDO), International Centre for Science (ICS) & High Technologies, Area Science Park, Trieste, Italy. Scientific Consultantat Ranbaxy Herbal Drug Research, Ranbaxy Laboratories Ltd (2001-2009). Scientific Adviser at Zandu Pharmaceutical Works, Mumbai (2000 to 2007) and then was on its Board of Directors (2007-2008). Scientific Consultant Emami Group Health Care since 2009 till date. Consultant Glaxo Smith Kline (GSK) Asia Pacific (2010-17).

He has also served on various national and international committees involved in developing standards and policies for the development of phytopharmaceuticals and herbal extracts. Prof Handa (Ph.D.) is a long-standing member of Indian Drugs Editorial Advisory Board.

One major objective is to investigate the multivalent and multi-target actions of plant constituents present in the active fraction with the aim to understand and rationalize the therapeutic superiority of manyphyto-pharmaceuticals over single isolated constituents. Mixtures of interacting constituents produced by plants may provide important combination therapies that simultaneously affect multiple pharmacological targets and provide clinically efficacy beyond the reach of single molecule-based (NCE) drugs. Developing innovative scientific methods for discovery, validation, characterization and standardization of these multicomponent botanical therapeutics (MCBT) is essential for their acceptance into main stream medicine.

During the second half of the 20th Century, there had been considerable decline in the number of monographs on plants and plant products in the major Pharmacopoeias of the World such as United States Pharmacopoeia (USP), European Pharmacopoeia (EP) British Pharmacopoeia (BP) and even in Indian Pharmacopoeia (IP). It is heartening to note that during 21st Century there is an upsurge of the re-appearance of a number of monographs on Plants & Plant Products in such Pharmacopoeias. For example in USP nearly 100, in European Pharmacopoeia 300, in BP over 320 monographs and in Indian Pharmacopoeia over 150 monographs on medicinal/aromatic plants and their products have re-appeared. This exhibits revival and resurgence of interest in drugs from plants.

There is increased awareness for industry-academia partnership in pharmaceutical research. It is noteworthy to mention that certain CSIR research laboratories are endeavoring to contribute to new drug-discovery programs, the Department of Biotechnology is actively engaged in promoting bio-based product development and Indian Council of Medical Research welcomes projects on clinical trials of phyto-pharmaceuticals. All the above mentioned premier scientific research organisations are keen to support new drug discovery from our natural bio-resources and an inter-ministerial expert Committee has been constituted for joint projects on new phyto-pharmaceutical drug discovery. Our Pharmaceutical Industry has exhibited excellent progress in generics and biotechnological products but for innovative new drug discovery, pharmaceutical industry needs to pay much more attention. The promulgation of the new phyto-pharmaceutical drug category and the readiness of all the three premier organizations have created a favourable landscape for pharmaceutical industry to come forward and join this endeavor to new drug discovery through the phyto-pharmaceutical drug route.

Source: Indian Drugs-Guest Editorial, Vol. 57 (04) April 2020

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Email: actadm@idmaindia.com / accounts@idmaindia.com

Tel.: 022 - 2494 4624 / 2497 4308 /
Fax: 022 - 2495 0723

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COVID-19 – Amendments/Relaxations/Compliances

(For the period 18 March 2020 to 31 May 2020)

Courtesy: ***Mr B G Barve,*** *Chairman-Excise & Taxation Committee, IDMA*

Special Measures in view of Covid -19

The Government acknowledged that due to Covid- 19, there was severe economic disruption for companies and intervention was required by the Government to ease the financial and compliance burden of the companies and individuals. Accordingly, it came out with a slew of relief measures vide a range of different notifications from time to time. This issue highlights the various changes in law that have been brought about from 18th March, 2020 till date.

MINISTRY OF CORPORATE AFFAIRS (MCA)

Conduct of meetings thru Video Conferencing or Other Audio Visual Means

- Board meetings can be held via Video Conferencing (VC) or Other Audio Visual Means (OAVM) to discuss approval of financial statements & related matters, as a special case upto 30th June 2020, which is otherwise not allowed as per Companies Act, 2013.
  (Notification dated 19.03.2020)

- Extra-ordinary General Meetings can also be held thru VC or OAVM to discuss important matters upto 30th June 2020.
  (Notification dated 13.04.2020)

- Govt. further allowed Annual General Meetings to be held thru VC or OAVM for the Calendar year 2020. It has also laid down procedure for the same.
  (Notification dated 05.05.2020)

MINISTRY OF CORPORATE AFFAIRS (MCA)

Notification dated 24.03.2020

Particulars	Due date
Additional fees waived on any form filed during moratorium period of 01.04.2020 to 30.09.2020	30.09.2020
Time gap between 2 consecutive board meetings is allowed to be more than 180 days instead of 120 days	30.09.2020
The Companies (Audit Report) Order, 2020 will be effect from FY 20-21 instead of 19-20.	30.09.2020
The criteria u/s 149(3) which requires atleast one director to stay in India for 182 days, has been relaxed for the financial year 2019-20, therefore, failure to stay in India for 182 days shall not be treated as a non-compliance.	30.09.2020

CORPORATE SOCIAL RESPONSIBILITY (CSR)

MCA vide notification dated 23.03.2020 allowed Spending of CSR Funds for Covid-19. Further vide notification dated 10.04.2020 MCA clarified the eligibility of such spends as under.

Eligible Spends		Ineligible Spends
Prime Minister's Cares Fund (item VIII of Schedule VII)	CSR	Chief Minister's Relief Fund or the State Relief Fund
State Disaster Management Authority		Salary / Wages to employees / workers during the lockdown period
Ex-gratia payment made to temporary / casual workers/ daily wage workers over and above the disbursement of wages, specifically for the purpose of fighting COVID 19, the same shall be admissible towards CSR expenditure as a onetime exception provided there is an explicit declaration to that effect by the Board of the company, which is duly certified by the statutory auditor.		Payment to Casual / Temporary / Daily Wage workers during the lockdown period.

Insurance Laws

Notification dated 23.03.2020

- In case of life insurance policies, a grace period of additional 30 days if desired by policyholders for renewal payments was to be granted by all the Insurers
- In case of health insurance policies, the insurers may condone delay in renewal up to 30 days without deeming such condonation as a break in policy.

Notification dated 09.05.2020

- IRDA extended grace period provided in notification dated 23.03.2020 in case of Life Insurance Policies due in March and April 2020 to further period of 31.05.2020.

Any further extension beyond 31.5.2020 yet to be notified by IRDA, hence it is advisable to check with your Broker/Agent for further clarification

Employees Provident Fund Act

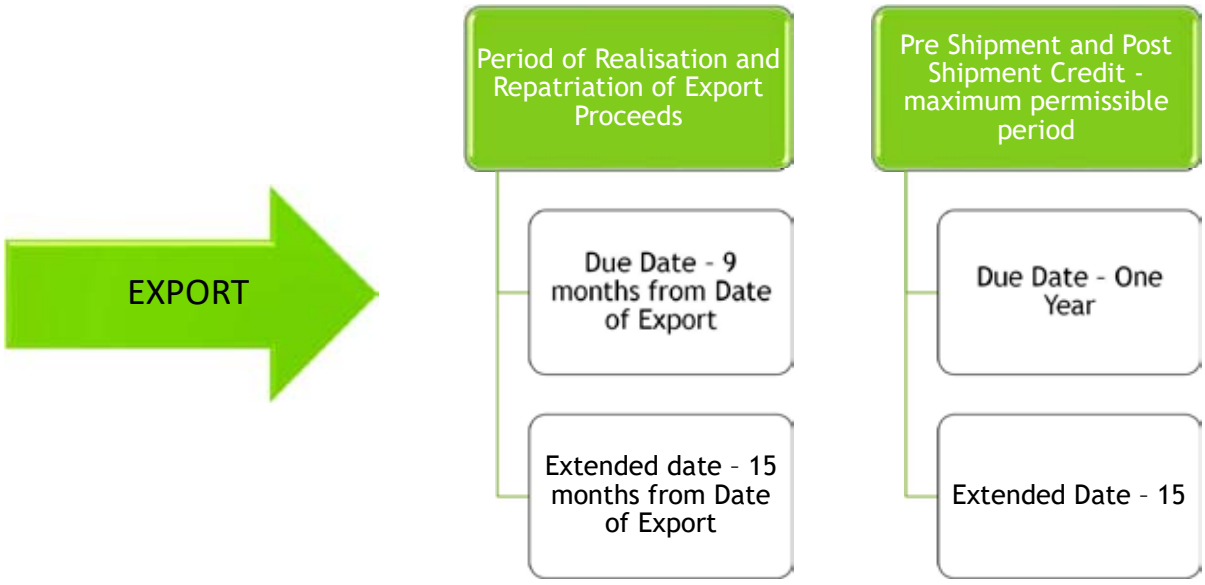
Particulars	Notification date
Extension of ESI Contribution on Account of Corona	16.03.2020
A scheme to implement the PMGKY package for credit of employees & employer's share of EPF & EPD contribution (24 % of wages) for three months by Govt. of India.	26.03.2020
Govt. is allowing withdrawal from EPF as non-refundable advance to EPF members in the event of break of Covid -19 epidemic or pandemic.	Notification GSR 225/E dated 27.03.2020
Extension of time in filing February 2020 ESI Contribution during the Covid-Pandemic	14.04.2020
Waiver of penalty and Interest for payment of Provident fund for respective months extended by 30 days	15.04.2020
No levy of penal damages for delay in deposit of dues during lockdown period under EPF & MP Acts	15.05.2020
EPFO has given Establishments the option to contribute at a rate of 10% instead of 12% for period March 20 to May 20.	18.05.2020
Relaxation for employers on Filing of ESI Contribution for the contributing period April 2019 to March 2020	18.05.2020

Income Tax

Particulars	Due Date	Extended Date
Filing of original or revised income tax returns for F.Y. 2018-19	31.03.2020	30.06.2020
Tax Audit Report filing for F.Y. 2019-20	30.09.2020	31.10.2020
Income Tax Return filing for F.Y. 2019-20	31.10.2020	30.11.2020
Individual income tax returns for F.Y. 2019-20	31.07.2020	30.11.2020
Date of Tax Assessments for F.Y. 2017-18	30.09.2020	31.12.2020
Date of Tax Assessments for F.Y. 2017-18	30.09.2020	31.12.2020
Date of Tax Assessments for F.Y. 2018-19	31.03.2021	31.09.2021
Due dates for all statutory filings and compliance is extended	Due between 20.03.2020 & 29.06. 2020	30.06.2020
Aadhaar-PAN linking	31.03.2020	30.06.2020
Vivad se Vishwas scheme	31.03.2020	31.12.2020

Income Tax

Particulars	Due Date	Extended Date
Interest rate reduced from 12% to 9% for delayed payments of Income tax	Due between 20.03.2020 & 29.06.2020	30.06.2020
Nil/Lower Deduction Certificate w.r.t TDS already holding for F.Y 2019-20	31.03.2020	30.06.2020 or Date of Issuing new certificate, whichever is earlier
Rate of TDS for Non-salaried payments and TCS shall be reduced by 25% of the existing rates	Reduced TDS & TCS rate applicable from 14.05.2020 to 31.03.2021	
The payment for investment/payment for claiming deduction under Chapter-VIA-B of IT Act {Section 80C (LIC, PPF, NSC etc.), 80D (Mediclaim), 80G (Donations), etc} can be made up to 30.06.2020	31.03.2020	30.06.2020
Donation under PM Care Fund- Corporate paying concessional tax on the income of FY 2020-21 can claim donation u/s 80G against income of FY 2019-20		30.06.2020



Notification	Particulars	Contents	Due Date	Extended Date
30/2020 dated 03.04.2020	Amendment in the CGST Rules so as to allow taxpayers opting for the Composition Scheme for the FY 2020-21 to file their option in FORM CMP-02 till 30.06.2020 and to allow cumulative application of the condition in rule 36(4) for the months of Feb 2020 to Aug 2020 in the return for tax period of Sept 2020.	Intimation in CMP-02 for opting for composition Scheme for FY.2020-21	31.03.2020	30.06.2020
		Filing of ITC-03	30.05.2020	31.07.2020

Notification 31/2020 dated 03.04.2020 - A lower rate of interest subject to condition that due tax is paid by filing return in FORM GSTR-3B by the date(s) as specified in the Notification.			
Taxpayers having an aggregate turnover of more than rupees 5 crores in the preceding financial year			
Tax period	Due Dates	Interest	
		Nil if filed (Within 15 days from due date) 9% p.a,if filed between	Nil if filed (Within 15 days from due date) 9% p.a,if filed between
Feb-20	20.03.2020	04.04.2020	5th April to 24th June 2020
Mar-20	20.04.2020	05.05.2020	6th May to 24th June 2020
Apr-20	20.05.2020	04.06.2020	5th June to 24th June 2020
May-20	27.06.2020	NA	NA
Taxpayers having an aggregate turnover of more than rupees 1.5 crores and up to rupees five crores in the preceding financial year			
Tax period	Due Dates	Nil, If filed till	Late fee waived if till
Feb-20	22.03.2020/24.03.2020	29.06.2020	29.06.2020
Mar-20	22.04.2020/24.04.2020	29.06.2020	29.06.2020
Apr-20	22.05.2020/24.05.2020	30.06.2020	30.06.2020
May-20	12.07.2020/14.07.2020	NA	NA
Taxpayers having an aggregate turnover of up to rupees 1.5 crores in the preceding financial year			
Feb-20	22.03.2020/24.03.2020	30.06.2020	30.06.2020
Mar-20	22.04.2020/24.04.2020	03.07.2020	03.07.2020
Apr-20	22.05.2020/24.05.2020	06.07.2020	06.07.2020
May-20	12.07.2020/14.07.2020	NA	NA

Notification 32/2020 dated 03.04.2020 - Notification under section 128 of CGST Act for waiver of late fee for delay in furnishing returns in FORM GSTR-3B for the tax periods of February, 2020 to April, 2020.		
Taxpayers having an aggregate turnover of more than rupees 5 crores in the preceding financial year		
Tax period	Due Dates	Late Fee waived if filed on or before
Feb-20	20.03.2020	24.06.2020
Mar-20	20.04.2020	24.06.2020
Apr-20	20.05.2020	24.06.2020
May-20	27.06.2020	NA
Feb-20	20.03.2020	24.06.2020
Taxpayers having an aggregate turnover of more than rupees 1.5 crores and up to rupees five crores in the preceding financial year		
Feb-20	22.03.2020/24.03.2020	29.06.2020
Mar-20	22.04.2020/24.04.2020	29.06.2020
Apr-20	22.05.2020/24.05.2020	30.06.2020
May-20	12.07.2020/14.07.2020	NA
Taxpayers having an aggregate turnover of up to rupees 1.5 crores in the preceding financial year		
Feb-20	22.03.2020/24.03.2020	30.06.2020
Mar-20	22.04.2020/24.04.2020	03.07.2020
Apr-20	22.05.2020/24.05.2020	06.07.2020
May-20	12.07.2020/14.07.2020	NA

Notification 33/2020 dated 03.04.2020 - Notification under section 128 of CGST Act for waiver of late fee for delay in furnishing the statement of outward supplies in FORM GSTR-1

GSTR -1		
Tax period	Due Dates	Late Fee waived if filed on or before
Jan 20 to March 20	30.04.2020	30.06.2020
April 2020 to June 2020	31.07.2020	NA
GSTR – 1		
Feb-20	11.03.2020	NA
Mar-20	11.04.2020	30.06.2020
Apr-20	11.05.2020	30.06.2020
May-20	11.06.2020	30.06.2020

Notification 34/2020 dated 03.04.2020 - Extension of due date of furnishing statement, containing the details of payment of self-assessed tax in FORM GST CMP08 for the quarter ending 31st March, 2020 and filing FORM GSTR-4 for the FY ending 31st March, 2020

Particulars	Existing Date	Revised Due Date
File of CMP-08 for Quartet January to March 2020	18th April 2020	7th July 2020
GSTR-4 for FY 2019-20	30th April 2020	15th July 2020

Notification 35/2020 dated 03.04.2020 - Notification under section 168A of CGST Act for extending due date of compliance which falls during the period from the 20th day of March, 2020 to the 29th day of June 2020, to 30th day of June, 2020.

Also where an e-way bill has been generated under rule 138 of the Central Goods and Services Tax Rules, 2017 and its period of validity expires during the period 20th day of March, 2020 to 15th day of April, 2020, the validity period of such e-way bill shall be deemed to have been extended till the 30th day of April, 2020.

Notification 36/2020 dated 03.04.2020 - Extension of due date for furnishing FORM GSTR-3B for supply made in the month of May, 2020

Particulars	Period	Due Date	Revised Due Date
For taxpayers having an aggregate turnover of more than rupees 5 crore rupees -	May-20	20-06-2020	27-06-2020.
For taxpayers having an aggregate turnover of up to rupees five crore rupees in the previous financial year, whose principal place of business is in the States of Chhattisgarh, Madhya Pradesh, Gujarat, Maharashtra, Karnataka, Goa, Kerala, Tamil Nadu, Telangana, Andhra Pradesh, the Union territories of Daman and Diu and Dadra and Nagar Haveli, Puducherry, Andaman and Nicobar Islands or Lakshadweep -	May-20	22-06-2020	12-06-2020
For taxpayers having an aggregate turnover of up to rupees five crore rupees in the previous financial year, whose principal place of business is in the States of Himachal Pradesh, Punjab, Uttarakhand, Haryana, Rajasthan, Uttar Pradesh, Bihar, Sikkim, Arunachal Pradesh, Nagaland, Manipur, Mizoram, Tripura, Meghalaya, Assam, West Bengal, Jharkhand or Odisha, the Union territories of Jammu and Kashmir, Ladakh, Chandigarh or Delhi -	May-20	24-06-2020	14-07-2020

Instruction No. 2/1/2020-GST dated 09.04.2020 - Special GST Refund Disposal Drive - Implementation of decision to expedite pending GST and IGST refund claims.

Instruction F. No. 390/Misc/3/2019-JC dated 27.04.2020 - Guidelines for conduct of personal hearings in virtual mode under Customs ACT, 1962 - Conduct of Personal hearing in respect of any proceeding under Customs Act, 1962 through video conferencing with a view to ensure social distancing and reduce physical presence.

Notification no. 38/2020 dated 05.05.2020 - Notification issued to allow registered persons registered under the Companies Act, 2013, to furnish return under FORM GSTR-3B through electronic verification code (EVC) during the period 21st April 2020 to 30th June 2020.

It allows a registered person to furnish Nil return under FORM GSTR-3B through short messaging services (SMS) using the registered mobile number and one time password (OTP).

Notification no. 39/2020 dated 05.05.2020 - Notification issued to prescribe that the special procedures as provided in the Notification No.11/2020- Central Tax, dated the 21st March, 2020, shall not be applicable to those Corporate debtors who have already furnished the statements under section 37 and the returns under section 39 of the CGST Act for all the tax periods prior to the appointment of IRP/RP.

It extends the time limit for registration by the Corporate debtor as distinct person as stated in the Notification No.11/2020- Central Tax, dated the 21st March, 2020. The said person shall be liable to register within thirty days of the appointment of the IRP/RP or by 30th June, 2020, whichever is later

Particulars	Due Dates	Revised Due Date
Notification 40/2020 dated 05.05.2020 - Notification issued to provide that where the E-waybill was generated on or before 24th March 2020 and the validity of such E-waybill expires between 20th March 2020 to 15th April 2020		
Where the E-way bill was generated on or before 24th March 2020 and the validity of such E-way bill expires between 20th March 2020 to 15th April 2020, then the validity of such E-waybill shall be deemed to have been extended	20th March, 2020 to 15th April, 2020	31st May 2020
Notification 41/2020 dated 05.05.2020 - Notification issued to extend the time limit to furnish Annual return specified under section 44 i.e. FORM GSTR 9 for the Financial year 2018-2019.		
To extend the time limit to furnish Annual return specified under section 44 i.e. FORM GSTR 9 for the Financial year 2018-2019	30th June 2020	30th September 2020
Notification 42/2020 dated 05.05.2020 – Notification issued to extend the time limit for filing returns under Form GSTR 3B for the tax period November 2019 to February 2020 till 24th March 2020, for those registered persons whose principal place of business is in the Union territory of Jammu and Kashmir and Ladakh		
Return in FORM GSTR-3B for the months of Nov 2019 to Feb 2020 for registered persons whose principal place of business is in the Union territory of Jammu and Kashmir	on or before the 20th day of the month succeeding such month	On or before the 24th March, 2020
Return in FORM GSTR-3B for the months of Nov 2019 to Dec 2019 for registered persons whose principal place of business is in the Union territory of Ladakh	on or before the 20th day of the month succeeding such month	On or before the 24th March, 2020
Return in FORM GSTR-3B for the months of Jan 2020 to March 2020 for registered persons whose principal place of business is in the Union territory of Ladakh	on or before the 20th day of the month succeeding such month	on or before the 20th May, 2020.

CDSCO

The 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 trails, etc..

- Fast track approvals of Hand Sanitizers mfg. licences.
- Fast track approvals for new drugs, including vaccines, r-DNA derived products, etc.
- Survey & monitoring of the availability of Hydroxychloroquine (HCQ) formulation
- Facilitation for import of consignments of vaccines, critical in-vitro diagnostics and blood products for ensuring early accessibility
- Monitoring the availability of essential drugs required for treating the patients infected with COVID-19 and to take necessary measures to ensure their availability.
- Revised modalities to address challenges arises during conduct of clinical trial
- Allowing the manufacturer of industrial oxygen to manufacture the oxygen for medical use within 24 hours.

CDSCO

The 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 trails, etc..

- Revised modalities for permitting the import of drug with residual shelf life less than 60% to ensure availability of drugs.
- Acceptance of self-attested document instead of notarized/ apostilled documents from overseas Indian embassy for Import and Registration of drugs and medical devices.
- Collecting State-wise data regarding Pharma Units
- Extension of validity of BA/BE study centres.
- Extension of validity of WHO GMP/CoPP certificate. (March - Aug)
- Fast track approval of diagnostic kits for COVID - 19.
- Clarification on manufacturing of new drug by a mfg. in their own multiple mfg sites.

CDSCO

The 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 trails, etc..

- Modalities on drugs meant for dual use.
- Setting of Public Relations Office at all Zonal and Sub-Zonal offices of CDSCO.
- Clarification on submission/ processing & granting of fast track approvals of applications for manufacturing/ import of new drugs for test and analysis, CT or BA/BE study.
- Clarification on requirement of process validation report for permission to conduct clinical trial/ BA/BE studies & Streamlining the timeline for processing the application for BA/BE permission and import licence for export.
- Consideration of stability data generated during development stage for grant of WHO GMP and COPP.
- Clarification on sequence of approval process of new drugs and fixed dose combinations (FDC) containing that particular new drug.
- Submission and processing of application Registration Certificate and import License in parallel with New Drug application.
- Timeline for testing of new drugs.

Other Developments

Particulars
Trademarks - The due dates with respect to the timelines/periods prescribed under the IP Acts and Rules falling due from 15-03-2020 to 17-05-2020, were extended to 01-06-2020
MSME definition changed as under: ▪ Micro enterprises – investment upto Rs.1 crore and turnover upto Rs.5 crore ▪ Small enterprises – investment upto Rs.10 crore and turnover upto Rs.50 crore ▪ Medium enterprises – investment upto Rs.20 crore and turnover upto Rs.100 crore
On March 23, 2020, the Supreme Court passed an order, taking into account the difficulties faced by the litigants across the country on account of the Covid-19 pandemic and extended the period of limitation in all proceedings before all courts / tribunals with effect from 15th March, 2020 until further orders. Suo Moto Writ Petition (Civil) No. 3/2020.
The Govt. has modified its FDI norms so that investments from neighbouring countries will not be permitted under Automatic Route (Press Note No. 3/2020 DPIIT – FDI Policy Section)

Ministry of Consumer Affairs OM on Continued Availability of Hand Sanitizer in the market Attachments area - reg.

MoCA,F&PD OM dated 16th June 2020

To
Department of Consumer Affairs
(Kind attention: Shri A.K. Chaudhary, Economic Adviser)
Krishi Bhawan, New Delhi.

1. The undersigned is directed to refer to Department of Consumer Affairs Notification dated 19th March 2020 *(reproduced below)* for inclusion of raw material(s) for manufacture of hand sanitizer as essential commodity and notification dated 21st March, 2020** (copies enclosed) for fixing the retail prices of hand sanitizer.

2. Both these notifications are in force till 30 June, 2020. As the lockdown conditions have been relaxed, it is expected that the demand for hand sanitizer may further increase in the near future and its continued availability is of paramount importance. Keeping in view the role of hand sanitizer in the fight against the pandemic and in order to ensure its availability at affordable rates, it is requested that validity of both the notifications, in respect of hand sanitizer, may be further extended till 31st December, 2020.

3. This issues with the approval of competent authority.

Encl: As above

No.F.1(2)/2020-SP-I

Vivek Shukla, Direttor (SP), Department of Food & Public Distribution, Ministry of Consumer Affairs, Food & Public Distribution, New Delhi.

*(**not reproduced here)*

Prices of the Ingredients as Raw Materials of Essential Commodities Order, 2020 – reg.

Gazette Notification No.S.O.1169(E), dated 19th March 2020

In exercise of the powers conferred by sub-section 2A and section 3, of the Essential Commodities Act, 1955 (10 of 1955), the Central Government, hereby makes the following Order, to regulate the production, quality, distribution, prices and other aspects of alcohols used in manufacturing the Hand Sanitizers for preventing infections due to virus and bacteria, namely;

1. **(1). This order may be called the ingredients and prices of the ingredients as raw materials of Essential Commodities Order, 2020.**

   (2). It shall come into force from the date of its publication in the Official Gazette.

2. (1). In the Essential Commodities Act, 1955, the raw material used in manufacturing as essential commodity shall be treated as essential commodity.

   (2). The prices of the alcohols used in manufacturing the hand sanitizers shall not exceed from those prevailing on 05.03.2020 without concurrence of the Central Government.

3. This Notification shall remain in force for a period up to **30th June, 2020** from the date of its publication in the Official Gazette.

F. No.S-26/1/2020-ECR&E

A K Choudhary, Economic Adviser, Department of Consumer Affairs, Ministry of Consumer Affairs, Food and Public Distribution, New Delhi.

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Amendment in Export Policy of Hydroxychloroquine API and its Formulations - reg.

DGFT Notification No. 13/2015-2020 dated 18th June, 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 in the Notification No. 54 dated 25.03.2020** amending the Schedule 2 of the ITCHS Export Policy related to export of Hydroxychloroquine and its formulations, with immediate effect:

Sr.No.	ITC HS Codes	Description	Present Policy	Revised Policy
207 E	29334900 29333990 29339900	Hydroxychloroquine	Prohibited	Free
207 F	30049059 30049099	Formulations made from Hydroxychloroquine	Prohibited	Free

2 . Effect of this Notification:

The Notification No. 54 dated 25.03.2020 has been amended to change the export policy of Hydroxychloroquine API and its formulations from "Prohibited" to "Free", with immediate effect.

File No. 01/91/180/21/AM20/EC/E-21154

Amit Yadav, Director General of Foreign Trade & Ex-Officio Additional Secretary, Department of Commerce, Ministry of Commerce & Industry, Udyog Bhawan. New Delhi. E-mail: dgft@nic.in

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MINISTRY OF SCIENCE & TECHNOLOGY PRESS RELEASE

CSIR-CDRI's candidate drug Umifenovir secures DCGI approval for Phase III Clinical Trial against COVID-19

Developed the process technology for Umifenovir in record time

MoS&T Press Release dated 18th June 2020

CSIR constituent lab CSIR-Central Drug Research Institute (CDRI) Lucknow, has received permission for carrying out Phase III randomised, Double blind, Placebo controlled trial of efficacy, safety and tolerability of antiviral drug Umifenovir. The Phase III Clinical Trials will be carried out at King George's Medical University (KGMU), Dr Ram Manohar Lohia Institute of Medical Sciences (RMLIMS) and ERA's Lucknow Medical College & Hospital, Lucknow.

This drug has a good safety profile and acts by preventing entry of virus into human cells and also by priming the immune system. Umifenovir is mainly used for treatment of influenza and is available in China and Russia, and has recently come into prominence due to its potential use for Covid-19 patients. To evaluate its efficacy in Indian patients, CSIR-CDRI has taken up the Clinical Trial. Further it has developed the process technology for Umifenovir in record time and licensed the economical process technology for manufacturing and marketing the drug to M/s Medizest Pharmaceuticals Private Ltd., Goa, who have already received test license from DCGI.

Prof Tapas Kundu, Director, CSIR-CDRI, said that all the raw materials for the drug are indigenously available and if the Clinical Trial is successful, Umifenovir can be a safe, efficacious, affordable drug against COVID-19 and can be part of National Program against COVID-19. Prof Kundu also added that this drug has the potential for prophylactic use.

Dr Shekhar Mande, DG-CSIR highlighted that this Clinical Trial is an integral part of the CSIR strategy of repurposing drugs for Covid-19 and complimented the team of scientists of CSIR-CDRI Nilanjana Majumdar, Ajay Kumar Srivastava, Chandra Bhushan Tripathi and Nayan Ghosh, who were coordinated by Dr Ravishankar Ramachandran, Nodal Scientist. The formulation and documentation team included P R Mishra, V Bhosale, R K Tripathi & S Sharma of CSIR-CDRI.

The Clinical Trial application was processed on high priority as per the DCGI's initiative against COVID-19. The next steps of the trial are being fast tracked to enable the availability of the drug to Indian patients as soon as possible.

Source: PIB, MoS&T Press Release, 18.06.2020

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COMPANIES LAW AMENDMENTS

Scheme for relaxation of time for filing forms related to creation or modification of charges under the Companies Act, 2013 - reg.

Corporate Affairs Circular No.23/2020 dated 17th June, 2020

To
All Regional Directors,All Registrar of Companies,
All Stakeholders.

1. The companies are required to file forms related to creation or modification of charges within the timelines provided in section 77 of the Companies Act, 2013 (Act), i.e. a total of 120 days of the creation or modification of charge. In case, the company fails to register the charge within the period of thirty days referred to in sub-section (1) of section 77, the charge holder may file the form related to creation or modification of charges under section 78 of the Act, within the overall timelines for filing of such form under section 77.

2. On account of the pandemic caused by the COVID-19, representations have been received in this Ministry, requesting that the timelines related to filing of certain charge related forms may be suitably relaxed so as to provide a window of compliance for the registration of charges. Under the Companies Fresh Start Scheme, 2020 as laid out in the General Circular No.12/2020, dated 30.03.2020, the benefit of waiver of additional fees was not extended to the charge related documents. Therefore, it has been suggested that some dispensation may be provided for filing of charge related documents as well.

3. In view of the above, the Central Government in exercise of its powers under section 460 read with section 403 of the Act and the Companies (Registration Offices and Fees) Rules, 2014 (Fees Rules) has decided to introduce a Scheme, namely **"Scheme for relaxation of time for filing forms related to creation or modification of charges under the Companies Act, 2013"**for the purpose of condoning the delay in filing certain forms related to creation/ modification of charges.

4. The details of the scheme are as under:

(i) The scheme shall come into effect from the date of issue of this Circular.

(ii) **Applicability**: The scheme shall be applicable in respect of filing of Form No.CHG-1 and Form No.CHG-9 (both referred as 'form'or 'forms') by a company or a charge holder, where the date of creation/modification of charge:

(a) is before 01.03.2020, but the timeline for filing such form had not expired under section 77 of the Act as on 01.03.2020, **or**

(b) falls on any date between 01.03.2020 to 30.09.2020 (both dates inclusive).

(iii) **Relaxation of time:**

(a) In case a form is filed in respect of a situation covered under sub-para (ii)(a) above, the period

beginning from 01.03.2020 and ending on 30.09.2020 shall not be reckoned for the purpose of counting the number of days under section 77 or section 78 of the Act. In case, the form is not filed within such period, the first day after 29.02.2020 shall be reckoned as 01.10.2020 for the purpose of counting the number of days within which the form is required to be filed under section 77 or section 78 of the Act.

(b) In case a form is filed in respect of a situation covered under sub-para (ii)(b) above, the period beginning from the date of creation/modification of charge to 30.09.2020 shall not be reckoned for the purpose of counting of days under section 77 or section 78 of the Act. In case, the form is not filed within such period, the first day after the date of creation/modification of charge shall be reckoned as 01.10.2020 for the purpose of counting the number of days within which the form is required to be filed under section 77 or section 78 of the Act.

(iv) **Applicable Fees:**

(a) In regard to sub-para (iii)(a) above, if the form is filed on or before 30.09.2020, the fees payable as on 29.02.2020 under the Fees Rules for the said form shall be charged. If the form is filed thereafter, the applicable fees shall be charged under the Fees Rules after adding the number of days beginning from 01.10.2020 and ending on the date of filing plus the time period lapsed from the date of the creation of charge till 29.02.2020.

(b) In regard to sub-para (iii)(b) above, if the form is filed before 30.09.2020, normal fees shall be payable under the Fees Rules. If the form is filed thereafter, the first day after the date of creation/ modification of charge shall be reckoned as 01.10.2020 and the number of days till the date of filing of the form shall be counted accordingly for the purposes of payment of fees under the Fees Rules.

(v) **The Scheme shall not apply, in case:**

(a) The forms i.e. CHG-1 and CHG-9 had already been filed before the date of issue of this Circular.

(b) The timeline for filing the form has already expired under section 77 or section 78 of the Act prior to 01.03.2020.

(c) The timeline for filing the form expires at a future date, despite exclusion of the time provided in sub-para (iii) above.

(d) Filing of Form CHG-4 for satisfaction of charges.

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

File No.02/05/2020-CL-V

K M S Narayanan, Assistant Director (Policy),
Ministry of Corporate Affairs,
New Delhi.

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CUSTOMS MATTERS

CBIC notifies New Exchange Rates w.e.f. 5th June 2020 - reg.

Customs Notification No. 49/2020 dated 4th June, 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.46/2020-Customs(N.T.), dated 21st May, 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 5th June, 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	53.30	51.05
2.	Bahraini Dinar	206.80	193.85

3.	Canadian Dollar	56.90	55.00
4.	Chinese Yuan	10.75	10.45
5.	Danish Kroner	11.55	11.15
6.	EURO	86.30	83.20
7.	Hong Kong Dollar	9.95	9.60
8.	Kuwaiti Dinar	253.30	237.60
9.	New Zealand Dollar	49.85	47.55
10.	Norwegian Kroner	8.10	7.80
11.	Pound Sterling	96.45	93.15
12.	Qatari Riyal	21.40	20.10
13.	Saudi Arabian Riyal	20.80	19.50
14.	Singapore Dollar	54.80	53.00
15.	South African Rand	4.60	4.30
16.	Swedish Kroner	8.25	8.00
17.	Swiss Franc	80.15	77.15
18.	Turkish Lira	11.55	10.85
19.	UAE Dirham	21.25	19.95
20.	US Dollar	76.45	74.75

SCHEDULE-II

Sr. No.	Foreign Currency	Rate of exchange of 100 units of foreign currency equivalent to Indian Rupees	
1.	Japanese Yen	70.60	68.10
2.	Korean Won	6.40	6.00

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

Gaurav Singh, Deputy Secretary,
Central Board of Indirect Taxes and Customs ,
Department of Revenue, Ministry of Finance, New Delhi.

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Need to bring in more advancement in respiratory diagnosis to identify root cause of infections: Amit Chopra

Stressing for the need to bring in more advancements in respiratory diagnosis to identify whether an infected patient is suffering from viral, bacterial or fungal infection, Amit Chopra, Managing Director of Thermo Fisher Scientific (India and Middle East) observed that unless and until advanced diagnostics and testing methods are evolved it becomes difficult to identify the root cause of infection in a patient. Unless the root cause is not identified it becomes difficult for the doctors to prescribe the right kind of medicines to treat the disease effectively.

According to Chopra, for most respiratory diseases and for the present COVID-19, diagnostic tests being carried out in India are one-size-fit-all. "Often this kind of imprecise diagnostic tests leads to inaccuracy in results, making it difficult for doctors to prescribe for the most effective treatment plan. This poses a serious threat especially for children, senior citizens, adults, the immuno-compromised, and the chronically ill. This leads to deceiving prescription by doctors and may lead to the intake of improper antibiotics and prolongs the patient's sickness. It increases healthcare costs and contributes to the growth of global antibiotic resistance," Chopra expressed concern.

As the COVID-19 pandemic is widely spreading in India and even today the health authorities are confining their testing measures to symptomatic individuals. It is high time that at least now healthcare policy decision makers focus their energies to help the scientific community to develop more efficient and precise diagnostic kits. "In India, to date, the testing measures are confined to symptomatic individuals and contact tracing leading to a surge for efficient and precise diagnostic kits. Amidst the preventive chaos, there is a pressing need for a more precise risk-assessment methodology to help triage COVID-19 patients," says the MD.

Respiratory diseases in a human body range in its severity from mild common colds to pneumonia. Commonly, patients get a virus first, weakening their immune system and making them susceptible to bacterial infections like pneumonia.

Sharing more knowledge on various new advances in respiratory disease diagnosis, Chopra said that respiratory disease detection kits with quantitative polymerase chain reaction (qPCR) syndromic panels help detect the root cause of respiratory diseases.

The qPCR-based technique is used to detect, identify, and quantify certain characteristics in the DNA that may be present in the sample. The syndromic panels test, used for multiple elements can identify whether a respiratory pathogen is viral, bacterial, or fungal, as well as to detect the presence of Multi-Drug Resistance Genes (MDRGs) that may limit the effectiveness of certain antibiotics.

Biomarker assays can provide an early indication of drug efficacy. An assay is an investigative procedure in laboratory medicine, widely used to assess the risk of bacterial co-infection. The preemptive utilization of BRAHMS PCT biomarker helps identify patients at high risk for bacterial infection alongside the presence of the COVID-19 virus.

Early diagnosis of sepsis helps provide accuracy in treatment and mitigate fatal complications. Septic shock in patients with suspected or confirmed lower respiratory tract infections (LRTI), Community-Acquired Pneumonia (CAP), Hospital-Acquired Pneumonia (HAP), Ventilator-Associated Pneumonia (VAP), and Acute Exacerbations of COPD (AECOPD) can be precisely assessed through the biomarker assay.

Newly developed multiplex RT-PCR TaqPath Covid-19 Combo Kit contains both the assays and controls needed for the RT-PCR detection of RNA from the virus. COVID-19 RNA control kit helps validate the performance of molecular tests for detecting COVID-19.

Source: A Raju, Pharmabiz, 12.06.2020

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A protein that helps to fight viruses can also block lung damage repair

Researchers at the Francis Crick Institute have found that a protein which is initially helpful in the body's immune response to a virus, can later interfere with the repair of lung tissue. The work, published in Science, highlights the need for careful consideration regarding the use of this protein to treat viruses, including Coronavirus.

When a virus infects the lungs, the body attempts to defend itself and fight off the infection. One defensive

mechanism is the activation of a protein, called interferon lambda, which signals to surrounding lung tissue cells to switch on anti-viral defences. Interferon lambda is currently being investigated in clinical trials as a potential treatment for COVID-19, so understanding the biology underlying its anti-viral effects is important.

The research team investigated the effects of this protein in the lab and found that if it is active for an extended period, it inhibits the repair of the lung tissue. This could prolong lung damage and increase the risk of subsequent bacterial infections.

The Crick scientists observed that in mice with influenza, having increased levels of this protein in their lungs meant that their epithelial cells multiplied less. These cells make up the lining of the airspaces in the lung and need to multiply to replace damaged cells and repair damage. This was the case for mice treated with the protein experimentally and also mice that had produced the protein naturally, as a result of their response to the virus. Furthermore, cultures of human lung epithelial cells treated with this protein were also less able to grow.

Andreas Wack, author and group leader of the Immunoregulation lab at the Crick says, "This is a really potent protein with many different functions. At the beginning of a viral infection, it is protective, triggering functions that help to fight the virus. However, if it remains in the tissue for too long, it could become harmful.

"This means, for any anti-viral treatment that uses this protein, there is a really careful balance that must be made. Clinicians should consider the timing of the treatment, the earlier this better, and the duration of treatment." While this research studied mice infected with influenza, the effects of this protein should be similar for other viruses that also cause lung damage, including Coronavirus. The paper has been published alongside research from Harvard Medical School, which found that severe COVID-19 patients showed strong expression of this protein in their lungs.

Jack Major, lead author and Ph.D., student in the Immunoregulation lab at the Crick says, "Understanding how our bodies respond to infection has never been more important. Differences in our immune responses have huge implications for whether a treatment will work and what the side effects might be.

"Our results suggest that before pursuing treatment with interferon lambda, doctors should consider at what stage of the disease patients are, as treatment late in infection may increase the risk of prolonged damage." The Crick researchers will continue to study inflammatory pathways in lung infections, including infection with Coronavirus.

(Materials provided by The Francis Crick Institute. Note: Content may be edited for style and length).

Source: The Francis Crick Institute, Science Daily, 12.06.2020 (Excerpts)

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Promising path found for COVID-19 therapeutics

A team of researchers at the University of Georgia has successfully demonstrated that a set of drug-like small molecules can block the activity of a key SARS-CoV-2 protein - providing a promising path for new COVID-19 therapeutics. Led by Scott Pegan, Director of UGA's Center for Drug Discovery, the team was the first to evaluate the SARS-CoV-2 protein PLpro, known to be essential in other Coronaviruses for both its replication and its ability to suppress host immune function.

"The PLpro from SARS-CoV-2 behaved differently than its predecessor that caused the SARS outbreak in 2003. Specifically, our data suggests that the SARS-CoV-2 PLpro is less effective at its immune suppression roles," said Pegan, Professor of pharmaceutical and biomedical sciences in the College of Pharmacy. "This may be one of the underlying reasons why the current virus is not as fatal as the virus from the 2003 outbreak."

The COVID-19 pandemic has affected more lives globally than the SARS outbreak of 2002-03, but its mortality rate is lower based on available numbers in early June. After the SARS outbreak, the World Health Organization reported 8,098 cases and 774 deaths--a mortality rate of nearly 10%. According to Johns Hopkins University's COVID-19 dashboard on June 3, there were 6,435,453 confirmed cases globally and 382,093 deaths--a mortality rate of nearly 6%.

From an evolutionary standpoint, it's not good for a virus to be fatal for the host, and SARS in 2003 was particularly lethal, according to Pegan. "The COVID-19 virus infects, but people don't run a fever before they are contagious, so there's a lot of focus on how virulence factors like PLpro have been modified by nature to give the virus a better chance, from its perspective, to coexist with us," he said. "Obviously we would not like for it to coexist, but COVID-19 seems to have solved the Goldilocks paradox

of being in the right place at the right time and with the right infection level."

Pegan collaborated with UGA scientists David Crich, Ralph Tripp and Brian Cummings to explore inhibitors designed to knock out PLpro and stop replication of the virus. They began with a series of compounds that were discovered 12 years ago and shown to be effective against SARS, but development was cut short since SARS had not reappeared.

"Obviously now we see the current Coronavirus is probably going to be with us for a while--if not this one, then probably other types of Coronaviruses," Pegan said. "These compounds are a good starting point for therapeutic development. They have all the properties you would typically want to find in a drug, and they have a history of not being considered toxic." These compounds, naphthalene-based PLpro inhibitors, are shown to be effective at halting SARS-CoV-2 PLpro activity as well as replication. They offer a potential rapid development path to generating PLpro-targeted therapeutics for use against SARS-CoV-2.

"The kind of small molecules that we're developing are some of the first that are specifically designed for this Coronavirus protease," Pegan said. "Up till now, most therapeutic work against SARS has targeted another virulence factor, C3Lpro. This is a great start with a different target. Our hope is that we can turn this into a starting point for creating a drug that we can get in front of the Food and Drug Administration."

Four UGA labs, including students, brought their expertise to the project. Pegan's lab used modeling techniques to locate the differences between PLpro in the 2003 outbreak and the current outbreak, revealing the comparative weakness of the SARS-CoV-2 PLpro and suggesting potential inhibitors for testing.

Medicinal chemist David Crich, Professor and Georgia Research Alliance and David Chu Eminent Scholar in Drug Design, provided guidance on understanding the attributes of the inhibitors and is working to synthesize new compounds with improved properties.

Testing of compounds against the virus was led by Ralph Tripp, an expert in respiratory viruses and related diseases who is Georgia Research Alliance Eminent Scholar of Vaccine and Therapeutic Studies and Professor of infectious diseases in the College of Veterinary Medicine. Brian Cummings, Professor and Head of pharmaceutical and biomedical sciences, covered toxicology, ensuring that the compounds tested killed their intended targets without causing toxic effects for the host.

Source: University of Georgia, Science Daily, 11.06.2020 (Excerpts)

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Scientists identify targets for COVID-19 vaccine

Researchers have identified regions of the SARS-CoV-2 virus to target with a vaccine, by harnessing tools used for the development of cancer immunotherapies.

The researchers at Children's Hospital of Philadelphia (CHOP) in the US employed the same approach used to elicit an immune response against cancer cells to stimulate an immune response against the novel coronavirus.

Using this strategy, the researchers believe a resulting vaccine would provide protection across the human population and drive a long-term immune response.

"In many ways, cancer behaves like a virus, so our team decided to use the tools we developed to identify unique aspects of childhood cancers that can be targeted with immunotherapies and apply those same tools to identify the right protein sequences to target in SARS-CoV-2," said John M Maris, a pediatric oncologist at CHOP, and a professor at the University of Pennsylvania.

"We think our approach provides a roadmap for a vaccine that would be both safe and effective and could be produced at scale," said *Maris, senior author of the research published in the journal Cell Reports Medicine.*

To increase the likelihood that a vaccine is both safe and effective, the research team prioritised parameters in identifying regions of the virus to target.

The researchers looked for regions that would stimulate a memory T-cell response that, when paired with the right

B cells, would drive memory B cell formation and provide lasting immunity and do so across the majority of human genomes.

They targeted regions of SARS-CoV-2 that are present across multiple related coronaviruses, as well as new mutations that increase infectivity, while also ensuring that those regions were as dissimilar as possible from sequences naturally occurring in humans to maximise safety.

The researchers propose a list of 65 peptide sequences that, when targeted, offer the greatest probability of providing population-scale immunity.

The team will now test various combinations of a dozen or so of these sequences in mouse models to assess their safety and effectiveness.

Source: PTI, Express Pharma, 11.06.2020

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Up to 45 percent of SARS-CoV-2 infections may be asymptomatic

An extraordinary percentage of people infected by the virus behind the ongoing deadly COVID-19 pandemic never show symptoms of the disease, according to the results of a Scripps Research analysis of public datasets on asymptomatic infections.

The findings, published in Annals of Internal Medicine, suggest that asymptomatic infections may account for as much as 45 percent of all COVID-19 cases, playing a significant role in the early and ongoing spread of COVID-19. The report highlights the need for expansive testing and contact tracing to mitigate the pandemic.

"The silent spread of the virus makes it all the more challenging to control," says Eric Topol, MD, founder and Director of the Scripps Research Translational Institute and Professor of Molecular Medicine at Scripps Research. "Our review really highlights the importance of testing. It's clear that with such a high asymptomatic rate, we need to cast a very wide net, otherwise the virus will continue to evade us."

Together with behavioral scientist Daniel Oran, Topol collected information from testing studies on 16 diverse cohorts from around the world. These datasets--gathered via keyword searches of PubMed, bioRxiv and medRxiv, as well as Google searches of relevant news reports--included data on nursing home residents, cruise ship passengers, prison inmates and various other groups.

"What virtually all of them had in common was that a very large proportion of infected individuals had no symptoms," says Oran. "Among more than 3,000 prison inmates in four states who tested positive for the Coronavirus, the figure was astronomical: 96 percent asymptomatic."

The review further suggests that asymptomatic individuals are able to transmit the virus for an extended period of time, perhaps longer than 14 days. The viral loads are very similar in people with or without symptoms, but it remains unclear whether their infectiousness is of the same magnitude. To resolve that issue, we'll need large-scale studies that include sufficient numbers of asymptomatic people.

The authors also conclude that the absence of symptoms may not imply an absence of harm. CT scans conducted on 54 percent of 76 asymptomatic individuals on the Diamond Princess cruise ship, appear to show significant subclinical lung abnormalities raising the possibility of SARS-CoV-2 infection impacting lung function that might not be immediately apparent. The scientists say further research is needed to confirm the potential significance of this finding.

The authors also acknowledge that the lack of longitudinal data makes distinguishing between asymptomatic and presymptomatic individuals difficult. An asymptomatic individual is someone who is infected with SARS-CoV-2, but never develops symptoms of COVID-19, while a presymptomatic person is similarly infected, but will eventually develop symptoms. Longitudinal testing, which refers to repeated testing of individuals over time, would help differentiate between the two.

"Our estimate of 40 to 45 percent asymptomatic means that, if you're unlucky enough to get infected, the probability is almost a flip of a coin on whether you're going to have symptoms. So to protect others, we think that wearing a mask makes a lot of sense," Oran concludes.

Source: World Pharma News, 12.06.2020 (Excerpts)

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Hydroxychloroquine trials in turmoil

While negative results lead some researchers to cancel studies, other will push ahead

Clinical studies continue to suggest that the antimalarial drugs Chloroquine and Hydroxychloroquine do not help treat or prevent COVID-19. One high-profile study published in the Lancet even concluded that the drugs may increase the risk of death. Those results prompted several groups, including the World Health Organization (WHO) and the pharmaceutical company Sanofi, to suspend or terminate trials of the drugs.

But soon after its May 22 publication, the Lancet study came under criticism and the authenticity of its data was called into question. That led WHO to resume its trials. The study was ultimately retracted on June 5. That same tumultuous week, two other groups announced negative results from large Hydroxychloroquine studies.

Researchers at the University of Minnesota conducted a study of 821 people to see if Hydroxychloroquine could prevent sickness in those who were recently exposed to someone with COVID-19. Among those who received the drug, 11.8% became sick, versus 14.3% who received a placebo. The difference was not statistically significant (N. Engl. J. Med. 2020, DOI: 10.1056/NEJMoa2016638).

Benjamin Rome, a primary care physician at Brigham and Women's Hospital, applauds the trial's rigor. "This is exactly the sort of evidence we need," he says, adding that the results suggest that Hydroxychloroquine is unlikely to protect against COVID-19. "If there is any benefit, it would have to be quite small to not be picked up by this trial."

In the UK, investigators announced preliminary results from a study involving more than 4,600 people hospitalized with COVID-19. In the study, called the RECOVERY Trial, 25.7% of 1,542 people who got Hydroxychloroquine died after 28 days, compared with 23.5% of 3,132 people who received standard care. Again, the difference was not statistically significant.

There are more than 130 active or planned clinical trials testing the ability of Hydroxychloroquine or Chloroquine to treat or prevent COVID-19. With negative results from two major trials, some scientists now wonder if the chloroquine craze is over. "RECOVERY is an excellent trial, and probably the best evidence we will have," says Paul Glasziou, Director of the Institute for Evidence-Based Healthcare at Bond University. "We need more trials on other treatments."

Some researchers say there is no definitive proof that Hydroxychloroquine is ineffective, however. Novartis and the US National Institutes of Health are both pushing ahead with independent placebo-controlled trials of the drug in people hospitalized with COVID-19.

Other groups say the Minnesota study is not the final word on prevention. They are continuing their own post-exposure studies to assess whether the drug can help prevent infection in thousands of people recently exposed to the virus.

Researchers are also proceeding with even larger pre-exposure studies this summer, in which tens of thousands of healthy health-care workers will be given Chloroquine or Hydroxychloroquine to see if the drugs can prevent infection. Results are expected by late summer or early fall.

Source: Ryan Cross, Chemical & Engineering News, (Vol.98, Issue 23), 12.06.2020

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Department of Pharma has approved lifting ban on export of Hydroxychloroquine: Gowda

The Department of Pharmaceuticals has given its nod for lifting of ban on the export of Hydroxychloroquine, Union Minister D V Sadananda Gowda said on Wednesday, 10.06.2020.

India had banned export of Hydroxychloroquine on March 25, with some exceptions, amid views in some quarters that the drug could be used to fight COVID-19. On April 4, it completely banned the exports without any exception.

"Department of Pharmaceuticals has approved the lifting of ban on export of Hydroxychloroquine API as well as formulations. Manufacturers except SEZ/EOU Units have to supply 20 percent production in the domestic market," the Minister of Chemicals and Fertilisers said in a tweet.

The Directorate General of Foreign Trade (DGFT) has been asked to issue formal notification in this regard, he added.

In another tweet, Gowda said he held discussions with representatives of pharma companies along with some of his ministerial colleagues on the challenges being faced by the industry and on the roadmap to boost exports.

"Had detailed discussion with representatives of pharma companies & association, stakeholder Ministries along with Hon Ministers @piyushGoyal ji, @HardeepSPuri ji, & @MansukhMandviya ji on entire gamut of challenges faced by the industry as well as strategies to boost Pharma export," Gowda tweeted.

India exported Hydroxychloroquine API (Active Pharmaceutical Ingredient) worth USD 1.22 billion in April-January 2019-20.

During the same period, exports of formulations made from Hydroxycholoroquine was at USD 5.50 billion.

(*This story has not been edited by Outlook staff and is auto-generated from news agency feeds).*

Source: PTI, Outlook, 11.06.2020

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Domestic Pharma industry to grow 3-5 pc this fiscal, little impact of lockdown: Ind-Ra

India Ratings and Research (Ind-Ra) on Wednesday, 10.06.2020 said the country"s pharmaceutical sector is expected to grow 3-5 percent year-on-year in the current financial year despite Coronavirus-led lockdown.

The domestic rating agency also expects monthly revenue improvements of drug firms from June.

"Additionally, the seasonality in the Indian domestic business will support the recovery. Also, the continuous rise in the number of COVID-19 cases in the country will result in further volume growth in related therapies," Ind-Ra noted.

Besides, Pharma companies" large cash balances and sufficient headroom under debt covenants along with diversified funding sources will mitigate any impact of the ongoing lockdown, it added.

The COVID-19 impact on the pharmaceutical sector has been less pronounced than observed in other sectors, as it falls under the essential service category and is exempt from restrictions under the nationwide lockdown, the rating agency said.

Manufacturing volumes after declining to 50-60 percent in April, given the strict lockdown, has improved significantly to 60-80 percent of the original capacities during the May-June period so far, Ind-Ra noted.

However, the companies have refrained from new launches during the lockdown due to lack of effective marketing campaigns, the rating agency said.

Further, companies may take price hikes on non-DPCO (Drug Price Control Order) products up to 8 percent unlike the earlier average price hike of 5 percent (max limit 10 percent) due to an increase in raw material cost and the additional cost incurred towards raw materials, logistics and manpower, it added.

(This story has not been edited by Outlook staff and is auto-generated from news agency feeds.)

Source: PTI, Outlook, 11.06.2020

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Greater Health spending to spur Pharma demand: IDMA

The Pharmaceutical Industry is expecting medicine demand to surge in the near future with spending on healthcare as a percentage of GDP slated to increase, said a top official of Indian Drug Manufacturers' Association (IDMA). "I am very sure about the statements from various Ministers that the GDP spend on healthcare, which is hovering around 1.5%-2%, is going to go up, which means demand for pharmaceutical medicines is going to go up in the near future," said Milan Patel, who has been appointed the new Chairman of IDMA's Gujarat State Board (GSB) for two years. Patel is Joint Managing Director of Troikaa Pharmaceuticals Ltd.

IDMA-Gujarat State Board also appointed Dr Shrenik Shah as Senior Vice-Chairman, Sanchit Chaturvedi and Jay Patel as Vice-Chairmen for two years.

Source: The Times of India, 10.06.2020 (Excerpts)

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Maharashtra FDA assures DCGI of adequate stock of medical oxygen for treating critically ill COVID-19 patients

Following Drugs Controller General of India (DCGI)'s directive to the State Drug Controllers to assess stock position of medical oxygen for the last 18 months, the

Maharashtra Food and Drug Administration (FDA) has assured the DCGI of adequate availability of medical oxygen for treating critically ill COVID-19 patients in the state.

As of today, there are 80 manufacturers in Maharashtra which have been licensed to produce medical oxygen based on the DCGI directive. "There are around 20,000 oxygen cylinders available in the state. More licenses will be issued to help manufacturers take up production of medical oxygen based on the growing demand," informed J B Mantri, Joint Commissioner (HQ), Maharashtra FDA and State Drug Controlling Authority.

Meanwhile, DCGI also received a list of major medical oxygen manufacturers from the Union Commerce Ministry which are based in Tamil Nadu, Puducherry, Karnataka, Chhattisgarh, West Bengal, Jharkhand, Maharashtra, Orissa Gujarat, Assam, Andhra Pradesh, Uttar Pradesh, Jammu and Kashmir, Punjab and Uttarakhand to discuss preparedness for availability of medical oxygen in the country.

The national drug regulator is currently in talks with some of the major manufacturers on the same.

The state drug regulator had sent across a directive to all the industrial gas manufacturers in the state to produce medical grade oxygen to cater to the growing demand for treating critically ill COVID-19 patients in the country.

DCGI had earlier directed state licensing authorities (SLAs) to urgently grant permission to manufacturers of industrial oxygen to manufacture medical oxygen in the light of COVID-19 outbreak. Supplemental oxygen therapy is a part of the clinical management of COVID-19. It is the use of oxygen as a medical treatment. This also includes supplementing oxygen for low blood oxygen, carbon monoxide toxicity, cluster headaches and to maintain enough oxygen while inhaled anesthetics are given.

All India Industrial Gases Manufacturers' Association (AIIGMA) had earlier proposed for allowing manufacturers of industrial oxygen to manufacture oxygen for medical use. As per the DCGI directive to the SLAs, it has been decided in public interest 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 the submission of application and fees as per the Drugs and Cosmetics (D&C) Act. An undertaking need to be furnished in writing to manufacture medical oxygen in compliance with standards prescribed in Indian Pharmacopoeia (IP) and labeling requirement as per the D&C Act and Rules.

Oxygen therapy is the single most effective supportive measure in COVID-19 patients. Children with emergency signs (obstructed or absent breathing, severe respiratory distress, central cyanosis, shock, coma or convulsions) should receive oxygen therapy during resuscitation.

The state drug regulator had recently met with the Union Commerce Ministry to discuss the availability of medical grade oxygen and cylinders and is in the process of collecting the data on the same besides the storage capacity of oxygen with the existing producers.

Union Ministry of Commerce and Industry and the Central Drug Standard Control Organization (CDSCO) regulate the medical gases in India.

Source: Shardul Nautiyal, Pharmabiz, 12.06.2020

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Commerce Ministry extends time limit for exporters to submit reimbursement claims for expenses under MAI Scheme from 3 to 6 months

The Union Ministry of Commerce and Industry has extended time limit for submission of claims by exporters for reimbursement of expenditure incurred on statutory compliances abroad for the year 2019-20 and 2020-21 under Market Access Initiative (MAI) Scheme from three months to six months following representation from Pharmaceuticals Export Promotion Council of India (Pharmexcil).

Pharmexcil has made a representation to the Ministry on the issues being faced by the exporters in filling the MAI claim applications within 90 days from the date of issue of registration certificates due to the outbreak of COVID-19 and lockdown.

Considering Pharmexcil's representation, the Ministry has extended the time limit prescribed at Sr. No.11 of the Table, below para 6.1 of the Guidelines for Funding under the MAI Scheme, related to submission of claims by the exporters for reimbursement of expenditure incurred on statutory compliances abroad, to the concerned Export Promotion Council (EPC)/Federation of Indian Export Organisations (FIEO) from 90 days to 180 days, for the claims pertaining to the financial years 2019-20 and 2020-21.

Pharmexcil has called upon members to take note of the circular and file their claims within 180 days from

the date of issue of registration certificates for the claims pertaining to fiscal year 2019-20 and 2020-21 only.

All the applications for FY 2019-20 and 2020-21 will be processed and forwarded to Commerce Ministry according to first in first out basis, it stated.

The MAI Scheme which was already in existence provides reimbursement of expenditure incurred by exporters on statutory compliance in the export market/ nation. The scheme also avails other benefits like Marketing Projects Abroad, Capacity Building in specific nation/ countries, support for statutory compliance, different studies related to market, export surveys, studies related to evolving WTO compatible strategy, project development and for the development of foreign trade facilitation web portal. All these benefits already provide considerable assistance to Indian exporters.

Last year the Ministry had revised MAI Scheme and increased the ceiling amount to be reimbursed for the Indian exporters under MAI Scheme from Rs. 50 lakh per annum to Rs. 2 crore.

The revised MAI scheme is applicable to those who have applied for product registrations and received certification on or after January 7, 2019. All those who have applied for reimbursement before January 7, 2019 under MAI will be reimbursed up to only Rs. 50 lakh as per earlier provisions.

According to the new guidelines, any exporting company can claim reimbursement of charges incurred towards statutory compliance on a 50:50 sharing basis up to a maximum amount of Rs. 2 crore in a year.

Source: Laxmi Yadav, Pharmabiz, 12.06.2020

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China dumping key medicine in India

The Government has found sufficient evidence that China is dumping a key medicine -- Ciprofloxacin Hydrochloride -- below cost in the Indian market and hurting the domestic pharmaceutical industry, two officials aware of the development said. The medicine is used to treat bacterial infections, including skin, bone, respiratory and urinary tract infections, and certain types of diarrhoea.

After a thorough investigation, the Government has found that the volume of Ciprofloxacin Hydrochloride imported from China has increased significantly and at a pace that is undercutting prices in the domestic industry, the officials cited above said, requesting anonymity. China alone accounts for about 98% of the total Indian imports of the medicine.

"Domestic medicine had a price disadvantage of up to $3.3 per kg over Chinese products," an official of a pharmaceutical association said on condition of anonymity. Even as domestic manufacturing capacity of the medicine has increased, actual production and sales of local industry have declined and the market share of Chinese Ciprofloxacin Hydrochloride in India has increased, causing losses to the Indian pharma industry, the officials said.

"DGTR (Directorate General of Trade Remedies) on June 15 provisionally concluded that the domestic industry has suffered material injury and its preliminary findings favoured the imposition of an anti-dumping duty on Chinese import," one of the officials said. DGTR may take a final view on the matter after hearing all interested parties again next month, he added.

DGTR, previously known as the Directorate General of Anti-dumping and Allied Duties, is an arm of the Ministry of Commerce and Industry and acts as a single-window agency providing a level playing field to domestic industry against unfair trade practices.

The Finance Ministry will consider imposing an anti-dumping duty on the Chinese medicine if DGTR recommends such a step, the second official cited above said. DGTR had initiated the investigation against the dumping of Ciprofloxacin Hydrochloride from Chine in January after domestic manufacturers accused the neighbouring country of engaging in an unfair trade practice.

Dumping is an unfair trade practice that entails the export of a product at a price lower than its value and is countered by a punitive duty, which is an acceptable measure under multilateral trade agreements, the second official said. Complaints have been received by domestic industry that China was dumping several products. All such complaints are being investigated, he said.

HT reported on May 11 that India could extend anti-dumping duties and safeguards on more than two dozen Chinese goods ranging from calculators and USB drives to steel, solar cells and Vitamin-E amid concern that a flood of imports would kill domestic manufacturers who will lose duty protection soon against such products. Anti-dumping duties on these products were imposed five years ago and are expiring this year.

India has taken a tough position against unfair Chinese trade practices as it is committed to protecting domestic industry under the Government's Make in India campaign, the officials said.

India-China bilateral trade is heavily tilted in favour of China. According to trade figures released by the General Administration of Customs of China (GACC) in mid-January 2020, India's trade deficit with China was $56.77 billion in 2019; bilateral trade amounted to about $92.68 billion last year, a 1.6% annual increase.

"Dumping of goods below their actual cost harms the domestic industry, and anti-dumping duty is one of the means to protect local manufacturing from such unfair trade practices," Indian Drug Manufacturers' Association (IDMA) Executive Director Mr Ashok Madan said.

Source: Rajeev Jayaswal, Hindustan Times, 17.06.2020

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HCQ's emergency use revocation by US may not hit India's exports

Even as the US Government revoked emergency use of Hydroxychloroquine (HCQ) for treating Coronavirus (Covid-19) patients, smaller players in India do not see much impact on export of the drug. This is because while the emergency authorisation for treating Covid was a recent move, the drug has been used since years for Rheumatoid Arthritis (RA) and autoimmune lupus.

"Revocation of the emergency use approval means that the drug can be reused in future when approved after a clinical study. However, the decades-old drug is used in RA and lupus which still continues. Use of HCQ for treating Covid has been a recent phenomena, although it did create a huge buzz around the drug. However, the impact on exports will be minimal for the industry, especially in Gujarat," said Dr Viranchi Shah, Senior National Vice-President of the Indian Drug Manufacturers' Association (IDMA).

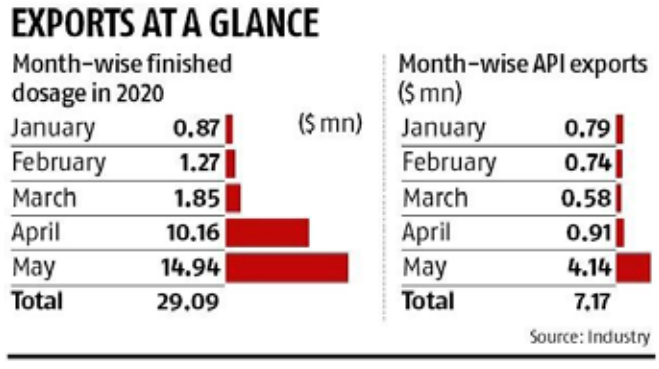
A senior Government official said the share of HCQ in India's overall Pharma exports is miniscule. So, it does not impact exports as such. "Smaller firms had seen an opportunity and started exports to several countries across the globe. They did not need to alter their product line for making HCQ, which is a simple drug to make. Therefore, unless they have piled up lot of inventory of HCQ Active Pharmaceutical Ingredients (API), there should not be a problem," he said.

India exported about $15 million of HCQ in May, almost 50 percent up from $10 million in April. Since HCQ is a low-value item (Rs 2 or so per tablet), it means the export volumes have been high – over 400-600 million tablets per month.

Gujarat, in recent times, has been one of the largest makers and exporters of HCQ in the country, with the state Food and Drug Control Administration granting licence to scores of players in recent times. It is estimated that there are nearly 70 Pharma units with licence of HCQ formulations while there are three Active Pharmaceutical Ingredient (API) manufacturers for the drug in the state. Cadila Healthcare (Zydus Cadila) is the largest of them.

"HCQ is a decades-old drug used in rheumatoid arthritis and lupus, among others. Hence, demand for the drug is still strong. Gujarat supplies 60-70 percent of the US's HCQ for RA and lupus alone. Recently, the US had repurposed use of HCQ for Covid which it has now revoked. However, HCQ exports may still continue for treating the primary disorders it is meant for," said Dr H G Koshia, Commissioner, Food and Drug Control Administration (FDCA), Gujarat.

In the domestic market, the Government has picked up stock for 100 million tablets by April. Each patient requires either five to nine tablets. Going by that, the stock would last for months as it can cater to about 10 million people. Meanwhile, the industry, involved in HCQ manufacturing in India, is awaiting certain study results around the drug's efficacy in treating Covid-19 being conducted in the UK. According to industry sources, depending on the study results, export of HCQ from India could either be positively or negatively impacted.



Source: Vinay Umarji, Business Standard, 16.06.2020

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DoP comes out with draft guidelines for Rs. 6,940 crore PLI scheme to promote domestic production of bulk drugs

The Department of Pharmaceuticals (DoP) has come out with draft guidelines for the Rs. 6,940 crore Production Linked Incentive (PLI) scheme for promotion of domestic manufacturing of identified critical Key Starting Materials (KSMs)/drug intermediates (DIs)/Active Pharmaceutical Ingredients (APIs) in India.

The DoP has discussed the draft guidelines with representatives of the drug industry at a meet on June 13, 2020. It will soon send guidelines to NITI Aayog for consideration. Following this, the final guidelines will be released by next month. The guidelines were prepared by a technical committee, headed by the Joint Drugs Controller (I), CDSCO Dr S Eswara Reddy, constituted by DoP on April 17, 2020 after detailed consultations with industry, experts and other relevant stakeholders.

The major objective of the PLI scheme is to reduce import dependency and boost the domestic production of bulk drugs. Currently, India imports nearly 68 percent of API, by value, from China. The import of APIs has risen at a CAGR of 8.3 percent from 2012 to 2019 and the bulk drug import reached a value of Rs. 249 billion in 2019. Incentives are limited to KSMs instead of the APIs to reduce import dependency and effectively utilise funds under the scheme. The 41 eligible products for which the scheme is proposed covers the 53 APIs which have been approved by the Government.

The eligible products are four fermentation based KSMs/DIs, ten fermentation based KSMs/DIs, four chemical synthesis based KSMs/DIs (with backward integration) and 23 chemical synthesis based KSMs/DIs/ APIs (with backward integration). The tenure of the scheme is 7 years for chemically synthesized eligible products and 8 years for eligible products manufactured by fermentation based technology. Rate of incentive for fermentation products for the first four years (2022-2023 to 2025-2026) would be 20%, 2026-27- 15% and 2027-28-5%. Rate of incentive for chemically synthesized products for the entire scheme (2021-2022 to 2025-2027) would be 10%.

A gestation period of 2 years is provided for eligible products manufactured by fermentation process and 1 year for chemically synthesized eligible products. If no investment has been made by the manufacturer within 6 months from the date of approval, the bank guarantee shall be forfeited and the manufacturer shall no longer remain a beneficiary under the scheme.

As per the guidelines, it should be a Greenfield project and the threshold investment ranges from Rs. 20 crore to Rs. 400 crore as per project. Investment made for the purchase of land shall not be considered as threshold investment. Building, plant and machinery may constitute about 45% of the threshold investment. Besides this, the threshold investment comprises of investment in ETP, incinerators, Effluent lines/tanks/treatment, supply lines of water/sewerage/solvents/gases, solvent recovery, solid waste treatment plant, QC equipment-infrastructure/R&D equipment infrastructure, pilot plants, warehousing and other ancillary areas etc.

The applicants require to make threshold investment to manufacture the eligible product post approval to make themselves eligible for the scheme. There is no upper limit cap on the investment. FDI, if any, shall be as per applicable laws. The applicant using novel technologies like flow chemistry or continuous manufacturing known for safety, low environment & solvent burden; biocatalysts/ novel enzymes; substitution of noble metals with cheaper metals; green chemistry/zero discharge or low polluting technologies with in situ or in-process recoveries will be given preference.

The scheme is applicable to eligible products manufactured with complete backward integration. Under the category of four fermentation based KSMs/DIs which include Penicillin G/6-amino penicillanic acid (6-APA, CephC/7-amino cephalosporanic acid (7ACA), erythromycin thiocynate (TIOC), clavulanic acid, the maximum number of eligible manufacturers for each product is two and Rs. 400 crore is threshold investment.

The minimum annual production capacity for Penicillin G/6, CephC/7, erythromycin thiocynate and clavulanic acid stands 5,000 metric tonnes (MT), 1,000 MT, 800 MT and 1.5 lakh kg respectively.

A total of Rs. 3,600 crore will be disbursed as incentive for these four products from fiscal year 2022-23 to fiscal year 2027-28. Of Rs. 3,600 crore, an incentive of Rs. 720 crore will be given from FY 2022-23 to FY 2025-26. Rs. 540 crore will be disbursed for FY 2026-27 and Rs. 180 crore will be provided for FY 2027-28. Each of the two manufacturers of Penicillin G/6 and each of two manufacturers of CephC/7 will get Rs. 120 crore as incentive per annum while each of two manufacturers of

erythromycin thiocynate and clavulanic acid will receive an incentive of Rs. 60 crore per annum.

There are ten fermentation based niche KSMs/ drug intermediates/APIs—neomycin, gentamycin, betamethasone, dexamethasone, prednisolone, rifampicin, vitamin B1, clindamycin phosphate/clindamycin HCL, streptomycin, tetracycline/oxytetracycline/doxycycline.

The maximum number of eligible manufacturers for each product is two and Rs. 50 crore is threshold investment. The minimum annual production capacity for neomycin, gentamycin, betamethasone, dexamethasone, prednisolone, rifampicin, vitamin B1, clindamycin phosphate/clindamycin HCL, streptomycin, tetracycline/ oxytetracycline/ doxycycline is 175 MT, 40 MT, 2 MT, 2 MT, 15 MT, 100 MT, 200 MT, 60 MT, 50 MT and 450 MT respectively.

A total of Rs. 1,000 crore will be disbursed as an incentive from FY 2022-23 to FY 2027-28. Of them, Rs. 200 crore will be given as incentive from FY 2022-23 to FY 2025-26. There will be Rs. 150 crore and Rs. 50 crore distributed as an incentive for FY 2026-27 and FY 2027-28 respectively. Each of two eligible manufacturers of each of ten products will get an incentive of Rs. 10 crore per annum.

There are four key chemical synthesis based KSMs/ DIs-- cyclohexane diacetic acid (CDA), 2-methyl-5 nitro-imidazole (2-MNI), dicyandiamide (DCDA), para amino phenol. For each product, the maximum number of eligible manufacturers is four and Rs. 50 crore is threshold investment. The minimum annual production capacity for CDA, 2-MNI, DCDA and para amino phenol stands 1,500 MT, 800 MT, 8,000 MT and 8,000 MT respectively.

A total of Rs. 960 crore will be given as an incentive for these four products from FY 2021-22 to FY 2026-27. Of them, Rs. 160 crore will be doled out as incentive every year. Each of four eligible manufacturers of each of the four products will get an incentive of Rs. 10 crore per annum.

There are 23 other chemical synthesis based KSMs/drug intermediates/APIs. The minimum annual production capacity for 21 out of 23 products which include meropenem, atorvastatin, olmesartan, valsartan, losartan, levofloxacin, sulfadiazine, ciprofloxacin, ofloxacin, norfloxacin, artesunate, telmisartan, aspirin, diclofenac sodium, levetiracetam, carbidopa, acyclovir, carbamazepine, oxcarbazepine, vitamin B6, levodopa stands at 10 MT, 30 MT, 25 MT, 25 MT, 80 MT, 115 MT, 20 MT, 300 MT, 100 MT, 15 MT, 35 MT, 80 MT, 2,800 MT, 175 MT, 140 MT, 175 MT, 65 MT, 65 MT, 35 MT, 10 MT respectively.

There is no minimum annual production capacity mentioned for ritonavir and lopinavir. The maximum number of eligible manufacturers for each product is four and Rs. 20 crore is threshold investment. A total of Rs. 1,380 will be disbursed as incentive for these 23 products from fiscal year 2021-22 to fiscal year 2026-27. Every year Rs. 230 crore is proposed to be distributed as incentive. Each of four eligible manufacturers of each of the 23 products will get an incentive of Rs. 2.5 crore per annum.

Source: Laxmi Yadav, Pharmabiz, 15.06.2020

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Experts recommend gloves, coveralls, masks intended for medical use to conform to BIS standards as per MD Rules

In order to ensure patient safety at the point of care, experts have recommended that gloves, coveralls and masks intended for medical use to conform to Bureau of Indian Standards (BIS) as per Medical Device Rules 2017. This also complements the Government's self-reliant and Make in India campaign to boost domestic industry in the wake of COVID-19 crisis.

BIS is the National Standard Body of India established under the BIS Act 2016 for the harmonious development of the activities of standardization, marking and quality certification of goods for minimizing health hazards to consumers.

As of today, Personal Protective Equipment (PPE) which include gloves, coveralls, goggles and masks are not being effectively regulated as medical devices as manufacturers have yet to get themselves registered voluntarily on the portal-cdscomdonline.gov.in as per the mandate of medical device rules, 2017. The Drugs Controller General of India (DCGI) has also recently issued an advisory to the PPE manufacturers to voluntarily register on the portal. PPE coverall is an important medical device for healthcare workers handling COVID-19 patients.

"Since PPEs for healthcare are to be regulated under medical device rules (MDR) 2017 which prescribes compliance to BIS standards as first option, Union Health Ministry should amend its guidelines to include BIS standards as an option. BIS should also adopt international

standards unless there is justification to deviate which would promote exports as well. Since MDR 2017 uses concept of notified bodies, certificates of conformity from any notified body of Central Drugs Standard Control Organisation (CDSCO) should be acceptable with National Accreditation Board for Certification Bodies (NABCB) logo," recommended Anil Jauhri, former CEO, National Accreditation Board for Certification Bodies (NABCB).

To promote the supply of quality PPEs during the ongoing pandemic, BIS has also permitted relaxation in its norms of having in-house testing facilities for the following PPEs like filter half masks to protect against particles of Class FFP2 as per IS 9473:2002, surgical face masks as per IS 16289:2014 and eye protectors as per IS 5983:1980.

This has been done to enable more manufacturers to be brought in the ambit of BIS product certification scheme, which will in turn result in greater quantity of BIS certified PPEs being made available to the users.

However, for such manufacturers, testing of samples for conformity to the specified requirements is being done in laboratories of BIS licensees who have in-house testing facilities, or in BIS recognized or empanelled private/ government labs. Those domestic manufacturers who are interested in applying for a BIS licence may register themselves and submit their application online through BIS website **www.bis.gov.in**

"This is a good initiative from BIS to address the shortage problem of PPE components. We would suggest that BIS shall extend the same to all PPE components including surgical gowns. There is also urgent need for complying with QMS system like ICMED/ISO 13485 to be made mandatory for stricter controls of quality output from manufacturers," explained Sanjiiv Relhan, Chairman, Preventive Wear Manufacturer Association of India (PWMAI).

Echoing similar views, Rajiv Nath, forum coordinator, Association of Indian Medical Devices Industry (AiMeD) concluded, "While the issue of adequate manufacturing capacity to meet the rising demand in COVID-19 times is being rapidly addressed, AiMeD has also been initiating steps to ensure that the new PPE manufacturers get trained to ICMED/ ISO 13485 voluntary quality assurance (QA) certification as well negotiated with BIS with help of Union Ministry of Textiles (MoT) and Department of Pharmaceuticals (DoP) to provide relaxation on temporary basis to get third party testing done. This will enable quality verification and compliance to BIS standards and seek ISI mark to demonstrate compliance to address concerns of buyers who wish to procure from a wider supply base of domestic suppliers but with due quality credentials."

Source: Shardul Nautiyal, Pharmabiz, 15.06.2020

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Indian Pharma sees US FDA norms on use of flow restrictors to provide safety for oral liquid pediatric formulations

Indian pharma is of the opinion that the US FDA recommendations on the use of restricted delivery systems to limit unintentional ingestion of oral liquid drug products by children will safeguard accidental consumption of medicines.

The recommendations in the guidance apply broadly to oral liquid drug and biological products. Hence this rule is intended for manufacturers of oral liquid drug which could be marketed under the over-the-counter (OTC) or even holders of New Drug Applications (NDAs), Biologics License Applications (BLAs), and Abbreviated New Drug Applications (ANDAs).

"We see Child Resistant Packaging (CRP) is regarded as an important public health safety tool to prevent incidence of harmful health outcomes related to unintentional ingestions. World Health Organization (WHO) has noted that one child receives hospital emergency treatment due to medicine poisoning every 8 minutes," said the industry officials.

Many oral liquid drugs are marketed with CRP features. However, even with the availability of this safety tool, adverse events related to unintentional ingestion of drug products, including oral liquids, continue to be reported. One analysis of the National Electronic Injury Surveillance System-Cooperative Adverse Drug Event Surveillance (NEISS-CADES) data estimated that children younger than 6 years old account for more than 9,500 annual Emergency Department (ED) visits attributed to the unintentional ingestion of oral liquid drug products.

Hence a dedicated guidance was needed. Additional measures should also be considered to reduce unintentional ingestion of oral liquids, including safe and secure product storage. Exposure-limiting packaging, such as a restricted delivery system, is one such measure that complements CRP. Specifically, restricted delivery systems are intended to restrict the flow of liquid from

the opening of a container. But it is not a replacement for CRP. Rather, manufacturers should consider using a combination of CRP and restricted delivery systems to further reduce unintentional ingestion of oral liquids, said the guidance.

An example of a restricted delivery system is a flow restrictor, which can be added to the neck of a bottle to restrict or control the flow of liquid. This can be added to a container at the site of manufacture, or can be co-packaged with the drug product and added to the container at the time of use. Here the regulatory authority has noted that a closed flow restrictor limits access to a single-unit volume at one time. This can be designed with a self-closing valve that opens when the dosing device is inserted and resealed.

In the case of an open flow restrictor it allows for a continuous, controlled volume. When an oral syringe is used, an open flow restrictor does not reseal after removal of the oral syringe and when the bottle is inverted it permits a slow flow of liquid from the container.

The efficacy of flow restrictors has been demonstrated in the pediatric population. Children of 3 to 4 years are able to empty the entire contents of bottles without flow restrictors within 2 minutes. However, when a bottle fitted with a flow restrictor, children of the same age were prevented from completely emptying the bottle contents within a 6-minute period. In cases of unintentional liquid acetaminophen ingestions, the average individual dose was lower in cases that involved bottles with flow restrictors. Therefore, flow restrictor reduces the total volume of liquid children are able to extract from liquid medicine bottles. Here the Pharma industry sees the importance of a guidance to stall accidental consumption of the medicines.

Source: Nandita Vijay, Pharmabiz, 15.06.2020

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COVID-19 outbreak led to implementation of unattended reforms towards building a 'Self-Reliant' healthcare model

COVID-19 outbreak has led to implementation of unattended policy changes by governments at the centre as well as states that were pending for long like the Production Linked Incentive (PLI) scheme for promoting domestic manufacturing of medical devices, Active Pharmaceutical Ingredients (APIs), sanctioning 141 new medical colleges and telemedicine guidelines among others, according to Salonie Chawla, Health Policy Advocacy Specialist.

The launch of the 'Self-Reliant India' campaign has further fuelled the much needed policy interventions in healthcare towards building a 'Self-Reliant' healthcare model, she added. To ensure availability of affordable medical electronics with strong linkages with the electronic industry, the Government has announced the PLI scheme offering incentives up to Rs. 48,000 crore to enhance electronics manufacturing.

"To create public health as primary focus, such schemes could mandate investments by companies in health information technology (IT) and medical electronics. Likewise, the Government has also announced incentive schemes for domestic manufacture of APIs," Chawla further explained.

According to the Government's plan, the PLI scheme has been envisaged for promotion of API or bulk drug parks to finance common infrastructure facilities in three bulk drug parks with financial implication of Rs. 3,000 crore for next five years. PLI Scheme is for promotion of domestic manufacturing of critical KSMs/Drug Intermediates and APIs in the country with financial implications of Rs. 6,940 crore for the next eight years, according to official sources.

"Union Finance Ministry in early April also exempted import duty from ventilators, surgical masks and Personal Protection Equipment (PPE) and other necessary medical equipment for six months. In the current scenario of creating opportunity from crisis, the Government should also extend the exemption for essential equipment to help Indian patients," Chawla said. Our long-standing goal to become self-reliant can only be accomplished when we look at the current crisis as a social experiment to implement public healthcare reforms, she suggested. According to the National Health Policy, India had aimed to increase its health budget to 2.5% of GDP, but as per the National Health Profile 2019, the public health expenditure remained at 1.28% of the GDP.

Public health infrastructure is inadequate to cater to the healthcare needs of 1.35 billion population. Additionally, India has doctor-population ratio of 1:1,456 and 1.7 nurses per 1,000 population, both falling short of the WHO norms of 1:1,000 and 3:1,000 respectively, added Chawla. She explains that one of the major reasons of this shortage is the lack of primary healthcare facilities

and public hospitals in semi-urban and rural areas. As per the Economic Survey 2019, the Government in the last five years sanctioned 141 new medical colleges. This would ensure adequate number of doctors and trained health professionals. It is a different issue that the doctors and health professionals do not want to go and practice in villages – a perennial problem to which only technology like telemedicine can provide a solution.

While healthcare demand comes from all strata of the society, the supply side of health insurance is dominated by the private sector which accounts for 80% of healthcare availability in India. This has an economic implication for uneven supply of good health care.

"To be amongst the first states to be affected by COVID-19 with migrant Indians in the Middle East returning, Kerala has used its solid public healthcare and education infrastructure to control the pandemic spread ably helped by the information technology," Chawla further explained. In the current situation, the building blocks for creating a self-sufficient health system would be to place patient centric norms as focus, increase human resources in healthcare and invest heavily in primary health centers and infrastructure.

According to a study by Internet and Mobile Association of India, rural India had 227 million active internet users surpassing the urban India by 10%. "The creation of demand for internet under the Digital India programme can be leveraged by telemedicine as well, if the Government promotes the uncontested space of telemedicine service providers and endorses e-health for last mile accessibility," Chawla concluded.

Source: Shardul Nautiyal, Pharmabiz, 15.06.2020

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Gilead announces results from Phase 3 Trial of remdesivir in patients with moderate COVID-19

Gilead Sciences, Inc. (Nasdaq: GILD) announced topline results from the Phase 3 SIMPLE trial in hospitalized patients with moderate COVID-19 pneumonia. This open-label study evaluated 5-day and 10-day courses of the investigational antiviral remdesivir plus standard of care, versus standard of care alone. The study demonstrated that patients in the 5-day remdesivir treatment group were 65 percent more likely to have clinical improvement at Day 11 compared with those in the standard of care group (OR 1.65 [95% CI 1.09-2.48]; p=0.017). The odds of improvement in clinical status with the 10-day treatment course of remdesivir versus standard of care were also favorable, trending toward but not reaching statistical significance (OR 1.31 [95% CI 0.88-1.95]; p=0.18). No new safety signals were identified with remdesivir across either treatment group. Gilead plans to submit the full data for publication in a peer-reviewed journal in the coming weeks.

"Our understanding of the spectrum of SARS-CoV-2 infection severity and presentations of COVID-19 continues to evolve," said Francisco Marty, MD, an infectious diseases physician at Brigham and Women's Hospital, and Associate Professor of medicine at Harvard Medical School. "These study results offer additional encouraging data for remdesivir, showing that if we can intervene earlier in the disease process with a 5-day treatment course, we can significantly improve clinical outcomes for these patients."

Remdesivir is currently approved in Japan as a treatment for patients infected with SARS-CoV-2, the virus that causes COVID-19. Outside of Japan, remdesivir is an investigational, unapproved drug. The U.S. Food and Drug Administration (FDA) granted remdesivir an Emergency Use Authorization for the treatment of hospitalized patients with severe COVID-19; the authorization is temporary and does not take the place of the formal new drug application submission, review and approval process.

In this study, hospitalized patients with confirmed COVID-19 infection and evidence of pneumonia without reduced oxygen levels were randomized (1:1:1) to receive open-label remdesivir for 5 or 10 days or standard of care alone. The primary endpoint was the clinical status as assessed by a 7-point ordinal score at Day 11, ranging from hospital discharge to increasing levels of oxygen and ventilatory support to death. The secondary study objective was the rate of adverse events in each remdesivir treatment group compared with standard of care.

At Day 11, a higher proportion of patients in the 5-day treatment group achieved improvement in clinical status versus the standard of care group, achieving statistical significance for a ≥ 1-point improvement in ordinal scale (p=0.026). In addition, non-statistically significant increases in clinical worsening or death were observed

in the standard of care only group compared with the remdesivir groups.

"We now have three randomized, controlled clinical trials demonstrating that remdesivir improved clinical outcomes by several different measures. Today's results showed that when treating moderate disease, a 5-day course of remdesivir led to greater clinical improvement than standard of care, adding further evidence of remdesivir's benefit to previously released study results. The National Institute of Allergy and Infectious Diseases' placebo-controlled study showed that remdesivir enabled more rapid recovery and that earlier treatment improved clinical outcomes. Our SIMPLE-Severe study showed that when treating patients with severe disease, 5 days of remdesivir led to similar clinical improvements as a 10-day course," said Merdad Parsey, MD, Ph.D., Chief Medical Officer, Gilead Sciences. "The additional data we have in hand today will further guide our research efforts, including evaluating treatment earlier in the course of disease, combination studies with other therapies for the most critically ill patients, pediatric studies and the development of alternate formulations."

Remdesivir was generally well-tolerated in both the 5-day and 10-day treatment groups. The most common adverse events occurring in more than 5 percent of patients in both treatment groups were nausea (5-day: 10%/10-day: 9%/SOC: 3%), diarrhea (5-day: 5%/10-day: 5%/SOC: 7%) and headache (5-day: 5%/10-day: 5%/S).

Source: World Pharma News, 12.06.2020 (Excerpts)

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Pharma MSMEs urge DoP to evolve criteria for them in PLI scheme for incentivising API production

Small and Medium Pharma manufacturers have urged the Department of Pharmaceuticals (DoP) to evolve criteria for MSME sector in the proposed production-linked incentive (PLI) scheme aiming at incentivising Active Pharmaceutical Ingredient (API) manufacturers in the country in line with announcements made by Prime Minister Narendra Modi to strengthen MSMEs.

MSME Pharma manufacturers have expressed gratitude towards the Prime Minister for giving special focus on the MSME sector in his kind announcement recently to encourage and financially rehabilitate the sector.

The Government announced distribution of Rs 3 lakh crore Emergency Credit Line Guarantee Scheme for MSMEs as well as Rs. 20,000 crore subordinate debt for stressed MSMEs. It also announced Rs. 50,000 crore equity infusion for MSMEs, which will strengthen their growth potential and will enable them to get listed on stock exchanges.

While appreciating the Government's initiative in supporting MSMEs to tide over the crisis due to COVID-19 lockdown, Small and Medium Pharma Manufacturers' Association (SMPMA) has urged it to waive off bank guarantee of loan up to Rs. one crore for MSME units.

In order to sort out the constraints faced by MSMEs manufacturing APIs, SMPMA suggested DoP to appoint a nodal officer so as to ensure better coordination and oversee that unnecessary delays do not occur in execution of the projects such as pollutions approvals etc. To implement the PLI scheme, an empowered committee (EC) will be formed. The EC will consider applications as found eligible by the project management agency under the scheme for approval.

SMPMA Chairman Nipun Jain appealed to DoP to include Secretary, MSME in the EC. Jain also urged the department to extend incentives to all the segments of the MSME sector.

It is learned that the Government will provide Rs. 10 crore each to domestic companies setting up plants to produce 41 products covering 53 crucial APIs for which the domestic drug industry is completely dependent on imports from China. Besides, four fermentation products including penicillin G will get an annual incentive of Rs. 720 crore.

The incentive is part of a Rs. 10,000-crore PLI scheme approved by the Cabinet in March to speed up manufacturing of critical bulk drugs and APIs in India. The incentive will be given to companies investing in Greenfield plants to manufacture 53 crucial APIs of anti-TB drugs, steroids and vitamins.

Source: Laxmi Yadav, Pharmabiz, 13.06.2020

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Even pharmaceutical companies are struggling to find their way through a global health crisis

Turns out the white coats are as confused as the rest of us

A pharmaceutical company seems like a good place to go for some insight into the COVID-19 crisis, so I got in touch with Bausch Health Cos. Inc., Canada's most important drug maker.

It turns out the white coats are as confused as the rest of us. Joseph Papa, Chief Executive of Laval, Que.-based Bausch Health, spoke with me for about half an hour last week and I couldn't tell if he sees opportunity in the chaos, or if he's seriously worried. "The world will change," he said. "One hundred percent, I think it's going to change."

Look closely and you'll see that those who are surest about where we're headed tend to have the least to lose. Anyone with a fiduciary responsibility has a backup plan. Papa is marching into the second half of the year with four different budgets: his original 2020 road map and separate scenarios that assume the rebound comes at the end of the second quarter, the end of the third quarter, and not until 2021.

"We see a return to business starting in the third quarter, the July time frame," he said on June 4. "As to how far, how fast? It depends." Call that wishy-washy if you want, but that's how forecasting is done in the real economy. Only professional forecasters — and, yes, the financial press — are obsessed with assigning numbers and shapes to the recession and recovery. There are too many variables. All you can do is hope for the best while preparing for the worst.

"We have an aesthetic business," Papa said from Bridgewater, N.J., the base of Bausch Health's day-to-day operations. "We're seeing a dramatic falloff. Dental, we're seeing a dramatic falloff. But we do expect to see them come back. It's somewhat of a situational question that not everybody's going to come back at the same time, but we're tracking each of those individually to think about where we're going."

COVID-19 has killed some 410,000 people, sickened more than seven million others and pushed tens of millions into unemployment. Amidst all that grief, investors have anointed two undisputed champions: Big Tech and Big Pharma. The digital outfits that make social distancing tolerable and working from home possible, and the companies that might discover the medicines to keep more of us alive are the reason stock markets have recovered almost all their losses from February and March.

Some of Canada's flag carriers in information-technology are having a good crisis. Shares of Shopify Inc. have surged about 85 percent this year, and the Ottawa-based e-commerce company now jockeys with Royal Bank of Canada for bragging rights as the biggest company on the S&P/TSX composite index.

Bausch Health, formerly Valeant Pharmaceuticals International Inc., the disgraced firm that was once the country's most valuable publicly traded company, has so far missed the wave that has carried other health-care companies higher over the past couple of months — its shares are down about 40 percent from the start of the year. Otherwise, Papa has been holding his own against his peers by boosting revenue, narrowing losses and paying off the mountain of debt he inherited when he took over in 2016.

The company has baggage, but anyone who still wishes it ill because of previous managers' sins should probably get over it. Health care is a growth industry, and one that generates an outsized share of valuable intellectual property. The world's strongest economies all are players in the pharmaceutical game.

Canada's entry is Bausch Health, a global player with enough size to support a local ecosystem of researchers and smaller firms. The company relocated production of one its most profitable drugs to its factory in Steinbach, Man., and the Canadian market is generally among the first to receive new medications. On June 12, Bausch Health announced that Health Canada had approved Duobrii, a prescription lotion that treats an inflammatory skin condition called plaque psoriasis.

"We're doing a lot of things to try to expand our footprint in Canada and I expect that will continue," Papa said.

Bausch Health is also part of the chase to discover ways to treat COVID-19, though not a vaccine, the holy grail because broad immunity is the clearest path back to normal. But Papa, once a pharmacist, has an opinion about how long it's going to take to make that discovery. "You want to make sure it's a very clean vaccine," he said. "It's going to be at least another year before we find out if we have one. I hope it's faster, to be clear, but I think it's going to take at least another year. *We're doing a lot of things to try to expand our footprint in Canada and I expect that will continue.*

While some of his counterparts seek a vaccine, Papa thinks one of Bausch Health's existing drugs, Virazole, which hospitals use to treat respiratory infections in infants and children, might be able to help adults suffering from COVID-19.

Last month, Bausch Health received approval from Health Canada to start a trial, and Papa said he hoped to have results in six months. "As we looked through our portfolio, we said we know there are places where we can help," he said. "Virazole is a very good anti-viral product. It has been used for respiratory problems, so we said may be it's a chance for us to see if we can help ease COVID-19."

It's counter-intuitive, but the global push to find ways to treat COVID-19 actually complicates matters because local populations can only absorb so many clinical trials at once. Companies find a way, but the phenomenon is just another reason why even a pharmaceutical company is struggling to find its way through a global health crisis.

"We're into a new COVID normal," Papa said. "It's going to take some time for all of us to adapt. What we've tried to do is be as flexible as possible, realizing that we are going to have to deal with this virus."

Source: Kevin Carmichael, Financial Post, 12.06.2020

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The most common use of AI in pharmaceuticals is in drug discovery: Gyan Pandey, Global & Group CIO, Aurobindo Pharma

How do you see Covid- 19 impacting the pharma industry and the challenges therein?

The Pharma industry is bound by many factors like transparency, quality, safety, efficiency and of course regulatory. Complex processes and stringent requirements are a way of life for the pharma sector. When we all are facing a crisis of mammoth proportions, our responsibility to make sure that the required medicines reach the end consumer in the right condition and at the right time. Digital technologies are enabling us to adapt to the highly dynamic and volatile times of today. Technologies like IoT, AI, blockchain, RFID, etc are helping us to have an end to end visibility of the whole process and thus, making sure that the highest quality product reaches the customer.

Do you think AI can play a lead role in resolving the problems faced by the industry?

AI and connected devices are driving success stories from the pharma sector. Like any other sector, AI and its subsets like automation, ML are changing the face of the pharma sector. Using AI does not mean replacing human but to provide additional support. The most common use of AI in pharmaceuticals is in drug discovery, where AI is mobilised to scan through all available data on a particular molecule for a drug. Other than the application of AI in pharma offers advantages such enhanced parameters of growth. It customizes sales and marketing messaging for greater customer engagement and automation of sales and marketing messages across channels. AI embedded Software-as-a-Service applications help utilise AI to automate the pharmaceutical supply chain management.

How can the adoption of other technologies in the pharma industry help to mitigate the other challenges?

The pharma industry has been a little reluctant in adopting the new technology and mostly been focussed on using technology in R&D and production. However, lately, trends have been pointing towards offering comprehensive services to consumers. The online consultations, telemedicine, devices and wearables, home testing kits all are merging digital technology and medical sciences. With the advent of wearables, the pharma companies have an opportunity to turn this massive real-time data into a treasure trove of data-driven decisions in terms of marketing, R&D etc. Technologies like blockchain help the sector in keeping the data safe and secure, while making sure that no counterfeit drug reaches the market. Other technologies like AR, VR has the potential to change the face of the pharma sector. With the continuous evolvement in the pharma industry, pharmaceutical enterprises are required to offer the top-notch range of medical products and services to stay on the top. And given the current trends, the ability to do that not only comes from medical expertise but also technical expertise. So, it's time for pharmaceutical players to keep an eye on the trends and start collaborating with technology partners that can ultimately help them conceptualize and create a completely new set of products, services, and processes.

How the supply chain has been disrupted due to Covid-19 and the steps taken to overcome them?

Digitisation has a great impact on the pharma towards complete transformation. As an industry, we deal with sensitive information that is required to comply with several regulations. The law impacts the participants of the entire supply chain which includes the manufacturers, repackagers, wholesale distributors, and retailers. Adoption of technology seems more of a necessity to obtain greater transparency throughout the supply chain as these supply chains are complex in nature. Oracle ERP solutions have proven to boost business processes resulting in improved communication with advanced features. Our supply chain is highly dependent on the changing regulatory requirements which makes it highly challenging to put complete trust in technology, avoiding any barge in the overall mechanism.

We integrated our ERP, Oracle Transport Management on cloud and Logistics Service providers systems, and have been able to address most of the operational challenges successfully. We have brought operational excellence, cost optimization that too with a lean team. We have automated around 80% manual process related to export operations which have helped us in reducing the FTEs by 30%. Going forward, as part of OTM Phase II, we plan to include our import-related logistic process as well on the Oracle Transport Management cloud. This will include financial controls related to Imports and Domestic transactions –- 100% financial transaction control and visibility. The pharma industry is a bit too conservative to make bold choices like adopting the technology. Best way to overcome the bespoken obstacles one should choose swift modes of adaptation giving out a material impact on the businesses.

What are the lessons you have learned from covid 19?

How will you be implementing them in the new normal? We divided all the activities into two buckets – activities affected by regulations and activities that are not affected by regulations. The activities in the finance, HR, Admin, etc. Here, it is comparatively easier to implement technology and manage changes. The other set of activities, which fall under regulatory, includes operational technology. Here the decisions are owned by Operations, Regulatory, QC, and QA teams. These people will do a comprehensive study of the solution, successful PoC (Proof of Concept) – a bit more difficult than the other category.

All and said, the digitalization is an evolving journey. One needs to start slow but have a bigger vision. Already matured processes will be easier to digitalize. However, above all, you need to have a plan on how you will manage the change and adoption of digital, in accordance with your organizational culture. The significant benefits that we have seen are - Efficiency and Transparency of the processes, Quick decision making, analytics to bring the business insight across the process, cost optimization, and higher level of collaboration and hence better compliance and a single source of truth.

Source: Shahid Akhter, ETHealthworld, 12.06.2020

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