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RNI REGN. NO. 18921/1970
REGN NO. MCW/95/2018-20

IDMA BULLETIN

VOL. NO. 51 | ISSUE NO. 26 (PAGES: 44) | 08 TO 14 JULY 2020 | ISSN 0970-6054 | WEEKLY PUBLICATION

Indian APIs & Formulations for Global Healthcare

INDIAN DRUG MANUFACTURERS' ASSOCIATION

HIGHLIGHTS

A Publication of
Indian Drug Manufacturers' Association
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Published on 7th, 14th, 21st and 30th of every month

Annual Subscription
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₹ 4000/- *(for non-members)* **US$ 400** *(Overseas)*
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Indian Drug Manufacturers' Association

IDMA BULLETIN

Vol. No. 51 **Issue No. 26** **08 to 14 July 2020**

IDMA Representation to CBIC seeking clarification on GST rate for Alcohol Based Hand Sanitisers manufactured under license - reg.

The Association has made the following representation on 8th July 2020 to Shri M Ajit Kumar, IRS, Chairman, Central Board of Indirect Taxes and Customs, Ministry of Finance with copies to Dr Ajay Bhushan Pandey, IAS, Revenue Secretary & Ex-Officio Secretary to the GST Council, Ministry of Finance and Dr V G Somani, Drugs Controller General (India), CDSCO, New Delhi on Classification of Alcohol Based Hand Rubs (ABHR) - GST liability on Hand Sanitizer to be under Drug Category HSN Code 3004:

"Greetings from Indian Drug Manufacturers' Association.

The Drugs Controller General of India had issued an urgent Public Notice on 17 March 2020 directing all State Drug Controllers "...to expedite the licensing process for manufacture of hand sanitisers by taking proactive measures to meet the present challenges of increased demand...." *(copy enclosed)*.*

The Indian Pharma industry rose to the occasion and to address the sudden spurt in demand for hygiene products due to COVID-19 pandemic, many Members of our Association took up manufacturing and marketing of hand sanitizers containing Ethanol or Isopropyl alcohol as an active ingredient, after obtaining licenses from the State FDAs.

In the pharmaceutical industry, manufacturers and marketers of hand sanitizers are facing some regulatory challenges like requirement of drug license for manufacture, stock and sale, Price Control and regulatory uncertainties about applicability of GST rate of 18% or 12% as applicable on almost all pharmaceutical products.

In this regard, we wish to highlight the following points:

1. The DCG(I) in his directive referred above has clearly stated that "As you are aware that the hand sanitisers are licensed under Drugs and Cosmetics Rules 1945. The standards of such products shall be as prescribed in the Second Schedule of Drugs & Cosmetics Act, 1940 and Rules thereunder".
2. Hand sanitizers manufactured by Pharma Manufacturers are hence drugs which are used to sanitize hands on regular basis, similar to other external pharmaceutical applications, such as ointments, rubs etc.
3. Hand sanitizers manufactured by Pharma manufacturing facilities are to be treated like any other medicine in GMP environment after getting license from **concerned drug department in Form 25.**
4. Pharma grade ABHRs contain pharmaceutical ingredients that have prophylactic properties.
5. It is claimed on the label that the ABHR 'kills' germs, as it would mean that the product is not for cosmetic application but for medicinal application as the product contains preventive ingredients.
6. The Drugs and Cosmetics Act, 1940 and Rules, 1945 mandates that every drug stocked or sold in India must be sold under a license unless the drug, or the person stocking or selling the drug, is exempt by law from this requirement.
7. There is no such exemption for ABHRs. Therefore, the entire supply chain, including retailers of ABHRs, are required to sell them under a stock and sale license under the provisions of Drugs and Cosmetics Act and Rules. Even the courts in India are yet to specifically opine on exemption of ABHRs in general from the requirement of stock and sale license.
8. Hand sanitizers manufactured by Pharma industry are invariably as per the **formulations recommended by WHO.**

FORMULATION 1 – Final concentrations	FORMULATION 2 – Final concentrations
Ethanol 80% (v/v),	Isopropyl alcohol 75% (v/v),
Glycerol 1.45% (v/v),	Glycerol 1.45% (v/v),
Hydrogen peroxide 0.125% (v/v)	Hydrogen peroxide 0.125% (v/v)

9. Accordingly, manufacturers and marketers in the Indian Pharmaceutical Industry are using HSN code 3004 with tariff of 12%.

We are informed that the Government has opined that such manufacturers are wrongly classifying the said

item under tariff heading 3004 whereas the said item is liable to be classified under tariff heading 3808 having 18% GST Rate. The opinion is based on classification opinion of World Customs Organisation wherein WCO has inferred that Alcohol based Hand Sanitizers are correctly classifiable under heading 3808 of HSN (Precisely under sub-heading 3808.94).

For the sake of reference, the HS Reference heading of 3004 and 3808 in the "Rate of GST on Goods" provided by CBIC are reproduced as under:

3004: Medicaments (excluding goods of heading 3002, 3005 or 3006) consisting of mixed or unmixed products for therapeutic or prophylactic uses, put up in measured doses (including those in the form of transdermal administration) or in forms or packings for retail sale including Ayurvedic, Unani, Homeopathic Siddha or Bio-chemic systems medicaments, put up for retail sale

Chapter 30 deals only with Pharmaceutical products. Hence, all Pharma Manufacturers are manufacturing the Hand sanitizers under HSN Code 3004 with GST tariff of 12%.

For example, Dettol which is for external use is also marketed under HSN code 3004 @12% GST.

3808: "Insecticides, rodenticides, fungicides, herbicides, anti-sprouting products and plant-growth regulators, disinfectants and similar products, put up in forms or packings for retail sale or as preparations or Articles.

It is not fair to club medicaments such as human Hand sanitizers manufactured by Pharma industry as drug with valid drug license **in Form 25** as PESTICIDE

Jurisprudence:

- In the case of Marico Industries Ltd - **Medicinal Purpose Vs Cleansing Purpose**, the Hon'ble Supreme Court held that Mediker used for anti-lice treatment is drug because of its medicinal effect. Once it is drug, it cannot be shampoo.
- In the case of Johnson Prickly Powder, in Muller & Philips (India) Ltd – **Medicinal Purpose Vs General Purpose**, the powder was held to be a medicament because it was not an ordinary talcum powder but a powder to be used to get rid of the problem of prickly heat.
- In the case **IPCA Health products (P) Ltd – Prophylactic use Vs General Use,** The Hon'ble Supreme Court has held that products hexiprep, hexiscrup and hexiaque used for cleaning of wounds and abrasions and minor cuts and disinfecting the skin prior to surgery are classifiable under CET sub-heading 3003.10 and not under chapter heading 38.08 since these products have therapeutic properties and prophylactic use.
- In the case **Sarvotham Care Ltd – Limited Use Vs Regular Use,** The Hon'ble Supreme Court in this case held that suggestion that shampoo should be used once a week and on other days, normal shampoos may be used, showed it was to be used like medicine, unlike other normal Shampoos. It was more so as it was not used for cleaning hair. Hence, shampoo was classifiable as medicine under sub-heading 3003.10 of Central Excise Tariff and not under sub-heading 3305.99 ibid as 'preparation for use on hair'.
- In the case **Colfax Laboratories Ltd – Intention of Use for Prevention of Disease,** The Hon'ble Supreme Court in this case held that intended use of an article must be for treatment, mitigation or prevention of disease to come within definition of 'medicinal preparations' under Section 2(g) of Drugs and Cosmetics Act, 1940.
- In the case **Ciens Laboratories – Importance of Pharmaceutical Ingredients,** The Hon'ble Supreme Court held that the following guiding principles emerge from the discussion; when a product contains **pharmaceutical ingredients** that have therapeutic or prophylactic or curative properties, the proportion of such ingredients is not invariably decisive. What is of importance is the **curative attributes of such ingredients** that render the product a medicament and not a cosmetic though a product is sold without a prescription of a Medical Practitioner, it does not lead to the immediate conclusion that all products that are sold over/ across the counter are cosmetics. There are several products that are sold over-the-counter and are yet, medicaments.

Summary:

From the above settled legal principles, it may be summarized that while classifying the pharmaceutical products following factors are to be considered;

- Curative effect of the product (therapeutic use).
- Preventive effect of the product (prophylactic use).
- Product contains curative/preventive ingredients even in small quantities.
- License to manufacture, store and sell by FDA **in Form 25.**

Considering different practices with different impressions, it is therefore submitted that there is an urgent need for the Central Board of Indirect Taxes and Customs to examine the matter and issue a clarification as regards the applicability of HSN 3004 or 3808.

Since the matter is of considerable significance and has implication on the mis-classification of product manufactured by vast section of the industry, it is earnestly requested that the clarification may kindly be issued as early as possible. This would put an end to the prevailing confusion and uncertainty, reduce litigation and ensure uniformity of compliance.

We request your urgent indulgence and appropriate clarification in this matter".

*(*Not reproduced here)*

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"Pandemic has shown Indian Pharma Asset for World": PM at Global Event

Prime Minister Narendra Modi delivered the inaugural address at the India Global Week 2020

Prime Minister Narendra Modi today delivered the inaugural address at the India Global Week 2020.

Prime Minister Narendra Modi invited the world to invest in India, saying the economy here is already "putting up green shoots of recovery". Addressing the inaugural event at the India Global Week 2020 -- pitched as one of the biggest international events on India's globalization -- the Prime Minister said, "We are rolling out a red carpet for all global companies to come and establish their presence in India. Very few countries will offer the kind of opportunities India does today".

The three-day virtual event -- themed "Be The Revival: India and a Better New World" --- is expected to discuss ways to boost the world economy, which sustained a huge hit following the lockdown induced by the Coronavirus pandemic. Earlier this week, the World Bank had predicted that the global economy will shrink by 5.2 percent this year -- the steepest downturn since the Great Depression of the 1930s. India's growth rate for 2020 will be 1.9 percent, the International Monetary Fund said in April.

Inviting the 5,000-plus delegates of the event to invest in India anywhere from agriculture sector to defence and space industry, he said, "Indians have the spirit to achieve what is believed to be impossible... India is ready to do whatever it can to further global good and prosperity. This is an India that is reforming, performing and transforming". Over the last six years, PM Modi said, India has made great gains in areas such as "total financial inclusion, record housing and infra construction, ease of doing business, bold tax reforms including the Goods and Services Tax".

Reforms have been made in the sector of Micro, Small and Medium Enterprises, which will complement big industry, the Prime Minister said, highlighting the recent loan initiative to boost the flagging MSME sector, which has been hit hard by the lockdown. "There are investment opportunities in the defence sector... Now, there are more opportunities for private investment in space sector. This will mean greater access to commercial use of space technology for the benefit of people," he said.

"The pandemic has once again shown that India's Pharma industry is an asset not just for India but for the entire world. It has played a leading role in reducing the cost of medicines especially for developing countries," the Prime Minister said, drawing attention to the Pharma industry, which has come under limelight following the Coronavirus outbreak.

Around 250 speakers will address the virtual meet on geopolitics, business, technology, banking and finance, Pharma, defence and security, and arts and culture. PM's cabinet colleagues Foreign Minister S Jaishankar and Commerce and Industry Minister Piyush Goyal are also expected to speak at the meet.

Speakers from abroad will include UK's Foreign Secretary Dominic Raab and Home Secretary Priti Patel, US Ambassador to India Ken Juster and others, the Prime Minister's Office said in a statement.

In a display of the country's soft power, three of the most eminent students of Pandit Ravi Shankar will pay a tribute to the sitar maestro on his 100th birth anniversary. There will also be a special performance -- "*Atmanirbhar Bharat*" by Madhu Nataraj, the PM's Office said. Isha Foundation Founder Sadhguru and spiritual leader Sri Sri Ravi Shankar are also expected to address the meet.

Source: Anindita Sanyal, ndtv.com, 09.07.2020

Clarification on CSR contribution to PM CARES Fund - reg.

Corporate Affairs Circular No.25/2020, dated 25th June, 2020

To,
All Stakeholders;

1. In view of the amendment in Schedule VII of the Companies Act, 2013 vide Gazette Notification No. G.S.R.313(E) dated 26th May, 2020, deemed to have come into force on 28th March 2020, the Office Memorandum No.CSR-05/1/2020-CSR-MCA dated 28.03.2020 is redundant and hence stands superseded.

2. This issues with the approval of competent authority.

F.No.13/18/2019-CSR

Shobhit Srivastava, Deputy Director, Ministry of Corporate Affairs, Government of India, New Delhi.

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CBIC extends anti-dumping duty on import of Phenol originating in or exported from South Africa upto and inclusive of 9th January, 2021 - reg.

Notification No.18/2020-Customs (ADD) dated 9th July, 2020

Whereas, the designated authority *vide* initiation notification No.7/25/2019-DGTR dated the 27th December, 2019, published in the Gazette of India, Extraordinary, Part I, Section 1, dated the 27th December, 2019, has initiated review in terms of sub-section (5) of section 9A of the Customs Tariff Act, 1975 (51 of 1975) (hereinafter referred to as the Customs Tariff Act) and in pursuance of rule 23 of the Customs Tariff (Identification, Assessment and Collection of Anti-dumping Duty on Dumped Articles and for Determination of Injury) Rules, 1995 (hereinafter referred to as the said rules), in the matter of continuation of anti-dumping duty on imports of **'Phenol'**originating in or exported from **South Africa**, imposed *vide*notification of the Government of India, in the Ministry of Finance (Department of Revenue) No.32/2015-Customs (ADD) dated the 10th July, 2015, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), *vide* number G.S.R.552(E) dated the 10th July, 2015, and has requested for extension of the said anti-dumping duty for a period of six months in terms of sub-section (5) of section 9A of the Customs Tariff Act.

Now, therefore, in exercise of the powers conferred by sub-sections (1) and (5) of section 9A of the Customs Tariff Act, read with rules 18 and 23 of the said rules, the Central Government hereby makes the following amendment in the notification of the Government of India, in the Ministry of Finance (Department of Revenue), No.32/2015-Customs (ADD) dated the 10th July, 2015, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), *vide* number G.S.R.552(E) dated the 10th July, 2015, namely-

In the said notification, after paragraph 2 and before the Explanation, the following paragraph shall be inserted, namely:

"3. Notwithstanding anything contained in paragraph 2, the anti-dumping duty imposed under this notification shall remain in force up to and inclusive of the 9th January, 2021, unless revoked, superseded or amended earlier.".

F.No.354/124/2002-TRU (Pt-V)

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

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CBIC increases rate of duty of customs on imports of Phthalic Anhydride originating in Korea RP and imported under the India-Korea Comprehensive Economic Partnership Agreement - reg.

Customs Notification No.29/2020, dated 6th July, 2020

Whereas in the matter concerning imports of **"Phthalic Anhydride"** (hereinafter referred to as the subject goods) falling under tariff item 2917 35 00 of the First Schedule to the Customs Tariff Act, 1975 (51 of 1975) (hereinafter referred to as the Customs Tariff Act), the Director General of Trade Remedies (hereinafter referred to as the Authority) initiated an investigation in terms of the India-Korea Comprehensive Economic Partnership Agreement (Bilateral Safeguard Measures) Rules, 2017 (hereinafter referred to as the said rules) *vide* initiation notification under F.No.22/8/2019-DGTR, dated the 1st October, 2019 published in the Gazette of India, Extraordinary dated the 1st October, 2019 in order to determine whether the imports of the subject goods from Korea RP constitute increased imports and whether the increased imports have caused or are threatening to cause serious injury to the domestic industry.

And whereas, in the preliminary findings of the Bilateral Safeguard investigation issued *vide* F.No.22/8/2019-DGTR, dated the 11th May, 2020, published in the Gazette of India, Extraordinary dated the 11th May, 2020, the Authority has provisionally concluded that:

(i) the domestic industry has suffered serious injury as a result of duty concessions granted to Korean imports leading to increased imports of the subject goods from Korea at low prices;

(ii) the domestic industry is faced with continued threat of serious injury from imports from Korea;

(iii) that injury to the domestic industry has been caused by the increased imports and there is a causal link between increased imports of subject goods from Korea and serious injury and threat of serious injury to the domestic industry as a result of duty concessions granted to Korean imports;

(iv) the factors present constitute critical circumstances and are affecting the overall performance of the domestic industry, justifying imposition of provisional bilateral safeguard measure, and has recommended imposition of the provisional bilateral safeguard measure of increasing the rate of customs duty on subject goods originating in Korea RP imported under the Comprehensive Economic Partnership Agreement between the Republic of India and the Republic of Korea (hereinafter referred to as the Trade Agreement), to the level of Most Favoured Nation duty on the subject goods as on the date of application of the bilateral safeguard measure or Most Favoured Nation duty on the subject goods on the day immediately preceding the date of entry into force of the Trade Agreement, whichever is less, for a period of 200 days.

Now, therefore, in exercise of the powers conferred by sub-section (1) of section 25 of the Customs Act, 1962 (52 of 1962) read with rule 9 of the said rules, the Central Government, on being satisfied that it is necessary in the public interest so to do, hereby makes the following further amendments in the notification of the Government of India in the Ministry of Finance (Department of Revenue), No.152/2009-Customs, dated the 31st December, 2009, published in the Gazette of India, *vide* number G.S.R.943(E), dated the 31st December, 2009, namely

In the said notification;

(i) in the Table, for serial number 230 and the entries relating thereto, the following serial number and entries shall be substituted, namely:

(1)	(2)	(3)	(4)
"230.	2917 33 to 2917 34	All goods	0.00";

(ii) in the Table, after serial number 230 and the entries relating thereto, the following serial numbers and entries shall be inserted, namely:

(1)	(2)	(3)	(4)
"230A.	2917 35 00	All goods	0.00
230B.	2917 35 00	All goods	7.50";

(iii) after the Table, the following shall be inserted, namely:

"Provided that, to give effect to the provisional bilateral safeguard measure, as recommended by the Director General of Trade Remedies,-

(a) nothing contained in serial number 230A and entries relating thereto in the said Table shall have effect up to and inclusive of the 21st day of January 2021, and

(b) the entries contained in serial number 230B in the said Table shall have effect up to and inclusive of the 21st day of January 2021; unless revoked, superseded or amended earlier.".

F.No.354/51/2020-TRU

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

Note: *The Principal Notification No.152/2009-Customs, dated the 31st December, 2009 was published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-Section (i) vide number G.S.R.943(E), dated the 31st December, 2009 and was last amended vide Notification No.36/2019-Customs, dated the 30th December, 2019, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-Section (i), vide number G.S.R.964(E), dated the 30th December, 2019.*

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Extension of last date of re-import by three months, where the last date of re-import falls between 01.02.2020 and 31.07.2020 due to the outbreak of COVID-19 pandemic - reg.

Customs Notification No.30/2020, dated 10th July, 2020

1. In exercise of the powers conferred by sub-section (1) of section 25 of the Customs Act, 1962 (52 of 1962), the Central Government, on being satisfied that it is necessary in the public interest so to do, hereby makes the following further amendments in the notification of the Government of India in the Ministry of Finance (Department of Revenue) No.9/2012-Customs, dated the 9th March, 2012, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), vide number G.S.R.129(E), dated the 9th March, 2012, namely:

2. In the said notification, in condition no. (iii), the following proviso shall be inserted, namely:

"Provided that for the cases where the last date of re-import falls between the 1st February, 2020 and the 31st July, 2020, the last date stands extended by three months;".

F.No.DGEP/EOU/08/2020

Gopal Krishna Jha, Director, Drawback, Central Board of Indirect Taxes and Customs, Department of Revenue, Ministry of Finance, New Delhi.

Note. *The Principal Notification No.09/2012–Customs, dated the 9th March, 2012 was published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), vide G.S.R.129(E), dated the 9th March, 2012 and was last amended by notification No.60/2017-Customs, dated the 30th June, 2017, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), vide G.S.R.738(E), dated the 30th June, 2017.*

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Turant Customs – Turant Suvidha Kendra and Other Initiatives for Contactless Customs - reg.

Customs Circular No.32/2020, dated 6th July, 2020

To,
All Principal Chief Commissioners/Chief Commissioners of Customs/Customs (Preventive),
All Principal Chief Commissioners/Chief Commissioners of Customs & Central tax,
All Principal Commissioners/Commissioners of Customs/ Customs (Preventive),
All Principal Commissioners/Commissioners of Customs & Central tax,

1. Under its flagship 'Turant Customs' programme aimed at providing a 'Faceless, Contactless and Paperless' Customs administration, Board has recently introduced a number of initiatives that leverage technology in order

to enhance the efficiency in the Customs clearance processes thereby leading to speedy clearances, transparency in decision making, ease of doing business and very importantly, reduce physical contact in the prevailing pandemic situation. These initiatives include, amongst others, automated clearances of Bills of Entry, digitisation of Customs documents, paperless clearance, Faceless Assessment and establishment of Turant Suvidha Kendra at Bengaluru and Chennai vide Circulars No.05/2020-Customs, dated 27.01.2020, No.19/2020-Customs, dated 13.04.2020 and No.28/2020-Customs, dated 05.06.2020 respectively.

2. Continuing with the aforementioned initiatives and with a view to further prepare the ground for applying the reforms pan-India, Board has now decided to take certain measures, which are detailed below.

3. Turant Suvidha Kendra in All Customs Formations:

3.1 Circular No.28/2020-Customs, dated 05.06.2020 provided for setting up Turant Suvidha Kendras (TSK) for the purpose of implementation of 1st Phase of Faceless Assessment at Bengaluru and Chennai and Instruction No.09/2020-Customs, dated 05.06.2020, details the roles and functions of TSKs. Considering the benefits ushered in by providing single point interface, Board has decided to extend TSKs to all the Customs formations for carrying out the functions mentioned in para 5 of the said Circular. The Principal Chief Commissioners of Customs/Chief Commissioners of Customs are advised to set up the TSKs in all Customs stations by **15.07.2020**. This step is being taken in advance of the pan-India rollout Faceless Assessment, which would be done in phases to be announced soon. To reiterate, the broad scheme of the TSK would be as follows:

(i) The document verification by Customs officers at Assessment and Customs Compliance Verification (CCV) stages would normally be based on the documents uploaded in the e-Sanchit, not requiring physical submission of documents. However, if in any exceptional situation the physical submission of documents is required by Customs, for defacement or validation, such submission would be made only at the TSKs.

(ii) Documents requiring verification during examination for validation with goods would continue to be done during examination, as at present.

(iii) One or more TSKs may be set up for the convenience of the trade.

(iv) Suitable procedures are to be devised for handling & safe keeping of the documents produced at TSKs. Ideally these documents should also be kept in electronic form.

3.2 The Principal Chief Commissioners of Customs/ Chief Commissioners of Customs are advised to give wide publicity regarding the place, timings and contact details of the TSKs.

4. At the behest of Board, DG Systems, CBIC has enabled w.e.f. today i.e., **06.07.2020** certain functionalities in ICEGATE which would reduce the need for physical interaction between Customs and trade and also speed up the Customs clearance process. These new functionalities are explained below.

4.1. Registration of Authorised Dealer Code, Bank Accounts through ICEGATE:

4.1.1. Exporters are presently required to register their Authorised Dealer (AD) Code and Bank Account(s) for purposes of remittances and availing export benefits respectively at every Customs station. Even though it is an one-time procedure, it requires physical interaction between the Customs and the trade and submission of physical documents by the latter. Being a manual process, it causes delays impacting exports besides requiring the exporters or their representatives to personally visit the Customs Houses. Same is the case for the process of updation of Bank Account details. On review, this procedure has been done away with.

4.1.2. The Directorate General of Systems, CBIC has now enabled a functionality within ICEGATE login which allows the exporters to make an online request for registration/modification of their AD Code/Bank Account(s) and also electronically submit the Passbook copy or Bank Authorisation letter through e-Sanchit. The exporters would also have access to a Dashboard to view the status of approval and acceptance at PFMS, for quick rectification at their end. The detailed step-by-step guide is available on the ICEGATE portal at **https://www.icegate.gov.in/Download/Bank_Account_Management_Advisory.pdf.**

4.1.3. The Principal Commissioner/Commissioner of Customs is advised to ensure that the concerned Customs officer completes the approval process for registration/ updation of the Authorised Dealer (AD) Code and Bank

Account(s) details in ICES within the same working day of receiving the applications, if all requirements are submitted in ICEGATE. Further, if any deficiencies are noticed, the same shall be communicated to the exporter via the Customs Automated system, who would then make required rectification through ICEGATE portal.

4.2. Automated debit of bond after Assessment:

4.2.1. Presently, importers or their representatives are required to physically visit Customs House for physical debit of Bonds after the Bill of Entry is returned (to the importer) for the payment of duty. On review, it has been decided to do away with this requirement. Instead, ICES would automatically debit the Bond and reflect the same in the first copy of the Bill of Entry, provided the details of the Bond are provided during submission of the Bill of Entry. As has been re-iterated earlier, trade is encouraged to use a continuity bond to avoid procedures related to repeat submission of Bonds.

4.3. Simplified Registration of Importers/ Exporters in ICEGATE:

Although simplified Registration module for importers/exporters based on verification provided in associated GSTIN has been provided without the requirement of digital signature, since many importers/exporters have not availed the same, various functionalities available in the ICEGATE portal cannot be accessed by them. These functionalities are useful to the importers/exporters and would help them in their management of imports and exports. Some of these functionalities are Management of Bank Accounts, Ledger View, IGST Refund status, Query Reply etc. Therefore, importers/exporters are advised to register on ICEGATE and conduct their Customs clearances through electronic interface. The simplified registration on ICEGATE can be done easily in few moments by following the steps given in the link at **https://www.icegate.gov.in/Download/Advisory_for_Simplified_%20Registration_at_ICEGATE_v1.pdf.**

5. The aforementioned initiatives are expected to enhance trade facilitation as well as improve the efficiency of the Customs processes. Therefore, the trade is advised to make full use of the new initiatives and make their Customs clearance process a pleasant experience. Any difficulties, in this regard, may please be brought to notice of Board.

F.No.450/78/2020

Eric C Lallawmpuia, OSD (Customs IV), Central Board of Indirect Taxes & Customs, Department of Revenue, Ministry of Finance, New Delhi.

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DGFT extends Temporary changes in the Trade Remedy investigation processes due to COVID-19 Pandemic – reg.

DGFT Trade Notice No.03/2020, dated 9th July 2020

Reference is invited to Trade Notice No.01/2020 dated 10th April, 2020 (*reproduced below*) on the above subject. Since the restrictions imposed by different countries, including India, to tackle the COVID-19 pandemic continue, the validity of the aforesaid Trade Notice is hereby extended till **30th September, 2020 or until further orders whichever is earlier.**

Bidyut Behari Swain, Special Secretary and Director General, Directorate General of Trade Remedies, Department of Commerce, Ministry of Commerce and Industry, New Delhi.

Temporary changes in the Trade Remedy investigation processes due to COVID-19 pandemic – reg.

DGFT Trade Notice No.01/2020, dated 10th April 2020

1. The worldwide outbreak of COVID-19 and consequent restrictions imposed by different countries, including India, to tackle this pandemic, are having an adverse impact on the conduct of trade remedy investigations by DGTR. It has, therefore. become essential to make certain temporary changes in the investigation process to facilitate the interested parties to apply for and participate in the investigations as well as enable the officers of the DGTR to conduct the investigations.

2. The following procedural modifications are, therefore. prescribed for the trade remedy Investigations as a temporary measure:

New Investigations:

Filing of Applications:

a) There shall be no necessity of filing of a hard copy (i.e. paper copy) of the application or any supporting document.

b) The applications may be signed, scanned and emailed with supporting documents to the email address **ad11-dgtr@gov.i**n. It should be ensured that the narrative part of the application/document is in searchable PDF/MS Word format and data files are in MS Excel format.

Ongoing Investigations:

Filing of Submissions/Documents:

c) Interested parties should file questionnaire responses, submissions and any other communication (both Confidential and Non-Confidential versions) by e-mail to the concerned team handling the investigation. It should be ensured that the narrative part of the submission/document is in searchable PDF/MS Word format and data files are in MS Excel format.

Oral hearings/Consultations:

d) Oral hearings/consultations shall be held through video conferencing. The relevant details shall be communicated to the interested parties in the notice of the hearing/consultation.

e) Written submissions and rejoinders should be emailed to the concerned investigation team/other interested parties. It should be ensured that the narrative part of the submission/document is in searchable PDF/MS Word format and data files are in MS Excel format.

Verification of information:

f) Since it would not be possible for the investigating teams to undertake on-site visit(s) to verify the information provided by interested parties, all parties should ensure provision of all supporting data/ information in respect of the submissions made. In order to facilitate verification of data, interested parties should also furnish supplementary information, like back up documents in the form of (i) accounting and management records (ii) all worksheets (usually MS/Excel files and/or other extractions from the company's databases) used for preparing data for the application/questionnaire response (iii) explanation on how the worksheets were compiled and how to

reconcile the figures and data in the worksheets with the figures and data submitted in the application/ questionnaire response.

Miscellaneous:

g) The Designated Authority may waive any other prescribed procedural requirement as may be deemed fit in the current circumstances.

3. This Trade Notice shall come into effect from the date of issue and shall be valid till 30th June 2020 or till further orders, whichever is earlier.

Bhupinder S Bhalla, Additional Secretary & Designated Authority, Directorate General of Trade Remedies, Department of Commerce, Ministry of Commerce & Industry, New Delhi.

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NPPA MATTERS

NPPA revises CP of Budesonide Inhaler - reg.

NPPA Notification No.S.O.2292(E), dated 10th July 2020

In implementation of directions given in line with review orders issued by the Department of Pharmaceuticals (DoP) vide order(s) specified in column (6) of the table herein below passed by the Department of Pharmaceuticals under para 31 of Drugs (Prices Control) Order, 2013 and in exercise of the powers conferred by paragraphs 4, 6, 10, 11, 14, 16, 17 and 18 of the Drugs (Prices Control) Order, 2013, read with S.O. 1394(E) dated the 30th May, 2013 and S.O. 701(E) dated 10th March, 2016 issued by the Government of India in the Ministry of Chemicals and Fertilizers, and in supersession of the Order(s) of the Government of India in the Ministry of Chemicals and Fertilizers (National Pharmaceutical Pricing Authority) specified in the Column (7) of the table regarding formulation specified as mentioned in the table in so far as it relates to formulation pack mentioned in the table below, except in respect of things done or omitted to be done before such supersession, the National Pharmaceutical Pricing Authority, hereby fixes/revises the price as specified in column (5) of the table herein below as ceiling price, exclusive of goods and services tax applicable, if any, in respect of the Scheduled formulation(s) specified in the corresponding entry in column (2) of the said Table with the dosage form & strength and unit specified respectively in the corresponding entries in columns (3) and (4) thereof:

TABLE

Sr. No.	Name of the Scheduled Formulation	Dosage form & Strength	Unit	Ceiling Price (Rs.)	Review Order number and date	Existing SO number and date
1.	Budesonide	Inhalation (MDI) 200mcg/ dose	Per Metered Dose	1.76	31015/5/2019-Pricing dated 01.05.2020	1213(E) dated 25.03.2019 (at Sl. No. 119)

Note:

(a) All manufacturers of scheduled formulations, selling the branded or generic or both the versions of scheduled formulations at a price higher than the ceiling price (plus goods and services tax as applicable) so fixed and notified by the Government, shall revise the prices of all such formulations downward not exceeding the ceiling price specified in column (5) in the above table plus goods and services tax as applicable, if any.

(b) All the existing manufacturers of above mentioned scheduled formulations having MRP lower than the ceiling price specified in column (5) in the above table plus goods and services tax as applicable, if any, shall continue to maintain the existing MRP in accordance with paragraph 13 (2) of the DPCO, 2013.

(c) The manufacturers may add goods and services tax only if they have paid actually or if it is payable to the Government on the ceiling price mentioned in column (5) of the above said table.

(d) The ceiling price for a pack of the scheduled formulation shall be arrived at by the concerned manufacturer in accordance with the ceiling price specified in column (5) of the above table as per provisions contained in

paragraph 11 of the Drugs (Prices Control) Order, 2013. The manufacturer shall issue a price list in Form–V from date of Notification as per paragraph 24 of the DPCO, 2013 to NPPA through IPDMS and submit a copy to State Drug Controller and dealers.

(e) As per para 24(4) of DPCO 2013, every retailer and dealer shall display price list and the supplementary price list, if any, as furnished by the manufacturer, on a conspicuous part of the premises where he carries on business in a manner so as to be easily accessible to any person wishing to consult the same.

(f) Where an existing manufacturer of scheduled formulation with dosage or strength or both as specified in the above table launches a new drug as per paragraph 2 (u) of the DPCO, 2013 such existing manufacturer shall apply for prior price approval of such new drug to the NPPA in Form I as specified under Schedule-II of the DPCO, 2013.

(g) The manufacturers of above said scheduled formulations shall furnish quarterly return to the NPPA, in respect of production/import and sale of scheduled formulations in Form-III of Schedule-II of the DPCO, 2013 through IPDMS. Any manufacturer intending to discontinue production of above said scheduled formulation shall furnish information to the NPPA, in respect of discontinuation of production and/or import of scheduled formulation in Form-IV of Schedule-II of the DPCO, 2013 at least six months prior to the intended date of discontinuation.

(h) The manufacturers not complying with the ceiling price and notes specified hereinabove shall be liable to deposit the overcharged amount along with interest thereon under the provisions of the Drugs (Prices Control) Order, 2013 read with Essential Commodities Act, 1955.

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

PN/208/76/2020/F

F. No. 8(76)/2020/D.P./NPPA-Div.II

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

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CDSCO MATTERS

Timeline for Import of Drugs with Shelf life less than 60% extended till 31st October 2020 – reg.

DCG(I) Circular dated 10th July 2020

To
All Port Offices of CDSCO;

In light of representation received and Covid-19 pandemic situation, the effective date of the circular of even number dated 17.04.2020* issued on subject cited above is extended up to 31st October, 2020 or till further order whichever is earlier.

File No.DCGI/Misc/2020(110)

Dr V G Somani, Drugs Controller General (India), Central Drugs Standard Control Organisation, Directorate General of Health Services, Ministry of Health and Family Welfare, New Delhi.

*(*Published in IDMA Bulletin dated 30 April 2020)*

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CGST Rules amended - reg.

Central Tax Notification No.50/2020, dated 24th June, 2020

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

1. (1) These rules may be called the **Central Goods and Services Tax (Seventh Amendment) Rules, 2020.**

(2) They shall come into force with effect from the 01st day of April, 2020.

2. In the Central Goods and Services Tax Rules, 2017, in rule 7, for the Table, the following Table shall be substituted, namely:

"TABLE

Sr. No.	Section under which composition levy is opted	Category of registered persons	Rate of tax
(1)	(1A)	(2)	(3)
1.	Sub-sections (1) and (2) of section 10	Manufacturers, other than manufacturers of such goods as may be notified by the Government	half percent of the turnover in the State or Union territory
2.	Sub-sections (1) and (2) of section 10	Suppliers making supplies referred to in clause (b) of paragraph 6 of Schedule II	two and a half percent of the turnover in the State or Union territory
3.	Sub-sections (1) and (2) of section 10	Any other supplier eligible for composition levy under sub-sections (1) and (2) of section 10	half percent of the turnover of taxable supplies of goods and services in the State or Union territory
4.	Sub-section (2A) of section 10	Registered persons not eligible under the composition levy under sub-sections (1) and (2), but eligible to opt to pay tax under sub-section (2A), of section 10	three percent of the turnover of taxable supplies of goods and services in the State or Union territory.".

F.No.CBEC-20/06/09/2019-GST

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

Note: *The Principal Rules were published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i) vide notification No.3/2017-Central Tax, dated the 19th June, 2017, published vide number G.S.R.610(E), dated the 19th June, 2017 and last amended vide Notification No.48/2020-Central Tax, dated the 19th June, 2020 published vide number G.S.R.394(E), dated the 19th June, 2020.*

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CBIC provides relief by lowering of interest rate for prescribed time for tax periods from February, 2020 to July, 2020 - reg.

GST Central Tax Notification No.51/2020, dated 24th June, 2020

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

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

"Provided that the rate of interest per annum shall be as specified in column (3) of the Table given below for

the period mentioned therein, for the class of registered persons mentioned in the corresponding entry in column (2) of the said Table, who are required to furnish the returns in **FORM GSTR-3B,** but fail to furnish the said return along with payment of tax for the months mentioned in the corresponding entry in column (4) of the said Table by the due date, namely:-

TABLE

Sr.No. (1)	Class of registered persons (2)	Rate of interest (3)	Tax period (4)
1.	Taxpayers having an aggregate turnover of more than rupees 5 crores in the preceding financial year	Nil for first 15 days from the due date, and 9 per cent thereafter till 24th day of June, 2020	February, 2020, March 2020, April, 2020
2.	Taxpayers having an aggregate turnover of up to rupees 5 crores in the preceding financial year, whose principal place of business is in the States of Chhattisgarh, Madhya Pradesh, Gujarat, Maharashtra, Karnataka, Goa, Kerala, Tamil Nadu, Telangana or Andhra Pradesh or the Union territories of Daman and Diu and Dadra and Nagar Haveli, Puducherry, Andaman and Nicobar Islands and Lakshadweep	Nil till the 30th day of June, 2020, and 9 per cent thereafter till the 30th day of September, 2020	February, 2020
		Nil till the 3rd day of July, 2020, and 9 per cent thereafter till the 30th day of September, 2020	March, 2020
		Nil till the 6th day of July, 2020, and 9 per cent thereafter till the 30th day of September, 2020	April, 2020
		Nil till the 12th day of September, 2020, and 9 per cent thereafter till the 30th day of September, 2020	May, 2020
		Nil till the 23rd day of September, 2020, and 9 per cent thereafter till the 30th day of September, 2020	June, 2020
		Nil till the 27th day of September, 2020, and 9 per cent thereafter till the 30th day of September, 2020	July, 2020
3.	Taxpayers having an aggregate turnover of up to rupees 5 crores in the preceding 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 or the Union territories of Jammu and Kashmir, Ladakh, Chandigarh and Delhi	Nil till the 30th day of June, 2020, and 9 per cent thereafter till the 30th day of September, 2020	February, 2020
		Nil till the 5th day of July, 2020, and 9 per cent thereafter till the 30th day of September, 2020	March, 2020
		Nil till the 9th day of July, 2020, and 9 per cent thereafter till the 30th day of September, 2020	April, 2020
		Nil till the 15th day of September, 2020, and 9 per cent thereafter till the 30th day of September, 2020	May, 2020
		Nil till the 25th day of September, 2020, and 9 per cent thereafter till the 30th day of September, 2020	June, 2020
		Nil till the 29th day of September, 2020, and 9 per cent thereafter till the 30th day of September, 2020	July, 2020.".

F.No.CBEC-20/06/09/2019-GST

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

Note: *The Principal Notification number 13/2017–Central Tax, dated the 28th June, 2017, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i) vide number G.S.R.661(E), dated the 28th June, 2017 and was last amended vide eNotification number 31/2020–Central Tax, dated the 3rd April, 2020, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i) vide number G.S.R.231(E), dated the 3rd April, 2020.*

(CBIC has issued similar GST Notifications vide Notification No.05/2020-Integrated Tax, dated 24th June 2020 (under F.No.CBEC-20/06/09/2019-GST) and also Notification No.02/2020-Union Territory Tax, dated 24th June 2020 (under F.No. F.No.CBEC-20/06/09/2019-GST)

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CBIC provides one time amnesty by lowering/waiving of late fees for non furnishing of FORM GSTR-3B from July, 2017 to January, 2020 and also to provide relief by conditional waiver of late fee for delay in furnishing returns in FORM GSTR-3B for tax periods of February, 2020 to July, 2020 - reg.

GST Central Tax Notification No.52/2020, dated 24th June, 2020

In exercise of the powers conferred by section 128 of the Central Goods and Services Tax Act, 2017 (12 of 2017) (hereafter in this notification referred to as the said Act), read with section 148 of the said Act, the Government, on the recommendations of the Council, hereby makes the following further amendments in the notification of the Government of India in the Ministry of Finance (Department of Revenue), No.76/2018–Central Tax, dated the 31st December, 2018, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i) vide number G.S.R.1253(E), dated the 31st December, 2018, namely:–

In the said notification,

(i) in the third proviso, for the Table, the following Table shall be substituted, namely:–

"TABLE

Sr.No. (1)	Class of registered persons (2)	Tax period (3)	Condition (4)
1.	Taxpayers having an aggregate turnover of more than rupees 5 crores in the preceding financial year	February, 2020, March, 2020 and April, 2020	If return in **FORM GSTR-3B** is furnished on or before the 24th day of June, 2020
2.	Taxpayers having an aggregate turnover of up to rupees 5 crores in the preceding financial year, whose principal place of business is in the States of Chhattisgarh, Madhya Pradesh, Gujarat, Maharashtra, Karnataka, Goa, Kerala, Tamil Nadu, Telangana or Andhra Pradesh or the Union territories of Daman and Diu and Dadra and Nagar Haveli, Puducherry, Andaman and Nicobar Islands and Lakshadweep	February, 2020	If return in **FORM GSTR-3B** is furnished on or before the 30th day of June, 2020
		March, 2020	If return in **FORM GSTR-3B** is furnished on or before the 3rd day of July, 2020
		April, 2020	If return in **FORM GSTR-3B** is furnished on or before the 6th day of July, 2020
		May, 2020	If return in **FORM GSTR-3B** is furnished on or before the 12th day of September, 2020
		June, 2020	If return in **FORM GSTR-3B** is furnished on or before the 23rd day of September, 2020
		July, 2020	If return in **FORM GSTR-3B** is furnished on or before the 27th day of September, 2020
3.	Taxpayers having an aggregate turnover of up to rupees 5 crores in the preceding 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 or the Union territories of Jammu and Kashmir, Ladakh, Chandigarh and Delhi	February, 2020	If return in **FORM GSTR-3B** is furnished on or before the 30th day of June, 2020
		March, 2020	If return in **FORM GSTR-3B** is furnished on or before the 5th day of July, 2020
		April, 2020	If return in **FORM GSTR-3B** is furnished on or before the 9th day of July, 2020
		May, 2020	If return in **FORM GSTR-3B** is furnished on or before the 15th day of September, 2020
		June, 2020	If return in **FORM GSTR-3B** is furnished on or before the 25th day of September, 2020
		July, 2020	If return in **FORM GSTR-3B** is furnished on or before the 29th day of September, 2020

(ii) after the third proviso, the following provisos shall be inserted, namely:–

"Provided also that the total amount of late fee payable for a tax period, under section 47 of the said Act shall stand waived which is in excess of an amount of two hundred and fifty rupees for the registered person who failed to furnish

the return in **FORM GSTR-3B** for the months of July, 2017 to January, 2020, by the due date but furnishes the said return between the period from 01st day of July, 2020 to 30th day of September, 2020:

Provided also that where the total amount of central tax payable in the said return is nil, the total amount of late fee payable for a tax period, under section 47 of the said Act shall stand waived for the registered person who failed to furnish the return in **FORM GSTR-3B** for the months of July, 2017 to January, 2020, by the due date but furnishes the said return between the period from 01st day of July, 2020 to 30th day of September, 2020.".

F.No.CBEC-20/06/09/2019-GST

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

Note: *The Principal Notification No.76/2018-Central Tax, dated 31st December, 2018 was published in the Gazette of India, Extraordinary, vide number G.S.R.1253(E), dated the 31st December, 2018 and was last amended vide Notification number 32/2020–Central Tax, dated the 3rd April, 2020, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i) vide number G.S.R.232(E), dated the 3rd April, 2020.*

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CBIC provides relief by waiver of late fee for delay in furnishing outward statement in FORM GSTR-1 for tax periods for months from March, 2020 to June, 2020 for monthly filers and for quarters from January, 2020 to June, 2020 for quarterly filers - reg.

GST Central Tax Notification No.53/2020, dated 24th June, 2020

In exercise of the powers conferred by section 128 of the Central Goods and Services Tax Act, 2017 (12 of 2017), the Government, on the recommendations of the Council, hereby makes the following further amendment in the notification of the Government of India in the Ministry of Finance (Department of Revenue), No.4/2018–Central Tax, dated the 23rd January, 2018, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i) *vide* number G.S.R.53(E), dated the 23rd January, 2018, namely:–

In the said notification, for the third proviso, the following proviso shall be substituted, namely:–

"Provided also that the amount of late fee payable under section 47 of the said Act shall stand waived for the registered persons who fail to furnish the details of outward supplies for the months or quarter mentioned in column (2) of the Table below in **FORM GSTR-1** by the due date, but furnishes the said details on or before the dates mentioned in column (3) of the said Table:-

TABLE

Sl.No. (1)	Month/Quarter (2)	Dates (3)
1.	March, 2020	10th day of July, 2020
2.	April, 2020	24th day of July, 2020
3.	May, 2020	28th day of July, 2020
4.	June, 2020	05th day of August, 2020
5.	January to March, 2020	17th day of July, 2020
6.	April to June, 2020	03rd day of August, 2020.".

F.No.CBEC-20/06/09/2019-GST

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

Note: *The Principal Notification No.4/2018–Central Tax, dated the 23rd January, 2018, was published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i) vide number G.S.R. 53(E), dated the 23rd January, 2018 and was last amended by Notification No.33/2020-Central Tax, dated the 3rd April, 2020, published in the Gazette of India, Extraordinary, vide number G.S.R.233(E) dated the 3rd April, 2020.*

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CBIC extends due date for furnishing FORM GSTR-3B for supply made in the month of August, 2020 for taxpayers with annual turnover up to Rs. 5 crore - reg.

GST Central Tax Notification No.54/2020, dated 24th June, 2020

In exercise of the powers conferred by section 168 of the Central Goods and Services Tax Act, 2017 (12 of 2017), read with sub-rule (5) of rule 61 of the Central Goods and Services Tax Rules, 2017 (hereafter in this notification referred to as the said Rules), the Commissioner, on the recommendations of the Council, hereby makes the following further amendments in the notification of the Government of India in the Ministry of Finance (Department of Revenue), No.29/2020–Central Tax, dated the 23rd March, 2020, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i) vide number G.S.R.212(E), dated the 23rd March, 2020, namely:–

In the said notification, in the first paragraph, after the fifth proviso, the following provisos shall be inserted, namely:–

"Provided also that, 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, the return in **FORM GSTR-3B** of the said rules for the month of August, 2020 shall be furnished electronically through the common portal, on or before the 1st day of October, 2020:

Provided also that, 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, the return in **FORM GSTR-3B** of the said rules for the month of August, 2020 shall be furnished electronically through the common portal, on or before the 3rd day of October, 2020".

F.No.CBEC-20/06/09/2019-GST

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

Note:*The Principal Notification number 29/2020–Central Tax, dated the 23rd March, 2020, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i) vide number G.S.R.212(E), dated the 23rd March, 2020 and was last amended vide Notification number 36/2020–Central Tax, dated the 3rd April, 2020, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i) vide number G.S.R.236(E), dated the 3rd April, 2020.*

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CBIC extends due date of compliance which falls during the period from "20.03.2020 to 30.08.2020" till 31.08.2020 - reg.

GST Central Tax Notification No.55/2020, dated 27th June, 2020

In exercise of the powers conferred by section 168A of the Central Goods and Services Tax Act, 2017 (12 of 2017), read with section 20 of the Integrated Goods and Services Tax Act, 2017 (13 of 2017), and section 21 of the Union Territory Goods and Services Tax Act, 2017 (14 of 2017), the Government, on the recommendations of the Council, hereby makes the following further amendment in the notification of the Government of India in the Ministry of Finance (Department of Revenue), No.35/2020-Central Tax, dated the 3rd April, 2020, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), vide number G.S.R.235(E), dated the 3rd April, 2020, namely:

In the said notification, in the first paragraph, in clause (i);

(i) for the words, figures and letters "29th day of June, 2020", the words, figures and letters "30th day of August, 2020" shall be substituted;

(ii) for the words, figures and letters "30th day of June, 2020", the words, figures and letters "31st day of August, 2020" shall be substituted.

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

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

***Note**: The Principal Notification No.35/2020-Central Tax, dated the 3rd April, 2020 was published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i) vide number G.S.R.235(E), dated the 3rd April, 2020 and was last amended by Notification No.47/2020–Central Tax, dated the 9th June, 2020, published in the Gazette of India, Extraordinary vide number G.S.R.362(E), dated the 9th June, 2020.*

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CBIC notifies further extension period to pass order under Section 54(7) of CGST Act till 31.08.2020 or in some cases upto fifteen days thereafter - reg.

GST Central Tax Notification No.56/2020, dated 27th June, 2020

In exercise of the powers conferred by section 168A of the Central Goods and Services Tax Act, 2017 (12 of 2017), read with section 20 of the Integrated Goods and Services Tax Act, 2017 (13 of 2017), and section 21 of the Union Territory Goods and Services Tax Act, 2017 (14 of 2017), the Government, on the recommendations of the Council, hereby makes the following amendment in the notification of the Government of India in the Ministry of Finance (Department of Revenue), No.46/2020-Central Tax, dated the 9th June, 2020, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), vide number G.S.R.361(E), dated the 9th June, 2020, namely:

In the said notification, in the first paragraph,

(i) for the words, figures and letters "29th day of June, 2020", the words, figures and letters "30th day of August, 2020" shall be substituted;

(ii) for the words, figures and letters "30th day of June, 2020", the words, figures and letters "31st day of August, 2020" shall be substituted.

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

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

***Note**: The Principal Notification No.46/2020-Central Tax, dated the 9th June, 2020 was published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i) vide number G.S.R.361(E), dated the 9th June, 2020.*

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CBIC amends Section 6 of the Taxation and Other Laws (Relaxation of Certain Provisions) Ordinance, 2020 (2 of 2020) - reg.

GST - *(Central Tax)* Ordinance Notification dated 27th June, 2020

In exercise of the powers conferred by section 6 of the Taxation and Other Laws (Relaxation of Certain Provisions) Ordinance, 2020 (2 of 2020), the Central Government hereby specifies that,

(i) the 29th day of September, 2020 shall be the end date of the period during which the time limit specified in, or prescribed or notified under, the Central Excise Act, 1944 (1 of 1944), the Customs Act, 1962 (52 of 1962) (except sections 30, 30A, 41, 41A, 46 and 47), the Customs Tariff Act, 1975 (51 of 1975) or Chapter V of the Finance Act, 1994 (32 of 1994) falls for the completion or compliance of such action as specified under clause (a) or (b) of the said section; and

(ii) the 30th day of September, 2020 shall be the end date to which the time limit for completion or compliance of such action shall stand extended.

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

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

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Cabinet approves proposal to extend EPF contribution of 24% (12% employees share and 12% employers share) for another three months from June to August 2020 under PMGKY/*Aatmanirbhar Bharat*

Cabinet Press Release dated 8th July 2020

The Union Cabinet chaired by the Prime Minister Shri Narendra Modi has given its approval for extending the contribution both 12% employees' share and 12% employers' share under Employees Provident Fund, totaling 24% for another 3 months from June to August, 2020, as part of the package announced by the Government under Pradhan Mantri Garib Kalyan Yojana (PMGKY)/Aatmanirbhar Bharat in the light of COVID-19, a Pandemic.

This approval is in addition to the existing scheme for the wage months of March to May, 2020 approved on 15.04.2020. The total estimated expenditure is of Rs.4,860 crore. Over 72 lakh employees in 3.67 lakh establishments will be benefitted.

Salient Features:

The salient features of the proposal are as under:

i. For the wage months of June, July and August, 2020, the scheme will cover all the establishments having upto 100 employees and 90% of such employees earning less than Rs. 15,000 monthly wage.

ii. About 72.22 lakh workers working in 3.67 lakh establishments will be benefited and would likely to continue on their payrolls despite disruptions.

iii. Government will provide Budgetary Support of Rs.4800 crore for the year 2020-21 for this purpose.

iv. The beneficiaries entitled for 12% employers' contribution for the months of June to August, 2020 under *Pradhan Mantri Rozgar Protsahan Yojana* (PMRPY) will be excluded to prevent overlapping benefit.

v. Due to prolonged lockdown, it was felt that businesses continue to face financial crisis as they get back to work. Therefore, the Hon'ble FM, as part of *Aatmanirbhar Bharat,* announced on 13.05.2020 that the EPF support for business and workers will be extended by another 3 months viz for the wage months of June, July, and August, 2020.

The steps taken by the Government from time to time to ameliorate the hardships faced by the low paid workers are well accepted by the stakeholders.

Source: PIB, Cabinet Press Release, 08.07.2020

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Study shows Coronavirus damages the endocrine system

People with endocrine disorders may see their condition worsen as a result of COVID-19, according to a new review published in the Journal of the *Endocrine Society.*

"We explored the previous SARS outbreak caused by the very similar virus SARS-CoV-1 to advise endocrinologists involved in the care of patients with COVID-19," said Noel Pratheepan Somasundaram of the National Hospital of Sri Lanka in Colombo, Sri Lanka. "The virus that causes COVID-19—SARS-CoV-2—binds to the ACE2 receptor, a protein which is expressed in many tissues. This allows the virus to enter endocrine cells and cause the mayhem associated with the disease."

SARS-CoV-2 can cause loss of smell and gain entry to the brain. In past Coronavirus infections such as the SARS epidemic in 2003, many patients developed a post-viral syndrome with fatigue. This could in part be caused by adrenal insufficiency, a condition where the adrenal glands do not make enough cortisol, as a result of damage to the pituitary system. During the SARS epidemic, patients who developed adrenal insufficiency typically recovered within one year.

"Testing for cortisol deficiency and treating patients with steroids may become a vital treatment strategy," Somasundaram said. "Very recent studies have demonstrated lowered mortality in severely-ill patients with COVID-19 treated with the steroid dexamethasone."

COVID-19 also could lead to new cases of diabetes and worsening of existing diabetes. The SARS-CoV-2 virus attaches to ACE2, the main entry point into cells for Coronavirus, and disrupts insulin production, causing high blood glucose levels in some patients. The authors highlight the need for strict glucose monitoring in patients with COVID-19 as a measure to maximize recovery.

"People with vitamin D deficiency may be more susceptible to Coronavirus and supplementation could improve outcomes, though evidence on the subject is mixed," Somasundaram said.

Other authors include: Ishara Ranathunga, Vithiya Ratnasamy, Piyumi Sachindra Alwis Wijewickrama, Harsha Anuruddhika Dissanayake, Nilukshana Yogendranathan, Manilka Sumanatilleke and Kavinga Kalhari Kobawaka Gamage of the National Hospital of Sri Lanka; Nipun Lakshitha de Silva of the National Hospital of Sri Lanka and the General Sir John Kotelawala Defence University in Colombo, Sri Lanka; Prasad Katulanda of the National Hospital of Sri Lanka and the University of Colombo in Sri Lanka; and Ashley Barry Grossman of the University of Oxford and Queen Mary University of London in the United Kingdom.

Endocrinologists are at the core of solving the most pressing health problems of our time, from diabetes and obesity to infertility, bone health, and hormone-related cancers. The Endocrine Society is the world's oldest and largest organization of scientists devoted to hormone research and physicians who care for people with hormone-related conditions.

Source: Pharmabiz, 06.07.2020

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Remdesivir can save more lives where ICUs are overwhelmed

Amid news that the United States has bought up virtually the entire global supply of Remdesivir, a new Boston University School of Public Health (BUSPH) study outlines how the drug could save lives in countries with less hospital capacity, such as South Africa, where COVID-19 is beginning to overwhelm intensive care units (ICUs). Recent research has suggested that Remdesivir can reduce deaths from COVID-19 by as much as 30%, but has a more significant effect on how long patients need intensive care, from an average of 15 days down to an average of 11 days.

The peer-reviewed study, published in the journal *Clinical Infectious Diseases,* estimates that Remdesivir's ability to shorten ICU stays could increase the number of patients treated in South Africa's ICUs by more than 50%. This increased capacity could save as many as 6,862 lives per month as the country's cases peak. Add to that the potential lives saved directly from Remdesivir treatment, and the drug could prevent the deaths of as many as 13,647 South Africans by December.

"There are many countries with limited ICU capacity that could benefit from this double impact on mortality," says study lead author Dr Brooke Nichols, Assistant Professor of Global Health at BUSPH. "Why would you use a drug - that has limited availability - to save one life when that same drug could be used to save two lives? Nichols says she is worried by the news that the US has bought up the Remdesivir supply, especially if the Government doesn't even make sure that priority goes to overwhelmed US locations. "Because more lives can be saved per person treated when using Remdesivir in places where ICU resources are breached, using Remdesivir when ICU resources are not breached would be a misallocation of scarce resources," she says.

Nichols and study co-authors in Boston and South Africa have been modeling South Africa's COVID epidemic to help the country's Government make informed decisions, and previously predicted that the country's ICU capacity could be overwhelmed as early as this month. The hardest-hit province, the Western Cape, exceeded ICU capacity in June.

For the Remdesivir study, the researchers used their South African National COVID-19 Epidemiology model to look at the estimated three to six months when severe cases will exceed the country's 3,450 available ICU beds. If every one of South Africa's ICU patients with COVID received Remdesivir, reducing the average ICU stay, the researchers estimated that the number of patients treated in ICUs from June to December would increase from between 23,443 and 32,284 patients to between 36,383 and 47,820.

The mortality rate for COVID-19 in ICUs varies from country to country and hospital to hospital, so the number of lives saved from increased ICU capacity would also vary. The researchers modeled several different scenarios, finding increased ICU capacity in South Africa could save 685 lives per month if a patient who needed intensive care was just as likely to die in an ICU as outside of one. At the other extreme, the Researchers estimated that the increased ICU capacity from Remdesivir could save as many as 6,682 lives per month if almost all patients who required but didn't receive ICU care died, but those who did receive ICU care had a 50-50 change of surviving.

If direct treatment with Remdesivir also saved the lives of an additional 30 percent of patients--the current estimate for the drug - then the researchers estimated that Remdesivir's "double impact" could save as many as 13,647 lives in South Africa by December.

Source: Boston University School of Medicine-EurekAlert/ World Pharma News, 07.07.2020 (Excerpts)

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Cell ''membrane on a chip'' may speed up screening of COVID-19 drugs

A new human cell ''membrane on a chip'' allows continuous monitoring of how drugs and infectious agents interact with our cells, an advance that may be employed to test potential drug candidates for COVID-19, scientists said on Monday, 06.07.2020.

According to the researchers from the University of Cambridge in the UK, Cornell University and Stanford University in the US, the device could mimic any cell type -- bacterial, human or even the tough cells walls of plants.

The devices have been formed on chips while preserving the orientation and functionality of the cell membrane, according to the results published in two papers in journals Langmuir and ACS Nano. They have been successfully used to monitor the activity of ion channels, a class of protein in human cells which are the target of more than 60 percent of approved pharmaceuticals, the researchers said.

Cell membranes play a central role in biological signalling, controlling everything from pain relief to infection by a virus, acting as the gatekeeper between a cell and the outside world, they said. The team set out to create a sensor that preserves all of the critical aspects of a cell membrane -- structure, fluidity, and control over ion movement -- without the time-consuming steps needed to keep a cell alive.

The device uses an electronic chip to measure any changes in an overlying membrane extracted from a cell, enabling the scientists to safely and easily understand how the cell interacts with the outside world. It integrates cell membranes with conducting polymer electrodes and transistors.

To generate the on-chip membranes, the team first optimised a process to produce membranes from live cells and then, coaxed them onto polymeric electrodes

in a way that preserved all of their functionality. The hydrated conducting polymers provide a more ''natural'' environment for cell membranes and allows robust monitoring of membrane function.

The team optimised the polymeric electrodes for monitoring changes in the membranes. The device no longer relies on live cells that are often technically challenging to keep alive and require significant attention, and measurements can last over an extended time period.

"Because the membranes are produced from human cells, it's like having a biopsy of that cell's surface -- we have all the material that would be present including proteins and lipids, but none of the challenges of using live cells," said Susan Daniel, Associate Professor at Cornell and senior author of the Langmuir paper.

"This type of screening is typically done by the pharmaceutical industry with live cells, but our device provides an easier alternative," said Roisín Owens from Cambridge, and senior author of the ACS Nano paper. "This method is compatible with high-throughput screening and would reduce the number of false positives making it through into the R&D pipeline," said Owens.

The device can be as small as the size of a human cell and easily fabricated in arrays, which allows scientists to perform multiple measurements at the same time, said Anna- Maria Pappa, also from Cambridge and joint first author on both papers. Given the significant risks involved to researchers working on SARS-CoV-2, the virus which causes COVID-19, the scientists said they will focus on making virus membranes and fusing those with the chips.

The virus membranes are identical to the SARS-CoV-2 membrane but don't contain the viral nucleic acid, they said. This way new drugs or antibodies to neutralise the virus spikes that are used to gain entry into the host cell can be identified, according to the researchers.

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

Source: PTI, Outlookindia.com, 07.07.2020

Pharma SMEs will overcome short-term disruptions: CRISIL SME Tracker

Short-term disruptions include high input costs and various operational challenges

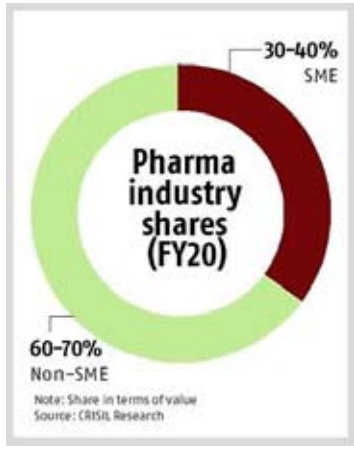
Pharmaceuticals, being an essential commodity, is better-placed than other sectors to weather the storm

The Indian pharmaceuticals industry is very fragmented, with Small and Medium Enterprises (SMEs) accounting for 35-40 percent of production in value terms. The industry is currently facing uncertainty in the wake of the Covid-19 pandemic. However, going ahead, SMEs in this sector will overcome the short-term disruptions, as demand in both export and domestic markets remains robust.

Short-term disruptions include high input costs and various operational challenges. Although China has gradually resumed production of raw materials following disruptions in February and March this year, the cost of inputs remains high. While Indian companies have started receiving supplies, their average cost has risen 20-30 percent. In addition to price hikes, timely availability of raw materials also remains a concern in the wake of India-China trade tensions.

SMEs also face other operational challenges, such as lower capacity utilisation, high cost of freight and working capital constraints, among other things. Fixed expenses and an increase in receivable days are also pushing working capital needs upwards. Consequently, the margins of SME players are likely to decline in the current fiscal year.

Pharmaceuticals, being an essential commodity, is better-placed than other sectors to weather the storm. SMEs in the export segment are likely to fare better than those in the domestic market. Rupee depreciation and stable demand should provide support to export-focused players.



However, the domestic market faced negative growth in April and March owing to demand disruptions caused by the lockdown. Hence, domestic market growth is likely to be relatively slower in the current financial year.

Source: Business Standard, 07.07.2020

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Code on wages likely to be implemented by September, Government circulates Draft Rules

The draft rules on the Code would be open for public feedback for 45 days from July 7, 2020, the day when the Labour Ministry notified those in the gazette

Labour Minister Santosh Gangwar (Photo: Hindustan Times)

The Code on Wages, 2019, the first law under labour reforms, is likely to be implemented by September as the Ministry of Labour and Employment has put Draft Rules of the law in public domain for feedback, a senior official said. Parliament in August last year approved the code to enable introduction of a minimum wage for every worker besides addressing issues like delay in payment to employees.

The Labour Ministry has put the Draft Rules issued on July 7 in the official gazette. "The Draft Rules on the Code would be open for public feedback for 45 days from

July 7, 2020, the day when the Labour Ministry notified those in the gazette. If everything goes well then the draft rules would be implemented by September after taking into consideration public comments," a senior Labour Ministry official told.

Labour Minister Santosh Gangwar at the time of passage of the code had asserted in Parliament that it will benefit about 50 crore workers in the country. The Code on Wages Bill, 2019 seeks to amend and consolidate laws relating to wages, bonus and matters connected therewith. It was passed in Rajya Sabha on August 2, 2019. Lok Sabha passed the bill on July 30, 2019.

The Code will subsume four labour laws -- Minimum Wages Act, Payment of Wages Act, Payment of Bonus Act and Equal Remuneration Act. After its enactment, all these four Acts would be repealed. The Code universalised the provision of minimum wages and timely payment of wages to all employees irrespective of the sector and wage ceiling, he said. At present, the provisions of both Minimum Wages Act and Payment of Wages Act apply on workers below a particular wage ceiling working in Scheduled Employments only.

There are 12 definitions of wages in different labour laws leading to litigation besides difficulty in implementation. The definition has been simplified in the Code and is expected to reduce litigation and also reduce compliance cost for employers. The Code will effectively address the problems relating to delay in payment of wages whether on monthly, weekly or daily basis. The Code will ensure that there is no discrimination between male and female as well as transgenders in getting wages.

The draft rules provide for eight hours working day under the Code of Wages. Thus there is no change in the working hours provision as provided under the Factory Act. There were apprehensions that the working hours may be increased. During lockdown some states had taken the decision to increase the working hours to make up for the production loss.

The Code provides that the floor wage will be computed based on minimum living conditions which would benefit about 50 crore workers across the country. As per the draft rules, a central advisory board would fix the floor level minimum wages taking into account the minimum living standard including the food, clothing, housing and any other factors considered by the Government.

The Code on Wages is part of labour reforms and the first law under the central Government's initiative which would be implemented. The central government has been working to concise 44 central labour laws into four broad codes on wages, industrial relations, social security and Occupational Health & Safety (OCH).

The Industrial Relations Code, 2019, The Occupational Safety, Health and Working Conditions Code, 2019, and The Code on Social Security, 2019 were introduced in Lok Sabha last year and sent for scrutiny by the Parliamentary Standing Committee on Labour. The panel had submitted reports on codes on industrial relations and OCH. The report on social security code is awaited.

Source: PTI, livemint.com, 09.07.2020

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India needs to seize opportunities thrown up by COVID-19 to boost Pharma export & medical tourism: Dr R B Smarta

Even though Pharma being a para medical business is playing courageously as a first line warrior to streamline production, manufacturing and supply of drugs to deal with COVID-19 pandemic, it is better placed to seize opportunities thrown up by the pandemic to ramp up exports, strengthen medical tourism and encourage medical diplomacy, say experts.

Currently, India's leverage of massive drug production allows it to meet healthcare needs of other countries by boosting pharmaceutical exports. The country can also become a preferred medical tourist destination for those seeking affordable treatment in quality secondary/tertiary healthcare facilities. It can also pursue medical diplomacy by providing medical training and technical expertise to other developing countries whose healthcare systems are much worse than India, said Dr R B Smarta, Chairman and Managing Director of Interlink Marketing Consulting.

Dr Smarta said India accounts for about 10% of world's pharmaceutical production by volume and 1.5% by value. The industry is the world's largest supplier of generic drugs and controls around 18% of the global market. Globally Indian drugs are in high demand due to its quality and affordability. Besides this, global NGOs such as UNICEF, UNITAID predominantly rely on cheap Indian generics for their aid programmes.

Hence it's high time India's pharmaceutical sector potentially increases trade partners both regionally and in other parts of the world. The Government can promote

it by funding Research and Development of drugs in the country and offer incentives to private players to increase their production for export purposes, he added.

He further said Indian Pharma is seeking an opportunity to supersize its own ingredient manufacturing to combat Chinese dominance in the market. Indian Government has plans to invest US$ 1.3 billion to ramp up production of generic domestically. It has identified and prioritized production of 53 raw materials and Active Pharmaceutical Ingredients (APIs) as part of its "China-plus-one" policy to fill in supply gaps of affordable medicines, said Managing Director of Interlink Marketing Consulting.

Talking about strengthening medical tourism, he said since 2014, it has been observed that the number of people coming to India for medical treatment has grown annually at about 55%. The Indian medical tourism industry is growing at 18% CAGR year-on-year and is expected to be worth US$ 9 billion by 2020. As per 2019 report, the Indian medical tourism had 18% global market share. Issuing fast-track medical visas and rapid airport clearance for medical treatments is a way ahead applied by Indian Government to promote India as a better medical tourist destination.

Shedding light on medical diplomacy, Dr Smarta said "Post COVID-19 in the world, healthcare would emerge as a focal point for many nations across the world. Healthcare security will attract nations to seek competitive partners having facilities for providing essential drugs, medical proficiency and capability for medical-aid and service to other nations. Though a long way to go, it can prove a great beginning to reorient and outreach our services internationally".

Source: Laxmi Yadav, Pharmabiz, 07.07.2020

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Union Health Ministry issues Guidelines for mental healthcare during COVID-19

Union Health Ministry has come out with Guidelines for general medical and specialised mental health care settings in the times of COVID-19. The Guidelines by the National Institute of Mental Health and Neuro-Sciences (NIMHANS) said the management and treatment of severe mental disorders should not be interrupted as far as possible and emergency care services must remain functional and be bolstered to handle additional influx of patients anticipated during the situation.

The online training sessions for the mental health professionals across the country should be conducted regarding their role in this time of pandemic COVID-19, stated the document. The guidelines further stated that the mental health team also needs to be aware of the various schemes or policies the Government has made in order to alleviate public anxiety about the pandemic and its economic impact.

The management and community care of at-home patients with severe mental disorders should be ensured through liaison existing community outreach programs, like the District Mental Health Programme (DMHP). The Mental Health Professional Associations and other related institutions should assemble experts with expertise in post-disaster psychological crisis intervention, to frame guidelines and provide technical guidance and emergency psychological crisis intervention under the coordination of the Government's health authority, stated the guidelines. NIMHANS stated that psychological crisis intervention should be integrated into the overall system of pandemic prevention and control, with the premise of reducing potential psychological damage caused by the pandemic and promoting social stability.

Persons with pre-existing mental illnesses and substance use are particularly disadvantaged during the lockdowns. For persons with mental illness or epilepsy, reduced access to medication can lead to relapse of symptoms, as can the compounded stress, stated the document. The guidelines said, "Pregnant mothers can have a host of concerns, from worries about whether or not to go for ante-natal examinations, worries about risks to the unborn child, worries about their contracting the infection and concerns about the future. Gender perspectives also need attention as times like this can amplify an abusive relationship and increase intimate partner violence. In any of these situations, it is important to anticipate that stress, depression and anxiety, if not effectively recognised and handled can transform into more severe distress, even leading to negative thoughts about the future, helplessness, hopelessness and suicidal thoughts and feelings".

"We need to constantly update ourselves, as mental health specialists on the changing information concerning risk prevention, signs and symptoms, criteria and tests for diagnosis, safe management of the psychiatrically ill patients with COVID-19 infection, in addition to providing psychological support to persons affected in a myriad of ways in the present situation," the document said.

Source: Pharmabiz, 06.07.2020

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How Atmanirbhar is India's pharma sector?

Since 2020, imports from China have witnessed disruption, first for COVID-19 and then due to India- China standoff. Total size of Pharma market in the country is nearly $35 billion (exports $15 billion and domestic $20 billion) and the sector is heavily dependent on API imports.

According to a CFA India Society research, 70 percent of India's imports totalling $2.4 billion of APIs comes from China and the country currently has a significant edge over India in API manufacturing in terms of taxation, low utility cost, low interest loans etc. Indian drugs account for nearly 30 percent (by volume) and about 10 percent (by value) in the $70-80 billion US generics market, according to the research.

Disruption will impact drug makers and Indian API suppliers, which rely on Chinese imports and could also lead to a sharp increase in raw material prices.

While majority of the imports come in for the sector, there are certain companies which are heavily dependent on China. The following excerpts are taken from management interaction, annual reports and conference calls:

IOL Chemicals: Nearly 35-40 percent APIs and intermediates come from Wuhan province.

Cipla: A big chunk of its Pharma value chain is linked to China. China has a significant value chain linkage for all Pharma companies.

Granules: The company will be impacted if China import hold-up goes on for a few weeks. 30-35 percent of sales will be impacted if paracetamol imports are impacted.

Solara: Dependence on China is about 30 percent in terms of raw material. The company says it will try to bring down dependence. There are domestic suppliers for one of those key raw materials which it buys.

IPCA: A lot of key starting materials come from China. Focus is on building these all 7, 8 intermediates which they have high dependence on China. The company says it will reduce those kind of dependence in time to come.

Alembic: Dependence on China is 15 percent of the overall imports.

Aurobindo: Annual Report: A major portion of the Company's raw material sourcing comes from China, and it is a concern for the company. While the Government has introduced policies to reduce dependence on China by allocating 7,000 crore worth of funds to provide production linked incentives, it remains to be seen how quick the execution happens and how *Atmanirbhar* India becomes a reality in times to come.

Source: Sonal Bhutra, cnbctv18.com, 08.07.2020

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Regulatory systems need to be reformed to leverage R&D activities, says Prof Vijay Raghavan

Principal Scientific Advisor to the Government of India, Professor K Vijay Raghavan stated that regulatory systems need to be reformed and broadening of CSR mechanism to leverage Research and Development activities. Speaking in the high-level Industry consultation for the formulation of new Science, Technology & Innovation Policy, (STIP) 2020, Professor Raghavan focused on the need for more incentives and recognition to encourage industry to fund R&D and ways to leverage the use of CSR funds for the purpose.

Chandrajit Banerjee, Director General, Confederation of Indian Industry (CII), re-emphasized the critical facets of R&D that needs to be immediately strengthened. Secretary, Department of Science and Technology, Professor Ashutosh Sharma emphasized on the need for a robust policy for a long term, which could attract industry investment in the field of Science and Technology.

The first-ever high-level industry consultation roundtable for the formulation of a Science, Technology, and Innovation Policy in the country was held in partnership with Confederation of Indian Industry and Science Policy Forum.

Source: Pharmabiz, 06.07.2020 (Excerpts)

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NPPA directs companies to ensure production & adequate stock of methyl prednisolone, heparin & dexamethasone for COVID-19 management

The National Pharmaceutical Pricing Authority (NPPA) has directed all manufacturers to ensure production and stock of 138,710 vials of methyl prednisolone, 30,15,442 vials (40 mg) of heparin (enoxaparin) and 14,07,206 vials

(60 mg) up to July 31, 2020 and also 33 lakh tablet (6mg) of dexamethasone uptil August 15, 2020 for COVID-19 disease management. It has also directed State Drug Controllers (SDCs) to issue instructions to all the concerned manufacturers to ensure availability and production of these medicines.

This directive is with reference to Union Health Ministry's letters dated, March 18, 2020, June 24, 2020, June 27, 2020 and June 29, 2020 regarding requirement and availability of drugs across the country as part of the clinical treatment protocol of COVID-19. Director General of Health Services (DGHS) has also informed requirement for the same to the NPPA.

Methyl-prednisolone is used to treat conditions such as arthritis, blood disorders, severe allergic reactions, certain cancers, eye conditions, skin, kidney, intestinal, lung diseases and immune system disorders. It may also be used with other medications in hormone disorders. Heparin is an anticoagulant (blood thinner) that prevents the formation of blood clots. It is used to treat and prevent blood clots caused by certain medical conditions or medical procedures. It is also used before surgery to reduce the risk of blood clots. Dexamethasone is a corticosteroid used to treat conditions such as arthritis, blood/hormone/immune system disorders, allergic reactions, certain skin and eye conditions among others.

The national drug pricing regulator has also through a letter stated to immediately intimate details regarding production or sale of drugs during the last 2 years, stock lying with the company as on date, production schedule for next six months, details of suppliers from whom sourcing API for the drugs is done and problems if any being faced in such sourcing, details of procurement orders placed by state Governments and other additional details.

In order to ensure adequate stocks and ensure supply across the country, NPPA had recently revised the prices of blood thinner drug heparin upwards by 50 percent until December, 2020 for its consistent availability in view of the increase in API costs from China in COVID-19 scenario. Price revision was based on Union Health Ministry committee report which states that there has been a 211 percent increase in the price of heparin's API as of today when compared to the base year of September 2018.

Upward price revision was also attributed to the fact that heparin is among the essential drugs listed by the Union Health Ministry that need to be manufactured taking into consideration its commercial viability for its consistent availability in the country. Heparin injection in dosage form and strength of 1,000 IU/ml which used to cost Rs 15.31/ml and heparin injection in dosage form and strength of 5,000 IU/ml which used to cost Rs 37.99/ml will now cost Rs 24.39 per 1 ml in dosage and strength of 1,000 IU/ml and Rs 60.54 in dosage and strength of 5,000 IU/ml 1 ml respectively, as per the NPPA order.

The national drug pricing regulator invoked its extraordinary powers in public interest under para 19 of DPCO 2013 for upward revision of the ceiling prices of heparin injection 1,000 IU/ml and heparin injection 5,000 IU/ml by giving one time increase of 50 percent from the present ceiling price to be applicable up till December 31, 2020.

Source: Shardul Nautiyal, Pharmabiz, 08.07.2020

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Pharma industry sees partnerships with academia not only creates synergy but a multiplier effect to scale up projects

Industry and academia partnerships not only creates a synergy but a multiplier impact to develop and scale up solutions at a pace which is needed in the current scenario of the COVID-19 pandemic, said Rakesh K Chitkara, Senior Director, Global Government Affairs, South Asia, Abbott Healthcare.

India needs to do a lot more in this area compared to what is already happening globally where industry and academia work seamlessly in priority areas with major patents coming. The major discoveries coming out from these partnerships are seen to have the potential for commercialising, he added.

During the last three months of the COVID-19 pandemic, India had showed tremendous capability collaborating with the industry and academia besides the Government which indicated seamless working together. This tempo should be sustained to study how the current disease COVID-19 is changing and evolving, otherwise we will be left behind. Hence there is definitely a need to either scout of industry and academia partnerships or strengthen the existing ones, Chitkara said that the CII session to deliberate on various critical aspects involved in successful industry-academia collaboration in pharmaceuticals.

Quoting a study, he said that industry and academia collaborations have gone up 100 points globally. Even this has not happened that much in India, there is ample

potential for collaborations. This is the time to act when India badly needs a vaccine to prevent COVID-19 as there is a huge need for various vaccine candidates to undergo testing.

Now to kick start collaborations Pharma companies including Abbott have teamed up with Universities of Boston, Massachusetts, Harvard and Oxford. From a country specific stand point, the Indian Council of Medical Research (ICMR) is doing quite a bit of work. But the way global academia institutes collaborate and translate clinical trials to scale it up and take it to patients are seen to spend time in establishing those partnerships. Now in India, we need to spend time on R&D activities with these Government Research Institutes and also assess if the industry funding is sufficient for the same, said Chitkara.

Now industry and academia could work closer. If they have the mindset a lot can happen. We just continue with the copycat versions of generics, said Dr Dinesh Dua Chairman, CII Northern Regional Committee on Life Science, Chairman, Pharmexcil and Executive Director, Nectar Lifesciences.

Reinstating the need for collaboration, Chitkara said Pharma industry views associating with academia to spur commercialisation of Research and Development.

Source: Nandita Vijay, Pharmabiz, 08.07.2020

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Pharma sales recover in June after decline in April and May

Sales of medicines recorded a growth of 2.4% year-on-year (y-o-y) in June, indicating a recovery from two consecutive months of decline caused by the lockdown to prevent the spread of Covid-19. Sales for the month came in at Rs.11,250 crore, with all segments, especially chronic drugs, showing a rebound, according to data from market research firm AIOCD-AWACS.

"There is evidence of significant revival in some therapies. Cardiac [drugs] registered a monthly growth of 13.9% compared with 3.9% in May, [while] anti-diabetic registered growth of 8.5% compared with 1.1% in May," AIOCD-AWACS said in a statement. Respiratory drugs also registered a 4% y-o-y growth compared with a 6% decline in May.

In April and May, overall Pharmaceutical sales were down 11% and 9% respectively as visits to clinics and out-patient departments of hospitals shrank and elective surgeries were postponed for fear of contracting Covid at healthcare facilities. In June, while acute segments such as anti-infective drugs also showed some recovery, the rate for some continued to be negative.

Anti-infective medicines were among the worst-hit during the lockdown as the chances of contracting infection reduced with more people staying home and with visits to the doctor falling. In June, sales of anti-infectives were down 10% y-o-y, better than the 21% decline recorded in May. Pain and analgesics segment also record a 2% decline, against a 17% slump in May.

Gastrointestinal drugs showed a marginal growth of 0.4% y-o-y in June, against the 13% slump in May. Vitamins and minerals posted a 6% growth against a 9% decline in May. Among the 20 largest drug makers, the market-leader for Hydroxychloroquine, Ipca Laboratories, recorded the highest growth of 19% in June. The company also had the highest growth in sales for April-June at 10%.

Unlike the preceding two months, when most firms recorded decline in sales, only two drugmakers recorded a fall in June—Alkem Laboratories Ltd and GlaxosmithKline Pharmaceuticals Ltd. With sales of respiratory drugs recovering, market leader Cipla also recorded a 7% rise in sales in June, against the 13% decline in May. India's largest multi-national also posted a similar trend.

However, growth for other industry leaders such as Sun Pharmaceutical Industries, Dr Reddy's Laboratories Ltd and Zydus Cadila were not stellar, with sales increasing in the range 0.2-1.8%, against the industry average of 2.4%.

Source: Livemint, 10.07.2020

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ICMR clarifies on timeline for completion of clinical trials for COVID-19 vaccine 'Covaxin'

The Indian Council of Medical Research (ICMR) has clarified that timeline for completion of all clinical trials for the COVID-19 vaccine 'Covaxin' and its deadline for public launch is not August 15 this year. Instead, the new vaccine will be launched as per the timeline from Clinical Trials Registry of India (CTRI) and Bharat Biotech International Limited (BBIL) which is a year and three months. The premier research agency further stated that currently clinical trial subjects are being enrolled with oversight from empanelled hospitals of the clinical trials based on ICMR directive.

According to an ICMR spokesperson, "August 15, 2020 timeline should not be talked about as it was meant to prompt and motivate principal investigators at all clinical trial sites to expedite clinical trial process as per global regulatory norms to come out with a vaccine as soon as possible."

"It was meant to tighten the entire process of multi-stakeholder engagement involving accountability from hospitals ethics committees and the sponsor company conducting clinical trials which is Bharat Biotech International Limited. ICMR has played its role as a regulator to bring about clinical research in the country in an efficient and timely manner," he further added.

In a statement earlier, ICMR had stated, "It has been envisaged to launch the Covaxin vaccine for public health use latest by August 15, 2020 after completion of all clinical trials." In fact, ICMR Director General Dr Balram Bhargava on July 2 had written to all 12 trial sites for the COVID-19 vaccine candidate, Covaxin, that all clinical trials had to be completed by August 15, in time for a public launch. As per CTRI, the expected duration of the trial for Covaxin vaccine is one year and three months.

BBIL successfully developed Covaxin, India's first vaccine candidate for COVID-19, in collaboration with ICMR-National Institute of Virology (NIV). The SARS-CoV-2 strain was isolated in NIV, Pune and transferred to BBIL. The indigenous, inactivated vaccine candidate was developed and manufactured in Bharat Biotech's BSL-3 (Bio-Safety Level 3) High Containment facility located in Genome Valley, Hyderabad, India.

Commenting on the development, Dr Chirag Shah, Senior Director, business strategy, Cliantha Research Limited, a leading global clinical research company, said, "ICMR clarification is very much aligned to the global vaccine research norms and as per the clinical trial design for a pandemic like COVID-19, it might take around one month for the phase I human trial, which will do the safety assessment and 4 to 6 months in phase–II, which will assess both safety and immunogenicity of the vaccine".

"Phase –II human trials will help us know how many antibodies have been generated in the trial subject to understand proper efficacy of the vaccine," Dr Shah further explained. Medical fraternity had raised an alarm over the issue with reference to the vaccine development for safety and efficacy stating that all three phases of clinical trials for a vaccine candidate in a month's time is totally uncalled for and defies scientific rationale. A vaccine usually goes through three phases of human trials. DCGI has given approvals for phase I and II trials so far.

Moreover, regulatory experts have also raised concern that Covaxin is an attenuated vaccine and not a recombinant vaccine which again requires high level of testing and protocols and hence will take longer time than prescribed.

Attenuated vaccine is a vaccine created by reducing the virulence of a pathogen, but still keeping it viable (or live). A recombinant vaccine is a vaccine produced through recombinant DNA technology. This involves inserting the DNA encoding an antigen (such as a bacterial surface protein) that stimulates an immune response into bacterial or mammalian cells, expressing the antigen in these cells and then purifying it from them.

"Announcing a timeline without calculations has already raised unrealistic hope and expectations amongst Indian patients. Immune response observations in human testing for a vaccine need to follow a prescribed time span without compromising scientific standards. However, on July 04, 2020, ICMR had revised it's statement highlighting vaccine process will be fast-tracked but without bypassing necessary protocols," remarked Ahmedabad based pharma expert Dr Sanjay Agrawal.

DCGI granted permission to BBIL to initiate phase I and II human clinical trials after the company submitted results generated from preclinical studies, demonstrating safety and immune response.

Announcing the vaccine development milestone, Dr Krishna Ella, Chairman and Managing Director, BBIL had said, "We are proud to announce Covaxin, India's first indigenous vaccine against COVID-19. The collaboration with ICMR and NIV was instrumental in the development of this vaccine. The proactive support and guidance from DCGI has enabled approvals to this project. Our R&D and manufacturing teams worked tirelessly to deploy our proprietary technologies towards this platform.

Expedited through national regulatory protocols, the company accelerated its objective in completing the comprehensive pre-clinical studies. Results from these studies have been promising and show extensive safety and effective immune responses."

Speaking about BBIL expertise, Suchitra Ella, Joint Managing Director had said, "Our ongoing research and expertise in forecasting epidemics has enabled us to successfully manufacture a vaccine for the H1N1

pandemic. Continuing our focus on creating the only BSL-3 containment facilities for manufacturing and testing in India, BBIL is committed to advancing vaccine development as a matter of national importance to demonstrate India's strength in handling future pandemics".

Source: Shardul Nautiyal, Pharmabiz, 09.07.2020

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Industry urges Govt to simplify guidelines of EIA Notification to fast-track approvals for API production

In order to increase production of Active Pharmaceutical Iingredients (APIs) in the country, the pharmaceutical industry in the country has urged the Union Ministry of Environment, Forest and Climate Change (MoEFCC) to simplify guidelines of draft Environment Impact Assessment (EIA) Notification, 2020 to remove numerous layers of permissions as presently required before being able to produce bulk drugs.

At least for API manufacturing, a simplified version is the need of the hour. Consent as broad category of "API and Intermediates" with no control over quantity of production is the need of the hour, said Indian Drug Manufacturers' Association (IDMA) in a representation to the Secretary, MoEFCC and Mohammed Farhan, Technical Consultant (Pharma), Pharma Bureau, Department of Pharmaceuticals (DoP) on draft EIA Notification, 2020.

EIA Notification 2020 continues with the cumbersome procedures and highly technical guidelines which can be understood by very few. Most MSMEs (which comprise bulk of API manufacturers in the country) cannot understand the fine print of the 83 pages document. What we need is simplified guidelines which eliminate various approvals as currently required to manufacture the API, and which still continue to be part of the new document, stated IDMA.

To boost API production, it is absolutely necessary that the Government does away with the cumbersome archaic guidelines of environmental controls which presently also control manufacturing activities of API producers along with the effluent characteristics, said the industry body.

Nobody disputes the need to ensure environment is not polluted. But that can be achieved simply by ensuring adequate Common Effluent Treatment Plants (CETPs) are installed so that all discharges from API units are fed to them. Then all that is needed is to just monitor functioning of CETPs and discharge from them, leaving API units to concentrate on manufacturing of drugs, it added. For grant of prior-environmental clearance to bulk drug and drug intermediate projects, IDMA suggested more liberal exemption criteria, adding that declaration of 'no increase in pollution load' should suffice instead of prior permission.

In order to ensure time bound clearances of all applications, wherever timelines are specified, it should be added that "if no decision is taken within that stipulated period then the application will be deemed to have been approved," it concluded.

MoEFCC in its March 27, 2020 notification had made an amendment to EIA Notification 2006 saying all projects or activities in respect of bulk drugs and intermediates, manufactured for addressing various ailments, have been re-categorized from the existing category 'A' to 'B2' category. Projects falling under B2 category are exempted from requirement of collection of baseline data, EIA studies and public consultation.

The re-categorization of such proposals has been done to facilitate decentralization of appraisal to state level so as to fast track the process of giving environmental approval. The compliance monitoring of conditions prescribed in respect of prior-environmental permissions for category 'B2' projects, shall be carried out by the State Pollution Control Boards (SPCB) or Union Territory Pollution Control Committee (UTPCC).

Source: Laxmi Yadav, Pharmabiz, 09.07.2020

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Pharma technology propels rapid advancement of medicine in India during COVID-19 pandemic: Dr B Suresh

The rapid adoption of technology in Pharma has enabled medical breakthroughs and faster development of innovative treatments which is evident during the COVID-19 pandemic.

According to Dr B Suresh, President, Pharmacy Council of India, medical advancements will become better and effective medication will make patients heal quickly with access to world class healthcare. Even the clinical trials for COVID-19 vaccine are taking place in such a short time span and it has been possible only with the progress of Science and Technology driven data access.

The volume of medical knowledge is doubling every 73 days and over a 365-day period its growth would be 5 times. Pharma technology is riding on the wave of the fourth industrial revolution which is characterised by the convergence of digital, biological and physical world. The growing interest in Artificial Intelligence (AI), cloud computing, robotics, 3-D printing, Internet of Things, genetic engineering and quantum computing among others has ushered a new era of healthcare disruption with precision medicine becoming a reality, said Dr Suresh who was speaking at a webinar on 'Impact of Pharma technology on healthcare' organised by the RR College of Pharmacy.

In order to reinstate the importance of technology, Dr Suresh who is also the Pro Chancellor, JSS Academy of Higher Education and Research, Mysuru said that a report from the Intelligence Unit of The Economist indicated that healthcare would see 45 percent of digital adoption with the remaining shared by sectors like Education, Finance and Energy. When healthcare is the key beneficiary, Pharma technology will play a key role here.

Also Pharma technology will no longer allow longer incubation period in drug discovery. The age of synthesizing 10,000 molecules is redundant as technology will bolster drug discovery reducing the time of research. Therefore, our Pharma researchers need to be equipped with the new age digital skills. Particularly AI and machine learning are undoubtedly next big drivers even for the Pharma industry. For instance, AI is already used by the healthcare industry to perform repetitive tasks such as data entry, lab tests and analysis.

Yet another major transition is blockchain as it brings in decreased cost and increased transparency besides trust for all particularly in protecting intellectual property interests. Even 3D printing is gaining popularity in manufacturing to improve drug quality and consistency. This technology has already transformed medical sciences as synthesising and development of organs to chip in the body, he said.

Pharmaceutical companies can play a central role in the digital revolution of healthcare. But, capturing this opportunity requires identifying the right initiatives. Digital technology has the ability to deliver more personalized patient care, engage more with physicians and patients, besides use data to drive decision making.

Therefore a pharmacy professional needs to keep pace with the medical advances and technology developments. We need to practice what works and is relevant. We cannot be complacent with the current practices but rather need to question ourselves on how to get better with technology, stated Dr Suresh concluding that science fiction is the new fact with the adoption of stem cell therapies becoming a reality.

Source: Nandita Vijay, Pharmabiz, 09.07.2020

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Experts ask Government to ensure access to Remdesivir, raise concerns about supply shortage

Amidst rising cases of Coronavirus infection and limited treatment options, there are reports about supply shortage of Remdesivir injections in the country. Members of the healthcare fraternity and public health activists have raised concerns about this situation and requested the government to intervene and resolve this issue at the earliest.

Prof Bejon Misra, Founder Director, Patients Safety and Access Initiative said, "Following the vision of accessibility and affordability, the NPPA and other regulatory authorities need to play a proactive role in such a situation to ensure that the medicines used for the treatment of COVID-19 are not in short supply. However, we are seeing that one of the ICMR recommended medicines, 'Remedisivir' is in shorter supply and creating a panic situation in the country."

A Medical Practitioner from the Mumbai suburbs who is treating the COVID-19 patients informed, "We are seeing positive results after administrating Remdesivir injection on patients. However, in the last couple of days, we have observed a shortage of supply, which is affecting treatment".

He added, "The Pharma companies and the Government should ensure continuity in the supply of such medicines. Besides, there is also a need to reduce the price of each vial because in India affordability in itself an issue especially during the pandemic situation".

The supply so far…

Last month, the Drug Controller General of India (DCGI) gave permission to Cipla and Hetero Labs to manufacture and market Gilead Sciences' anti-viral drug Remdesivir for "restricted emergency use" on hospitalised patients. Recently, it has also granted approval to Mylan Laboratories to manufacture and market the drug in India. Hetero has already launched its product in the market, under the brand name 'Covifor'.

It is priced at Rs 5400 for each vial. The company's first batch comprising over 30,000 vials have already been supplied, approximately 20,000 vials were delivered to the private hospitals and the remaining have been given to government institutions across the country. Cipla is yet to launch its product, Cipremi, in the market. It is likely to launch it post July 9, 2020. A source from the company informed that Cipla is also now geared to supply Remedisivir injection. It has the capacity to meet the growing demand.

Mylan has not announced a launch date for its product yet. Reportedly, the company's consignments from China carrying some of the intermediates required to manufacture Remdesivir was stuck at the Air Cargo Complex, Mumbai for a couple of days. It got clearances recently.

Measures to ramp up supply:

A source from Hetero Labs informed that the Tamil Nadu Government has procured around 10000 vials of Covifor at Rs 4250 each. Other State governments have also approached the company these injections. For instance, through a tender, the Maharashtra Government has placed an order for 15000 vials. Each vial is priced at Rs.4144. The company's second batch the drug will be available in the market post-July 9, 2020, and this time the company is planning to release approximately one lakh vials of Covifor.

An industry observer also informed that companies are trying their best to meet the demand, and new stock from Cipla and Hetero is likely to arrive in the market soon.

Black marketing of Remdesivir?

Recently, many have alluded to illegal marketing of remdesivir in the country. Reportedly, the drug is being sold at exorbitant prices per vial through an emerging black market.

Speaking against such practices, Misra stated, "It is the role of the regulatory authority to ensure affordability and accessibility so that patients are not compelled to purchase medicines at prices higher than the MRP. There should be a choice given to the patients by medical practitioners to play a proactive role, especially during the COVID-19 crisis."

Express Pharma spoke to a few stakeholders to understand the situation better. **Mahesh Doshi, National President, Indian Drug Manufacturers' Association (IDMA) said, "There is a short supply of the Remedisivir injection in the market, but it is equally important to understand that black marketing of the said medicines is not by our member companies. Our member companies are trying their best to make the medicines available in the market on a priority."**

Dharmesh Shah, CMD, BDR Pharmaceuticals, commented, "It is a very sad situation to know that some unethical marketing practices are taking place in the country amidst the pandemic situation. It is happening not from our industry but, through some unauthorised ways, it is taking place from the neighbouring country. However, I would like to inform you that in the next two to three days' time there will be enough stock of the Remdesivir injections in the market". Response from other Pharma associations and stakeholders is awaited and the story will be updated accordingly.

Source: Express Pharma, 06.07.2020

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INTERNATIONAL NEWS

WHO agrees for first time that COVID-19 can spread through air, soon to release revised regulatory guidelines to contain virus spread

The World Health Organization (WHO) has for the first time agreed that the possibility of Coronavirus spreading in the form of minute airborne droplets through air is very high.

After 239 scientists from 32 countries had recently written letters to the World Health Organization about their research and shared their evidential data that the possibility of spreading Coronavirus through air is very high, the authorities of WHO have for the first time agreed that the possibility of COVID-19 spreading through air.

According to Dr Benedetta Allegranji, representative from WHO observed that of late they have taken cognizance

of various evidences about Coronavirus spreading through air in the form of minute airborne drop lets. "The possibility of spreading the deadly virus in open and narrow crowded areas through air cannot be completely ignored. In areas where there are crowded groups with no proper ventilation such as light and free flow of air, the danger of spreading the virus is very high. In fact, experts at WHO are also working on to find out how effective this virus can spread through air and what are the repercussions of the same. We are also trying to find out ways and means as to what measures can be taken to contain the spread of this virus through air," informed Dr Benedetta Allegranji.

However, Dr Benedetta said that still some more studies need to be carried out before coming out with the possible revised regulatory guidelines and norms to contain the spread of the virus through air. In fact, earlier, the WHO had only claimed that the Coronavirus can spread from one person to the other when sneezing or coughing through minute droplets and even said that the possibility of these droplets travelling through air to larger distances is highly impossible and therefore there the deadly COVID spreading through air is not at all possible.

But experts and lead scientists from across various nations who had been doing research did not agree to the WHO's idea and had put forward various evidences of the virus spreading through air. "It is true that the Coronavirus drop lets with light weight can go airborne and can travel to certain distance, but it doesn't mean that the entire air gets contaminated. Virus particles can survive in air only for a temporary period and there is no need to get panicked about this new finding," observed Dr Rakesh Mishra, Director of Hyderabad based CCMB. As already the WHO in its guidelines has advised use of masks and maintain social distancing, with more findings about the recent revelation of virus spreading through air, it is expected WHO may come out with some more regulatory guidelines to contain the spread of the deadly virus.

Source: Pharmabiz.com, 09.07.2020

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Medicine manufacturing 33 percent cheaper in India than US: Ambassador Sandhu

Indian drug manufacturers have a clear cost advantage as compared to their US counterpart as the cost of the drug manufacturing costs almost one-third lower in India, stated India's Ambassador to the US, H E Taranjit Singh Sandhu. Speaking at a special web conversation organized by The Associated Chambers of Commerce and Industry of India (ASSOCHAM) - 'Energising Commercial Activity between India and the USA in the time of COVID-19', Ambassador Sandhu stated that India has fast become a key emerging market for medical devices and diagnostics.

"Healthcare, pharmaceutical, and life sciences research and cooperation will be a significant area of collaboration as providing equitable, affordable and timely access to health products and technologies will be a priority for both countries. India has inherent strengths and has proved to be a reliable partner in pharmaceuticals in the past and during the COVID-19 crisis," he said. Ambassador Sandhu mentioned that it is for the same reason that there are at least three on-going collaborations between Indian and US companies and institutions to co-develop and produce a COVID-19 vaccine.

"American firm Gilead has entered into licensing agreements with seven Indian companies, including Cipla, Jubilant Sciences, Dr Reddy's, to manufacture remdesivir and supply it to more than 127 countries," the Ambassador informed.

Source: Pharmabiz.com, 09.07.2020

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Drug Repurposing and its impact

Dr Balasubramanian Mahadevan

While using such repurposed drugs individually may ultimately not yield a significant clinical benefit, carefully combined cocktails could be very effective, writes ***Dr Balasubramanian Mahadevan,*** *Ex-Medical Director at P D Hinduja, Saifee, Bhatia, Shushrusha & Lilavati Hospitals in Mumbai.*

COVID-19 has now been declared a pandemic and new treatments are urgently needed as we enter a phase beyond containment. Developing new drugs from scratch is a lengthy process, thus impractical to face the immediate global challenge.

Drug repurposing is an emerging strategy where existing medicines, having already been tested safe in humans, are redeployed to combat difficult-to-treat diseases. While using such repurposed drugs individually may ultimately not yield a significant clinical benefit, carefully combined cocktails could be very effective, as was for HIV in the 1990s.

In the absence of any vaccines to prevent COVID-19, there are many clinical trials (CT) taking place to find a treatment. These CTs are mainly focusing on either repurposing or repositioning the existing molecules. WHO has published a landscape of therapeutics which could be used for treating COVID-19, and some of them are undergoing CTs as well. Generally speaking, patents are not a concern when it comes to old molecules under CTs because these molecules are already out of patent protection.

However, a few of these molecules are still under patent protection in many countries. Two in particular – Remdesivir and Favipiravir – are under patent protection in India. The generic availability of these medicines can facilitate compassionate use and CTs in India without depending on supply from the patent holders. Therefore, the Government of India should use the Compulsory License or Government use license to facilitate the generic production of these medicines.

Favipiravir:

Favipiravir is backed by strong clinical evidence, showing encouraging results in patients with mild to moderate COVID-19. It offers broad-spectrum RNA virus coverage with clinical improvement noted in 20-90 plus age group.

The approval of the drug was based on an interim report of phase three clinical trials. A source in the report said that Drug Controller General of India DCGI approved the drug even while the trial was ongoing as the interim results so far have been encouraging. Last month Glenmark Pharmaceuticals had conducted phase 3 clinical trials of Favipiravir as a COVID-19 with 150 patients, enrolled from 9 leading government and private hospitals across the country.

On June 19, Glenmark Pharmaceuticals has just received the manufacturing and marketing approval from India's drug regulator to launch the oral antiviral drug Favipiravir (FabiFlu®) for the treatment of mild to moderate COVID-19 patients in India. This approval has been granted based on the evaluation of data and in consultation with the Subject Expert Committee, as part of the accelerated approval process, considering the emergency situation and unmet medical need of the COVID-19 outbreak.

The drug will be available for restricted emergency use in India. Restricted use entails responsible medication use where every patient must have signed informed consent before treatment initiation. Notably, Favipiravir has been approved in Japan since 2014 for the treatment of novel or re-emerging influenza virus infections. It has a unique mechanism of action as it is converted into an active phosphoribosylated form (favipiravir-RTP) in cells and recognized as a substrate by viral RNA polymerase, thereby inhibiting RNA polymerase activity.

Last month, Glenmark had also announced that it is conducting another clinical trial to evaluate the efficacy of two antivirals Favipiravir and Umifenovir as a combination therapy in moderate hospitalized COVID-19 patients in India. It will be available under the brand name Fabi Flu as a prescription-based medication for Rs.103 per tablet, with a recommended dose of 1,800 mg twice a day on day 1 and 800 mg twice a day up to 14th day. The antiviral offers broad-spectrum RNA virus coverage with clinical improvement noted across age groups 20 to 90 years. Favipiravir can be used in COVID-19 patients with co-morbid conditions such as diabetes and heart disease with mild to moderate COVID-19 symptoms.

It offers a rapid reduction in viral load within 4 days and provides faster symptomatic and radiological improvement. It shortens the recovery period. Of most importance, Favipiravir has shown clinical improvement of up to 88 per cent in COVID-19 mild to moderate COVID-19 cases including those

with co-morbidities. Very few side effects such as rise in Uric Acid observed & alterations in liver function tests have been reported. However so far there is no documented evidence of Significant Reduction in mortality.

Remdesivir:

Remdesivir, an antiviral drug first developed for treating Ebola in 2014, is one of the possible Covid-19 treatments being investigated in the WHO's Solidarity Trial. It inhibits viral replication in the body. Last month, the US National Institutes of Allergies and Infectious Diseases released preliminary trial results showing recovery time of COVID patients given Remdesivir improved from 15 to 11 days. The Drug Controller General of India on June 1 approved a five-day regime of Remdesivir. Doctors are currently prescribing it for moderately to severely ill patients.

Remdesivir shortened the time to recovery in adult patients who were hospitalized with COVID-19 pneumonia, improved Oxygenation and reduced ventilatory requirements. The side effects reported in patients who received remdesivir included constipation, hypoalbuminemia, hypokalemia, anaemia, thrombocytopenia, and elevated bilirubin. Other drugs such as *Lopinavir–ritonavir* arbidol, chloroquine, interferons, immunoglobulins, and the plasma of patients who have recovered from COVID-19 infection have also been tried with varying degrees of success. The WHO had launched the "Solidarity" international trial to evaluate the four most promising therapies for the management of COVID-19 compared to the standard of care.

The various drugs included in this trial are remdesivir, chloroquine or hydroxychloroquine, lopinavir–ritonavir, and interferon-β1a. As of April 21, 2020, over 100 countries were participating in the trial. Tocilizumab Tocilizumab, a monoclonal antibody against the interleukin (IL)-6 receptor, is used as an immunosuppressive agent. According to a case series from China, significant lung damage is caused by the triggered immune response and cytokine release, and IL-6 appears to play a major role in the cytokine storm.

In a small series published by Xu *et al.,* it was observed that by day 5, 75% of the patients had a reduction in the oxygen intake and C-reactive protein levels and improved lung opacities on the CT thorax. No significantly elevated levels of transaminase, neutropenia, or infection were noted. Tocilizumab improved the clinical outcomes in critically ill patients and, thus, helped to reduce the mortality. It was also effective against the cytokine storm and, therefore, benefitted patients with COVID-19 Toclizumab has also been successful in treating patients with severe COVID-19 in civic hospitals in Mumbai. Several randomized trials are underway for this drug (tocilizumab dosed at 4–8 mg/kg intravenously or 400 mg with a single dose not exceeding 800 mg) in China. Based on the demonstration of pulmonary microthrombi in critically ill patients who succumbed to COVID-19, it was proposed to consider anticoagulants in the management of the disease. Coagulopathy, a feature observed in COVID-19, is associated with high mortality. Mortality in patients with severe COVID-19 reduced with the use of heparin. It is recommended that all patients should receive thromboprophylaxis, unless contraindicated, preferably with low-molecular-weight heparin.

Convalescent plasma:

Convalescent plasma or passive immunotherapy has been tried when no specific drugs or vaccines are available for infectious diseases. Its use has also been suggested by the WHO under the Blood Regulators Network for any emerging epidemic where treatment is not yet developed.

It has been found to benefit critically ill patients during the MERS and SARS outbreaks. Duan *et al* reported the safety of a single dose of 200 mL of convalescent plasma obtained from persons who had recently recovered from COVID and had neutralizing antibody titers over 1:640, in ten patients with severe COVID-19. The clinical outcomes of the patients improved, and 70% of the patients had a clearance of the viremia. A case series by Shen *et al* demonstrated that convalescent plasma improved the clinical status of five critically ill patients with COVID-19. Ye *et al*. also reported that the transfusion of convalescent plasma led to resolution of the ground-glass opacities (GGOs) and consolidation in five out of six patients and virus clearing in two out of six patients. A Phase II, open-label, randomised controlled trial (NCT04374487) has been approved by the Indian Council of Medical Research (ICMR) to assess the efficacy and safety of convalescent plasma in patients with COVID-19.

As the safety profile of convalescent plasma of patients recovered from COVID-19 is not much of a concern, the Phase I portion of the trial has been skipped. In addition, it is not necessary for a donor to test negative for COVID-19; however, resolution of symptoms for at least 2 weeks before the donation is essential. Many Patients in India have benefited from Plasma Therapy. Remedisvir has achieved better results in moderate to severe cases and Hospitalized patients. The absorption and bioavailability of the drug is better as it is used Intravenously. Favipiravir is used mainly in mild to Moderate cases and since it is available in Oral Form could be given at home. The number of tablets is more and is available only as 100 mg form. Compliance could be an issue that needs to be strictly monitored.

Source: Express Healthcare, 07.07.2020 (Excerpts)

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PUBLISHED ON 7th, 14th, 21st and 30th of Every Month

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LICENSED TO POST WITHOUT PREPAYMENT
LICENCE NO. MR/Tech/WPP-337/West/2018-20
RNI REGN. NO. 18921/1970, REGN.NO.MCW/95/2018-20
Published and Posted on 7th, 14th, 21st and 30th of every month
This issue posted at Mumbai Patrika Channel Sorting Office on 14.07.2020

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