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IDMA BULLETIN

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Indian APIs & Formulations for Global Healthcare

INDIAN DRUG MANUFACTURERS' ASSOCIATION

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IDMA BULLETIN

Vol. No. 51 **Issue No. 16** **22 to 30 April 2020**

IDMA Representation to DGFT to issue Guidelines for Export of Hydroxychloroquine

The Association has made the following representation on 21st April 2020 to Shri Amit Yadav, IAS, Director General of Foreign Trade, New Delhi with copies to Dr P D Vaghela, Secretary, Department of Pharmaceuticals, Dr Anup Wadhawan, Secretary, Department of Commerce, Shri Dammu Ravi, Additional Secretary, Ministry to External Affairs, New Delhi and Shri Ravi Udaya Bhaskar, DG, Pharmexcil, Ameerpet, Hyderabad on the above subject:

"Greetings from Indian Drug Manufacturers' Association.

We are thankful for lifting restrictions on exports of formulations made of Paracetamol (including FDCs) vide your Notification No. 3 dated 17th April, 2020.

We wish to submit that prohibition is still in operation on exports of Hydroxychloroquine and its formulations vide Notification No. 54 dated 25th March 2020 and Notification No. 01 dated 4th April, 2020.

A media response was issued by Ministry of External Affairs' official spokesperson Mr Anurag Srivasatava on 7th April, 2020 which stated: "With regard to Paracetamol and Hydroxychloroquine, they will be kept in a licensed category and their demand would be continuously monitored".

Release further mentions "it has been decided that India would licence Paracetamol and HCQ in appropriate quantities to all our neighbouring countries who are dependent on our capabilities. We will be supplying these essential drugs to some nations who have been particularly badly affected by Pandemic."

We have come across several news in media about the supply of Hydroxychloroquine to countries such as United States of America, Brazil, Israel, Afghanistan etc.

We are getting constant queries from our members with regard to Guidelines and procedure to get the license for exporting Hydroxychloroquine.

We request your esteemed office to kindly amend the Notifications and issue Guidelines setting out the procedure for permission to export Hydroxychloroquine and their formulations. Thanking with warm regards".

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IIDMA Request to DCG(I) for 6-month extension in validity of recently expired and near expiry RC & Form-10 for APIs and Formulations

The Association has made the following representation on 23rd April 2020 to Dr V G Somani, Drug Controller General (India), Central Drugs Standard Control Organization with copy to Dr Mandeep Bhandari, IAS, Joint Secretary, Ministry of Health & Family Welfare, New Delhi on the above subject:

"Greetings from Indian Drug Manufacturers' Association.

We are extremely happy and proud that "Made-in-India" drugs supplied to the developed economies such as the US, EU & other regulated/non-regulated markets, in this hour of crisis have once again strengthened India's status as a world leader in pharmaceuticals.

The COVID-19 pandemic has already caused severe supply-side disruptions in the pharmaceutical sector. Our members are working hard to ensure that the production of

medicines, essential in fighting the coronavirus pandemic as well as for other ailments, does not suffer.

In order to tide over such disruptions, on behalf of our members **we request to kindly grant a 6-month extension in validity of Registration Certificates & Import Licenses in Form-10 which have expired in the recent months since January, 2020 and also those which are expiring in the month of April & May 2020, respectively for both APIs and Formulations.**

Sir, this will be another step towards Ease of Doing Business and various emergency measures undertaken by the Government to allow the domestic pharmaceutical industry to work at maximum operational capacity and ensure availability of all essential medicines in the country."

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GOVERNMENT COMMUNICATIONS

Empowered Group requests Departments of Pharmaceuticals and Commerce to prohibit exports of Anti-TB drugs - reg.

Ref. D.O.No.T-18018/04/2019-TB, dated 17th April 2020

To
Shri Parameswaran Iyer, Secretary,
Department of Drinking Water and Sanitation &
The Chair, Empowered Group for
Facilitating Supply Chain & Logistic Management.

The country is undertaking various emergency measures to tackle COVID 19 pandemic. TB is a major Public health problem causing huge morbidity and mortality burden in India. In view of the emergency measures undertaken, the availability of limited number of manpower & material to the Pharmaceutical Industry, the production capacity of the leading anti-TB drugs manufacturers of India has been affected.

The TB drugs are essential for the treatment of TB patients under National TB Elimination Program (NTEP) and delay in production and receipt of supply may cause acute shortages of these drugs in the field. Such a situation will worsen the treatment of the TB patients within the country.

The suppliers has communicated that the anti TB drug supplies will be delayed because of "Force Majeure" due to COVID 19 response activities, limited material (API) for production, limited manpower (because of restrictions) and limited transportation facilities. The leading anti-TB drugs manufacturers and at present having contract agreement with the NTEP are MIS. Macleods and MIS. Lupin. Their major factories are at Ankeshwar & Bharuch in Gujarat, Baddl in Himachal Pradesh and Daman in Daman & Diu.

Under these circumstances, needless to emphasis that the situation calls for extraordinary measures to ensure that TB patients of the country Simultaneously don't face any challenges in accessing either the diagnosis or the treatment of the Tuberculosis across the country under the NTEP. Therefore, it is requested the empowered group may issue directions to Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers and Department of Commerce, Govternment of India for their intervention In this regard and also issue necessary direction for prohibiting export of anti-TB medicines while considering mandatorily the need of the country as overriding priority to ensure smooth supply of anti-TB drugs so that the NTEP does not face any problem in receiving these anti TB drugs.

The Chief Secretaries of concerned states/UTs should instruct the concerned authorities in the states to ensure the transportation services are available to maintain the supplies of finished product, the related officials/workers/ labour are able to reach production site from their different districts or from the nearby states of the manufacturing plant of these companies.

Preeti Sudan, Secretary, Department of Health and Family Welfare, Ministry of Health and Family Welfare, New Delhi.

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Clarification with respect to Application for Free Sale and Commerce Certificate - reg.

DGFT Trade Notice No. 7/2020-2021, dated 28th April, 2020

1. Regional Authorities of DGFT,
2. Members of Trade and Industry.

1. The issuance of Free Sale and Commerce Certificate (FSC) is governed by Para 2.37 of the Handbook of Procedures, 2015-2020. Due to the prevailing COVID-19 related lockdown, RAs are working with skeletal staff leading to delays in issuance of Free Sale and Commerce Certificates.

2. The matter has been examined and accordingly Trade and Industry is advised to send their applications for grant of Free Sale and Commerce Certificate at the official email ID of the concerned RA as per the format given in ANF 2H. The fee payment needs to be done through the e-MPS system.

3. RAs shall take cognizance of the applications for Free Sale and Commerce Certificate received on their official email ID without asking for the hard copy of the applications and issue the certificate through email. Any deficiency letter may also be sent through email.

This issues with the approval of the competent authority.

F. No.: 01/93/180/95/AM-16/PC-II(B)/e-25161

Gagandeep Singh,
Deputy Director General of Foreign Trade,
Ministry of Commerce & Industry,
Department of Commerce,
Directorate General of Foreign Trade,
New Delhi.

● ● ●

CBIC notifes effects to the provisions of rule 87 (13) and FORM GST PMT-09 of the CGST Rules, 2017 - reg.

GST-Central Tax Notification No.37, dated 28th April 2020

In exercise of the powers conferred by section 164 of the Central Goods and Services Tax Act, 2017 (12 of 2017) read with clause (c) of rule 9 and rule 25 of the Central Goods and Services Tax (Fourth Amendment) Rules, 2019 (hereinafter referred to as the rules), made vide notification No.31/2019–Central Tax, dated the 28th June, 2019, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), vide number G.S.R.457(E), dated the 28th June, 2019, the Government, hereby appoints the 21st day of April, 2020, as the date from which the said provisions of the rules, shall come into force.

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

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

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Electronic Sealing-Deposit in and removal of Goods from Customs Bonded Warehouses - reg.

Circular No.20/2020-Customs, dated 21st April, 2020

To,
The Principal Chief Commissioners/Chief Commissioners,
The Principal Commissioners/Commissioners.

1. Representations have been received from e-seal vendors to defer the implementation of Circular-10/2020-Customs dated 07th February, 2020. In view of the same, Board has decided to defer the implementation of Circular-10/2020-Customs till **30th June, 2020.**

2. The new date of implementation of the said Circular shall be **01st July, 2020.**

3. Difficulties if any may be brought to the notice of the Board.

F.No.484/03/2015-LC (Vol. II)

Dr Swati Bhanwala, OSD (Land Customs),
Central Board of Indirect Taxes & Customs,
Ministry of Finance, Department of Revenue,
New Delhi.

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CBIC notifies Measures to facilitate trade during lockdown period - section 143AA of the Customs Act, 1962 - reg.

Circular No.21/2020-Customs, dated 21st April, 2020

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

1. Kind attention is invited to Board's Circular No.17/2020 dated 03.04.2020 on 'Measures to facilitate trade during the lockdown period - section 143AA of the Customs Act, 1962' wherein relaxation was given to accept an undertaking in lieu of a bond required during customs clearance upto 30.04.2020, subject to conditions as underlined in the circular. The said circular was issued in the context of lockdown announced by the Government for the period 25.03.2020 to 14.04.2020 due to COVID-19 pandemic.

2. In the background of the recent announcement by the Government extending the lockdown till 03.05.2020 and taking into consideration that it might take sometime after the end of the lockdown for the situation to normalise, the Board has decided to further extend the facility of accepting undertaking in lieu of bond for the period till 15.05.2020. Consequently, the date for submission of proper bond in lieu of which the undertaking is being temporarily accepted is extended till 30.05.2020. This relaxation will be reviewed by the Board at the end of the lockdown period.

3. Furthermore, in reference to para 3.3 (ii) of the circular, the undertaking in lieu of bond is to be submitted by the registered email ID of the IEC holder or their authorised Customs Broker. In addition to this requirement, but not in substitution, customs zones may prescribe uploading of the undertaking on e-Sanchit.

4. With the exception of the above, all other conditions underlined in Circular No.17/2020 dated 03.04.2020 stand as they are.

5. Suitable Trade Notice/Standing Order may be issued to guide the trade and industry. Difficulty,if any, faced

in implementation of this circular may be brought to the notice of Board immediately.

F.No.473/02/2020-LC

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

● ● ●

IGST refunds on exports-extension in SB005 alternate mechanism - reg.

Circular No.22/2020-Customs, dated 21st April, 2020

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

1. Kind reference is invited to Board's Circulars 08/2018-Cus dt. 23.03.2018, 15/2018-Cus dt. 06.06.2018, 22/2018-Cus dt. 18.07.2018, 40/2018-Cus dt. 24.10.2018 and 26/2019-Cus dt. 27.08.2019 on the above subject of SB005 error resolution.

2. The above Board circulars have been issued in the spirit of trade facilitation and as interim measures to help trade adapt and acclimatize to changing requirements in the GST era. However, representations have been received till today on the same subject issue. There are still numerous Shipping Bills having invoice mismatches between the GST returns data and the customs data presented along with the Shipping Bills resulting in SB005 error. This results in blocking of the IGST refund disbursal, which is otherwise fully automated, except for the refund scroll generation.

3. The matter has been re-examined. Considering that the entire country is facing unprecedented challenges due to the COVID 19 pandemic, and that the exporters are facing genuine hard-ships due to the SB005 errors, it has now been decided to extend the facility of SB005 error correction in the Customs EDI system for Shipping Bills with date upto 31.12.2019.

4. All members of the trade, exporters, shipping lines, customs brokers are duly advised again to make efforts to understand the problems due to mismatch of invoices resulting in SB005 error, and to invest time and due precautions for preventing such error in the future.

5. Suitable Trade Notice/Standing order may please be issued to guide the trade and industry. Difficulty, if any, faced in implementation may be brought to the notice of Board immediately.

F.No.450/119/2017-Cus IV

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

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'Emails for facilitating faster refund cannot be misconstrued as harassment': CBDT Clarification

CBDT Communication dated 21st April 2020

The Central Board of Direct Taxes (CBDT) responding to some observations being circulated on social media alleging that the Income Tax Department is pursuing recovery proceedings and using arm-twisting methods by adjusting outstanding demands of the start-ups, today stated that these observations are completely unfounded and are total misrepresentation of facts.

The CBDT said that its email seeking clarification from all those who are entitled to get tax refund but also have outstanding tax to pay cannot be misconstrued as harassment. These computer generated emails have been sent to almost 1.72 lakh assessees which includes all classes of taxpayers – from individual to HUF to firms, big or small companies including start-ups and therefore to say that start-ups are being singled out and harassed is total misrepresentation of facts.

The CBDT said that these emails are part of the faceless communication which protects public money by ensuring that refunds are not released without adjusting against outstanding demand, if any. These emails are auto-generated u/s 245 of the I-T Act in refund cases where there is any outstanding demand payable by the assessee. In case the outstanding demand has already been paid by the taxpayer or it has been stayed by the higher tax authorities, the taxpayers are requested through these mails to provide the status update so that while issuing the refund, these amounts are not held back and their refunds are released forthwith.

The CBDT said that such communications are just a request for seeking an update response from the assessee for the proposed adjustment of refund with the outstanding demand and cannot be misconstrued as a notice of recovery or be perceived as so-called arm-twisting by the I-T department because the department is duty bound to protect public money by adjusting the outstanding demand before releasing the refund.

The CBDT further said that in order to provide hassle-free tax environment to the start-ups, a consolidated Circular no. 22/2019 dated 30th August 2019 was issued by the CBDT. Apart from laying down the modalities for assessment of start-ups, it also stipulated that the outstanding income tax demands relating to additions made under Section 56(2)(viib) would not be pursued. Any other income tax demand of such start-ups would also not be pursued unless the demand was confirmed by ITAT. Furthermore, a start-up cell was also constituted to redress grievances of start-ups and address other tax related issues of such concerns.

Explaining the extant procedure pertaining to recovery of outstanding demands in the case of an assessee, the CBDT said that an opportunity is provided by the department to the assessee to either clear the demand or intimate the status of said demand to the I-T Department. Invariably, such communication is made by the department by sending an email to the assessee informing it of the quantum of outstanding demand and providing an opportunity to pay the demand or respond with evidence regarding payment of the same if already made, or update the status of any other action on it.

The CBDT said that the assessee on its part is required to furnish details of the pending demand, whether it has been paid or has been stayed by any appellate/competent authority so that the department could keep the same in abeyance and do not deduct this amount from refund.

Thus, following the existing procedure of recuperation of outstanding demand, similar mails have also been sent to 1.72 lakh assessees including start-ups to intimate to the I-T department, the status of the demand outstanding and whether it has been stayed by the competent authority so that appropriate action can be taken for release of refunds without delay to the start-up. However, not providing such a response to the emails of I-T dept and raising false alarm is contrary to the spirit of the Circular 22/2019 of CBDT and is totally unjustified.

The CBDT further requested the start-ups to respond to its emails at the earliest so that further necessary action can be taken by the I-T Department to release the refunds

immediately wherever due, in accordance with the extant procedure.

The CBDT reiterated that pursuant to the 8th April 2020 declaration vide an earlier Press Release of the Government, the CBDT has till date issued nearly 14 lakh refunds involving an amount of over Rs. 9,000 crore to various taxpayers including individuals, HUFs, proprietors, firms, corporate, start-ups, MSMEs in order to help taxpayers in the COVID-19 pandemic situation. Many refunds are pending for the want of response from the taxpayers and will be issued at the earliest possible once the information is updated.

Source: DD News, 21.04.2020

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CDSCO MATTERS

DCG(I) directions to SDCs to monitor and ensure availability and supply of Paracetamol, API and its formulation in domestic market in wake of COVID-19

File No. DCGI/Misc/2020(102), dated 22nd April 2020

To,
All State/UT Drugs Controllers (SDCs)

Please refer to this office letter vide even no. dated 16.04.2020 on the subject cited above requesting to ensure that manufacturers continue to supply the quantity of Paracetamol API Tablets as usual to domestic market and to continuously monitor the availability of stock of Paracetamol in domestic market (Copy of letter dated 16.04.2020 enclosed)*.

In continuation of the above, it may please be noted that National Pharmaceutical Pricing Authority (NPPA), Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers vide letter no. 37001/2020/Div III/NPPA dated 22.04.2020, has further clarified that the manufacturers of Paracetamol tablets shall supply minimum quantity of Paracetamol but not less than their average supply of the past three months (January, February, March) in the domestic market.

Accordingly, you are requested to give necessary instruction to the manufacturers of Paracetamol tablets under your jurisdiction to ensure that they shall supply the minimum quantity of the Paracetamol tablets but not less than their average supply of the past three months (January, February, March) in the domestic market.

Action taken in this regard may be communicated by mail on enforcecell.div@cdsco.nic.in, dci@nic.in and vgsjdci@gmail.com.

Dr V G Somani, Drugs Controller General (India), DCGI Secretariat, Directorate General of Health Services, Central Drugs Standard Control Organization, New Delhi.

*(*Not reproduced here)*

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Permission for import of drug with residual shelf life less than 60% allowed under Special Condition - reg.

Circular File No. DCGI/Misc/2020/(110), dated 17th April 2020

To
All Port offices of CDSCO.

As per Rule-31 of Drugs and Cosmetics Rule, 1945 "No drug shall be imported unless it complies with the standard of strength, quality and purity", provided that the licensing authority shall not allow the import of drug having less than 60% residual shelf life period as on the date of import. However in exceptional cases the licensing

authority may, for reasons to be recorded in writing may allow, the import of any drug having lesser shelf life period, but before the expiry as declared on the container of the drug.

In light of present situation due to spread of COVID-19, Ministry of Health & Family Welfare, Government of India vide its letter X-11035/155/2020-DR dated 16.04.2020 has instructed to take various steps in order to ensure availability of sufficient quantity of drugs in the domestic retails market besides ensuring that the product conform to the prescribed specification. One of the steps including issuing immediate approvals to applications for the registration, manufacture and import of pharmaceuticals.

Further, representation has been received from Industry Association that there are challenges in clearance at port offices due to COVID-19 outbreaks and many products are losing shelf life and getting below the threshold of 60%. Therefore it has been requested for relaxing the requirement of minimum 60% residual shelf life of all drugs including vaccines/biological products at the time of import temporarily, for period 3 months until normal supply resumes.

In view of above, in light of the COVID-19 situation, it has been decided, in public interest, that the drugs having residual shelf life less than 60% may be permitted for import in accordance with the Rules after taking undertaking from the importers by the Port Officers of CDSCO that the drug will be utilized/consumed before the expiry date and no part of drug will be available for sale and distribution after it's expiry.

This will be effective for period of three months or till further order, whichever is earlier.

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

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GOVERNMENT NOTIFICATIONS

Government Delegates Powers of Para 3 of DPCO, 2013 to NPPA

Gazette Notification No.S.O.1249(E), dated 6th April 2020

In exercise of the powers conferred by sections 3 and 5 of the Essential Commodities Act, 1955 (10 of 1955), the Central Government hereby directs that National Pharmaceutical Pricing Authority, established vide Government of India in the Ministry of Chemicals and Fertilizers Resolution No. 33/7/97-PI-I dated the 29th August, 1997, published in Part I, Section 1 of the Gazette of India, Extraordinary, shall also exercise the functions of the Central Government in respect of paragraph 3 of the Drugs (Prices Control) Order, 2013 in addition to the functions specified in the Orders of the Government of India, in the Ministry of Chemicals and Fertilizers number S.O. 1394 (E), dated the 30th May, 2013 and S.O. 528(E), dated 15th February, 2016.

F.No.31026/8/2020-Pricing

Navdeep Rinwa,
Joint Secretary,
Ministry of Chemicals and Fertilizers,
Department of Pharmaceuticals,
New Delhi.

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DGFT notifies extensions in Import Validity period and Export Obligation period in Advance authorizations/DFIA - reg.

DGFT Policy Circular No. 35/2015-20, dated 23rd April 2020

To
All Regional Authorities of DGFT,
All Exporters/Member of Trade.

Attention is invited to Notification No. 5712015-20 dated 31.03.2020 and Public Notice No. 6712015-20 dated 31.03.2020 through which extension in the import validity period and the export obligation period for existing Advance Authorizations (AAs)/DFIA expiring from February to July has been granted.

In this regard, the following procedural formalities may be followed by DGFT RAs and Trade:

A) Automatic Extension of Import Validity period and EO period by 6 months for AAs under HBP Para 4.41(e) and Para 4.42(h) where no revalidation/ EO period extension has been granted till date: -

i. In all such cases where the facility of first or second extension in the import validity period or the EO extension period has not been availed by the exporter earlier, the revised or the extended import validity/E0 period, as per the relaxations permitted would be updated in the ICEGATE/Customs System automatically based on a defined protocol between the DGFT- NIC/ Customs in this regard.

ii. Once the bulk updation and transmission of authorisations have been done by NIC Division, NIC would send RA-wise list of such authorisations to individual RAs with an update script to be run on the local server (available in the Downloads section of the local server). All RAs are required to run this script immediately so that any further extensions/re-validations on the authorizations would take into account this change in the local RA sever also.

iii. In case of some individual cases, where the revised updated import validity or EO extension is not available in the ICEGATE, the exporter may approach the DGFT RA with an email/letter request for carrying out an amendment in the AA/DFIA. DGFT RA will accordingly examine the request expeditiously and endorse the extended validity/EO as per the provisions of FTP/HBP and transmit the amendment message electronically to DGFT/ICEGATE server.

B) Extension of Import Validity period and EO period by 6 months for AAs under HBP Para 4.41(e) and Para 4.42(h) where revalidation/EO period extension has been granted till date:

For those AAs where 1st or the 2nd re-validation or EO extension has been granted under the respective paras of HBP, automatic transmission of extended dates is not possible due to system architecture issues. In such cases, the exporters shall make an amendment request through email/letter to the concerned Regional Authority providing the details of the case. RAs, upon receiving such requests from the exporters, shall expeditiously verify the eligibility of the request, and then carry out the amendments for Revalidation /EOP Extension in the local server.

C) Extension of Validity/EO by 6 months for AAs under HBP Para 4.41(e) and Para 4.42(h) where authorizations are Physical (non-EDI) in nature:

For such authorisations, the procedure to be adopted would be similar to amendment requests as given in para (B) above. The authorizations need to be produced physically at the concerned Regional Authority with a request for extension in EO/re-validation. The concerned RA shall examine the request and endorse the extended validity/EO based on eligibility as per provisions of FTP/HBP.

D) Same procedure, as given in Para A, B & C shall apply for extension of validity of the DFIAs for import.

File No. 01/94/180/348/AM20/PC-4)

Vijay Kumar, Additional Director General of Foreign Trade, Directorate General of Foreign Trade, Policy Division, Department of Commerce, Ministry of Commerce and Industry, New Delhi.

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MHA clears misapprehension about penal action on Management if any employee is found to be COVID-19 positive - reg.

MHA Ref.No.40-10/2020-DM-1, dated 23rd April, 2020

To
Chief Secretaries of all States,
(As per standard list).

1. Please refer to MHA's Order of even number dated 15.04.2020 vide which consolidated revised guidelines on the measures to be taken by the Ministries/ of Government of India, Statel UT Governments and Statel UT Authorities for containment of COVID-19. In Annexure-l of these guidelines, National Directives for COVID-19 Management have been specified, and in Annexure-ll, Standard Operating Procedure (SOP) for social distancing and hygiene measures has been specified, which is to be followed by offices, workplaces, factories and other establishments.

2. Some apprehensions, based on wrong interpretation of the guidelines, have been raised in the media and by some companies having manufacturing facilities. Some of these are as under:

i. States may take legal action, including imprisonment of CEO, in case a COVID-19 positive employee is found in the factory.

ii. In such a situation, the premises of the factory would be sealed for 3 months.

iii. In case of non-compliance of precautionary measures, the factory may be closed down for 2 days and may be allowed to restart after full compliance.

3. **I would like to clarify that there is no such clause in the consolidated revised guidelines and therefore there is no basis for such misplaced apprehensions.**

4. COVID-19 being a highly infectious epidemic, it is important that all workplaces take measures to ensure social distancing and follow standard health protocols as notified by Ministry of Health and Family Welfare (MOHFW). Accordingly, appropriate safeguards at workplaces have been prescribed in the National Directives and SOP mentioned above. The workplaces and industrial and commercial establishments are required to follow these guidelines.

5. Secondly, the activities allowed under the consolidated revised guidelines dated April 15, 2020, except in containment zones, have subsumed all the earlier activities that were permitted under the earlier guidelines issued on March 24, 2020 (including those permitted under the addendums); in addition, certain new activities have also been permitted. Hence, it is clarified that the consolidated revised guidelines dated April 15, 2020 do not curtail the exemptions already provided earlier, unless the exempted activity falls within a containment zone. Therefore, no separatel fresh permissions are required from authorities for industries already permitted to operate prior to April 15, 2020, in areas falling outside containment zones.

6. Finally, it is emphasized that subject to compliance with the SOP on social distancing, no fresh license or statutory approval is required for resumption of permitted activities during the lockdown period. For example, an industrial activity, allowed to operate prior to the lockdown, needs no fresh statutory approval, once it has been included as a permitted activity under the consolidated revised guidelines, and has complied with the SOP on social distancing.

7. In light of the above, I would like to request all State/ UT Governments that the industrial field establishments and field offices may be apprised of the guidelines of lockdown measures which should be followed to prevent the spread of epidemic. These should not be misused to harass the management of any manufacturing/ commercial establishments.

Ajay Bhalla, Home Secretary, Government of India, New Delhi.

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Own immune cells to target infectious diseases including COVID-19

The engineering of specific virus-targeting receptors onto a patient's own immune cells is now being explored by scientists from Duke-NUS Medical School (Duke-NUS), as a potential therapy for controlling infectious diseases, including the COVID-19-causing virus, SARS-CoV-2. This therapy that has revolutionised the treatment of patients with cancer has also been used in the treatment of other infectious diseases such as Hepatitis B virus (HBV), as discussed by the School's researchers in a commentary published in the Journal of Experimental Medicine.

This therapy involves extracting immune cells, called T lymphocytes, from a patient's blood stream and engineering one of two types of receptors onto them: chimeric antigen receptors (CAR) or T cell receptors (TCR). TCRs are naturally found on the surfaces of T lymphocytes while CARs are artificial T cell receptors that are generated in the laboratory. These receptors allow the engineered T lymphocytes to recognise cancerous or virus infected cells.

"This therapy is classically used in cancer treatment, where the lymphocytes of the patients are redirected to find and kill the cancer cells. However, its potential against infectious diseases and specific viruses has not been explored. We argue that some infections, such as HIV and HBV, can be a perfect target for this therapy, especially if lymphocytes are engineered using an approach that keeps them active for a limited amount of time to minimise potential side effects," said Dr Anthony Tanoto Tan, Senior Research Fellow at the Duke-NUS' Emerging Infectious Diseases (EID) programme and the lead author of this commentary.

This type of immunotherapy requires specialised personnel and equipment, and it needs to be administered indefinitely. This makes it cost-prohibitive for treating most types of viral infections. However, in the case of HBV infections, for example, current anti-viral treatments merely suppress viral replication and cure less than 5% of patients. Treating these patients with a combination of anti-virals and CAR/TCR T cells could be a viable option. The team's approach using mRNA electroporation to engineer CAR/TCR T cells limits their functional activity to a short period of time, and hence provides enhanced safety features suited for its deployment in patients with chronic viral diseases.

"We demonstrated that T cells can be redirected to target the coronavirus responsible for SARS. Our team has now begun exploring the potential of CAR/TCR T cell immunotherapy for controlling the COVID-19-causing virus, SARS-CoV-2, and protecting patients from its symptomatic effects," said Professor Antonio Bertoletti from the Duke-NUS' EID programme, who is the senior author of this commentary.

"Infectious diseases remain a leading cause of morbidity and mortality worldwide, necessitating the development of novel and innovative therapeutics. Although immunotherapy is most commonly associated with the treatment of cancer or inflammatory diseases such as arthritis, this commentary accentuates the evolving role of this specialised treatment strategy for various infectious diseases," said Professor Patrick Casey, Senior Vice Dean for Research at Duke-NUS.

Source: World Pharma News, 22.04.2020 (Excerpts)

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Oxford COVID-19 vaccine programme opens for clinical trial recruitment

University of Oxford researchers working in an unprecedented vaccine development effort to prevent COVID-19 have started screening healthy volunteers (aged 18-55) for their upcoming ChAdOx1 nCoV-19 vaccine trial in the Thames Valley Region. The vaccine based on an adenovirus vaccine vector and the SARS-CoV-2 spike protein is already in production but won't be ready for some weeks still.

The team will enrol healthy volunteers aged between 18 - 55, who, if they pass screening, will be the first humans to test the new vaccine, called ChAdOx1 nCoV-19. The trial will provide valuable information on the safety aspects of the vaccine, as well as its ability to generate an immune response against the virus. Interested individuals can volunteer to participate on the COVID-19 vaccine website.

The trial, a collaboration between the University's Jenner Institute and Oxford Vaccine Group clinical teams, will recruit up to 510 volunteers, who will receive either

the ChAdOx1 nCoV-19 vaccine or a control injection for comparison. Whilst the team will start screening people now to see if they are eligible to take part in the study, participants will not receive the vaccine for some weeks. Detailed preclinical work is being done and the vaccine is being manufactured to clinical grade standard at the Clinical Biomanufacturing Facility at Oxford University. The trial has been approved by UK regulators and ethical reviewers. Researchers are working as quickly as possible to get the vaccine ready to be used in the trial, which includes further preclinical investigations and production of a larger number of doses of the vaccine.

Professor Adrian Hill, Director of the Jenner Institute at the University of Oxford, said, 'The Oxford team had exceptional experience of a rapid vaccine response, such as to the Ebola outbreak in West Africa in 2014. This is an even greater challenge. Vaccines are being designed from scratch and progressed at an unprecedented rate. The upcoming trial will be critical for assessing the feasibility of vaccination against COVID-19 and could lead to early deployment.'

Professor Andrew Pollard, Chief Investigator on the study, said: "Starting the clinical trials is the first step in the efforts to find out whether the new vaccine being developed at Oxford University works and could safely play a central role in controlling the pandemic coronavirus that is sweeping the globe."

Scientists around the world are working hard to develop a vaccine to prevent COVID-19, but there is a lot to be done. The Oxford team led by Prof. Sarah Gilbert, Prof Andrew Pollard, Prof. Teresa Lambe, Dr Sandy Douglas and Prof. Adrian Hill started work designing a vaccine on Friday 10th January 2020.

The vaccine is an adenovirus vaccine vector (ChAdOx1) and was developed at Oxford's Jenner Institute. It was chosen as the most suitable vaccine technology for a SARS-CoV-2 (COVID-19) vaccine as it can generate a strong immune response from one dose and it is not a replicating virus, so it cannot cause an ongoing infection in the vaccinated individual. This also makes it safer to give to children, the elderly and anyone with a pre-existing condition such as diabetes. Adenoviral vectors are a very well-studied vaccine type, having been used safely in thousands of subjects, from 1 week to 90 years of age, in vaccines targeting over 10 different diseases.

Coronaviruses have club-shaped spikes on their outer coats. Immune responses from other coronavirus studies suggest that these are a good target for a vaccine. The Oxford vaccine contains the genetic sequence of this surface spike protein inside the ChAdOx1 construct. After vaccination, the surface spike protein of the coronavirus is produced, which primes the immune system to attack the coronavirus if it later infects the body.

Professor Gilbert and team have previously developed a vaccine for another human coronavirus disease, which is Middle East Respiratory Syndrome (MERS), and this has shown promise in early clinical trials.

Professor Gilbert, lead researcher of the vaccine development programme, said: "Since the Ebola outbreak in West Africa in 2014, my research team has been working on new approaches to vaccine development to protect the population of the world against an outbreak of infectious disease or a pandemic. We are now working with a much larger team to bring these plans to fruition."

At the same time as conducting the first clinical trial, production of the vaccine is being scaled up ready for larger trials, and potentially, future deployment. By starting vaccine manufacturing scale-up immediately, the team can ensure that enough vaccine doses are available as soon as possible - especially for NHS workers, the elderly, and those with underlying health conditions - if the trials prove that the vaccine is safe and effective.

Dr Sandy Douglas, who is leading on the vaccine manufacturing scale-up project, said: "The scale of this epidemic poses a huge challenge for vaccine manufacturing. We need to follow rigorous safety standards and that takes time. By starting work on large-scale manufacturing immediately, we hope to accelerate the availability of high quality, safe vaccine."

Professor Teresa Lambe leading the early stages of our vaccine development said: "The commitment, compassion and helpfulness felt throughout the whole effort from everyone we have been working with has been amazing. We deeply appreciate the support of all our collaborators, funders and the teams around us in getting to this stage with the speed we have."

Source: World Pharma News, 21.04.2020 (Excerpts)

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CSIR-IICT initiatives to reduce dependency for APIs and drug intermediates

Active Pharmaceutical Ingredients (APIs) and intermediates are the key components of any drug that produces the intended effects. India is largely depended especially on China for supply of APIs and drug intermediates. Now Indian Institute of Chemical Technology (IICT), Hyderabad, is collaborating with another Hyderabad-based integrated pharmaceutical company, LAXAI Life Sciences, to develop and manufacture APIs and drug intermediates. The initiative may help in reducing the dependency of the Indian pharmaceutical sector on Chinese imports of these ingredients.

IICT, a laboratory under the Council of Scientific and Industrial Research (CSIR), is working with LAXAI for synthesis of drugs being used in the fight against the Corona Virus. The collaboration will primarily focus on Umifenovir, Remdesivir and a key intermediate of Hydroxy Chloroquine (HCQ).

India, one of the largest producers of anti-malarial drug HCQ, has seen a spurt in demand in the recent weeks. India has sent HCQ to over 50 countries over the last few days, including the United States. The collaboration will result in a cost-effective process with minimal dependency on China for key raw materials. In addition, Remdesivir, which has been previously administered to Ebola virus patients, is currently under clinical trials to evaluate efficacy and safety against COVID-19.

Realizing that drug security and undisrupted access to essential medicines are critical for public health, the Union Cabinet chaired by the Prime Minister, has approved a special package for promotion of bulk drug manufacturing in India and reduction of our dependence on China.

LAXAI Life Sciences Pvt Ltd was established in the year 2007, with a vision to accelerate the discovery chemistry campaign of global pharmaceutical companies. Today LAXAI has grown into an integrated pharmaceutical company with presence in API/formulation development as well as API manufacturing.

The collaboration will use the know-how for commercial manufacturing of the products. LAXAI Life Sciences shall be one of the first few to commercialize these products. The manufacturing of these APIs and intermediates will be taken up at U.S. Food and Drug Administration (US FDA)/Good Manufacturing Practice (GMP) approved plants held by LAXAI through its subsidiary, Therapiva Private Limited.

(For more details: Dr M Chandrasekharam, CSIR-Indian Institute of Chemical Technology, Hyderabad-500 007, India - Email: headkim@iict.res.in)

Source: NPIB Press Release, Ministry of Science & Technology, 25.04.2020

CDSCO anticipates low inventory of cardiac and anti-diabetic medicines, writes to all Pharma Associations

The National Pharmaceutical Pricing Authority has requested the CDSCO to provide the details of manufacture of cardiac and anti-diabetic drugs especially in respect of insulin, aspirin and atorvastatin.

The Central Drugs Standard Control Organisation (CDSCO) has issued a letter to all pharma industry associations expressing the low inventory level of cardiac and anti-diabetic medicines at the distributor level.

The CDSCO letter to all pharma associations states that it has received a communication from the National Pharmaceutical Pricing Authority (NPPA), letter No 37001/2020/ Div III/ NPPA dated April 24, 2020 wherein they have noted that cardiac and anti-diabetic drugs including insulin stocks level are below than normal.

Commenting on the market availability of these medicines in the market, Rajiv Singhal, General Secretary, All India Organisation of Chemists and Druggist (AIOCD) said, "We have recently checked the market stock availability of all the medicines through our C&F agent and realised that there is no shortages of any medicines as on date, also there are sufficient stock available with the companies to feed the market requirements."

Anil Khanna, Partner, Wisdomsmith Advisors LLP explained, "In the month of February, the inventory for both these therapies was nearly 40 days. And this inventory was at the stockists level. Add to it, nearly 7-10 days would

PharmaTrac - AIOCD AWACS - % Sales Apr Vs Mar Weekly & Cumulative					
Therapy	Therapy % MAT Mar20	1-22 Apr as % of 1-22 Mar	% Sales to Mar Corresp. dates		
			1-7 Apr	8-15 Apr	16-22 Apr
Pharma Market	**100**	**80**	**88**	**83**	**70**
Anti-Infectives	13.6	62	72	58	57
Cardiac	12.7	98	100	115	78
Gastro-Intestinal	11.1	82	88	83	76
Anti-Diabetic	9.8	106	105	126	83
Vitamins / Minerals	8.5	77	84	75	73
Respiratory	7.6	69	79	78	48
Pain/Analgesics	6.8	69	81	64	62
Derma	6.7	71	80	60	75
Neuro / CNS	6.0	89	95	91	81
Gynaecological	4.9	72	88	60	71
Oncology	2.1	77	89	90	49
Hormones	1.8	82	91	81	73
Opthal / Otologicals	1.8	66	76	63	60
Vaccines	1.6	37	49	18	48
Urology	1.3	88	95	94	74
Blood Related	1.2	76	79	80	68
Others	0.9	71	68	73	72
Sex Stimulants	0.5	62	68	54	63
Stomatologicals	0.5	76	90	72	67
Anti-Malarials	0.4	74	89	98	32
Sharp Drop compared to Week 2			Sharp Recovery		

be at the retail level, further add on inventory would be at the plant. So total inventory could be around 75 days. Hence, I don't feel that there would be shortage/ low level of inventory at the distributor level."

However, Sudarshan Jain, Secretary General, Indian Pharmaceutical Alliance (IPA) justifies the move and said, "This could be the market assessment exercise by the government to ensure that there is no shortage of medicines at any given point of time. As of now there is no shortage or low level of inventory of these medicines, including insulins in the market, however if the production is not resumed completely then there are possibilities of facing such problems."

Dr Shashank Joshi, Chairman International Diabetes Federation, South East Asia said, "At present, we have not come across with any information about the shortage of diabetes medicines or insulins. In fact, if at all, any patient is finding difficulties in sourcing them, we are ensuring from our team that get access to the medicines during the pandemic due to COVID-19."

The letter to all the associations from the CDSCO has also requested to take urgent, necessary action to ensure sufficient availability of anti-diabetic and cardiac medicines at all times. It also requested to issue instructions to the drug manufacturing companies to accelerate their operations and ensure the replenishment of stocks of medicines through wholesalers/distributors/retailer/ chemists so as to reach the hospital/ clinics and to patients as well.

In continuation to this, the NPPA has also requested the CDSCO to provide the details of manufacture of cardiac and anti-diabetic drugs, especially in respect of insulin, aspirin and atorvastatin like name of manufacture/ importers and contact details, manufacturing capacity, production of February, March and April 2020, average monthly import quantity, monthly import quantity of February, March and April 2020 and stock position as of March 31 and April 15, 2020.

Source: Usha Sharma, Express Pharma, 26.04.2020

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FSSAI gives grace period for renewal of food licences during lockdown

The Food Safety and Standards Authority of India (FSSAI) has announced grace period for food businesses, which are applying for renewal of licences or registration, set to expire during the period of nationwide lockdown amid the Covid-19 pandemic.

The FSSAI, in this regard, has issued an order saying that until June 30, 2020, the FBOs (Food Business Operators) would be allowed to function and not be charged late fees.

According to the order, the FBOs whose licence or registration has expired during the period of March 22, 2020, to May 31, 2020, are given grace period to apply

for renewal of the licence or registration till June 30, 2020, without any late fee.

"In the interim period, the FSSAI licence or registration shall be deemed to be valid," the order stated.

Reacting to the decision by FSSAI, Prabodh Halde, chairman, AIFPA, Maharashtra, said, "It's a good decision to give grace period to FBOs, as food comes under the essential commodities and it's important to continued supply of food to consumers. We also welcome the move and appeal to the FBOs to adhere with the FSSAI guidelines for safety in the light of Covid-19 pandemic."

Meanwhile, the FSSAI has also decided to revoke its earlier decision to allow FBOs in J&K and Ladakh to continue operations in the wake of no Internet services in the region. The order in this regards was given last year in October saying that until Internet services resume, the FBOs were allowed to operate if their licences or registration were expired by August 2019.

Now the Internet services were resumed, therefore the said order ceases to be in effect, says the apex food regulator. However, since there is lockdown going on across the country, the FBOs of J&K and Ladakh were also given grace period till June 30 to apply for renewal of their licences.

Source: Ashwani Maindola, FnBNews.com, 24.04.2020

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Government Working on a separate scheme to address delayed payments Issues of MSMEs - Shri Nitin Gadkari

Union Minister for MSME and Road Transport and Highways, Shri Nitin Gadkari said that Government is working on a separate scheme to address delayed payments issues of MSMEs wherein a dedicated fund will be created for payments to MSMEs.

While commenting on delayed payments to MSMEs, Gadkari said that all efforts should be made to make payments immediately and all Government Departments have been given such directions.He was speaking while interacting via video conferencing with the representatives of the Associated Chambers of Commerce of India (ASSOCHAM) on impact of COVID-19 on MSMEs.

Shri Gadkari called upon the industry that while the government has allowed certain industry sectors to start functioning, it is also needed to be ensured by industries that necessary preventive measures are taken to prevent the spread of COVID-19. He emphasized that organizations should ensure that their workers and executives are taken care of by providing food, shelter and maintaining social distancing norms.

He stressed that there is also need to focus on import substitution to replace foreign imports with domestic production. He urged enterprises to make use of technology and mentioned that research, innovation and quality improvement can play a major role in industrial development.

The Minister recalled that Government of Japan has offered special package to its industries for taking out Japanese investments from China and move elsewhere. He opined that it is an opportunity for India and which should be grabbed.

He mentioned that work on Green Express Highway has already started, and this is an opportunity for industry to make future investments in industrial clusters, industrial parks, logistics parks. He opined that there is a need to expand the horizon of industrial cluster in areas other than metro cities and urged that such proposals be submitted to Government. Shri Gadkari emphasized that all the related stakeholders should work together and tap the opportunities that will be created when the COVID-19 crisis gets over. He called upon all sectors to remain positive in adversity.

Some of the issues pointed out by the representatives and the suggestions given included: prioritizing launch of interest subvention scheme, opening the markets along with starting operations of the industries, effective implementation of RBI guideline related to providing additional liquidity to industries, etc.Shri Gadkari responded to the questions from representatives and requested for sending suggestions and assured all the help from the government. He informed that he would take up the issues with related departments/stakeholders to devise solutions at the earliest.

During this interaction, the representatives of ASSOCHAM expressed concerns regarding various challenges being faced by MSMEs amid COVID-19 pandemic along with few suggestions and requested support from the government to keep the MSME sector afloat

Source: Ministry of MSME Press Release, 24.04.2020

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Union Pharma Secretary has asked State Drug Controllers to help Pharmaceutical firms in augmenting production of medicines in the country

VC meeting held with SDCs to review issues of production and distribution of medicines

A meeting through Video Conferencing was held under the Chairmanship of Secretary, Department of Pharmaceuticals (DoP) along with Chairperson NPPA, DCG(I) with the State Drug Controllers (SDCs) of 20 States/ UTs to review working status of pharmaceutical and medical device manufacturing units pre-covid and post covid.

Secretary, DOP appreciated the efforts of all SDC's and requested them to provide all support to manufacturing units with the help of local administration and concerned authorities by regular intraction so that there is no shortage of medicines and medical devices. The production level, percentage manufacturing (pre and post covid) and availability of Drugs and Medical Devices in the country.

State Drugs Controllers (SDCs) were requested to ensure the availability of essential medicines and medical devices required in the management of COVID-19 treatment. They were also requested to ensure the utilization of manufacturing capacity to full extent so that sufficient stocks without any hindrance can be made available at all levels.

State Drugs Controllers assured that they are working hard to increase the production level, attendance of work force, logistics support so as to ensure the smooth manufacturing, distribution and availability of medicine and medical devices in the country. Increase the percentage of manufacturing to ensure its working to full extent and increasing the availability of drugs. Solving all problems relating to logistics, work force movement, ancillary unit required for drugs and devices in co-ordination with all concerned local authorities. Hoarding and price escalation of drugs and medical devices to be monitored & action to be initiated in such case. Information of drugs and devices manufacturing unit to be provided urgently in soft copy by all States. Availability of the Hydroxychloroquine, Azythromycin and Paracetamol formulation be monitored by all the State Drugs Controllers.

55+97 essential drugs circulated by the Ministry of Health & Family Welfare to be monitored on regular basis and data to be provided.

Source: PIB, Ministry of Chemicals and Fertilizers Press Release, 22.04.2020

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Coronavirus triggers sharp rise in prices of azithromycin & HCQ APIs

The prices of Active Pharmaceutical Ingredients (APIs) of azithromycin and hydroxychloroquine (HCQ) have increased two to ten times due to sharp rise in their demand to fight against COVID-19 pandemic.

The prices of azithromycin have jumped to Rs. 16,000 a kg from Rs. 9,000 per kg earlier. The API is imported from China. Taking a cue from Indian traders, the Chinese exporters have also increased the prices of azithromycin to US$ 150 a kg from US$ 90 per kg earlier.

Erythromycin thiocyanate is used as raw material to produce azithromycin, erythromycin stearate and erythromycin estolate. The prices of erythromycin thiocyanate have increased by 10 per cent which led to increase in prices of erythromycin stearate and erythromycin estolate by 10 per cent. Instead of 10 per cent rise, the prices of azithromycin have gone up 90 per cent due to its use in COVID-19 patients. On the other hand, the prices of HCQ API, being touted as game changer in COVID-19 treatment, have gone up ten times to Rs. 70,000 a kg from Rs. 7,000 per kg earlier. Drug makers such as Zydus Cadila and Ipca Laboratories are the major manufacturers of HCQ API in India. The HCQ API is also supplied from China.

As per the Union Health Ministry's recommendation, HCQ in combination with azithromycin is to be considered as an off-label indication in patients with severe COVID-19 who require ICU management, under close medical supervision and monitoring of its side effects. The Health Ministry has directed to all state and Union Territory Administrations to promote rational use of HCQ 2000 mg and azithromycin 500 mg tablets to ensure their availability in the domestic market in the wake of COVID-19 outbreak.

The ICMR has earlier recommended the use of anti-malarial drug HCQ as a preventive medication to health care workers and household contacts looking after a positive case. 18 nurses who tested positive at the Ruby Hall Clinic in Pune were administered HCQ along with Homoeopathy to build their immunity. They have shown speedy recovery with no respiratory problems.

The sharp rise in prices of HCQ and azithromycin APIs will severely impact their formulation manufacturers who cannot increase the prices of drugs immediately despite procuring raw material at exorbitant price. Currently azithromycin formulations are under price control. According to DPCO, prices of scheduled formulations can be increased once a year based on change in wholesale price index of medicines in preceding calendar year.

Besides use in COVID-19 patients, HCQ is used to treat rheumatoid arthritis, lupus, and porphyria cutanea tarda while azithromycin is used to treat a wide variety of bacterial infections such as respiratory infections, skin infections, ear infections, eye infections, and sexually transmitted diseases. A drug maker on condition of anonymity said the sharp rise in prices of HCQ and azithromycin needs immediate attention of the government. The bill of entry of the imported azithromycin needs to be examined to gauge the rise in prices of raw material in the local market.

It is high time the National Pharmaceutical Pricing Authority (NPPA) entrusted with the task of fixation/ revision of prices of pharmaceutical products (bulk drugs and formulations) looked into rising prices of HCQ and azithromycin APIs and put them under price control, he said. NPPA Chairman Subhra Singh has not responded to an email sent by Pharmabiz seeking her response over the issue. When contacted Dr P D Vaghela, Secretary, Department of Pharmaceuticals, said, "We will look into soaring prices of HCQ and azithromycin and requisite steps will be taken in this regard."

Source: Laxmi Yadav, Pharmabiz, 27.04.2020

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CIPMMA urges PM to declare 6-month GST holiday for pharma marketing and manufacturing cos in the wake of COVID-19

Stating that the entire business sector of Pharmaceutical Manufacturing and Marketing in Tamil Nadu is heading towards a recession due to the expanding COVID-19 pandemic, the Consortium of Indian Pharmaceutical Manufacturers and Marketers Associations (CIPMMA) has written to Prime Minister Narendra Modi to declare six months GST holiday for the pharmaceutical business sector from March to August.

Secondly, the Consortium urged the central government to announce an interest-waiver for the loans the companies have taken from banks and other financial institutions for the next one year period or until the industry recovers from the impact of the pandemic.

However, CIPMMA said the government should give utmost priority for containment of the pandemic, and for that the pharma marketers are committed to provide all support to the healthcare system to save the life of the people.

"We want a complete waiver of Goods and Services Tax at least for six months period, and also we need other relaxations like exemption in interest payments on loans from various financial institutions. Government wants the industry to retain all employees and do not make any cut in their salaries. The industry is struggling. Our representatives cannot work in the field, they are not entertained by doctors in clinics and no product is moving. We are unable to withstand the situation", says A Karunai Kadal, President of the Chennai-based CIPMMA.

Pharmaceutical marketing companies which were used to getting orders for lakhs of rupees per day until three months ago are now deprived of their revenues. Since doctors are not reaching hospitals and clinics, the number of prescriptions has come down and the situation does not pressure up on medical shop owners to replenish their shelves with new products as they are not getting depleted. Medical representatives and pharma marketers are forced to sit at home due to no work. The market situation has totally declined the turnover of all companies, says the letter sent to Prime Minister by CIPMMA.

CIPMMA has over 500 registered members who are both manufacturers and marketers of their own products. The members of the Consortium mainly focus on southern districts in Tamil Nadu for marketing business. But, their business representatives are not entertained by the doctors in the hospitals and clinics after the lockdown was imposed by the government. Kadal said all the doctors are scared of corona virus disease and they safely sit at their own homes. No private hospital in Tamil Nadu operates the OPDs of the specialties due to absence of doctors, he said.

In a telephonic interview with Pharmabiz, the President of CIPMMA has pointed out a serious issue the private hospitals in the state are facing today due to COVID-19. "In Tamil Nadu it is not the patients who do not come out of the houses, but it is the doctors who are staying at their own houses. Sitting at homes they prescribe medicines to the patients over telephone in hospitals where the pharmacists dispense the drugs on the advice of the doctors or on prescriptions issued three or four months ago. Even without getting diagnosed by doctors, the chronic patients purchase Schedule H and H1 drugs from the pharmacies of the hospitals by producing previous prescriptions. The doctors, whether they are specialists or super-specialists, do not want to meet their patients. Many of the chronic patients are suffering due to the apathy of the medical professionals", said Kadal.

Kadal, a Pharmacist-Cum-Marketer by profession, opined that the chronic patients of lifestyle diseases have to undergo several diagnostic tests and check-ups in every six months and on the basis of the results the doctors modify their prescriptions. Sometimes the doctors recommend different medicines or make changes in the routine medications or ask the patients to stop some medicines. All these factors depend on diagnosis and medical tests.

But, today, in the light of COVID-19 the doctors are advising the patients to continue the same medication prescribed three to six months ago and they do not want to meet the patients directly. Indirectly a tele-medicine system has emerged in the healthcare system of Tamil Nadu during this COVID -19 period, he further stated.

Source: Peethaambaran Kunnathoor, Pharmabiz, 27.04. 2020

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DoP to frame guidelines to set up three mega bulk drug parks

The Department of Pharmaceuticals (DoP) is in the process of framing guidelines to set up three mega bulk drug parks at different parts in the country. The Union Cabinet has already approved Rs. 3,000 crore under the scheme for promotion of these bulk drug parks.

"We are in the process of framing guidelines basis on which bulk drug parks will be set up in prospective states as the scheme envisages developing three mega bulk drug parks in India in partnership with states. It will also be determined where the parks will be set up based on the guidelines," according to a senior official associated with the development.

DoP has prepared a scheme for development of pharmaceuticals industry with the objective to ensure drug security in the country by increasing the efficiency and competitiveness of domestic pharmaceutical industry with the following sub-schemes like Assistance to Bulk Drug Industry for Common Facility Centre and Pharmaceutical Promotion Development Scheme (PPDS) among others.

According to the plan, the scheme has been envisaged for promotion of bulk drug parks to finance common infrastructure facilities in 3 bulk drug parks with financial implication of Rs 3,000 crore for next five years. This Production Linked Incentive (PLI) Scheme is for promotion of domestic manufacturing of critical KSMs/ Drug Intermediates and APIs in the country with financial implications of Rs 6,940 crore for the next eight years.

Government of India will give Grants-in-Aid to States with a maximum limit of Rs. 1,000 crore per Bulk Drug Park. Parks will have common facilities such as solvent recovery plant, distillation plant, power and steam units, common effluent treatment plant etc. According to the scheme, financial incentive will be given to eligible manufacturers of identified 53 critical bulk drugs on their incremental sales over the base year (2019-20) for a period of 6 years.

Out of 53 identified bulk drugs, 26 are fermentation based bulk drugs and 27 are chemical synthesis based bulk drugs. Rate of incentive will be 20% (of incremental sales value) for fermentation based bulk drugs and 10% for chemical synthesis based bulk drugs. A sum of Rs. 6940 crore has been approved for the next 8 years.

The scheme is expected to reduce manufacturing cost of bulk drugs in the country and dependency on other countries for bulk drugs. The scheme intends to boost domestic manufacturing of critical KSMs/Drug Intermediates and APIs by attracting large investments in the sector to ensure their sustainable domestic supply and thereby reduce India's import dependence on other countries for critical KSMs/Drug Intermediates and APIs. It will lead to expected incremental sales of Rs. 46400 crore and significant additional employment generation over 8 years.

The scheme will be implemented by State Implementing Agencies (SIA) to be set up by the respective State Governments and the target is to set up 3 mega Bulk Drug Parks. The scheme will be implemented through a

Project Management Agency (PMA) to be nominated by the Department of Pharmaceuticals. The Scheme will be applicable only for manufacturing of 53 identified critical bulk drugs (KSMs/Drug Intermediates and APIs).

Common infrastructure facilities would be created with the financial assistance under the sub-scheme in 3 bulk drug parks. It is expected to reduce manufacturing cost and dependency on other countries of bulk drug in the country.

India is significantly dependent on import of basic raw materials, viz., bulk drugs that are used to produce medicines. In some specific bulk drugs the import dependence is 80 to 100%. While Maharashtra, Gujarat and Karnataka are the front-runners, the Centre has also plans to set up bulk drug parks at Himachal Pradesh, Visakhapatnam, Ahmedabad and Tamil Nadu to boost bulk drug production in the country.

Source: Shardul Nautiyal, Pharmabiz, 27.04.2020

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Home Ministry's revised Guidelines make drug manufacturers jittery

The Union Ministry of home affairs (MHA)'s revised lockdown guidelines, issued recently, has sent the entire pharmaceutical industry into a tizzy as some of the punitive clauses in the guidelines have made the domestic drug manufacturers and the exporters jittery.

As per the new guidelines, the company executives will be punished for lapses in coronavirus control and an FIR will be lodged against factory owners or executives in case employees are found COVID-19 positive as well as all employees will be put under 14-28 days quarantine. The clause in the guidelines further said that the factory will be sealed if an employee is found COVID-19 positive and entire industrial area will be sealed if several coronavirus cases are detected.

As per the MHA guidelines, local authorities are empowered to decide if an executive has taken requisite precautions or not.

Companies fear this has provided an opportunity to police or local administration to harass owners or executives in the name of inspection on their premises to ensure whether or not they are complying with the lockdown guidelines. Currently 50-60 per cent industry is working at the capacity of 30-40 per cent. Pharma MSMEs are hard pressed due to lockdown.

The revised MHA guidelines are a double whammy to the drug industry as it is already grappling with logistics challenges as well as shortage of raw materials.

Dr Rajesh Gupta, President of Himachal Pradesh Drug Manufacturers Association (HDMA) said "The manufacturers are committed to fully adhere to government guidelines on measures to check the spread of Covid-19, they should not be penalized. Pharma industry falls under essential service category, clause on punitive action demoralizes the efforts of the industry which is acting as COVID-19 warrior."

Mr Daara Patel, Secretary General of Indian Drug Manufacturers' Association (IDMA) said, "Despite taking all precautions, if something goes wrong in the company, it should be given an opportunity to rectify the situation like putting employees in quarantine, sanitizing premises etc. Penal action should not be taken against such companies. Those who are found not taking preventive measures, they can be penalized."

The revised guidelines allowed manufacturing and industrial establishments functioning in Special Economic Zones (SEZ) and Export Oriented Units (EOU), industrial estates and industrial townships to resume operations after April 20. These establishments will have to make arrangements for the stay and transport of its workers as per requirements.

The provision has taken its toll on the functioning of pharma MSMEs operating on thin margin. The revised MHA guidelines have further aggravated challenges of exporters grappling with an increase in cargo and freight rates and logistics issues. They are reluctant to operate due to clause on punitive action in the guidelines. A significant number of drug exporters have decided to postpone the production for few days.

An exporter on condition of anonymity said that coronavirus can be spread through electrician, plumber, mechanic visited in the company. He said "The guidelines have not improved our situation. We are still facing logistic problems while dispatching finished products and sourcing raw materials."

Taking serious note of challenges faced by drug exporters in the wake of revised guidelines of MHA, Dinesh Dua, Chairman of Pharmexcil has reached out to commerce ministry urging it to address the concerns of exporters.

According to the Department of Pharmaceuticals, domestic pharmaceutical market turnover reached

Rs. 129,015 crore (US$ 18.12 billion) in 2018, growing 9.4 per cent year-on-year and exports revenue was US$ 17.28 billion in fiscal year 2018 and US$19.14 billion in fiscal year 2019.

Source: Laxmi Yadav, Pharmabiz, 23.04.2020

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Maha FDA asks industrial gas manufacturers to produce medical grade oxygen to treat critically ill COVID-19 patients

The Maharashtra Food and Drug Administration (FDA) has directed industrial gas manufacturers to produce medical grade oxygen to cater to the growing demand for treating critically ill COVID-19 patients in the country.

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

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

Meanwhile, the state FDA recently identified 73 industrial gas manufacturers and has issued product licenses to around 15 manufacturers to produce medical oxygen. "The storage capacity of storing medical oxygen is also assessed besides the medical grade cylinders as a preemptive measure to meet future emergencies for medical emergencies considering the ongoing increase of COVID-19 cases with over 21,000 positive cases and over 680 deaths," informed V K Biyani, Joint Commissioner, Maharashtra FDA.

This comes at a time when the government has set up 723 COVID-19 hospitals, two lakh isolation beds, 24 thousand ICU beds and 12,190 ventilators in the country.

Recognising the need of immediate availability of medical oxygen for severe and critical COVID-19 patients in India, the Union Health Ministry issued guidelines to the states on the methods of supplying oxygen to the medical facilities handling COVID-19 patients.

The Ministry also issued a list of 17 medical oxygen gas manufacturers, refillers, suppliers, seven cylinder manufacturers for medical oxygen and four manufacturers of liquid oxygen under the umbrella of the All India Industrial Gases Manufacturers Association (AIIGMA), the national representative body of industrial gas manufacturers and allied industries in India comprising members from public and private sector industries.

AIIGMA has over 270 members and supplies 95% of India's requirement of medical oxygen.Medical oxygen is used for oxygen therapy in hospitals and is designated as a drug and therefore must satisfy FDA requirements for compressed medical gas.

One of the requirements is that cylinders containing oxygen must always be completely evacuated to minimize the risk of contamination. Critically ill COVID-19 patients need oxygen support and in extreme cases use of ventilators.

Because the FDA classifies medical grade oxygen as a drug, manufacturer must have a prescription to purchase it as well as other oxygen-related medical devices such as oxygen concentrators. It may seem like an unnecessary step since the production and fulfillment of medical grade oxygen is already regulated, but a prescription is an extra step to ensure that the oxygen you are getting is safe to use.

Source: Shardul Nautiyal, Pharmabiz, 24.04.2020

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AIOCD asks govt to give relaxation in Section 40(A) (3) of IT Act for Pharma Retailers

The All India Organisation of Chemists and Druggists (AIOCD) has sought Prime Minister Narendra Modi's intervention in getting relaxation in Section 40(A)(3) of Income Tax (IT) Act to pharmaceutical retailers till June 30, 2020 or till the date of normalcy from COVID-19 pandemic returns.

Pharmaceutical stockists are registered under Goods and Services Tax (GST) Act and supply goods to retailers in GST invoices only.

"We therefore assure that there will not be any misuse of such relaxation if granted to our members. This relaxation is required to remove fear in the minds of retailers and ensure uninterrupted supply of essential medicines and in turn to ensure timely payment to pharmaceutical companies during this crucial period," says Rajiv Singhal, General Secretary, AIOCD.

Singhal added, "Our retailers are facing issues while making payment to stockists. In normal condition, our stockists supply medicine to retailer in the particular area and collect cheque, cash from the retailers periodically by sending salesmen to retailers.

Due to lockdown, movement of salesmen has been restricted and somehow stockists are managing supplies to retailers with the help of available third party small transporters".

AIOCD stated that collection cycle has been adversely impacted as retailers are not able to get cheque books from respective bank due to closure of courier services and banks are operating for limited time period and reluctant to handle cash deposits by our retail member. There will also be impact on small retailers as there will be no online application available or no connectivity in their area.

"Since medicines are listed in essential commodities, our members are working in risky situation and keeping supply of medicine to retailers in all adverse situations. Most of the retailers started depositing cash to stockists over and above the defined limit set under Section 40(A) (3) of IT Act 1961.

We expect you will consider our request and notify necessary relaxation in the interest of public at large," says AIOCD President J S Shinde. AIOCD also thanked all Central Ministers and Administrators, particularly, Union Health Minister for timely support to pharmaceutical trade and industry during the lockdown.

Source: Yash Ved, Pharmabiz, 24.04.2020

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ICMR urges healthcare institutions to use rapid antibody test for epidemiological surveillance as per prescribed Protocol

Following quality issues with imported rapid antibody kits, the Indian Council of Medical Research (ICMR) has urged all healthcare institutions in all the states in the country to use it as a tool for surveillance as per ICMR prescribed protocol and not to diagnose COVID-19 cases.

This comes close on the heels of ICMR having mandated states to stop using rapid testing kits for COVID-19 for two days for verifying complaints related to rapid antibody kits tests results. India had taken delivery of 500,000 rapid antibody test kits from China last week.

In an advisory to all states, ICMR stated that the national task force at ICMR has carefully reviewed the data evolving from various countries on use of such kits. Based on available evidence, the testing strategy for COVID-19 has been revised further.

As per protocol for using rapid antibody test for epidemiological studies and surveillance, gold standard frontline test for COVID-19 diagnosis is real time PCR based molecular test, which is aimed at early virus detection. The rapid antibody test cannot replace the frontline test. The rapid antibody test is a supplementary tool to assess the prevalence of the diseases within a specific area. The rapid antibody test will only be of utility after a minimum of 7 days of onset of symptoms. Data about these rapid tests is emerging and understanding of their utility for diagnosis is still evolving. The rapid tests are useful for epidemiological studies and surveillance purposes.

In case your state does not have a hot spot, these tests may be used for any hotspot which may emerge in future or as a surveillance tool for epidemiological purposes in such areas where cases have not emerged so far. Before starting the rapid test, it should be registered on covid19cc.nic.in/ ICMR and data related to the test should be reported on the same, ICMR stated.

The ICMR reference to the polymerase tests underlines that they are the "gold standard" for detecting COVID-19 infections and shows that states were not following the protocol that rapid tests are not for diagnostic purposes.

ICMR reference shows that states were not following the set protocol that rapid tests are not for diagnostic purposes. Following complaints that the antibody test kits are showing varying levels of accuracy, ICMR advised all the states that the tests be suspended pending field validation and investigation by its teams.The medical research body has told states that the test kits cannot replace the RT-PCR test. To further assist states, ICMR will collect data from various states to assess the scope and extent of utility of these rapid antibody tests in field conditions."We evaluated the feedback from the states. These kits are not meant for diagnosis of COVID-19 but only for surveillance. States are required to follow the ICMR protocol properly. Meanwhile, we will investigate it based on data collected from states," an ICMR official said

Source: Shardul Nautiyal, Pharmabiz, 24.04.2020

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CCMB provides training to technical researchers on COVID-19 testing

The Hyderabad-based CSIR-Centre for Cellular and Molecular Biology (CSIR-CCMB) has started providing training to the technical researchers with life sciences background from various universalities on coronavirus testing.

According to Dr. Rakesh Mishra, Director of CCMB, the main objective behind providing training to technical researchers from various universities is to boost the testing capacity for coronavirus in the state. "We have already started providing training to technical research students of school of life sciences from University of Hyderabad (UoH). They will all be given proper training on data entry, sample sorting, aliquoting and coordination with other testing labs," informed Dr. Mishra.

To begin with, a batch of 8 out of 15 technical researchers from University of Hyderabad is being trained on testing for COVID-19 using RT-PCR besides precautions that need to be taken. After one day training, they would be working at the Centre for DNA finger printing and diagnostics (CDFD) during late night shift.

Apart from research students from UoH, the CCMB scientists are also providing training to researchers from CSIR-Indian Institute of Chemical Technology (CSIR-IICT). To overcome the lockdown, the scientists are conducting theoretical discussions through video call and providing in lab training for the nitty-gritty of doing the actual tests.

As there are growing numbers of COVID-19 cases in the state with each passing day, the state government of Telangana and department of biotechnology have identified Hyderabad as a major testing cluster for coronavirus and CCMB has been playing a major role in training and equipping the technical researchers on various aspects of testing of the dreaded and highly contagious coronavirus disease.

With this, now Hyderabad has various centers like UoH, CDFD, CSIR-CCMB, National Institute of Animal Biotechnology and CSIR-IICT which are capable of conducting coronavirus tests in Telangana.

Source: A Raju, Pharmabiz, 24.04.2020

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Pharma MSMEs seek removal of restriction on export of ethanol-based hand sanitizers due to bumper supply of ethyl alcohol

The Pharma Micro, Small and Medium Enterprises (MSMEs) Manufacturing hand sanitizers have urged Directorate General of Foreign Trade (DGFT) to lift restriction on export of ethanol-based hand sanitizers in the wake of surplus production of ethyl alcohol in the country.

Besides benefitting MSMEs, who are major players in hand sanitizer segment, this will also benefit sugar mills, sugarcane cultivators and distilleries producing ethanol. Ethanol, an active ingredient in the production of hand sanitizers, is manufactured by sugar mills in India.

The hand sanitizer industry is expected to require 8-10 million litres of ethanol per month at full capacity utilization. Currently, India has an ethanol production capacity of 3.5 billion litres/year, as per official records. Hence the stock of ethanol available for domestic use is way more than the requirement.

There is no shortfall of hand sanitizer made of ethanol with the impurity of isopropyl alcohol (IPA) making it unfit for drinking. Closure of courier services for documentation, low attendance of staff and non-working transport have led to huge pile-up of goods at factory premises, resulting in short supply of hand sanitizers made of ethyl alcohol, said Nipun Jain, Chairman of Small & Medium Pharma Manufacturers Association (SMPMA).

With a sharp rise in number of manufacturers of hand sanitizers due to speedy clearance of product manufacturing licence, there is abundant supply of sanitizers in the domestic market. Lifting restriction on export of ethanol based sanitizers will benefit pharma MSMEs, sugarcane producers, sugar mills and distilleries sitting on excess ethanol, said Amit Chawla, Vice President of Laghu Udyog Bharati Indore unit.

The sanitizers thronged the local market are mostly made of ethyl alcohol which is available in great quantity. The ethyl alcohol is produced from molasses which are by product of sugar industry in the country which is largest producer of sugarcane after Brazil.

The use of molasses is either in the manufacturing of smoking tobacco and in mild steel casting industry for making mixture of molds and used in rubber industry and petroleum industry owned by governments like Indian

Oil and Hindustan Petroleum. The consumption of these fields is also not very high compared to high production. The molasses is also used in higher alcohols like isopropyl alcohol but India has only limited factories to produce IPA like Deepak Organics and VAM organics.

There are more than 3000 distilleries in the country. Punjab has three small distilleries Patiala Distillery, Rana Sugar Mill, and Pioneer Chemical in Pathankot and two big distilleries namely Hamira Distillery (Jagatjit Industries Limited), Khasa Distillery. The small distillery like Pioneer is making 1,25,000 litres of alcohol per day. The estimate of Hamira and Khasa distillery is 10 times more than this.

Haryana, Uttar Pradesh, Gujarat and South India are full of distilleries due to availability of molasses. The sugarcane production is considered in Punjab, Haryana and UP excluding South India (due to hot and humid and non-growing area of wheat) as a crop changer. So even without profit they have to grow sugarcane.

During this lockdown there is low sale of whisky and alcoholic drinks but the distilleries due to continuous process remained working. Now they are full of alcohol and molasses are under maturing condition. If the alcohol is not utilized, the storage capacity of the distillery will compel them to shut down and the molasses will become very hazardous due to enzymatic reactions. This reaction cannot be stopped. There is a need to watch the industry. Its high time the government allows export of ethanol based hand sanitizers so that excess supply of ethanol will be consumed, said SMPMA Chairman.

Our member companies are also ready to serve the nation with huge quantities if ordered. However, the importers in countries like USA, Europe, Africa etc have also placed orders with us. Hence we have requested DGFT to allow export of ethanol based hand sanitizers, so that we can fulfil our export obligation, said Jain in a letter to DGFT.

DGFT on March 24, 2020 imposed restriction on export of all sanitizers made of both ethanol and IPA to meet rising demand in the country due to coronavirus pandemic. The government brought hand sanitizers under the Essential Commodities Act on March 19 to prevent hoarding and also capped maximum retail price of 200ml bottle at Rs 100 until June 30 amid the tremendous rise in prices of this product since COVID-19 outbreak.

Source: Laxmi Yadav, Pharmabiz, 23.04.2020

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Ayush Ministry invites research proposals to evaluate Ayush interventions in prophylaxis and clinical mgt in COVID-19

The Union Ayush Ministry has directed the Principal Secretaries/Secretaries (Health/Ayush) and DGs/Director of Ayush and National Ayush Institutes to support short-term research proposals for evaluating the role and impact of Ayush interventions/medicines in the prophylaxis and clinical management of SARS-CoV-2 infection and coronavirus (COVID-19). The Ministry has designed a mechanism for the same. This mechanism is a modification of the existing Extra Mural Research (EMR) Scheme.

The Ayush Ministry has invited research proposals from eligible investigators to carry out research in the field of Ayush under the EMR scheme.

The Ayush ministry has asked scientists and researchers to look for a cure for the COVID-19 pandemic that has infected around 24 lakh people globally. So far, there is no cure for COVID-19, as with all viral infections. But over the last few days, the Ayush Ministry has received over 2,000 proposals claiming possible treatments.

The notification from the ministry came after Prime Minister Narendra Modi urged Ayush (Ayurveda, Yoga, Unani, Siddha, Sowa Rigpa and Naturopathy) practitioners to pitch in to tackle the pandemic.

Nearly 20,000 people contracted coronavirus in the country, of whom 640 people died and more than 3,800 people recovered. The Project proposals of maximum six months duration with IEC clearance will be considered for support up to Rs. 10 lakhs to meet the expenditure on engaging Ayush clinician, technical manpower, laboratory investigations and related contingencies.

The proposals are invited as per the following provisions of hospitals/institutions and applicant investigator/ researcher should be involved in the quarantine and/or clinical management of COVID-19 cases.

The Ministry of Ayush issued a statement recommending "self-care guidelines for preventive health measures and boosting immunity with special reference to respiratory health." The ministry said these guidelines are "supported by ayurvedic literature and scientific publications".

Source: Neethikrishna, Pharmabiz, 23.04.2020

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'CPT points to possible cure to COVID-19': Dr Gururaj Rao

The immunology of SARS (Severe Acute Respiratory Syndrome), which is related to COVID-19 genetically, is similar to that of early stage cancer, said Dr. Gururaj A Rao, Director, iCREST, HealthCare Global (HCG) Cancer Centre, Bengaluru.

"We feel that we can make good headway with a comprehensive approach since there is some similarity between cancer and SARS patients like low lymphocyte count, high neutrophil to lymphocyte ratios and abysmal CD-8 counts. Now we have proposed treatment options for early, mid and late stage COVID-19 patients. Under convalescent plasma therapy (CPT), which is a form of immunotherapy, patients in Stage-2 with COVID-19 infection, who have worsening symptoms but not progressed to acute respiratory distress, can be good candidates for passive immunity through immunoglobulins against COVID-19 present in convalescent plasma," Dr Gururaj told.

The CP protocol was submitted to DCGI and ICMR for approval and has been cleared for a phase I/II clinical trial by the regulatory authority, he added. HCG and Victoria Hospital, which is a Government identified hospital, will conduct the clinical trial on patients who have progressed to Stage-2 without ARDS (Acute Respiratory Distress Syndrome). "We are working out the details for the trials and hope to provide positive results from CPT. Patients will be included based on their clinical symptoms and could be in the age-group between 18 and 85 years," he said. When it comes to ethical concerns, informed consent of the patient and donor is mandatory. The study has been cleared by the Institutional Ethics Committee (IEC). With the state government's support, we can enrol more people over time, Dr Rao said. For clinical trials, the laboratory infrastructure for patient testing will be at Victoria Hospital while donor assessment will be done at HCG and government identified accredited labs.

The trial includes a study where their medical experts will be looking at the cytokine levels of the donor plasma. For the early-stage COVID-19 cases, the experts will look at immune rebalancing using cell-derived cytokines to prevent an increase in viral load. In the case of the late-stage patients who are in acute respiratory distress, our proposal which is under review with ICMR and DGCI, is to look at mesenchymal cells for lung inflammation, said Dr Rao.

For CPT, animal studies are not mandated. Safety and efficacy has been demonstrated in a few patients but results are anecdotal. This is why we proposed a phase I/II clinical trial. If the clinical trials prove to be successful, CPT could be a therapeutic option going forward. The government has been cooperative with us to help us reach this stage, said Dr Rao.

Source: Nandita Vijay, Pharmabiz, 23.04.2020 (Excerpts)

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CDSCO grants no objection for conduct of clinical trials for CP therapy for COVID-19 as per ICMR protocol

The Central Drugs Standard Control Organisation (CDSCO) has granted no objection for conduct of clinical trials for convalescent plasma (CP) therapy as per protocol developed by ICMR. Following the approval, it has Directed individuals, institutes and organisations, interested in conduct of trial to seek consultation with ICMR for conduct of clinical trial for CP therapy.

The proposal of ICMR for conducting the trial was reviewed through CDSCO subject expert committee (SEC) in a meeting on April 14, 2020 and CP therapy was approved under accelerated approval process in light of the current prevailing situation of COVID-19 and based on the recommendations of the committee. The same has been approved subject to certain amendments in the protocol and various conditions under the new drugs and clinical trial rules 2019.

ICMR has also shared a list of institutes with CDSCO which have shown interest in the conduct of said trial.

While deliberating the clinical trial protocols of other applicants for conduct of clinical trial with convalescent plasma in COVID-19 patients, the SEC in the said meeting opined that ICMR has developed a protocol for a controlled clinical trial with convalescent plasma in moderate COVID-19 patients and the same may also be considered by the applicants as appropriate.

As per the protocols, plasma donors will be explained the procedure of plasma donation and the adverse events associated with the process. Among the consenting donors and based on the results, donors will be asked to return on a specified date for plasma donation.

Plasma collection will be done by centrifugal separation using apheresis equipment at the healthcare facility.

Volume collected will not exceed 500 ml per sitting (as per Drugs and Cosmetics (Second Amendment) Rules, 2020). Throughout the procedure the extracorporeal volume of blood will never exceed > 15% of the total blood volume of the donor. Donor adverse events will be managed as per departmental SOP for Apheresis donations.

A unique donor identification number will be provided to the collected unit as per departmental SOP and the unit will be stored as per departmental SOP or issued for patient use. The collected plasma will be divided into smaller packs of 200 ml each for easy storage and transfusion.

The plasma will be stored at <-40 degree celsius. No pooling of plasma from different donors will be done. Successful plasma donors will be requested to repeat the donation. If the donor agrees for a repeat donation, such donation will be scheduled after at least 2 weeks of the first plasma donation. If there was a loss of red cells at the time of first donation owing to any procedural problems or otherwise the donor will be deferred for a period of 3 or 4 months for male or female donors respectively.

All the donor selection guidelines will also apply to repeat donation as well. In repeated plasmapheresis, total serum protein will be tested before the third procedure if done within four weeks and it should be 6gm/dl. The quantity of plasma separated from the blood of donor will not exceed 500 ml per sitting and once in a fortnight or shall not exceed 1000 ml per month.

Currently, there are no approved treatments for COVID-19. The CP therapy management plan is supportive care with supplemental oxygen and mechanical ventilation. Multiple trials are being done across the globe to assess the efficacy of various treatment strategies. US FDA has recently approved CP from patients recovered from COVID-19 for the treatment of severe or life threatening COVID-19 infections. In a small case series, five critically Ill COVID-19 patients with acute respiratory distress syndrome (ARDS) were treated with convalescent plasma containing neutralizing antibodies.

Source: Shardul Nautiyal, Pharmabiz, 21.04.2020,

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Government clarifies MHA order, no penalty for management of industrial establishments

The letter requests all State/UT Governments to apprise industrial establishments and field offices about the guidelines of lockdown measures but cautions that they shouldn't be used to harass the management of any manufacturing/ commercial establishment

The Secretary of Government of India has issued a letter clarifying that there is no penal provision for the management of any manufacturing/ commercial establishments in the consolidated revised guidelines of the Ministry of Home Affairs (MHA), order dated April 15, 2020. The MHA order comprises consolidated revised guidelines with regard to penal provisions, for ministries/ departments of the Government of India, State/UT authorities on the measures for containment of COVID-19 in the country during the extended lockdown until May 3, 2020. Now, the government has issued a letter which mentions that some apprehensions based on a wrong interpretation of the guidelines have been raised in the media and by some companies with manufacturing facilities. Many believed that States may take legal action, including imprisonment of the CEO if COVID-19 positive employees are found in the factory. Moreover, the premises of the factory would be sealed for three months for non-compliance of precautionary measures.

However, the government has clarified that there is no such clause in the consolidated revised guidelines and therefore there is no basis for such misplaced apprehensions. It also informs that the factory may be closed down for two days and will be allowed to restart after full compliance. This comes as a relief to the industry. There was a lot of apprehension on the MHA order and most of the companies opted to wait till May 3, 2020, to continue their due to certain legal provisions. And, at the state levels, several industry associations had also expressed their concerns and had opted to stop production activities.

Mr B R Sikri, Chairman, Federation of Pharma Entrepreneurs (FOPE) and VP, Bulk Drug Manufacturers Association (BDMA) said, "We appreciate the clarification given by the government on the revised guidelines issued by the MHA dated April 15, 2020, for the purpose of restarting industries in Green and Orange zones. Due to misinterpretation of the penal provision in the order, the industry was reluctant about continuing operations, however, with the clarification, the ambiguity in the given guidelines have been cleared. The industry will adhere with specified norms of the revised guidelines."

Mr Vinod Kalani, President, Rajasthan Pharmaceutical Manufacturers Association, (Jaipur) and Working President, Federation of Pharma Entrepreneurs (FOPE) said, "We, in

the pharma industry, really appreciate the quick action taken to resolve the issues faced by the industry in these difficult times. Such timely solutions are really helping the units working on the ground and facing all kinds of challenges. Our thanks to the MHA and the Government of India. We, in the pharma industry, are taking care of our workforce in the best possible manner, as we understand that they are nothing less than COVID-19 warriors to attend their work in such difficult circumstances."

Mr Harish Jain, Secretary, Karnataka Drugs and Pharmaceutical Manufacturers Association said, "It is a welcome and timely development. The clarification has removed the apprehensions which otherwise would have led to companies discontinuing operations. It is important that these clarifications should percolate down to the last man in the official hierarchy, in letter and spirit. Manufacture of drugs, medicine and allied products should be encouraged to continue uninterrupted in the larger national interest."

Dr Viranchi Shah, National Vice President, Indian Drug Manufacturers' Association (IMA-GSB) said, "This clarification will boost the confidence of a lot of entrepreneurs and businesses and will prompt more to start work. Earlier there were some apprehensions in minds of many MSMEs, this has cleared the doubts. We appreciate the clarification."

The letter states that appropriate safeguards at workplaces have been prescribed in the National Directives and SOPs mentioned, and commercial establishments are required to follow the given guidelines. But, it also clarifies that the consolidated revised guidelines dated April 15, 2020, does not curtail the exemption that already provided earlier unless the exempted activity falls within a containment zone. Therefore, no separate/ fresh permissions are required from authorities for industries already permitted to operate prior to April 15, 2020, in areas falling outside containment zones.

Source: Usha Sharma, Express Pharma, 24.04.2020

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Coronavirus impact: Top Pharma Companies fare better during lockdown

New launches stagnate as fresh prescriptions dry up

Kolkata-based Sutapa Sengupta (name changed) was experiencing pain in her lower back and limbs. Unable to reach out to her doctor because of the lockdown, she opted for a drug she thought was safe and a brand she was familiar with — Calpol.

The medicine, made by British multinational pharma major GlaxoSmithKline Pharmaceuticals (GSK), has seen a major jump in terms of monthly sales in March. According to data from market research firm AIOCD AWACS, Calpol saw sales of Rs 17.9 crore in December, when it was the number 3 drug in the category. However, its sales shot up to Rs 24.8 crore in March, making it number one in the category.

As such, top brands continue to do well despite the lockdown, when prescription generation has almost come to a standstill. In a recent report, CLSA said that for March the average growth of the top 10 brands was 15 per cent, much higher than 9 per cent growth seen by brands ranked 11 to 20, and 6.3 per cent growth seen by brands ranked 21 to 30.

CLSA noted that the top brands continue to be the key drivers of growth for companies — top brands clocked growth in the range of 5-21 per cent year-on-year in March. A GSK spokesperson said the company's strategy to focus on its top brands is auguring well in these times. The company is also conducting webinars with clinicians on several topics relevant to the Covid-19 pandemic. In fact, webinars have become the order of the day, with the pharma sales force taken off the field.

Mumbai-based JB Chemicals and Pharmaceuticals, which owns marquee brands like Metrogyl and Rantac, launched a cardiac (hypertension) product in March through a webinar right before the lockdown began. "We first trained our medical representatives (MRs) through webinars. Then we launched the product through webinars with doctors. This was right before the lockdown.

However, making it available at the retail level has been a challenge," said Pranabh Mody, President, J B Chemicals & Pharmaceuticals.Drug firms depend on fresh prescriptions for their new introductions, which are made available at medical stores near the clinics visited by MRs. The lockdown has made supplying drugs to the right retail outlets a challenge.

"Moreover, why would a chemist even stock a new brand when he knows fresh prescriptions will be rare," said a senior official at a drug firm.

As a result, new launches have fallen sharply. From 278 new product launches in February, the number slipped to 123 in March, and drug makers said April would hardly see any new launches. Pharma majors said the sales outlook

According to data from market research firm AIOCD AWACS, Calpol saw sales of ₹17.9 crore in December, when it was the number 3 drug in the category

for April is even grimmer. "For the anti-infectives segment (antibiotics primarily), the sales in the first 15 days of April are down by 67 per cent compared to the first 15 days of March," said the senior official of a Mumbai-based drug major. He reasoned that demand for antibiotics, and even

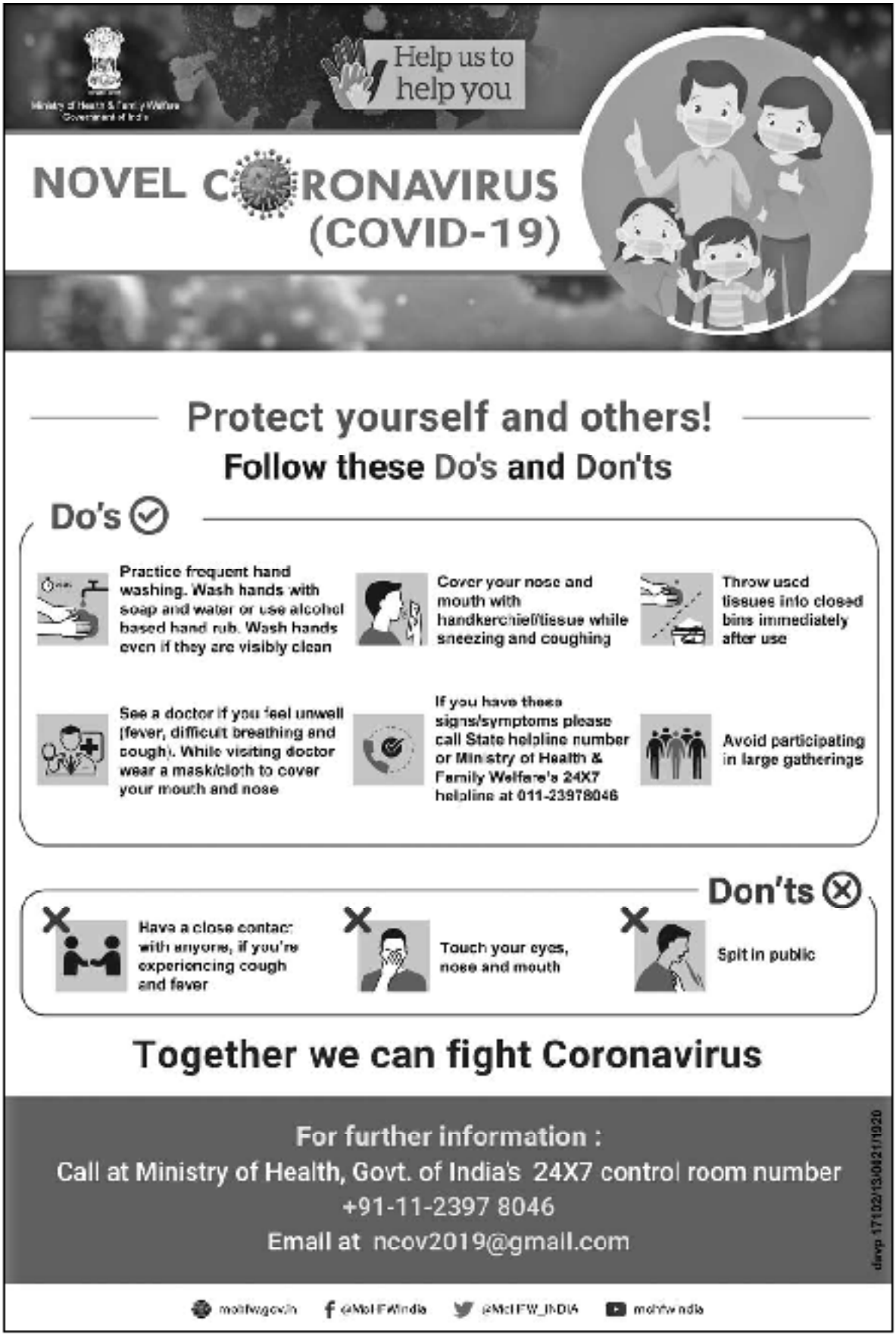
SALES OF TOP BRANDS

Pain and analgesics	Brand	Rank	Sales (₹cr)	Market share (%)
Dec 2019	Ultracet	1	23.7	2.94
	Volini	2	22.6	2.81
	Calpol	3	17.9	2.22
	Voveran	4	17.4	2.16
	Zerodol SP	5	16.8	2.08
Mar 2020	Calpol	1	24.8	3.22
	Ultracet	2	23.5	3.05
	Dolo	3	19.9	2.58
	Volini	4	19.3	2.50
	Zerodol SP	5	17.7	2.30

Source: AIOCD AWACS

gastrointestinal medicines etc. is slowing down, with people staying indoors, eating home-cooked food and taking care of their health. "The industry expects the value growth this year to slow down to 1.5-3 per cent if the crisis continues. Apart from new launches and smaller brands getting hit, logistics challenges will also affect overall sales," said CEO of a drug major on condition of anonymity.

Source: Sohini Das, Business Standard, 25.04.2020


Ministry of Health & Family Welfare
Government of India
Help us to help you
NOVEL CORONAVIRUS (COVID-19)
Protect yourself and others!
Follow these Do's and Don'ts
Do's
Practice frequent hand washing. Wash hands with soap and water or use alcohol based hand rub. Wash hands even if they are visibly clean
Cover your nose and mouth with handkerchief/tissue while sneezing and coughing
Throw used tissues into closed bins immediately after use
See a doctor if you feel unwell (fever, difficult breathing and cough). While visiting doctor wear a mask/cloth to cover your mouth and nose
If you have these signs/symptoms please call State helpline number or Ministry of Health & Family Welfare's 24X7 helpline at 011-23978046
Avoid participating in large gatherings
Don'ts
Have a close contact with anyone, if you're experiencing cough and fever
Touch your eyes, nose and mouth
Spit in public
Together we can fight Coronavirus
For further information :
Call at Ministry of Health, Govt. of India's 24X7 control room number
+91-11-2397 8046
Email at ncov2019@gmail.com
davp 17102/13-04/21/1920
mohfwgovin
@MoHFWIndia
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mohfwindia


व्यं राष्ट्रे जागृयाम
Rising to the Hon'ble Prime Minister's call..
SETU
A VOLUNTARY INITIATIVE OF IRTS OFFICERS
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