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RNI REGN. NO. 18921/1970
REGN NO. MCW/95/2021-23

IDMA BULLETIN

VOL. NO. 52 | ISSUE NO. 01 (PAGES: 44) | 01 TO 07 JANUARY 2021 | ISSN 0970-6054 | WEEKLY PUBLICATION

Indian APIs & Formulations for Global Healthcare

INDIAN DRUG MANUFACTURERS' ASSOCIATION

HIGHLIGHTS

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

Annual Subscription
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IDMA BULLETIN

Vol. No. 52 **Issue No. 01** **01 to 07 January 2021**

INDIAN DRUG MANUFACTURERS' ASSOCIATION

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ATTENTION MEMBERS

Invitation to participate in 'IDMA MARGI MEMORIAL BEST PATENT AWARDS 2019-20'

As you will be aware, the **IDMA Margi Memorial Best Patent Awards** recognize the **'Best Patent of the Year'**, both national and international. We request you to kindly send us details of your **patent/s granted in the last 12 months period (01.04.2019 to 31.03.2020)**. An Expert Panel will examine and evaluate the applications received and recommend their selection for the Award. A copy of the Patent granted should also be enclosed to enable the Panel to evaluate the Patent for the Award.

Applications should be forwarded in a closed and sealed envelope marked **'IDMA Margi Memorial Best Patent Awards 2019-20'** along with an ENTRY FEE of ₹10,000/- + GST @18% (Total ₹11,800/-) per Member Company immediately to reach us **latest by 15th January 2021.**

For the convenience of the panelists, soft copies of the application along with relevant supporting patent documents may also be sent separately.

Applications for the Award will need to comply with certain criteria as enumerated in the Guidelines (Do's and Don'ts) for IDMA Margi Memorial Best Patent Awards 2019-20 (as mentioned below). Kindly peruse the same before applying for the Award.

The winners will be notified by email after the Expert Panel finalizes selection of Award Winners. The Awards will be presented at the **IDMA 59th Annual Day Celebrations to be organized by end of February 2021 at Online Web.**

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GUIDELINES FOR SUBMISSION OF APPLICATIONS FOR PATENT AWARDS

The Expert Panel, constituted to scrutinise the Applications, has set the following **DOs and DON'Ts** for consideration for Awards as below:

DOs:

1. Applications must include Patents granted only during the financial year 2019-20 (1st April 2019 to 31st March 2020) for evaluation.
2. A Member-Company can apply for more than one Patent. Multiple Patents can be listed in a single application.
3. The Application is to be submitted both as Soft Copy as well as Hard Copies with Summary of the Patents. However, details of Patents may please be sent preferably only in Soft copy.
4. All Family Patents belonging to same invention will be considered as one patent. Country-wise validations for EU or ARIPO patents will not be considered as independent patents. Divisional patents granted with similar inventions will be considered along with parent patent.
5. Different inventions having same title with common priority document will be identified and considered as One Patent.
6. Group companies (including Research Centres) applying independently may indicate if they wish to be considered together or separately. If patent is granted to other than the applicant, the documents justifying the inclusion of such patents (group status) need to be attached.
7. Applications for Awards for Patents granted to individuals will be considered with documentary support of rights transferred to the Applicant (Member Company)
8. Applicants are requested to self-certify the authenticity of information submitted to minimise the review and verification work by IDMA.
9. The Application must be forwarded under a covering letter/or by email duly signed by an authorised signatory along with name, designation and contact details.
10. The covering letter should carry a declaration that *"We have read 'The Guidelines and Criteria for Evaluation of Patents submitted for IDMA Margi Memorial Patent Awards 2019-20 and abide by the same"*.

DON'Ts:

1. Please do not apply for Patents granted earlier than 1st April 2019 or after 31st March 2020. It will not be considered for this year's Awards.
2. Please do not apply for a pending patent. It will not be considered and will be disqualified.
3. Please do not apply for Patents which are already withdrawn, abandoned, not maintained or revoked will obviously not be considered.
4. An Application of a patent of the same family (of an invention which has already qualified for award in earlier years), even if granted in another country in the relevant year will not be considered.
5. If the data submitted is found to be not correct or factual, the applications will be disqualified.

(Note: The Decision of the Expert Panel will be Final).

Request to include Pharma Industry workforce in Priority List for COVID-19 Vaccination: IDMA representation to NITI Aayog

The Association has submitted the following representation on 30th December 2020 to Dr Vinod Paul, Member, Niti Aayog, New Delhi with copies to Ms S Aparna, Secretary, Department of Pharmaceuticals and Mr Rajesh Bhushan, Secretary, Department of Health and Family Welfare, New Delhi for including Pharmaceutical Industry workforce in the Priority List for COVID-19 vaccination:

"The Indian Drug Manufacturers' Association (IDMA) would like to thank you and the entire Government of India for supporting the industry consistently during COVID-19 pandemic and the earlier lockdown period.

As you are aware the pharmaceutical industry has been classified as essential goods and services industry wherein the employees and all stakeholders have been committed to ensure the consistent availability of medicines during the COVID-19 pandemic. We appreciate that the Government of India is in the process of approval of vaccines and is also preparing a plan for the distribution of vaccines. We understand that the priority groups include healthcare and frontline workers, persons over 50 years of age and/or with comorbid conditions.

We would like to request the Government of India to consider the Pharmaceutical industry workforce in the Priority List for COVID-19 vaccination. The COVID-19 vaccination will protect around 2 million Pharma workforce against the disease and will not only be a recognition to them, but also ensure uninterrupted manufacture and supply of Medicines in the Country.

The industry will be ready to support the Government for distributing and dispensing of vaccines. We once again assure you of the commitment of the pharmaceutical industry to support the Government at this critical juncture".

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Issues for discussion with DGFT: IDMA Representation to DoP

The Association has submitted the following representation/issues on 29th December 2020 to Shri Navdeep Rinwa, IAS, Joint Secretary, Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers, New Delhi re. issues for discussion with DGFT:

"Greetings from Indian Drug Manufacturers' Association.

This has reference to our discussions regarding the smooth functioning of the export activities of the Pharma sector. The subject of expeditious fixation of SION was also discussed in the last Task Force meeting on APIs. We would be most grateful to you to kindly arrange a VC with DGFT and other officials of Ministry of Commerce to address the issues raised by us in the attached note. Please let us know for any further clarification from us. With Best Wishes for coming 2021, Warm regards".

Issues for Discussion with DGFT, Ministry of Commerce

1. Expert Committee should meet at least twice a month to clear all pending applications for SION fixation. Same to be considered as deemed approved if no decision is taken in 30 days.
2. DGFT should appoint an adjudication cell for speedy clearance of all past "default' cases of advance licenses and give guidelines how to close them. This will lead to additional exports by those exporters whose IEC is blocked for several months/years and are thus unable to avail benefits available under the FTP.
3. Time lines need to be fixed for expeditious disposal of appeals at various stages as provided under the EP.
4. New system for Advance License is not stabilised. Suggest some parallel process to be available for some time as exporters are not able to apply.
5. MEIS application is blocked by system in case of exporters who are in DEL list. In many cases by the time IEC was removed from DEL list, MEIS application period became time barred. In spite of E-Comm number being generated within the time limit, there is no provision for system to subsequently accept the application. Need for procedure for generation of MEIS so the exporters are not deprived of their legitimate benefit against genuine exports.
6. MEIS applications for April '20 onwards are not accepted in the system. Further, for Indian Pharma exports to remain competitive, MEIS needs to be continued till RODTEP is ready to be rolled out.
7. IGST drawbacks held up by customs in cases where inadvertently exporters have claimed higher rate of drawback. There is no procedure for making correction of the mistake.

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INDIAN PHARMACOPOEIA COMMISSION

Upgradation and Inclusion of General Chapters and General Monographs in upcoming Edition of IP - reg.

ATTENTION MEMBERS

IDMA has received an email communication from Indian Pharmacopoeia Commission (IPC-Ghaziabad) along with draft General Chapter and General Monographs listed below for review and comments:

Interested Members are requested to access the draft documents from IPC website: **www.ipc.gov.in** or contact IDMA Secretariat at email:mail_idma@idmaindia.com for soft copies of the draft amendments. Comments/Suggestions are to be provided latest by **20th January, 2021:**

1. Pharmaceutical Preparations.
2. Pharmaceutical Substances.
3. 2.5.3 Consistency of Formulated Preparations.
4. 2.5.5. Friability of Uncoated Tablets. Page 309.
5. 5.10. Elemental Impurities.
6. Annexure A: 2.3.1. General Identification Reactions of Ions and Functional Groups. Page 129 Draft Amendments proposed for IP-2022.

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Procurement Guidelines for Pharmaceutical Formulations under PPO 2017 revised to promote local content – reg.

DPIIT Ref.F.No.31026/65/2020-MD, dated 30th December, 2020

Whereas Department for Promotion of Industry and Internal Trade (DPIIT), pursuant to Rule 153(iii) of the General Financial Rules 2017, has issued Public Procurement (Preference to Make in India) Order (PPO), 2017 vide no. P 4502/212017-B.E.-11 dated 15.06.2017, which is partially modified by Order no. P-45021/2/2017-PP (BE-ID dated 28.05.2018, Order no. P-45021/212017-PP (BE-11) dated 29.05.2019, Order no. P-45021/2/2017-PP (BE-II) dated 04.06.2020 and Order no. P-45021/2/2017-PP (BE-II) dated 16.09.2020.

Whereas it is the policy of the Government of India to encourage 'Make in India' and promote manufacturing and production of goods and services in India with a view to enhancing income and employment, and

Whereas DPIIT, in order to facilitate the implementation of the PPO, 2017, vide D.O. No. P-45021/2/2017-BE-II dated 14.08.2017 has identified Department of Pharmaceuticals (DoP) as the Nodal Department for implementing the provisions of the PPO, 2017 relating to goods & services related to Pharmaceuticals Sector.

Now, therefore, Department of Pharmaceuticals (DoP), in supersession of the guidelines issued earlier by DoP vide F.No. 3IO26/4/2018-Policy dated 01.01.2019, F.No. 31026/4/2018-Policy dated 14.01.2019 and F.No. 3 I 026/4/2018-Policy dated 25.02.2019, issues the following guidelines for implementation of the provisions of Public Procurement (Preference to Make in India) Order (PPO), 2017, as revised by DPIIT on 16.09.2020, with respect to public procurement of Goods & Services in Pharmaceutical Formulations:-

1. **Local Content:** 'Local content' means the amount of value added in India which shall be the total value of the item procured (excluding net domestic indirect taxes) minus the value of imported content in the item (including all customs duties) as a proportion of the total value, in percent.

2. **Formulation:** 'Formulation', as defined in the Drugs (Price Control) Order, 2013, means a medicine processed out of or containing one or more drugs with or without use of any pharmaceutical aids, for internal or external use for or in the diagnosis, treatment, mitigation or prevention of disease and, but shall not include:

   i. any medicine included in any bonafide Ayurvedic (including Sidha) or Unani (Tibb) systems of medicines;

   ii. any medicine included in the Homeopathic system of medicine; and

   iii. any substance to which the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) do not apply.

3. In exercise of provisions of Pam 5 of Public Procurement (Preference to Make in India) Order, 2017 revision dated 16.09.2020 of DPIIT, the minimum local content for Pharmaceutical Formulations are fixed as under:

   i. **Class-I Local supplier** means a supplier or service provider, whose goods, services or works offered for procurement, has local content equal to or more than 80%.

   ii. **Class-II local supplier** means a supplier or service provider, whose goods, services or works offered for procurement, has local content more than 50% but less than 80%.

   iii. **Non—Local supplier** means a supplier or service provider, whose goods, services or works offered for procurement, has local content less than or equal to 50%.

4. Verification of Local Content:

   a. The 'Class-I local supplier'/ Class-II local Supplier' at the time of tender, bidding or solicitation shall be required to indicate percentage of local content and provide self-certification that the item offered meets the local content requirement for 'Class-I local supplier'/ Class-II local supplier', as the case may be. They shall also give details

of the location(s) at which the local value addition is made.

b. In cases of procurement for a value in excess of Rs.10 crores, the 'Class-I local supplier'/ 'Class-II local supplier' shall be required to provide a certificate from the statutory auditor or cost auditor of the company (in the case of companies) or from a practicing cost accountant or practicing chartered accountant (in respect of suppliers other than companies) giving the percentage of local content.

c. The following Committee is being formed for independent verification of self-declarations and auditor's/accountant's certificate on random basis and in the case of complaints:

   1. Chairman — MD, Karnataka Antibiotics & Pharmaceuticals Limited
   2. Member — Representative from NIPER Ahmedabad
   3. Member — Representative from the NPPA
   4. Member — Representative from the CDSCO
   5. Member — Joint Director (Pricing), D/o Pharmaceuticals

d. In case of reference of any complaint by the concerned bidder, there would be a fee of Rs. 2 lakh or 1% of the value of the pharmaceutical formulations being procured (subject to a maximum of Rs.5 lakh), whichever is higher, to be paid by way of a Demand Draft to be deposited with the procuring entity, along with the complaint by the complainant. In case, the complaint is found to be incorrect, the complaint fee shall be forfeited. In case, the complaint is upheld and found to be substantially correct, deposited fee of the complainant would be refunded without any interest.

5. These guidelines shall be applicable to all Central Sector Schemes/Centrally Sponsored Schemes for procurement made by States and local bodies if project or scheme is fully or partially funded by Government of India.

6. All other provisions of Public Procurement (Preference to Make in India) Order 2017, as revised by DPIIT on 16.09.2020, shall be applicable as such and shall be adhered to by all procuring agencies for procurement of any pharmaceutical formulation.

7. These guidelines shall remain applicable, until further orders, from the date of issuance.

8. These guidelines will supersede the guidelines issued earlier by DoP vide Order No. 31026/4/2018-Policy dated 01.01.2019, Order No. 31026/4/2018-Policy dated 14.01.2019 and O.M. No. 31026/4/2018-Policy dated 25.02.2019.

F.No.31026/65/2020-MD

Dr Sumit Garg, Deputy Secretary, Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers, New Delhi.

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Remission of Duties and Taxes on Exported Products (RoDTEP) Scheme gets implemented from 01.01.2021

Ministry of Finance Press Release dated 31 December 2020

Taking a major step to boost exports, Government has decided to extend the benefit of the Scheme for Remission of Duties and Taxes on Exported Products (RoDTEP) to all export goods with effect from 1 January, 2021.

The RoDTEP scheme would refund to exporters the embedded Central, State and local duties/taxes that were so far not being rebated/refunded and were, therefore, placing our exports at a disadvantage. The refund would be credited in an exporter's ledger account with Customs and used to pay Basic Customs duty on imported goods. The credits can also be transferred to other importers.

The RoDTEP rates would be notified shortly by the Department of Commerce, based on the recommendation of a Committee chaired by Dr G K Pillai, former Commerce and Home Secretary. The final Report of the Committee is expected shortly. An exporter desirous of availing the benefit of the RoDTEP scheme shall be required to declare his intention for each export item in the shipping bill or bill of export. The RoDTEP shall be allowed, subject to specified conditions and exclusions. The notified rates, irrespective of the date of notification, shall apply with effect from 1 January, 2021 to all eligible exports of goods.

Source: PIB, MoF Press Release, 31.12.2020

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DCG(I) Dr V G Somani issues Restricted Emergency Use Approval for Serum Institute of India and Bharat Biotech COVID-19 Vaccines

MoH&FW Press Release dated 3rd January 2021

The Subject Expert Committee of Central Drugs Standard Control Organisation (CDSCO) met on 1st and 2nd January, 2021 and made recommendations in respect of proposal for Restricted Emergency Approval of COVID-19 virus vaccine of M/s Serum Institute of India and M/s Bharat Biotech as well as Phase III Clinical Trial of M/s Cadila Healthcare Ltd.

The Subject Expert Committee consists of domain knowledge experts from the fields of pulmonology, immunology, microbiology, pharmacology, paediatrics, internal medicine, etc. M/s Serum Institute of India, Pune has presented a Recombinant Chimpanzee Adenovirus vector vaccine (Covishield) encoding the SARS-CoV-2 Spike (S) glycoprotein with technology transfer from AstraZeneca/Oxford University.

The firm submitted safety, immunogenicity and efficacy data generated on 23,745 participants aged ≥ 18 years or older from overseas Clinical Studies. The overall vaccine efficacy was found to be 70.42%. Further, M/s Serum was granted permission to conduct Phase-II/III Clinical Trial on 1600 participants within the country.

The firm also submitted the interim safety and immunogenicity data generated from this trial and the data was found comparable with the data from the overseas clinical studies. After detailed deliberations Subject Expert Committee has recommended for the grant of permission for restricted use in emergency situation subject to certain regulatory conditions.

The Clinical Trial ongoing within the country by the firm will continue. M/s Bharat Biotech has developed a Whole Virion Inactivated Corona Virus Vaccine (Covaxin) in collaboration with ICMR and NIV (Pune), from where they received the virus seed strains. This vaccine is developed on Vero cell platform, which has

well established track record of safety and efficacy in the country & globally.

The firm has generated safety and immunogenicity data in various animal species such as mice, rats, rabbits, Syrian hamster, and also conducted challenge studies on non-human primates (Rhesus macaques) and hamsters. All these data has been shared by the firm with CDSCO.

Phase I and Phase II Clinical Trials were conducted in approx 800 subjects and the results have demonstrated that the vaccine is safe and provides a robust immune response. The Phase III efficacy trial was initiated in India in 25,800 volunteers and till date, ~22,500 participants have been vaccinated across the country and the vaccine has been found to be safe as per the data available till date.

The Subject Expert Committee (SEC) has reviewed the data on safety and immunogenicity of the vaccine and recommended for grant of permission for restricted use in emergency situation in public interest as an abundant precaution, in Clinical Trial mode, to have more options for vaccinations, especially in case of infection by mutant strains. The Clinical Trial ongoing within the country by the firm will continue. M/s Cadila Healthcare Ltd., has developed a Novel Corona Virus-2019-nCov-Vaccine using DNA platform technology. The firm initiated Phase-I/ II Clinical Trial in India in more than 1000 participants which is ongoing.

The interim data suggests that the vaccine is safe and immunogenic with three doses when administered intradermally. Accordingly, firm has sought permission to conduct Phase III Clinical Trial in 26000 Indian participants, which has been recommended by the Subject Expert Committee. M/s Serum and M/s Bharat Biotech vaccines have to be administered in two doses. All the three vaccines have to be stored at 2-8°C. After adequate examination, CDSCO has decided to accept the recommendations of the Expert Committee and accordingly, vaccines of M/s Serum and M/s Bharat Biotech are being approved for restricted use in emergency situation and permission is being granted to M/s Cadila Healthcare for conduct of the Phase III Clinical Trial.

Source: PIB, MoH&FW Press Release, 03.01.2021

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Advisory for RoDTEP (Remission of Duties and Taxes on Exported Products) Incentive Scheme

Advisory No.01/2021, dated 1st January 2021

1. A new scheme, RoDTEP (Remission of Duties and Taxes on Exported Products) has been launched by the Government for exporters. The scheme provides for rebate of Central, State and Local Duties/Taxes/ Levies which are not refunded under any other duty remission schemes. The broad provisions are as under:

I. To avail the scheme exporter shall make a claim for RoDTEP in the shipping bill by making a declaration.

II. Once EGM is filed, claim will be processed by Customs.

III. Once processed a scroll with all individual Shipping Bills for admissible amount would be generated and made available in the users account at ICEGATE.

IV. User can create RoDTEP credit ledger account under Credit Ledger tab. This can be done by IECs who have registered on ICEGATE with a DSC.

V. Exporter can log in into his account and generate scrip after selecting the relevant shipping bills.

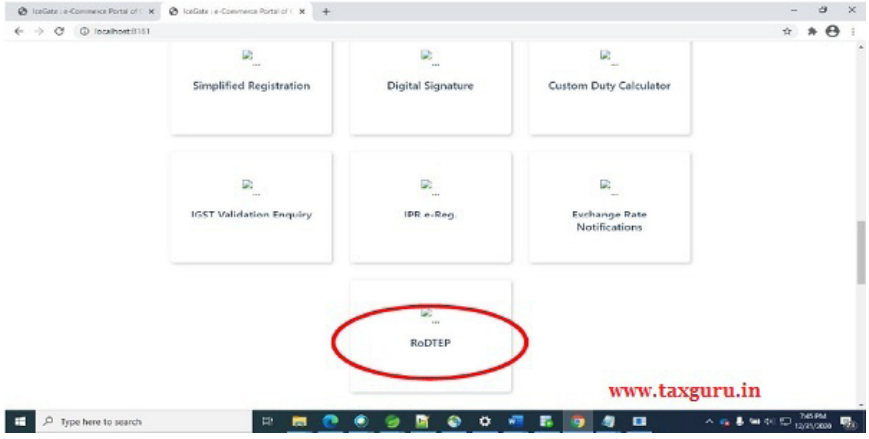
2. As of now the users can log into their ICEGATE account and create the RoDEP Credit Ledger Account, as scrip generation provision will be made functional on the issuance corresponding notification by the Department and availability of the budget. Implementation of Scheme in Custom Automated System has been developed. Details attached as Annexure A.

3. This advisory is a complete step-by-step guide for the user to create a RoDTEP credit ledger account, generate scrips and transfer the scrips to any other IEC.

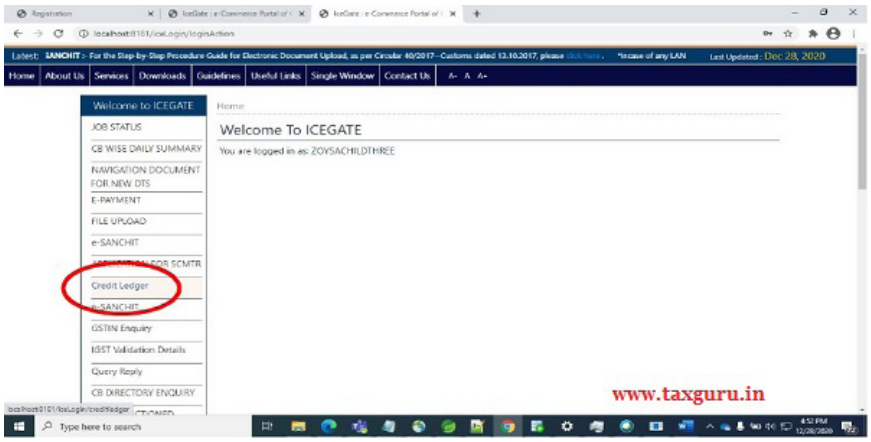
A) RoDTEP (Credit Ledger) Account Creation:

RoDTEP Credit Ledger can be used by the Importer/Exporter/CHA only after creating a successful credit ledger account at ICEGATE. Below are the steps to create a RoDTEP Credit Ledger Account with ICEGATE.

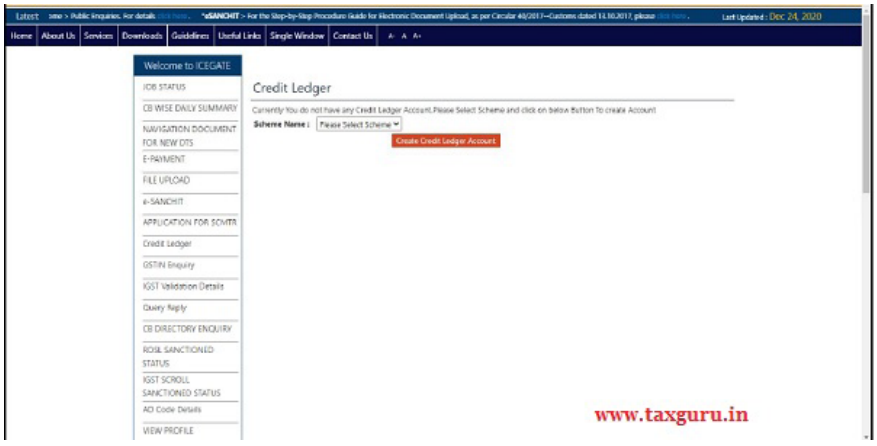
Step 1) User can select the option of RoDTEP (Credit Ledger) account creation by clicking on the "RoDTEP" tab under the "Our Services" section of **https://www.icegate.gov.in/** as indicated below:



Step 2) User will be directed to the login page. After log in using valid credentials, user will be able to see the Credit Ledger option on the left panel as shown below: If user is not registered they can get themselves registered as per advisory through this link: **https://icegate.gov.in/Download/JavaSetupForDSC.pdf**



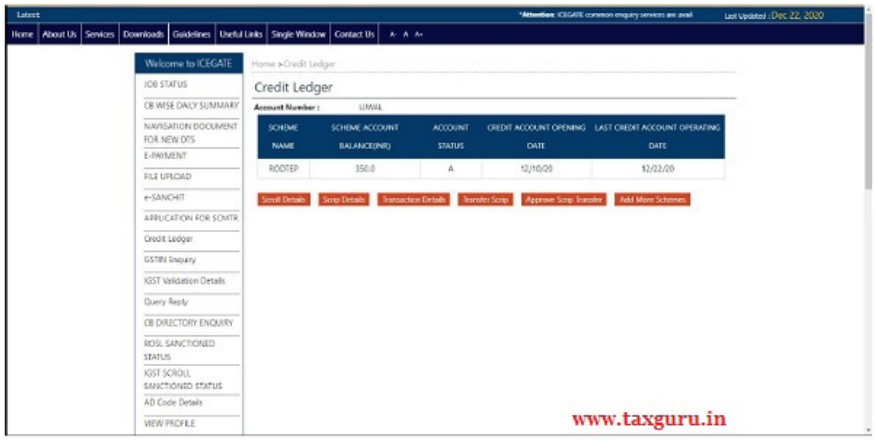
Step 3) Since the user has not created a credit ledger account initially, the following page will be displayed. The user can select the scheme name from the drop-down as RoDTEP



Step 4) After Credit Ledger account creation is done by the user, a grid view with the following details will be displayed to the user:

User can perform various operations mentioned as follows from this Home Page:

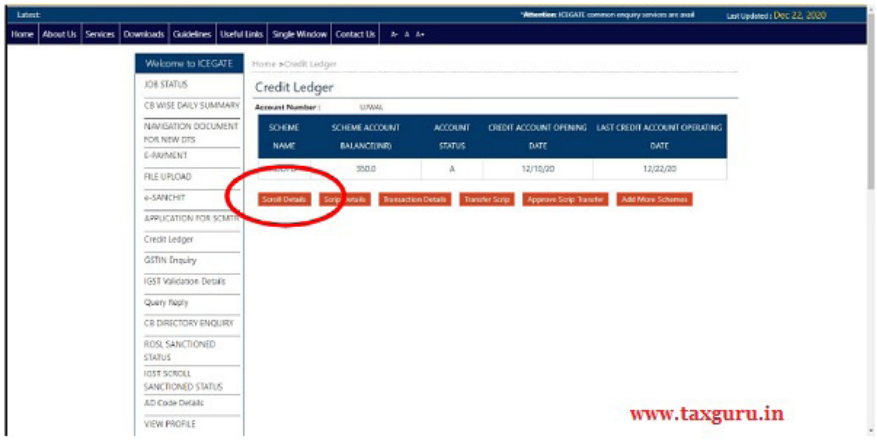
- Scroll Details
- Scrip Details
- Transaction Details
- Transfer Scrip
- Approve Scrip Transfer



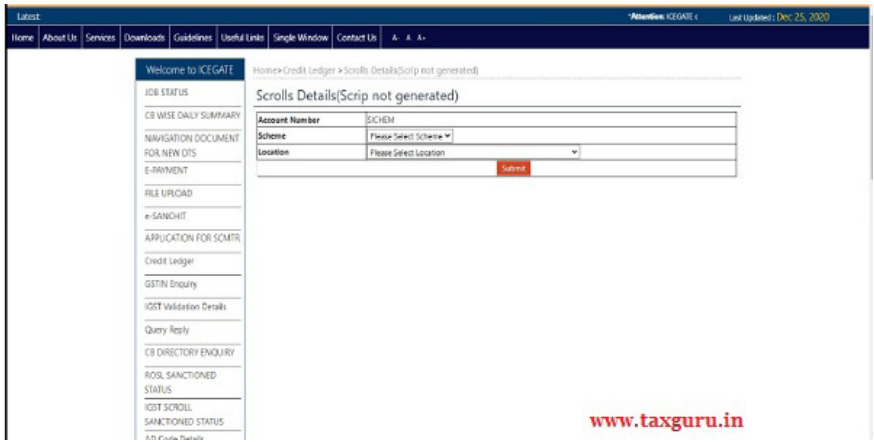
B) Scrip Management Module:

1) Scrip Generation

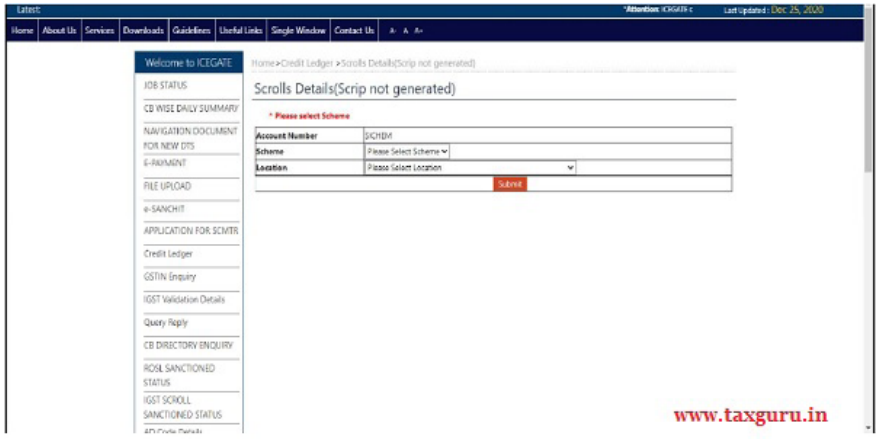
Step 1) From the credit ledger Home Page as shown below, user has to select Scroll Details Tab for scrip generation.



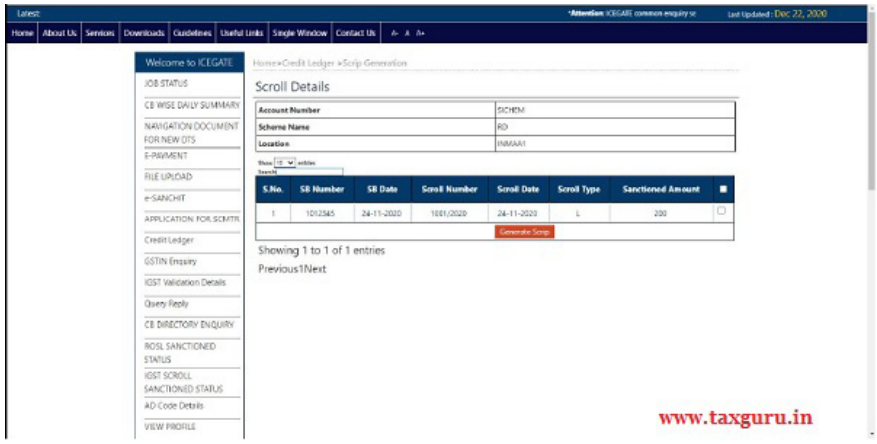
Step 2) User is provided with the feature of selecting Shipping bills/scrolls for which the scrips are to be generated. User has to select RoDTEP under scheme name and location as mentioned below:



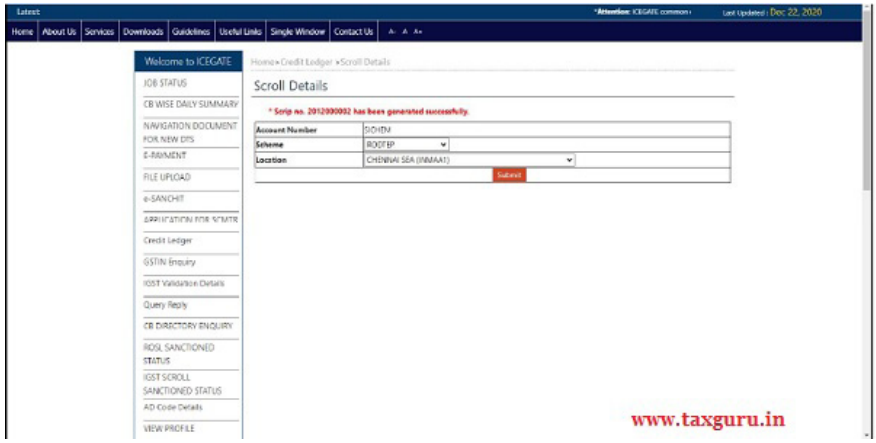
Step 3) An error message will be displayed if the scheme (mandatory) is not selected



Step 4) User can view and select the shipping bills and can generate the scrip

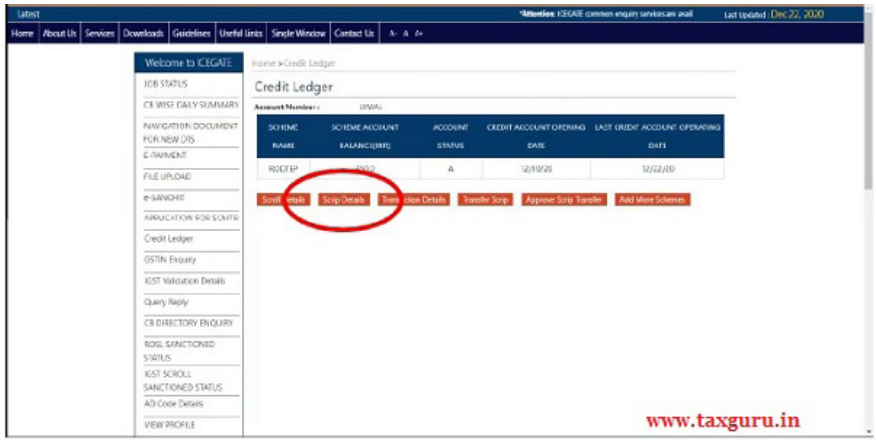


Step 5) Scrip will be generated for the selected shipping bill/scroll. After successful Scrip Creation the following message will be displayed on the screen



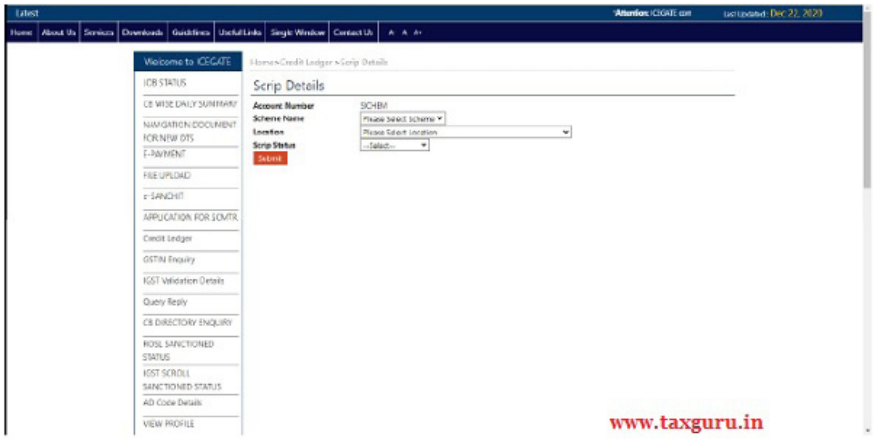
2) Viewing Scrip details:

Step 1) In the credit Ledger home page, user can select on the Scrip Details Tab to view the scrip details which has been generated.



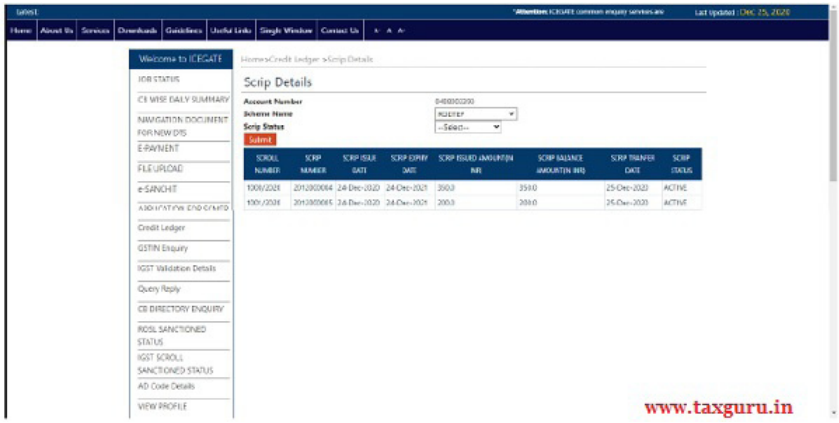
Step 2) A unique Scrip Number will be generated and tagged to every user. A credit entry will be made in the credit Ledger for that user. User can view scrip details after selecting from the following options in the scrip status drop down:

1. Active - Scrip which is still in active state.
2. Utilize - Scrip which is utilized by the user.
3. Transferred - Scrip for which the transfer request is approved by the transferee to whom the user has initiated transfer.
4. Transfer Pending- Scrip which is transferred by the user to another IEC holder but the latter has not approved the transfer request.
5. Expired - Scrip which is expired
6. Transfer Rejected - Scrip which is rejected by the transferor (who has initiated the scrip transfer request) or the transferee (to whom scrip transfer request is sent).
7. All - All scrips generated.



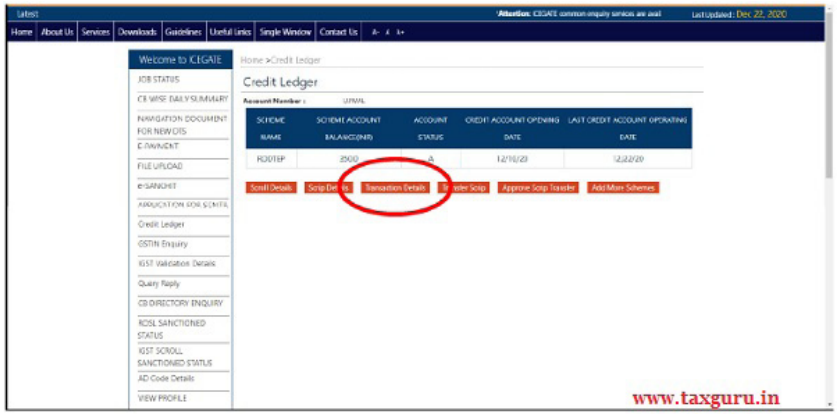
Step 3) Once the mandatory fields are selected, the data can be viewed in grid. User should be able to view the last 10 entries by default from the credit ledger. The user can click on next or previous link in case of more than 10 entries. The description of the data is given below:

1. Scroll Number: Unique scroll number.
2. Scrip Number: Unique scrip number.
3. Scrip Issue Date: Date on which scrip is generated.
4. Scrip Expiry Date: Date on which the scrip will expire.
5. Scrip Issued Amount: Amount for which the scrip is issued.
6. Scrip Balance Amount: Total balance after the scrip has been utilized.
7. Scrip Transfer Date: Date on which the transfer has been approved by the IEC to whom the scrip is transferred. This will be blank if transfer is not initiated.
8. Scrip Status: based on what scrip status user has previously selected as explained in the previous step (Step 2).



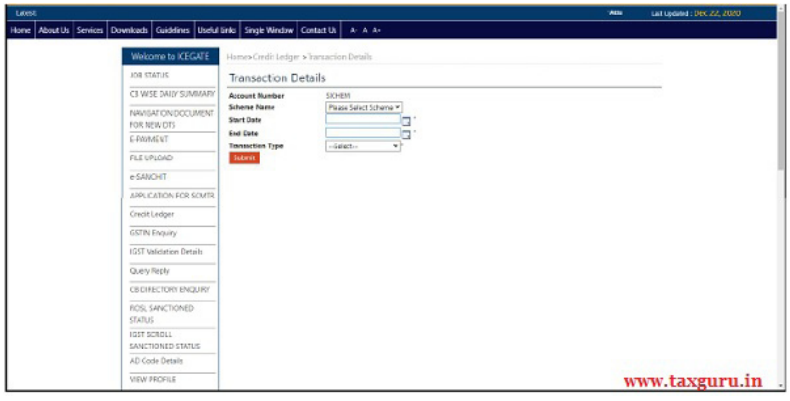
3) Transaction Details:

Step 1) In the credit Ledger Home Page, User can view the Transaction Details by clicking the tab as shown below:

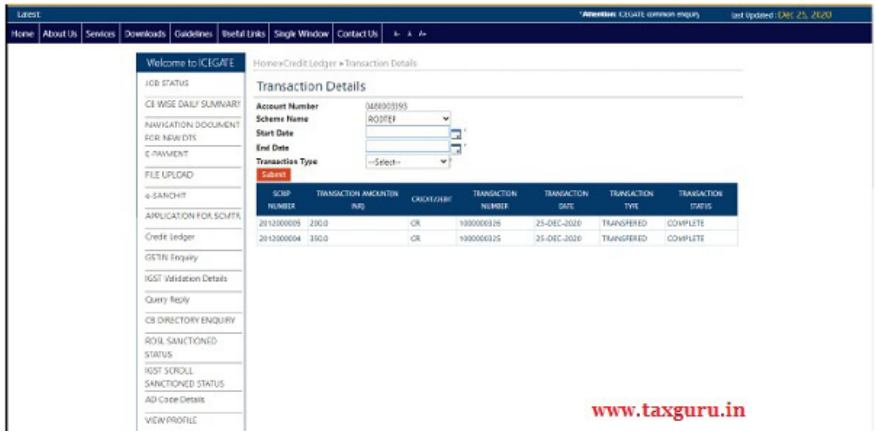


Step 2) User should be able to view the transactions basis multiple search criteria like start date, end date and transaction type. The Transaction Type field has a drop down with the following options to select. User can select the appropriate field:

1. Issued: To view the scrips been generated. The transaction status will be Complete for this transaction type.
2. Utilized: To view the scrips which are utilized. The transaction status will be Complete for this transaction type.
3. Transferred: To view the scrips which are transferred to another IEC holder. The transaction status will be Complete for this transaction type.
4. Transfer Pending: To view the scrips for which the approval for transfer is pending. The transaction status will be Pending for this transaction type.
5. All: To view all types of scrips.



Step 3) After selecting the appropriate fields, data will be displayed in a grid format as shown below

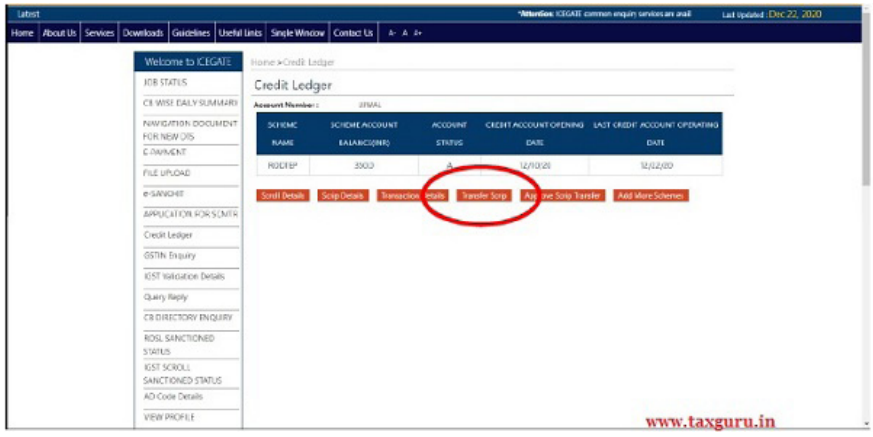


4) Scrip Transfer:

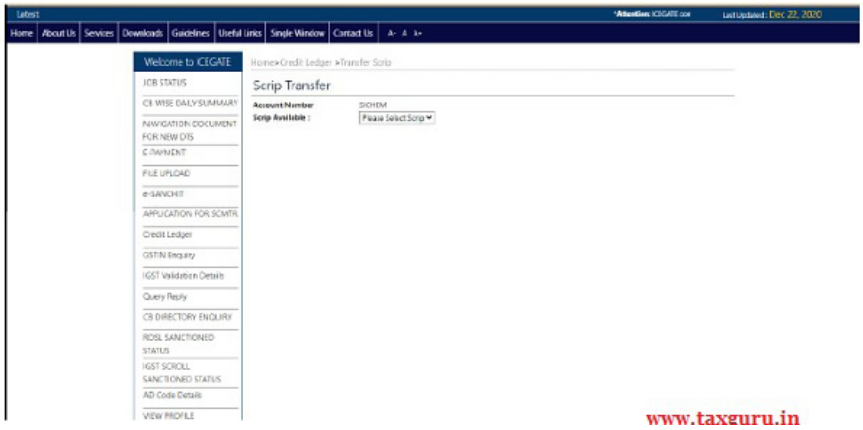
Any user who has created a credit ledger account can transfer a scrip to another user. The user to which the scrip is to be transferred also needs to have a valid credit ledger account

Below are the steps for scrip transfer:

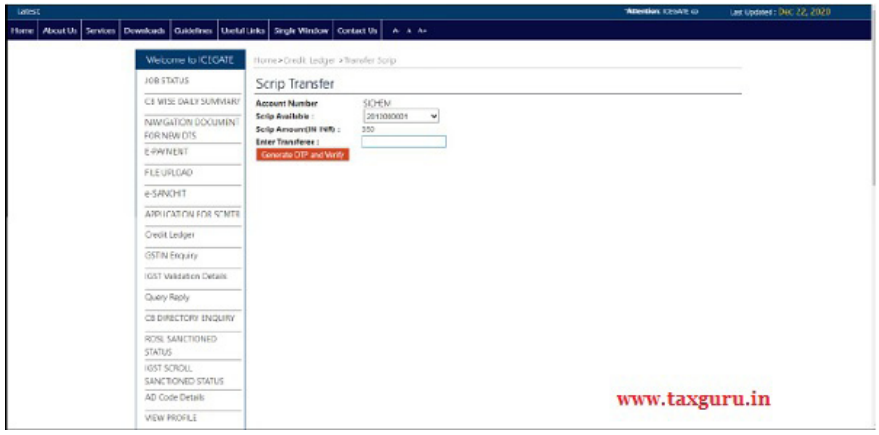
Step 1) From the credit ledger Home page, user can select the "Transfer scrip" tab to transfer a particular scrip to any other user:



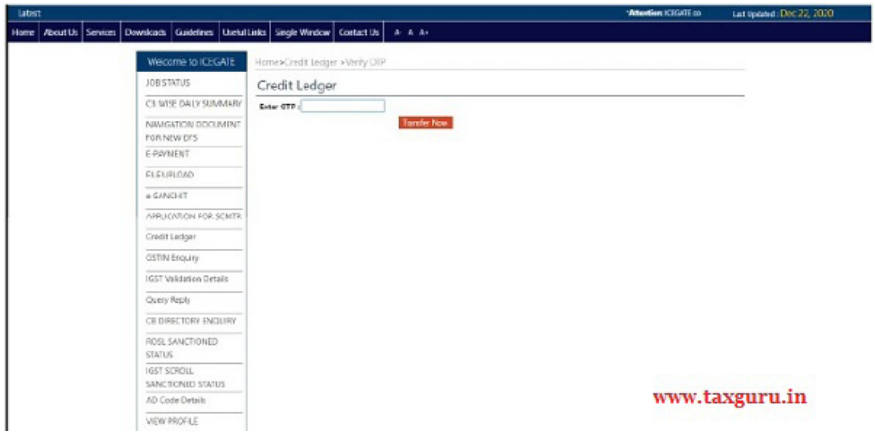
Step 2) The user can select the appropriate scrip to be transferred from the generated scrips. The list of the generated scrips is available in the drop-down menu along the "Scrip Available" Option.



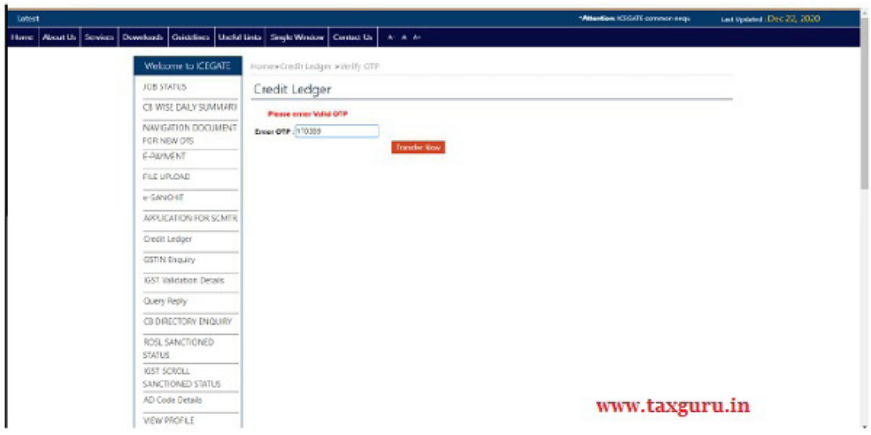
Step 3) After appropriate scrip selection, user can view scrip amount and enter IEC of the user to which the scrip is to be transferred. These details, of the IEC holder to whom the user wants to make transfer, can be entered in the textbox alongside “Enter Transferee” option.



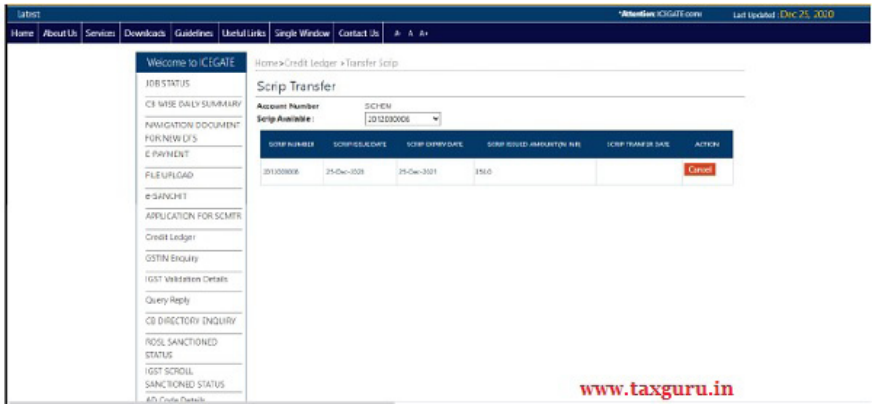
Step 4) OTP is generated and sent to the user who has initiated the transfer on the Registered Mobile Number and email ID. It has to be entered by that user to transfer the scrip successfully. This OTP is valid for a window of 15 minutes only.



Step 5) If the user has entered wrong OTP to transfer the scrip, an error message to select a valid OTP will be generated on the screen as shown below:



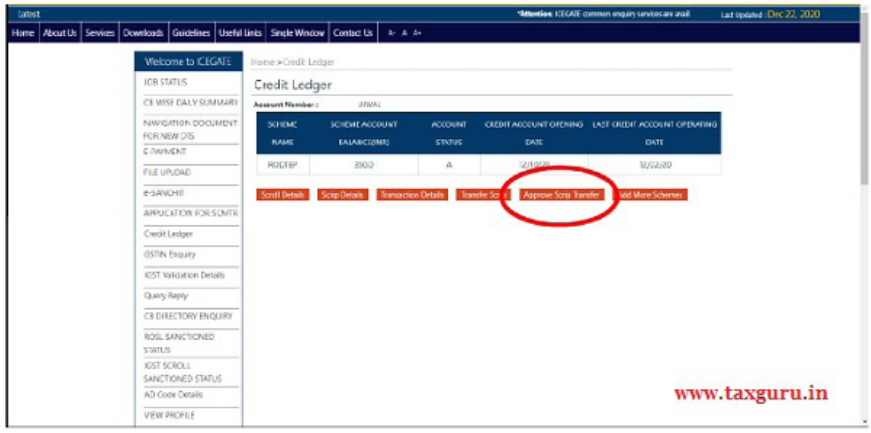
Step 6) After successfully transferring the request, Scrip will be viewed in a grid on the same page. User who has initiated the transfer scrip request can cancel the request at this stage using the cancel button as shown below:



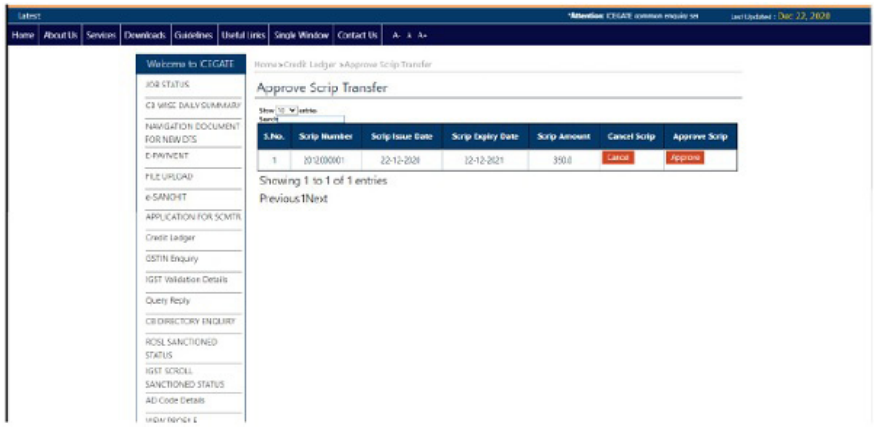
5) Approve Scrip Transfer Request

Step 1) An approval request is sent to the IEC for whom transfer request has been initiated by the user. This IEC holder who has to approve the request needs to login, select credit ledger tab from the left panel. He will have to create a Credit Ledger Account if not already created as mentioned in the 3 step process of Part A (RoDTEP (Credit Ledger) Account Creation) of this module.

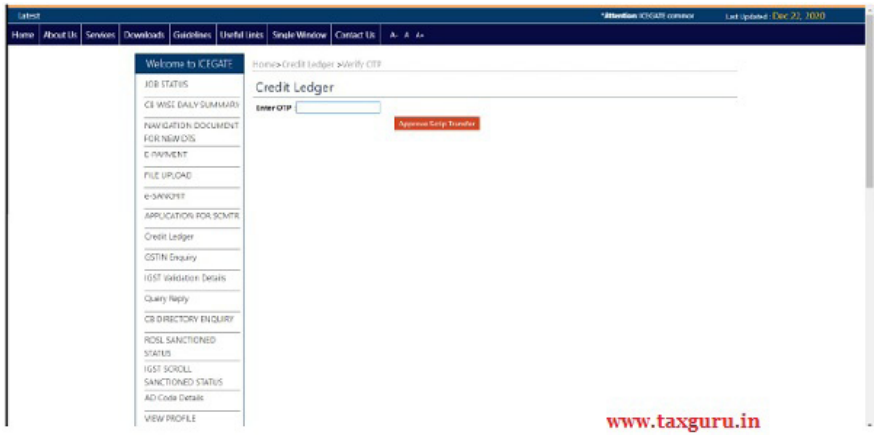
Step 2) From the credit ledger Home page, the user to whom a scrip is transferred can approve/cancel the transfer scrip request by clicking on the “Approve Scrip” tab as shown below:



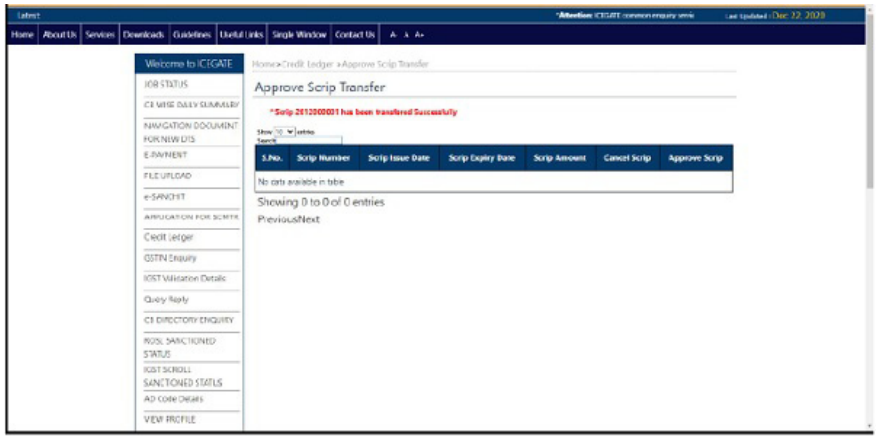
Step 3) User can view all scrips, which are transferred to him. User can cancel the request as well by clicking on the cancel button, if does not wish to accept the scrip.



Step 4) The transferee wants to approve the transfer scrip request after clicking the approve button, Transferee has to fill a valid OTP. After clicking the Approve button, the transferee is directed to fill OTP as shown below. This OTP is generated and sent to the transferee over registered Mobile number and email ID and is valid only for 15 minutes. In case the user fails to enter a valid OTP in 15 minutes, the user is redirected to generate a new OTP.



Step 5) The Scrip will be transferred to Transferee after successful OTP validation. Message is also generated and displayed on the screen as shown below:



Annexure A:

Implementation of RoDTEP Scheme in Customs Automated System – Declarations in Shipping Bill and further processing:

Kind reference is drawn to the Press Note dated 31.12.2020 issued by CBIC on the new RoDTEP scheme being operationalized from 01.01.2021. Necessary changes in the System have also been made to accept and process RoDTEP claims. Below is a detailed explanation on the provisions enabled in System in relation to the new scheme:

I. Claim in the Shipping Bill:

a. W.e.f. 01.01.2021, it is mandatory for the exporters to indicate in their Shipping Bill whether or not they intend to claim RoDTEP on the export items. This claim is mandatory for the items (RITC codes) notified under the new scheme. Since the final list of RITC codes eligible for RoDTEP scheme and the corresponding rates are yet to be notified by the Government, this declaration has been made **mandatory for all items in the Shipping Bill starting 01.01.2021.**

b. Unlike Drawback, there is no separate serial numbers based on a schedule for claiming RoDTEP. RoDTEP rates will be notified as per the RITC Code and therefore, there will be no need to declare any separate code or schedule serial number for RoDTEP.

c. The exporter will have to make following declarations is the SW_INFO_TYPE Table of the Shipping Bill for each item:

INFO TYPE = **DTY**

INFO QFR = **RDT**

INFO CODE = **RODTEPY** – If RoDTEP is availed

RODTEPN – if not availed.

INFO MSR = **Quantity** of the items **in Statistical UQC as per the Customs Tariff Act** for that item RITC

INFO UQC = **UQC** for the Quantity indicated in INFO_MSR

Additionally, for every item where RODTEPY is claimed in INFO CODE, a declaration has to be submitted in the **Statement Table** of the Shipping Bill as below:

STATEMENT TYPE = **DEC**

STATEMENT CODE = **RD001**

Submission of the above statement code for RoDTEP availed items would indicate that the exporter has made the necessary declaration as enclosed in **Annexure B**, while claiming RoDTEP benefit:

d. **It may be noted that if RODTEPY is not specifically claimed in the Shipping Bill, no RoDTEP would accrue to the exporter:** Even though the items and rates are not notified the Government for RoDTEP yet, the exporters must indicate their intent for claim at the time of Shipping Bill filing itself. Once the rates are notified, System would automatically calculate the RoDTEP amounts for all the items where RODTEPY was claimed. **No changes in the claim will be allowed after the filing of the EGM.**

e. There are some checks built in the System to disallow RoDTEP benefit where the benefit of certain other schemes like Advance Authorization, EOU, Jobbing etc has been availed. While some checks have been built in within the System at the time of filing the Shipping Bill, it is assumed that if the exporter (or the authorized Customs Broker) has submitted the statement as mentioned in para 2 (b) with the Shipping Bill, the claim to RoDTEP has been made with the undertaking that no undue benefit would be availed:

II. Processing of the Claim:

(a). Based on the declarations as per Para I above, System will be processed the eligible RoDTEP.

(b). The Shipping Bills with RoDTEP and/or Drawback claim will now be routed for officer intervention based on Risk based targeting by RMS. All the Shipping Bills will be sent to RMS after the EGM is filed. Based on the input by RMS, Shipping Bills will either come to officer for processing of RoDTEP/DBK benefits or will directly be facilitated to the scroll queue without any officer intervention.

(c). Once the Shipping Bill is processed for DBK and/or RoDTEP either by the officer or as per facilitation by RMS, it will move to the respective scroll queues. In case a suspension is placed on any exporter/Shipping Bill for Drawback, the same will also be applicable for the purpose of scrolling out of RoDTEP benefits.

III. Generation of Scroll:

(a). Options have been made available in System for officers to generate RoDTEP scrolls.

However, till the final rates are notified by the Government, these options will remain disabled in System.

(b). Once the scroll is generated, the respective amounts would be available with the exporter as credits on the ICEGATE portal.

IV. Claiming of Credits and Generation of Credit Scrips:

(a). Once the RoDTEP scroll is generated, the credits allowed will be available within their ICEGATE login of the exporter to claim and covert into a credit scrips. In case the exporters have not registered on ICEGATE already with their digital signatures, they may refer to this advisory

{v1.2_Advisory_Registration_APPROVED.pdf (icegate.gov.in} and complete registration in order to avail the benefits of RoDTEP.

(b). The exporter will be able to club the credits allowed for any number of Shipping Bills at a port and generate a credit scrip for the same on ICEGATE portal. Scrips once generated will reflect in the exporter's ledger and will be available for utilization in paying eligible duties during imports or for transfer to any other entity having IEC and a valid ICEGATE registration. A detailed advisory for the benefit of the exporter on the scrip generation, ledger maintenance and transfer facilities will be published soon on ICEGATE. These facilities will be made available once the final RoDTEP rates are notified and scroll generation is enabled.

V. Utilization of Scrips in Imports:

(a). These scrips can be used for the payment of import duties as would be notified by CBIC.

(b). The owner of the scrip (either the original exporter beneficiary or any other IEC to whom the scrip was transferred on ICEGATE portal) will be able to use the scrip in the Bills of Entry the same way as any other duty credit scrips issued by DGFT, by giving the details in the license table of the Bill of Entry. The scheme code to be used for these scrips would be "RD" along with the applicable Notification Number.

(c). An option to suspend any RoDTEP scrip will also be made available with the Customs officer once the scroll generation is enabled. If a scrip is under suspension, its utilization or transfer will not be allowed by System.

Annexure B

DECLARATION TO BE FILED AS PART OF SHIPPING BILL OR BILL OF EXPORT FOR EXPORT OF GOODS UNDER RoDTEP SCHEME:

"I/We, in regard to my/our claim under RoDTEP scheme made in this Shipping Bill or Bill of Export, hereby declare that:

1. I/ We undertake to abide by the provisions, including conditions, restrictions, exclusions and time-limits as provided under RoDTEP scheme, and relevant notifications, regulations, etc., as amended from time to time.
2. Any claim made in this shipping bill or bill of export is not with respect to any duties or taxes or levies which are exempted or remitted or credited under any other mechanism outside RoDTEP.
3. I/We undertake to preserve and make available relevant documents relating to the exported goods for the purposes of audit in the manner and for the time period prescribed in the Customs Audit Regulations, 2018."

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Last date for filing Declaration of Tax Arrear under Direct Tax Vivad se Vishwas Act, 2020 extended to 31 January 2021

Income Tax Notification No.92/2020, dated 31st December 2020

1. In exercise of the powers conferred by section 3 of the Direct Tax Vivad se Vishwas Act, 2020 (3 of 2020), the Central Government hereby makes the following amendment in the notification of the Government of India, Ministry of Finance, (Department of Revenue), Central Board of Direct Taxes, number 85/2020, dated the 27th October, 2020, published in the Gazette of India, Extraordinary, Part-II, Section 3, Sub-section (ii), vide number S.O.3847(E), dated 27th October, 2020, namely:-

In the said notification, in clause (a), for the words, figures and letters "the 31st day of December, 2020", the words, figures and letters "the **31st day of January, 2021"** shall be substituted.

2. This notification shall come into force from the date of its publication in the Official Gazette.

F.No.370142/35/2020-TPL

Vipul Agarwal, Director (Tax Policy and Legislation Division), Central Board of Direct Taxes, Department of Revenue, Ministry of Finance, New Delhi.

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Time-limit for Compliance under Income-tax Act, 1961 for AY 2020-21 extended - reg.

Income Tax Notification No.93/2020, dated 31st December 2020

1. In exercise of the powers conferred by sub-section (1) of section 3 of the Taxation and Other Laws (Relaxation and Amendment of Certain Provisions) Act, 2020 (38 of 2020) (hereinafter referred to the Act) and in supersession of the notification of the Government of India in the Ministry of Finance, (Department of Revenue) No.88/2020 dated the 29th October, 2020, published in the Gazette of India, Extraordinary, Part-II, Section 3, Sub-section (ii), vide number S.O.3906(E), dated the 29th October, 2020, except as respects things done or omitted to be done before such supersession, the Central Government hereby specifies, for the completion or compliance of action referred to in-

(A) clause (a) of sub-section (1) of section 3 of the Act, -

(i) the 30th day of March, 2021 shall be the end date of the period during which the time limit specified in, or prescribed or notified under, the specified Act falls for the completion or compliance of such action as specified under the said sub-section; and

(ii) the 31st day of March, 2021 shall be the end date to which the time limit for completion or compliance of such action shall stand extended:

Provided that where the specified Act is the Direct Tax Vivad Se Vishwas Act, 2020 (3 of 2020), the provision of this clause shall have the effect as if:

(a) for the figures, letters and words "30th day of March, 2021", the figures, letters and words "30th day of January, 2021" had been substituted; and

(b) for the figures, letters and words "31st day of March, 2021", the figures, letters and words "31st day of January, 2021" had been substituted:

Provided further that where the specified Act is the Income-tax Act, 1961 (43 of 1961) and completion or compliance of action referred to in clause (a) of sub-section (1) of section 3 of the Act is an order under sub-section (3) of section 92CA of the Income-tax Act, 1961, the provision of this clause shall have the effect as if:

(a) for the figures, letters and words "30th day of March, 2021", the figures, letters and words "30th day of January, 2021" had been substituted; and

(b) for the figures, letters and words "31st day of March, 2021", the figures, letters and words "31st day of January, 2021" had been substituted;

(B) clause (b) of sub-section (1) of section 3 of the Act, where the specified Act is the Income-tax Act, 1961 (43 of 1961) and the compliance for the assessment year commencing on the 1st day of April, 2020 relates to:

(i) furnishing of return under section 139 thereof, the time limit for furnishing of such return, shall:

(a) in respect of the assessees referred to in clauses (a) and (aa) of Explanation 2 to sub-section (1) of the said section 139, stand extended to the 15th day of February 2021; and

(b) in respect of other assessees, stand extended to the 10th day of January, 2021:

Provided that the provisions of the fourth proviso to sub-section (1) of section 3 of the Act shall, mutatis mutandis apply to these extensions of due date, as they apply to the date referred to in sub-clause (b) of clause (i) of the third proviso thereof;

(ii) furnishing of report of audit under any provision of that Act, the time limit for furnishing of such report of audit shall stand extended to the 15th day of January, 2021.

2. This notification shall come into force from the date of its publication in the Official Gazette.

F.No.370142/35/2020-TPL

Vipul Agarwal, Director (Tax Policy and Legislation Division), Central Board of Direct Taxes, Department of Revenue, Ministry of Finance, New Delhi.

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DGFT MATTERS

DGFT notifies Delegation of Financial Power - reg.

DGFT Notification No.53/2015-2020, dated 31st December, 2020

In exercise of the powers conferred by section 13 of the Foreign Trade (Development and Regulation) Act, 1992 (22 of 1992) and in supersession of the earlier Notifications mentioned below, the Central Government hereby authorizes the officers specified in column 2 of the table below, with reference to the limits specified against such officers in the corresponding entry in column (3) of the Table below, for the purposes of exercising powers under Section 13, read with section 11 of the Foreign Trade (Development and Regulation) Act, 1992, namely:-

Sr. No.	Designation of Officer	Value of goods or services or technology covered by an authorization issued, registration certificate/permits issued for import or export or in respect of goods or services or technology for which import or export is permitted without any authorization or the value of duty credit scrips issued
(1)	(2)	(3)
1.	Additional Director General of Foreign Trade	Without limit
2.	Joint Director General of Foreign Trade	Up to Rs.25 Crores
3.	Deputy Director General of Foreign Trade	Up to Rs.10 crores
4.	Assistant Director General of Foreign Trade	Up to Rs.5 crores

5.	Development Commissioner, Special Economic Zones	Without limit in respect of Export Oriented Units and units in Special Economic Zones
6.	Designated Officer, Department of Electronics & Information Technology	Without limit in respect of units in Software Technology Parks (STPs) and Electronic Hardware Technology Parks (EHTPs).

F.No.01/69/12/49/2018/O&M

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

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Amendment of Para 2.54 of the Handbook of Procedures, 2015-2020 - reg.

DGFT Public Notice No.36/2015-2020, dated 29th December, 2020

1. In exercise of powers conferred under paragraph 1.03 and 2.04 of the Foreign Trade Policy (2015-2020), the Director General of Foreign Trade hereby amends Para No.2.54 (d)(v)(ii) of the Handbook of Procedures (2015-2020) and extends the deadline to install and operationalise Radiation Portal Monitors and Container Scanners in the designated sea ports upto 31.03.2021.

2. Effect of this Notification: The period for installation and operationalisation of Radiation Portal Monitors and Container Scanner in the designated sea ports is extended upto 31 03 2021.

File No.01/89/180/53/AM-01/PC-2[B]/Vol.VIII/E-2382

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

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CUSTOMS MATTERS

Import and Export of Vaccines in relation to COVID-19 through Courier - reg.

Customs Circular No.56/2020, dated 30th December 2020

To,

All Principal Chief Commissioners/Chief Commissioners of Customs,

All Principal Directors General/Directors General of Customs,

All Principal Commissioners/Commissioner of Customs.

1. The COVID-19 pandemic has posed unprecedented challenges to Customs and other administrations the world over. Right from the onset of the pandemic, the Board has been taking various measures to keep import-export supply chains operational and ensure that critical goods are released expeditiously by the Customs. In this context the Board notes that efficient clearance and distribution of vaccines would be a critical requirement in the collective fight against the COVID-19 pandemic. The challenges in doing so is heightened by the fact that the vaccines need to be stored and transported under controlled temperatures and there are multiple stakeholders involved in this process. This necessitates putting in place efficient cross-border procedures for speedy evacuation of the vaccines. Accordingly the Board has proactively reviewed the extant process for cross-border movement of goods and focussed on especially facilitating the Customs clearance of imported/export of vaccines relating to COVID-19.

2. In order to facilitate the import/export of vaccines in relation to COVID-19 through Courier, at locations where the Express Cargo Clearance System (ECCS) is operational, the Board has issued the Courier Imports and Exports (Electronic Declaration and Processing) Amendment Regulations, 2020. These new regulations amend the Courier Imports and Exports (Electronic Declaration and Processing) Regulations, 2010 to provide the following:

(i) Imports of and exports of vaccines in relation to COVID 19 has been allowed without any value limitation.

(ii) Since the vaccines will be imported in durable containers equipped with the requisite temperature monitoring and tracking devices, sub-regulation (3) of regulation 6 and the declaration in Form H (CSB IV) of the Regulations have been suitably amended to provide for the export of the durable container including accessories thereof, imported in relation to COVID-19 vaccines. The clarifications contained in Circular No.51/2020-Customs, dated 20.11.2020 would apply for the temporary importation and re-export of the durable containers including accessories thereof imported in relation to the COVID-19 vaccines through Courier. Care should be taken to ensure compliance with the procedure contained in said Circular including execution of a continuity bond, declaration of the durable containers and accessories thereof as a separate item in the Customs declaration during import and re-export. Importers may be advised to indicate the unique identifier of the container and the accessories during import in the Courier Bill of Entry (CBE-V) and also at the time of re-export in the Courier Shipping Bill (CSB IV) for facilitating clearance.

3. Since multiple stakeholders will be involved in the process of clearance of the vaccines, effective coordination among the stakeholders would be necessary. Commissioners in charge of the International Courier Terminals where ECCS is operational, are therefore requested to immediately form a Task Force headed by an officer of the rank of Joint/Additional Commissioner of Customs and comprising of officials from relevant PGAs, Authorized Couriers, Custodians, Airlines and other relevant stakeholders. The Task force shall adopt a coordinated approach for efficient clearance of vaccines relating to COVID-19.

3.1 The details of the Task Force, and the name, designation and contact details of the Joint/ Additional Commissioner of Customs, heading the Task force may be given wide publicity through issue of Public Notices and should also be placed in a conspicuous location in the website of the Commissionerate/Zone.

4. Difficulties, if any in implementation of the Circular may be brought to the immediate notice of the Board.

F.No.451/22/2020-Cus.V

Temsunaro Jamir, Additional Commissioner (ICD), Central Board of Indirect Taxes & Customs, Department of Revenue, Ministry of Finance, New Delhi.

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CBIC amends Courier Imports and Exports (Electronic Declaration and Processing) Regulations, 2010 (1st Amendment of 2020) - reg.

Notification No.115/2020-Customs (N.T.), dated 30th December, 2020

In exercise of the powers conferred by section 157 read with section 84 of the Customs Act, 1962 (52 of 1962), the Central Board of Indirect Taxes and Customs hereby makes the following regulations further to amend the Courier Imports and Exports (Electronic Declaration and Processing) Regulations, 2010, namely:-

1. Short title and Commencement:

(1) These regulations may be called the **Courier Imports and Exports (Electronic Declaration and Processing) Amendment Regulations, 2020.**

(2) They shall come into force on the date of their publication in the Official Gazette.

2. In the Courier Imports and Exports (Electronic Declaration and Processing) Regulations, 2010,-

(i) in regulation 2, after sub-regulation (2), the following sub-regulation shall be inserted, namely:-

"(3) Notwithstanding anything contained in sub-regulation (2), these regulations shall apply to the import of and export of vaccines in relation to COVID-19.";

(ii) in regulation 6, in sub-regulation (3), for the words "for gifts, samples and prototype of goods", the words "for bonafide gifts, commercial samples and prototypes of goods and re-export of durable container including accessories thereof, imported in relation to COVID-19 vaccines" shall be substituted;

(iii) in Form H, in the declaration, in paragraph 2, after the words "prototypes of goods", the words and expression, "empty durable container including accessories thereof, imported in relation to COVID-19 vaccines" shall be inserted.

F.No.451/22/2020-Cus.V

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

Note: - The Principal Notification No.36/2010-Customs (N.T.), dated the 5th May, 2010 was published in the Gazette of India, Extraordinary, Part II, Section 3, sub-section (i), vide number G.S.R.385(E), dated the 5th May, 2010 and was last amended vide Notification No.74/2019 Customs (N.T.), dated the 9th October 2019, published in the Gazette of India, Extraordinary, Part II, Section 3, sub-section (i) vide Number G.S.R.764(E), dated the 9th October 2019.

● ● ●

Implementation of PGA eSANCHIT - Paperless Processing under SWIFT-Uploading of Licenses/Permits/Certificates/ Other Authorizations (LPCOs) by PGAs - reg.

Circular No.57/2020-Customs, dated 30th December, 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. CBIC's eSANCHIT application is successfully in operation since 01.04.2018. Aimed at further reducing physical interface between Customs/regulatory agencies and the trade and to increase the speed of clearance in both imports & exports, this application provides a facility to upload digitally signed Licenses/ Permits/Certificates/Other Authorizations (LPCOs) by Participating Government Agencies (PGAs) at all ICES locations across India. In this regard, kindly refer to Board's Circulars No. 44/2018-Cus dated 13.11.2018, No.13/2019-Cus dated 03.06.2019, No.19/2019-Cus dated 16.07.2019, No.03/2020-Cus dated 15.01.2020, No.11/2020-Cus dated 10.02.2020 and No.24/2020 dated 14.05.2020. Already 51 PGAs have been enabled for uploading their LPCOs on eSANCHIT. Reference is also invited to Circular No.55/2020-Customs dated 17.12.2020 vide which Board has decided that w.e.f. **15.01.2021**, the supporting documents for justification of claim of duty exemption notification or fulfilment of a CCR requirement etc, shall be mandatorily required to be uploaded in eSANCHIT along with the Bills of Entry.

2. Now, 2 more PGA namely Trade Promotion Council of India (TPCI) and Export Promotion Council for EOUs & SEZs (EPCES) with their LPCOs as detailed below are being brought on board eSANCHIT platform. With this, the total number of PGAs on Board eSANCHIT as on date becomes 53.

Sr. No.	Document Code	Document Name	Document Description and Name of the PGA	PGA Code
1	861TP1	Certificate of Origin (Non-Preferential	Certificate of origin (Non-preferential) is issued by Trade Promotion Council of India for certifying goods of India origin.	TPCI
2	101EP1	Membership Certificate	Membership Certificate issued by Export Promotion Council for EOUs & SEZs.	EPCES

3. Since the facility to upload the LPCOs is now being fully made available to above two PGAs, the beneficiaries (importer/exporters) and customs brokers would not be allowed to upload the previously issued LPCOs on eSANCHIT w.e.f. 15.01.2021. However, it may so happen that a beneficiary in possession of an already issued LPCO has so far not uploaded it. Since such uploading (by the beneficiary) would not be possible after 15.01.2021, to facilitate the beneficiaries, the above two PGAs are required to upload the LPCOs issued by them during the last 15 days from above cut-off date. Additionally, if requested by a beneficiary, LPCOs issued on a prior date may also be uploaded by the above two PGAs on eSANCHIT.

4. It is reiterated that the PGA will be communicating with the beneficiaries through the e-mail addresses registered on ICEGATE. Board had also introduced simplified auto registration process on ICEGATE based on email ids already provided by them for registration under GST without the use of digital signatures for limited purposes of eSANCHIT (communication and viewing) and the IRNs will be communicated to such email ids. In this regard, kindly refer to Board's Circular No.35/2018 Cus dated 01.10.2018 and Circular No.14/2019-Cus dated 03.06.2019. Since the facility of beneficiary uploading these documents on eSANCHIT will be deactivated from **15.01.2021**, beneficiary registration is of utmost importance. Hence, all the formations are requested to reach out to the beneficiaries to ensure that correct email addresses are reflected in the ICEGATE. Special efforts may be taken for wide publicity in this regard.

5. All Pr Chief Commissioners/Chief Commissioners of Customs are requested to issue public notices. Feedback and queries, if any, may be sent by email to **icegatehelpdesk@icegate.gov.in.**

6. Any difficulties, in this regard, may be brought to the notice of the Board.

F.No.450/148/2015-Cus IV(Pt.II)

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

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Sun Pharma exempted from Provisions of DPCO, 2013 under para 32 (i) for FDC of Silver Sulfadiazine IP and Chlorhexidine Gluconate – reg.

NPPA Notification No.S.O.4774(E), dated 30th December, 2020

1. Whereas the National Pharmaceutical Pricing Authority (NPPA) was established vide the Resolution of the Government of India in the Ministry of Chemicals and Fertilizers No.33/7/97-PI.I dated 29th August, 1997, inter-alia, to fix prices and notify the changes therein, if any, of bulk drugs and formulations, monitor the prices of non-scheduled drugs and formulations and oversee the implementation of the provisions of the Drugs (Price Control) Order (DPCO).

2. And whereas the Ministry of Chemicals and Fertilizers vide S.O.1394 (E) dated the 30th May, 2013, in exercise of the powers conferred by Section 3 and 5 of Essential Commodities Act, 1955 has delegated the powers in respect of specified paras of the DPCO, 2013, including para 32 of the said order to be exercised by the NPPA on behalf of the Central Government.

3. And whereas an application received from M/s Sun Pharmaceuticals Industries Limited, for exemption from the provisions of DPCO, 2013 under para 32 (i) of the said order in respect of Fixed Dose Combination (FDC) of Silver Sulfadiazine IP (Nanonized) 0.5% w/w and Chlorhexidine Gluconate 0.2% w/w topical cream which was duly approved by the Office of Central Drugs Standard Control Organisation (India) as 'new drug' under the Drugs and Cosmetics Act, 1940 and Rules thereunder. Further, the Patent office, India has granted Patent Certificate to M/s Sun Pharmaceutical Industries Ltd for an invention entitled 'A stable topical Pharmaceutical composition comprising Nanonized Silver Sulfadiazine' for the term of 20 years from 27th July 2016 in accordance with the provisions of the Patents Act, 1970 (Patent No.349599 and Date of Grant: 20.10.2020).

4. And whereas the NPPA at its 82nd meeting dated 23.12.2020 noted that M/s Sun Pharmaceutical Industries Ltd meets the requirement of para 32(i) of DPCO 2013 and decided that exemption may be granted to M/s Sun Pharmaceutical Industries Ltd under para 32(i) of DPCO, 2013 for their product Fixed Dose Combination (FDC) of Silver Sulfadiazine IP (Nanonized) 0.5% w/w and Chlorhexidine Gluconate 0.2% w/w topical cream.

5. Now, therefore, in exercise of the powers delegated under para 32 of the Drugs (Prices Control) Order, 2013 vide S.O.1394(E) dated 30th May, 2013 issued by the Government of India in the Ministry of Chemicals and Fertilizers, M/s Sun Pharmaceuticals Industries Limited is exempted from the provisions of DPCO, 2013 under para 32 (i) of the said order in respect of above said drug viz Fixed Dose Combination (FDC) of Silver Sulfadiazine IP (Nanonized) 0.5% w/w and Chlorhexidine Gluconate 0.2% w/w topical cream for a period of five years from the date of commencement of its commercial marketing by the manufacturer in the country. Further, the period of five years is co-terminus with the duration of Indian Patent.

6. The company shall inform NPPA the date of commercial marketing of 'Fixed Dose Combination (FDC) of Silver Sulfadiazine IP (Nanonized) 0.5% w/w and Chlorhexidine Gluconate 0.2% w/w topical cream' in the country and the Price to Retailer (PTR) and Maximum Retail Price fixed by the company in respect of above said formulation by issuing a Price List in Form V under DPCO, 2013.

PN/214/82/2020/F.
F. No. 8(82)/2020/D.P./NPPA-Div.II

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

Sustained cellular immune dysregulation in individuals recovering from COVID-19

COVID-19, which has killed 1.7 million people worldwide, does not follow a uniform path Many infected patients remain asymptomatic or have mild symptoms. Others, especially those with Comorbidities, can develop severe clinical disease with atypical pneumonia and multiple system organ failure. Since the first cases were reported in December 2019, the SARS-CoV-2 virus that causes COVID-19 has surged into a pandemic, with cases and deaths still mounting. Ongoing observational Clinical Research has become a priority to better understand how this previously unknown virus acts, and findings from this research can better inform treatment and vaccine design.

University of Alabama at Birmingham researchers, led by first-author Jacob "Jake" Files and co-senior authors Nathan Erdmann, M.D., Ph.D., and Paul Goepfert, M.D., have now reported their observational study, "Sustained cellular immune dysregulation in individuals recovering from SARS-CoV-2 infection," published in the *Journal of Clinical Investigation*.

In a commentary on the UAB study, published in the same issue, Phillip Mudd, M.D., Ph.D., and Kenneth Remy, M.D., both of Washington University, wrote, "The importance of these studies to provide context for the interpretation of immune responses generated by participants in COVID-19 vaccine trials, including how those responses change over time, cannot be over-emphasized. This information will be key in potential modifications to existing COVID-19 vaccines and treatments."

The UAB researchers obtained blood samples and Clinical data from 46 hospitalized COVID-19 patients and 39 non-hospitalized individuals who had recovered from confirmed COVID-19 infection. Both groups were compared to healthy, COVID-19-negative controls. Importantly, most individuals in the hospitalized group had active SAR-CoV-2 viruses in their blood and were in the hospital at the time of sample collection. All individuals in the non-hospitalized group were convalescent at the time of sample collection.

From the blood samples, researchers were able to separate specific immune cell subsets and analyze cell surface markers. From this complex information, immunologists can analyze how each individual's immune system is responding during infection and during convalescence. Some of these results can reveal whether immune cells have become activated and exhausted by the infection. Exhausted immune cells may increase susceptibility to a secondary infection or hamper development of protective immunity to COVID-19.

In addition, the researchers were able to analyze changes over time, in two ways. The first was observing changes in surface markers over time, defined as days since the onset of symptoms for non-hospitalized samples. The second was directly comparing the frequencies of these markers between the first and second clinic visits for non-hospitalized patients who had blood samples collected at two sequential time points. The most surprising finding involved non-hospitalized patients. While the UAB researchers saw upregulated activation markers in hospitalized patients, they also found several activation and exhaustion markers were expressed at higher frequencies in non-hospitalized convalescent samples.

Looking at these markers over time, it was apparent that immune dysregulation in the non-hospitalized individuals did not quickly resolve. Furthermore, the dysregulation of T cell activation and exhaustion markers in the non-hospitalized cohort was more pronounced in the elderly. "To our knowledge," the researchers reported, "this is the first description of sustained immune dysregulation due to COVID-19 in a large group of non-hospitalized convalescent patients." For details of the comprehensive look at immune cells subsets during and after COVID-19 infection in hospitalized and non-hospitalized people, see the study, which includes an in-depth characterization of the activation and exhaustion phenotype of CD4+ T cells, CD8+ T cells and B cells.

The B and T cells from both patient cohorts had phenotypes consistent with activation and cellular exhaustion throughout the first two months of infection. And in the non-hospitalized individuals, the activation markers and cellular exhaustion increased over time. "These findings," Mudd and Remy said in their commentary, "illustrate the persistent nature of the adaptive immune system changes that have been noted in COVID-19 and suggest longer-term effects that may shape the maintenance of immunity to SARS-CoV-2. A question now being explored, the UAB researchers say, is whether these observed immunologic changes are associated with symptoms experienced well beyond the acute infection, often described as "Long COVID."

(Co-authors with Files, Erdmann and Goepfert in the Journal of Clinical Investigation report are Sushma Boppana, Mildred D Perez, Sanghita Sarkar, Kelsey E Lowman, Kai Qin, arah Sterrett, Eric Carlin, Anju Bansal, Steffanie Sabbaj, Olaf Kutsch and James Kobie, Division of Infectious Diseases, UAB Department of Medicine; and Dustin M Long, Department of Biostatistics, UAB School of Public Health.

Files is a Graduate Student in the UAB MD-Ph.D., Medical Scientist Training Program. Erdmann and Goepfert are Assistant Professor and Professor, respectively, in the UAB Division of Infectious Diseases. At UAB, Goepfert holds the Edward W Hook, III, MD., Endowed Professorship in Infectious Diseases.

Story: Materials provided by University of Alabama at Birmingham. Original written by Jeff Hansen. Note: Content may be edited for style and length)

Source: University of Alabama at Birmingham, Science Daily, 29.12.2020

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Researchers to explore how Vitamin D affects Covid-19

After several studies linked high vitamin D supplementation with reduced Covid-19 effects, now researchers from Penn State University in the US, to study whether Vitamin D could help people ward off or reduce symptoms caused by Corona virus.

The research team, including one of Indian-origin, has received nearly $241,000 from the National Institutes of Health (NIH) for research on how vitamin D regulates the immune system in the gastrointestinal tract. Cantorna said the addition of two key collaborators in the study are virologist Troy Sutton and Girish Kirimanjiswara, Associate Professor whose research focuses on immunology and infectious diseases.

"Patients with acute respiratory infections have been shown to be Vitamin D deficient, and Vitamin D supplements have been touted as being useful in high doses for preventing seasonal influenza," Cantorna said. "Meanwhile, the emergence of SARS-CoV-2 has generated interest in the potential of high-dose Vitamin D supplements to prevent and treat severe disease associated with the Covid-19 pandemic," Cantorna added.

The research group has shown that Vitamin D plays an important role in maintaining health in the gastrointestinal tract. Higher levels of Vitamin D reduce susceptibility to inflammatory bowel disease and Crohn's disease, as well as gut and lung infections in animals and people. However, too much Vitamin D can be harmful. Cantorna noted that the local and systemic inflammation caused by SARS-CoV-2 infection is not well understood, and controlling such inflammation may improve outcomes for Covid-19 patients.

Although low Vitamin D status has been associated with acute respiratory diseases, research has not confirmed a causal relationship. "We don't yet fully understand the mechanisms underlying the effects of Vitamin D in the lung or how Vitamin D regulates host immunity to viral infection," she said. "These significant knowledge gaps have hindered the development of interventions and accurate messaging that include Vitamin D for the treatment and prevention of respiratory disease," she noted. Using mouse and hamster models, the research team will test whether supplemental vitamin D treatments will limit viral replication and inflammation in the lung leading to protection against severe SARS-CoV- 2 infection.

"We plan to determine the effects, dose and timing of possible Vitamin D interventions in infected animals," Cantorna said. "Because SARS-CoV-2 has been shown to infect the gastrointestinal tract, the benefits of vitamin D might include regulation of gastrointestinal immunity as well as lung immunity," the author wrote.

Source: IANS, ET Health World (The Economic Times), 01.12.2020 (Excerpts)

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Scientists develop new inhalation delivery system for vaccines

Scientists have developed an inhalation delivery system for vaccines that generates potent immune responses in mice and on-human primates, without causing lung damage, an advance that may lead to new therapeutics for respiratory diseases like Covid-19. The findings, published in the journal Med, suggests that a safe and effective lung delivery system could be developed for vaccines and

therapeutics against pathogens such as the novel Corona virus.

"This translational strategy potentially enables more effective delivery of therapeutics or vaccines while reducing the chance of toxic side effects," said study co-author Wadih Arap from Rutgers Cancer Institute in the US. According to the researchers, this mode of vaccine delivery has many advantages over other routes, particularly for the development of vaccines against respiratory infections as the therapeutics arrive directly at the site of the infection.

Inhalation-based vaccination is needle free and minimally invasive, they said adding that it is especially attractive for administrating multiple doses. The researchers said this method improves bioavailability and also reduces potential side effects by achieving a rapid on set of action.

The scientists believe lung delivery could protect against airborne pathogens that cause diseases such as tuberculosis, influenza, Ebola, measles, and Covid-19. However, they said this approach has not been adopted widely, partly because the underlying physiological mechanisms remain largely unknown. They said answering this question is critical for designing a general lung delivery system for widespread use. In the new study, the researchers devised and demonstrated a safe and effective lung delivery system.

They said the approach involves the use of phages -- viruses that can infect and replicate within bacterial cells. In certain types of vaccines, they said the phage particles that carry small proteins, or peptides, are used to trigger protective immune responses. First, the researchers screened for and identified a small protein -- CAKSMGDIVC -- that could efficiently deliver phage particles across the pulmonary barrier and into the bloodstream.

They found that the inhaled delivery of CAKSMGDIVC displaying phage particles elicited a robust antibody response against the phage particles in mice and nonhuman primates, without damaging the lungs. According to the scientists, the new lung delivery system is safe and effective, and has unique advantages for the development of vaccines and therapeutics against airborne pathogens.

They said the phage particles induce very strong and sustained immune responses, without producing toxic side effects. Since they do not replicate inside eukaryotic cells, their use is generally considered safe when compared to other classic viral-based vaccination strategies. In terms of practical implementation, the study noted that phage particles are highly stable under harsh environmental conditions, and their large-scale production is extremely cost-effective compared to traditional methods used for vaccine production.

Unlike conventional vaccines that often become inactivated, the new lung delivery system has no cumbersome, stringent, or expensive cold-chain requirements for field applications in the developing world, the scientists said. "In addition, phage particles are versatile and can be genetically engineered by standard molecular biology technology," Arap said. The researchers next plan to examine the kinetics of pulmonary transport after multiple doses and investigate cell-based immune responses.

Source: IANS, ET Health World, (The Economic Times), 11.12.2020 (Excerpts)

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AIIMS Rajkot will boost Health infrastructure and provide employment opportunities in Gujarat: Prime Minister

AIIMS Rajkot will boost Health Infrastructure, Medical Education and provide employment opportunities in Gujarat, stated Prime Minister, Narendra Modi while laying foundation stone of AIIMS Rajkot through a video conference. Union Minister Dr Harsh Vardhan, Governor Gujarat Acharaya Devvrat, Chief Minister Gujarat, Vijay Rupani were present on the occasion. Prime Minister Modi added about 5 thousand direct jobs and many indirect jobs would be created.

PM credited the robust medical infrastructure in Gujarat, for Gujarat's better handling of Corona challenge. He said two decades of relentless effort, dedication and resolve is behind this success of Gujarat in the medical sector. Lauding the efforts of Gujarat in fighting COVID, the Prime Minister said Gujarat has shown the path in fighting COVID. Speaking on the occasion, the Prime Minister remembered the efforts of the millions of doctors, health workers, scavengers and other frontline Corona warriors who have constantly put their lives at stake to protect humanity.

The Prime Minister remarked that this year showed that when India unites, it can effectively cope up with the most difficult crisis. He said India is in a much better position as a result of the effective steps and India's record of saving victims of Corona has been much better than other countries. He said in India, every necessary preparation about the vaccine is going on.

PM Modi said that efforts are in the final stages for making the vaccine made in India, rapidly reaching every nook and corner. He said India's preparation is in full swing, to run the world's largest immunization campaign. He called to move forward together to make vaccination successful just the way last year we tried to prevent infection.

The Prime Minister said even after so many decades after independence, only 6 AIIMS were established in the country. During Atalji's Government in 2003, steps were taken to establish 6 more AIIMS. He added that in the last 6 years, work on 10 new AIIMS has started and many have been inaugurated. He said along with AIIMS, 20 super specialty hospitals are also being constructed.

The Prime Minister emphasized that before 2014, different aspects of our Health sector were working towards different directions and approaches. He said after 2014, the Health sector has worked holistically and emphasis was on preventive care, while also giving priority to modern treatment facilities. He said that the Government reduced the cost of treating the poor and at the same time, also emphasized on increasing the number of doctors rapidly.

The Prime Minister said under Ayushman Bharat scheme, the work to establish about 1.5 million Health and Wellness Centers in remote areas is being undertaken and among those about 50,000 centers have already started functioning. About 5 thousand among those are in Gujarat alone. He said about 7,000 Jan Aushadhi Center provided medicines at low cost to about 3.5 lakh poor patients. He listed the initiatives of the Government for improving the Health of the people.

The Prime Minister said if 2020 was the year of Health Challenges, 2021 is going to become the year of health Solutions. The world will move towards Health solutions with better awareness. The Prime Minister stressed, India will play a major role in the Health solutions as it played in the meeting the challenges of 2020.

He said India's contribution for the Health solutions of 2021 will be critical for the scaling of the solutions. Given the competence of Indian medical professionals and service motivation, along with expertise like mass immunization experience India will provide smart and affordable solutions to the world. Health startups are integrating Health solutions and Technology and making health care accessible. "India is going to play an important role in both the future of health and health of the future" Modi said.

The Prime Minister said that as the diseases are becoming globalised, it is time for coordinated global response for global health solutions. India has done this as a global player. India proved its mettle by adapting, evolving and expanding as per demand. India moved with the world and did value addition in the collective efforts. India is emerging the nerve centre of global health, in 2021 we need to further strengthen this role of India, the Prime Minister added.

Source: Pharmabiz, 31.12.2020

Centre asks States to gear up for roll out of COVID-19 vaccine

With the objective of gearing up for the roll out of COVID-19 vaccine across the country, the Central Government has asked all States and UTs to ensure effective preparedness for the vaccine roll out. Union Health Secretary Rajesh Bhushan chaired a high-level meeting to review the preparedness at session sites for COVID-19 vaccination with Pr Secretaries (Health), NHM MDs and other Health Administrators of all States/UTs through video conference.

The dry run will be conducted by all the State and UT Governments on 2nd January 2021. The activity is proposed to be conducted in all State Capitals in at least 3 session sites; some States will also include districts that are situated in difficult terrain/have poor logistical support; Maharashtra and Kerala are likely to schedule the dry run in major cities other than their Capital.

The objective of the Dry Run for COVID-19 vaccine introduction is to assess operational feasibility in the use of CoWIN application in field environment, to test the linkages between planning and implementation and to identify the challenges and guide way forward prior to actual implementation. This is also expected to give confidence to programme managers at various levels. The planning for the vaccine introduction will be as per the Operational Guidelines issued by the Ministry on 20th December 2020. For each of the three Session Sites, the concerned Medical Officer In-charge will identify 25 test beneficiaries (healthcare workers).

The States/UTs have been asked to ensure that the data of these beneficiaries is uploaded in CoWIN. These beneficiaries will also be available at the session site for the dry run. The States and UTs shall prepare the facilities and users to be created on CoWIN application including uploading the data of Health Care Worker (HCW) beneficiaries.

The States/UTs have been asked to ensure physical verification of all proposed sites for adequacy of space, logistical arrangements, internet connectivity, electricity, safety etc; prepare at least three model session sites in each State (at State capital) for demonstration; ensure that the Model Sites have separate entry and exit in a 'three-room set-up' with adequate space outside for awareness generation activities; display all IEC material at these sites; ensure that all SOPs and protocols are being practiced at the identified sites in an ideal environment along with vaccination teams to be identified and trained in all aspects. The dry run will also equip the State and UT administration in management of vaccine supply, storage and logistics including cold chain management.

As the vaccine administrators will play an important role in the vaccination process, training of trainers and those who shall administer the vaccine has been taken up across various States. Around 96,000 vaccinators have been trained for this purpose. 2,360 participants have been trained in National Training of Trainers and over 57,000 participants trained in District level training in 719 districts. States are augmenting the State helpline 104 (which shall be used in addition to 1075) for any vaccine/software related query.

An important focus of the dry run will be on management of any possible Adverse Events Following Immunisation (AEFI). In addition, adherence and management of infection control practices at the session site, to prevent disease transmission. The mock drill will include concurrent monitoring and review at the block and district levels, and preparation of feedback. The State Task Force shall review the feedback and share with the Union Health Ministry.

States/UTs were also asked to address the communication challenges by taking in confidence all the concerned stakeholders and by augmenting the community engagement 'Jan bhagidari' through innovative strategies. Detailed checklist has been prepared by the Union Health Ministry and shared with the States/UTs to Guide them in the dry run.

The first round of the dry run was conducted in Andhra Pradesh, Assam, Gujarat, Punjab on 28-29th December 2020 in two districts each where five session sites with 25 beneficiaries each were identified. No major issues were observed in the operational aspects during this dry run. All States expressed confidence in the Operational Guidelines and IT platform for large scale programme implementation.

Source: Pharmabiz, 31.12.2020

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INSACOG will have high level inter-ministerial Committee to track new variant of Coronavirus: Dr Renu Swarup

The Indian SARS-CoV-2 Genomic Consortia (INSACOG), will have a high level inter-ministerial committee to

ascertain the status of a new variant of the Coronavirus, which will provide Guidance and oversight to the consortium specially for policy matters and it will have a Scientific Advisory Group for scientific and technical Guidance, stated Dr Renu Swarup, Secretary DBT. Coordinated by Department of Biotechnology (DBT) along with Union Health Ministry, ICMR, and CSIR, the strategy and roadmap of the National SARS-CoV-2 Genome Sequencing Consortium has been prepared.

The Government has launched the Indian SARS-CoV-2 Genomic Consortia, comprising 10 labs namely DBT-NIBMG Kalyani, DBT-ILS Bhubaneswar, ICMR-NIV Pune, DBT-NCCS Pune, CSIR-CCMB Hyderabad, DBT-CDFD Hyderabad, DBT-InSTEM/NCBS Bengaluru, NIMHANS Bengaluru, CSIR-IGIB Delhi, and NCDC Delhi.

The overall aim of the Indian SARS-CoV-2 Genomics Consortium is to monitor the genomic variations in the SARS-CoV-2 on a regular basis through a multi-laboratory network. This vital research consortium will also assist in developing potential vaccines in the future. The consortium will ascertain the status of new variant of SARS-CoV-2 (SARS-CoV-2 VUI 202012/01) in the country, establish a sentinel surveillance for early detection of genomic variants with public health implication, and determine the genomic variants in the unusual events/trends (super-spreader events, high mortality/morbidity trend areas etc).

As per DBT, these mutations are rapidly increasing the number of variants of the virus. This variant is significantly more transmissible than previously circulating variants, with an estimated potential to increase the reproductive number with an estimated increased transmissibility of up to 70%, it said.

The Indian SARS-CoV-2 Genomics Consortium will monitor the genomic variations on a regular basis through the multi-laboratory network. Knowledge generated though this vital research consortium will also assist in developing diagnostics and potential therapeutics and vaccines in the future.

DBT-NIBMG as the coordinating Unit of Genome Sequencing Consortium and will closely work with a Nodal Unit of NCDC on activities like SOPs, data annotation, data analysis, data release etc. NCDC will maintain a database of all samples of the new variants of public health significance.

Source: Pharmabiz, 31.12.2020

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Information, vaccine hesitancy, vaccine eagerness and COVID appropriate behaviour are four areas for communication strategy: Health Ministry

There are four key areas that will be addressed as part of interventions under the COVID-19 vaccine communication strategy such as information, vaccine hesitancy, vaccine eagerness and COVID appropriate behaviour, stated Health Ministry. The Ministry said, "In case of vaccine eagerness, given the context of the pandemic, people have been eagerly waiting for a vaccine. It is expected that once the vaccine is available there will be a huge demand to access it, which may lead to unrest, while in case of vaccine eagerness, it means a possible result of rumours, plain indifference or misinformation from anti-vaccination groups."

The Ministry said that there are the five key elements of the communication strategy have been developed in order to support the roll out and introduction of the COVID-19 vaccine at the national and state level such as advocacy, Adverse Events Following Immunisation (AEFI) crisis communication, capacity building, social mobilisation and community engagement and social media.

The communication strategy seeks to build trust and enable greater confidence in the COVID-19 vaccine amongst all people and this will be achieved by using the social influence or endorsements from experts and official voices; establishment of a National Media Rapid Response Cell (NMRRC) at Health Ministry and involving community mobilizers and frontline workers to engage with the community at various levels," the document said.

The objective of the COVID-19 vaccine communication strategy is generate awareness and understanding of the phased approach of prioritizing target groups.

The Ministry further stated that various stakeholders and experts will lead the advocacy campaigns at national, state and district level. These include (but are not limited to) PM, Parliamentarians, Health Ministry and line Ministries in the Central Government and their field-level networks, Professional bodies IMA, doctors and health workers, alternate medicine practitioners, Rotary and Lions Club, public and private sector companies, development partners, civil society, community based organizations.

Source: Pharmabiz, 31.12.2020

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DCGI extends deadline by 4 months to submit notarized documents for import and registration of Cosmetics

The Drugs Controller General of India (DCGI) has further extended deadline by 4 months or till normalization of COVID-19 scenario to submit notarized or apostilled regulatory documents for import and registration of cosmetics such as power of attorney, QMS certificate, Free Sale Certificate (FSC) and manufacturing license with legal signatures due to COVID-19 pandemic.

The DCGI's action in this regard comes in the background of the fact that his office had received representation from the industry about difficulties in submission of notarized or apostilled regulatory documents for cosmetics due to COVID-19 pandemic.

According to DCGI Dr V G Somani, "The matter has been examined carefully in view of the situation due to COVID-19 and in continuation of the notice dated April 20, 2020 and August 19, 2020, it has been decided that the applicant may submit applications for import registration as per the provisions of Drugs and Cosmetics (D&C) Act, 1940 and Rules made thereunder along with such documents which are self-attested and an undertaking. The undertaking stipulates that the applicant will submit the notarized or apostilled documents with legal signatures after obtaining the same from the concerned authority after normalization of the situation in the light of COVID-19 or within four months whichever is earlier."

Earlier the DCGI had also issued notice to submit applications for import license as per the provisions of Medical Device Rules (MDR) 2017 along with such documents which are self-attested and an undertaking that they will submit the notarized/apostilled documents after obtaining the same from the concerned authority after normalization of the situation in light of COVID-19 or within four months whichever is earlier.

The DCGI has further extended the deadline up till 4 months or till normalization of COVID-19 scenario to submit notarized documents through online Sugam portal for import of medical devices and *in vitro* diagnostics (IVDs) from the earlier deadline of April 24, 2020. In its April 24, 2020 notice, it had directed all the concerned to do the needful. DCGI office had received representation about difficulties in submission of notarized or apostilled regulatory documents such as power of attorney, QMS certificate, free sale certificate etc for applications for import of medical devices and *in vitro* diagnostic kits under MDR- 2017 due to COVID-19 pandemic.

Source: Shardul Nautiyal, Pharmabiz, 28.12.2020

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Big Data & AI to propel Growth of Indian Healthcare industry: Experts

Digital Technologies like extended reality, cloud systems, big data, and Artificial Intelligence take the centre-stage to enhance user-experience and increase process efficiency. These technologies have accelerated mHealth, remote patient monitoring and timely clinical protocols.

The Healthcare industry has seen rapid growth in 2020. We saw businesses opting for the digital technologies such as extended reality, cloud systems, big data, and Artificial Intelligence to enhance the user-experience and increase process efficiency. With COVID-19 disrupting the status quo in healthcare service delivery, telemedicine and remote patient monitoring are being increasingly adopted by service providers to virtually manage patients, predict and prevent illnesses, and improve Clinical outcomes, said Suhas Tamras, Global Head Medical Devices & Healthcare practice, Tata Elxsi.

Agreeing with Tamras was Ramesh Mamgain, Country Manager, India and SAARC, Commvault who said that the future can only be navigated successfully with optimised data management solutions, empowering the workforce and clients with robust endpoint protection framework, augmenting use of cloud native applications across environments and unleashing the potential of 5G.

For Dileep Mangsuli, Executive Director, Siemens Healthineers, it is the use of digital twins will increase in the medical domain. Advances in underlying computational models will be extensively applied to create an AI-powered personalized bio-physiological model of the patient to make medicine more precise and personalized. AI-powered digital twins enable the simulation of individual organ physiology to comprehend patient health, predict changes, and therapy outcomes.

Further Mangsuli said, "Patient avatar models, which are virtual representations of patients' physical bodies' shape and structure, will enhance procedure planning and improve the patient experience. Organ models, which

simulate the structure, mechanics, and functions of organs, will be used to virtually evaluate therapy options. Disease models, which represent some or all of the pathological processes observed in an actual disease, will be used to treat conditions better. Predictive models, which help predict outcomes, will be used to diagnose conditions. More importantly, digital twin technology will eventually serve as a wellness coach predicting individual risks and preventing sickness."

While 2020 is marked by the spread of the Coronavirus disease, it also saw technology-enabled processes transform healthcare services. In the coming year, too digital health applications & therapeutics, personal health wearables, and AI, NLP (Neural Language Processing), robotics process automation or the RPA-enabled process accelerators in clinical prediction, operational transformation and compliance improvement will further drive and shape the future of the healthcare and Pharma industry. We can witness significant changes over the next few years, as many companies are becoming more digitally mature and competent by applying 'next-gen' technology to varied functional value chain and improving the overall experience, said Tamras.

In 2020 digital adoption and cloud migration stole the show, opening up avenues for emerging technologies such as, intelligent data management, to be at the forefront of this accelerated transformational journey. Now 2021 and beyond looks promising and the onus lies with digital enterprises to choose the sustainable route and become future-ready. Ultimately, the decisions enterprises' make from here on, be it their IT systems or data security, should not just reflect the capabilities to stay successful but also to face uncertainties and threats of tomorrow, noted Mamgain.

Source: Nandita Vijay, Pharmabiz, 29.12.2020

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Health Ministry issues Guidelines for COVID-19 Vaccination

The Union Health Ministry has issued Guidelines for COVID-19 vaccines. As per the Guidelines, the Government is planning to vaccinate people with each session having 100 beneficiaries per day. "If the session site has adequate logistics and space available for waiting room and observation room along with arrangement for crowd management, one more vaccinator officer can be added to create a session for 200 beneficiaries," the Guidelines said.

The document said that COVID-19 Vaccine Intelligence Network (Co-WIN) system, a digital platform, will be used to track the enlisted beneficiaries for vaccination and COVID-19 vaccines on a real-time basis. At the vaccination site, only pre-registered beneficiaries will be vaccinated per the prioritization, and there will be no provision for on-the-spot registrations.

The COVID-19 vaccine will be offered first to healthcare workers, frontline workers and population above 50 years of age, followed by population below 50 years of age with associated co-morbidities based on the evolving pandemic situation, and finally to the remaining population based on the disease epidemiology and vaccine availability.

The Ministry added that the priority group of above 50 years may be further subdivided into those above 60 years of age and those between 50 to 60 years of age for the phasing of roll out based on pandemic situation and vaccine availability. The latest electoral roll for the Lok Sabha and Legislative Assembly election will be used to identify the population aged 50 years or more. The development of a vaccine is a time-consuming process that includes the following phases such as pre-clinical, phase 1 Clinical Trial, phase 2 Clinical Trial and phase 3 Clinical Trial. Under phase one of the vaccination, it is planned to vaccinate nearly 30 crore population.

The Ministry stated that all measures should be taken to avoid exposing the vaccine carrier, vaccine vials or icepacks to direct sunlight. Vaccines and diluents should be kept inside the vaccine carrier with the lid closed until a beneficiary comes to the center for vaccination. The requirements for management of the cold chain for COVID-19 vaccination will vary depending on the type of COVID-19 vaccine, as different vaccines have different storage temperature ranges as States/UTs must ensure adequate cold chain storage capacity for the COVID-19 vaccine campaign, the document stated.

"High-level coordination at the national, state and district levels must be established for effective cooperation and collaboration among the key departments. 19 ministries at national level, 23 departments at state/district and numerous developmental partners are involved in planning the COVID-19 vaccine introduction," stated Ministry.

The vaccination team will consist of five members such as vaccinator officer such as Doctors (MBBS/ BDS), staff nurse, pharmacist, Auxiliary Nurse Midwife (ANM), Lady Health Visitor (LHV); anyone authorized to administer an injection may be considered as a potential vaccinator; vaccination officer 1 as at least one person (Police, home guard, civil defense, National Cadet Corps (NCC), National Service Scheme (NSS), endr yuva kendra sangathan (NYKS) who will check the registration status of a beneficiary at the entry point and ensure the regulated entry to the vaccination session; vaccination officer 2, which is the verifier who will authenticate/verify the identification documents; and vaccination officer 3 and 4 are the two-support staff who will be responsible for crowd management and ensure 30 minutes of waiting time by beneficiary post-vaccination.

Source: Pharmabiz, 30.12.2020

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Indian Pharma companies to benefit from increasing demand in US, says Report


(Representative image)

Indian pharma companies are expected to benefit from improving demand in the US market, said India Ratings and Research (Ind-Ra). As per the ratings agency, these companies have garnered 45% of all new Abbreviated New Drug Application (ANDA) approvals over the past nine months.

Besides, Ind-Ra expects the regulatory environment to remain stringent. However, it said well-equipped companies would be able to take the advantage of a better pricing outlook emanating from supply shortages and recalls.

"Indian companies have received a higher share of new ANDA approvals since April 2020 led by significant manufacturing facility clearances, GDUFA-II (Generic Drug User Fee Amendments), and a strong filing momentum aided by historical investments in R&D," Ind-Ra added in a report.

"Ind-Ra has seen an increasing drug demand since the start of the Covid-19 pandemic led by supply chain issues, channel filling, and demand for Covid-19 led preventive products. In the past, too, there was drug shortage in the US due to the exit of the large generic players from unviable products."

"Overall drug shortages in the US are leading to moderate-to-stable pricing pressures." Furthermore, it cited that majority of the drug recalls (91%) from the US markets are from the non or least serious category (Class-II and III recall). Accordingly, only 'Class-I' drug recalls are serious in nature.

Source: IANS, ET Health World (The Economic Times), 19.12.2020

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Pharma exports achieve 15% growth, will hit $25 bn mark

Standing apart from all other sectors during Covid-19, pharma exports in India witnessed 15.3% so far in the financial year 2020-21 so far. According to the Pharmaceuticals Export Council of India (Pharmexcil), pharma exports are expected to touch $25 billion mark. Pharma exports recorded growth of 11.5% in November. Pharmexcil Director General R Uday Bhaskar told that more than 70% of exports are generic formulations.

R Uday Bhaskar said, “Pharma exports are doing well this financial year till November, and the same trend will continue. It is expected to do well in the next few months till March. For November, the quick estimate is around $1,989 million. The growth in November is 11.5%. So far this year, exports are around $15,868 million with a growth of 15.37%. By the end of the financial year, it will touch $25 billion.”

Pharma exports in financial year 2019-20 were $20.5 billion, Uday Bhaskar said, “More than 70%-75% of our exports are generic formulations other than APIs and vaccines. if we touch $25 billion in FY ‘21, we may touch $28 billion by FY22.” Regarding vaccines, he said, “We are capable of producing high volume of vaccines. Almost all the Indian vaccine manufacturers are tied up with overseas manufacturers/institutions in the development of Covid-19 vaccines.” Drug formulations and biologicals contribute 76% exports followed by 16% by bulk drugs and drug intermediates. Vaccines compromise 3% of exports.

Source: The Times of India, 28.12.2020

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Zydus Cadila gets permission from DCG(I) for phase-1 Clinical Trial of Novel Molecule ZYIL1

Drug firm Zydus Cadila on Monday, 07.12.2020 said it has received permission from Drug Controller General of India (DCGI) to initiate phase-1 Clinical Trial of its novel molecule ZYIL1, indicated for use as an inhibitor for inflammation condition 'NLRP3'. In a regulatory filing, Zydus Cadila said "it has received permission to initiate the phase 1 Clinical Trial of ZYIL1, a novel oral small molecule NLRP3 inhibitor candidate. NLRP3 inflammasomes are involved inthe inflammation process".

This harmful inflammation within the body leads to the onset and development of various kinds of diseases, including Acute Respiratory Distress Syndrome (ARDS), autoimmune diseases, inflammatory diseases, cardiovascular diseases, metabolic disorders, Gastro-intestinal diseases (Inflammatory Bowel Disease), renal diseases and CNS diseases, the company added.

Pankaj R Patel, Chairman, Cadila Healthcare said: "We will study the safety, tolerability, pharmacokinetics and pharmacodynamics of ZYIL1 in this phase I Clinical Trial in healthy human volunteers. We are committed to developing these pioneering novel treatments to the clinic for the patients in need." Last month, Zydus Cadila had filed the investigational new Drug Application for ZYIL1, positioned for management of critically ill Covid-19 patients.

Source: PTI, ET-Health World (The Economic Times), 08.12.2020 (Excerpts)

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INTERNATIONAL NEWS

AstraZeneca's Covid-19 vaccine has a 'winning formula': Chief Executive Pascal Soriot

The Covid-19 vaccine developed by the British drugs group AstraZeneca and the University of Oxford has achieved a "winning formula" for efficacy, the company's Chief Executive said on Sunday, 27.12.2020.

The vaccine, which is currently being evaluated by Britain's independent medicines regulator, provides "100 percent protection" against severe Covid disease requiring hospitalisation, Pascal Soriot said in an interview with the Sunday Times newspaper. He added he believes trials will show his firm has achieved a vaccine efficacy equal to Pfizer-BioNTech at 95 percent and Moderna at 94.5 percent.

"We think we have figured out the winning formula and how to get efficacy that, after two doses, is up there with everybody else," the CEO said explaining data would be published at "some point". The UK Government announced on December 23 that the developers of the Oxford AstraZeneca vaccine had submitted their data to the data to the Medicines and Healthcare products Regulatory Agency (MHRA) for approval for a mass rollout. The approval is expected to be granted on Monday, 28.12.2020 The Sunday Telegraph newspaper reported. The Pfizer-BioNTech vaccine was the first Coronavirus shot to be authorised for use by the UK's independent medicines regulator and has been given to hundreds of thousands of the country's most vulnerable people since its rollout last month.

The bulk of Britain's vaccine requirements are expected to be met by the jab developed by AstraZeneca and the University of Oxford, as the Government has ordered 100 million doses. Earlier trials had shown varying outcomes in the AstraZeneca shot's efficacy. The vaccine intially showed an average 70 percent effectiveness but that level jumped to 90 percent depending on dosage. Soriot said he was "surprised" by the initial findings. "We would have preferred a simpler set of results," he added.

Source: The Economic Times, 29.12.2020

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Glenmark inks pact with Menarini Group to commercialise nasal spray in Europe

Glenmark Pharmaceuticals on Wednesday, 02.12.2020 said its subsidiary has inked a licensing pact with Menarini Group for commercialising its nasal spray Ryaltris across

33 countries in Europe, including the Balkan region. Glenmark Specialty, a Switzerland-based unit of the company, has entered into an exclusive licensing agreement with the Menarini Group for Ryaltris, the Mumbai-based drug firm said in a statement.

The company's product is a novel Fixed-Dose Combination nasal spray of an antihistamine and a steroid, indicated for the treatment of symptoms associated Under the terms of the agreement, Glenmark will be responsible for the continued development and regulatory approval of Ryaltris in European markets while Menarini will be responsible for the scientific information and the commercialisation of the product in those markets, following regulatory approval.

As part of the deal, Glenmark will receive an upfront payment as well as launch and sales based milestone payments from Menarini for Ryaltris sales. “This partnership is another step in establishing Glenmark's respiratory focus in Europe. While Glenmark will launch Ryaltris through its own front ends in some markets, this arrangement will allow the product to compete across Europe,"Glenmark Pharmaceuticals Executive Vice President, Business Head EMEA-L (Europe, Middle East, Africa, Latin America) Achin Gupta said.

This is also aligned with the company's vision to make Ryaltris the first Global Brand by launching it in several markets across the world, he added. "Ryaltris is a perfect addition to our European respiratory and allergy portfolio and we can count on our established experience in the relevant the rapeutic area to bring this novel option to patients. We look forward to receiving Ryaltris registration and being able to launch operations as soon as practicable,” Menarini Group General Manager Pio Mei said.

Source: PTI, ET Health World, 23.12.2020

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EU warns of risks of Covid-19 vaccine race after UK approval of Pfizer shot

The European Union's drug watch dog and lawmakers warned against hasty approvals of Covid-19 vaccines on Wednesday, 02.12.2020 after Britain granted emergency authorisation to the experimental Covid-19 shot being developed by Pfizer and BioNTech.

Britain is the first Western country to approve a Covid-19 vaccine, a move that many see as a political coup for Prime Minister Boris Johnson's Government, which has faced criticism over its handling of the Coronavirus crisis. The decision was made under an emergency, ultra-fast approval process.

The European Medicines Agency (EMA), which is in charge of approving Covid-19 vaccines for the EU, said its longer procedure to approve vaccines was more appropriate as it was based on more evidence and required more checks than the emergency procedure chosen by Britain. Asked about the British approval of the Pfizer vaccine, the agency said: "EMA considers that the conditional marketing authorisation is the most appropriate regulatory mechanism for use in the current pandemic emergency." EMA had said on Tuesday, 01.12.2020 that, under that procedure, it would decide by Deceember 29 whether to authorise Pfizer's vaccine. EU lawmakers were critical of Britain's decision.

"I consider this decision to be problematic and recommend that EU Member States do not repeat the process in the same way," said Peter Liese, an EU lawmaker who is a member of German Chancellor Angela Merkel's party. "A few weeks of thorough examination by the European Medicines Agency is better than a hasty emergency marketing authorisation of a vaccine," said Liese, who represents the centre right grouping, the largest in the EU assembly. Under EU rules, the Pfizer vaccine must be authorised by EMA, but EU countries can use an emergency procedure that allows them to distribute in their domestic market a vaccine for temporary use. Britain is still subject to EU rules until it fully leaves the bloc at the end of the year. "There is an obvious global race to get the vaccine on the market as fast as possible," said Tiemo Wolken, an EU lawmaker from the socialist grouping, the second largest in the EU Parliament. "However, I do believe that it is better to take the time and make sure that the quality, effectiveness and safety is guaranteed and matches our EU standards."

Source: ET Health World, (The Economic Times), 04.12.2020 (Excerpts)

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

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LICENSED TO POST WITHOUT PREPAYMENT
LICENCE NO. MR/Tech/WPP-337/West/2021-23
RNI REGN. NO. 18921/1970, REGN.NO.MCW/95/2021-23
Published and Posted on 7th, 14th, 21st and 30th of every month
This issue posted at Mumbai Patrika Channel Sorting Office on 07.01.2021

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