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IDMA BULLETIN

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Indian APIs & Formulations for Global Healthcare

INDIAN DRUG MANUFACTURERS' ASSOCIATION

HIGHLIGHTS

A Publication of
Indian Drug Manufacturers' Association
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Indian Drug Manufacturers' Association

IDMA BULLETIN

Vol. No. 52 **Issue No. 15** **15 to 21 April 2021**

IDMA Representation to Secretary, Department of Pharmaceuticals on PLI Scheme

The Association has submitted the following representation on 16th April 2021 to Ms S Aparna, IAS, Secretary, Department of Pharmaceuticals with copy to Mr Amitabh Kant, IAS, Chief Executive Officer, NITI Aayog & Chairman - Empowered Committee for the Production Linked Incentive Scheme on Bulk Drugs & Medical Devices, New Delhi on PLI Scheme:

"Greetings from Indian Drug Manufacturers' Association!

We are pleased to know that there was a good response to the PLI Scheme for the Promotion of Domestic Manufacturing of critical KSMs/Drug Intermediates and APIs and the approvals are granted for most of the products.

We would like to bring to your notice a grave concern which has been expressed/ raised by our members regarding only one manufacturer being granted approval for certain products.

In Target Segment IV, 22 eligible products that are granted approval, 15 products are such in which the approval is granted to only one manufacturer & in one product though there are two manufacturers, they belong to the same group of companies (Oxcarbazepine).

We feel that more than one manufacturers should be encouraged in the scheme so that there is a better competition among manufacturers.

It will bring innovation, cost effectiveness & competition in the market which will help to keep the price of API in check. This will help in reducing the cost of medicine in the hands of the patient.

Otherwise all the Formulators will depend only on one manufacturer of the API. We are sure that the objective of the scheme was to have more manufacturers. Hence there was a criteria of approving maximum 4 applicants.

The manufacturers who had applied for the lesser capacity as per the scheme seems to have been not considered. Some of these manufacturers are already manufacturing these APIs and would now like to go for Backward Integration, as per the objective of the scheme.

In the current scenario over the period of time there will be only one manufacturer for one molecule which will create a MONOPOLY situation. This will make the medicines expensive in the hand of the Patient.

Though the approvals are granted as per the Criteria laid down by the Scheme, granting an approval to only one manufacturer will defeat the purpose of the scheme which is to be *AATMANIRBHAR,* Reduce the cost of medicine, create employment, encourage API manufacturing in India.

This may lead to some manufacturers stopping the production of API in eligible product list which they are making since many years, as it will be difficult for them to compete with another manufacturer (just one) who is enjoying the benefit of the scheme.

On behalf of our Members & the Indian Pharmaceutical Industry, we look forward to your kind consideration and positive response."

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IDMA Congratulates Mr B N Singh and Mr Sandeep Singh on bestowing with Certification: 'Alkem Laboratories Ltd is a Great Place to Work-Certified™ Organization'

Amidst the pandemic situation, where nothing was normal and the entire world was seen fighting a new battle for survival and existence, we as an organisation decided to go ahead and participate in the employee survey conducted by Great Place to Work Institute (India), in the month of January this year. Some of you had been a part of the survey and shared your valuable feedback. Post completion of the random employee survey, they studied our different people processes & practices as part of culture audit.

The results are just announced and I am delighted to announce that Alkem Laboratories Ltd is now a Great Place to Work-Certified™ organization in the large organization category across industries, consecutively for the second time in a row.

Every year, more than 10,000 organizations from over 60 countries partner with Great Place to Work® Institute for assessment, benchmarking and planning actions to strengthen their workplace culture. Great Place to Work® Institute's methodology is recognized as rigorous and objective and is considered as the gold standard for defining great workplaces across business, academia and government organizations. Great Place to Work® Certification Program is the first step for an organization in its journey to build a High-Trust, High-Performance Culture™ and our organization has successfully accomplished this milestone.

Presented by Mr Devesh Malladi, Chairman, NDPS Committee, IDMA at 'UN - CND side event on Designer Precursors' - Tuesday 13 April 2021

Indian Drug Manufacturers' Association Since 1961

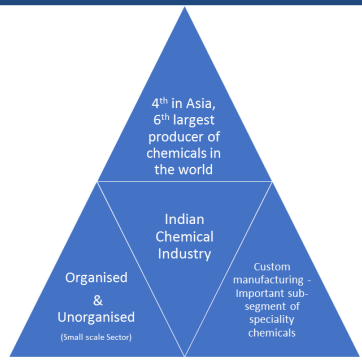
Challenges Faced by Indian Industry on the Misuse of Non-Scheduled, Designer Precursor Chemicals for Illicit Activities
&
Industry Perspective

64th Session of the Commission on Narcotic Drugs

13th April, 2021

Presentation By Devesh Malladi, Chairman NDPS Committee, Indian Drug Manufacturers' Association

Indian Chemical Industry



2

Chairman, NDPS Committee

Industry Challenges

- Licensing or registration system for manufacture of chemicals in India
- Comprehensive database of chemical units – Number of organized and unorganized units across India
- Awareness on ISSL list of non-schedule or designer precursor chemicals

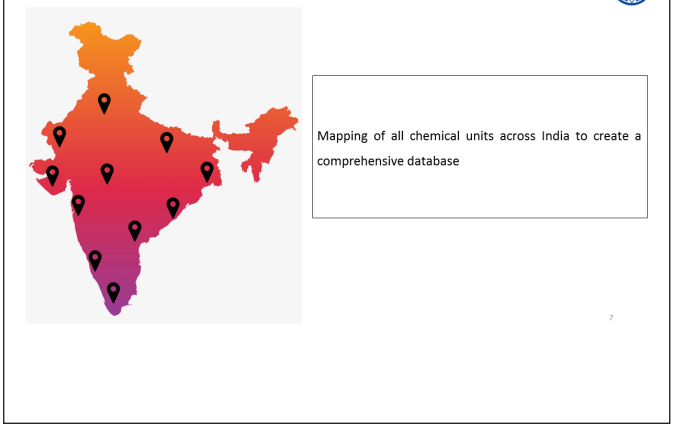
4

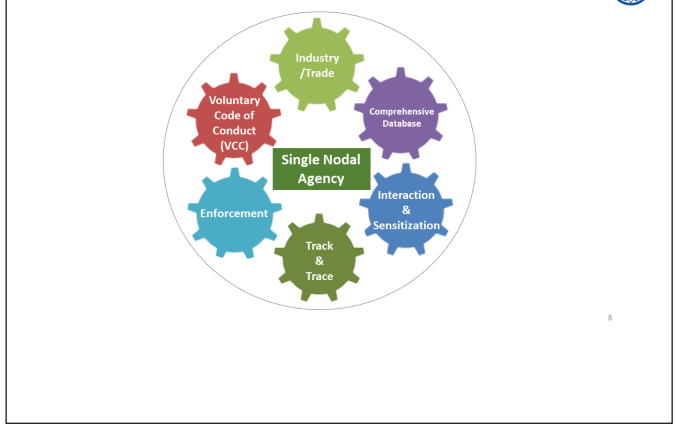
Law Enforcement Agencies

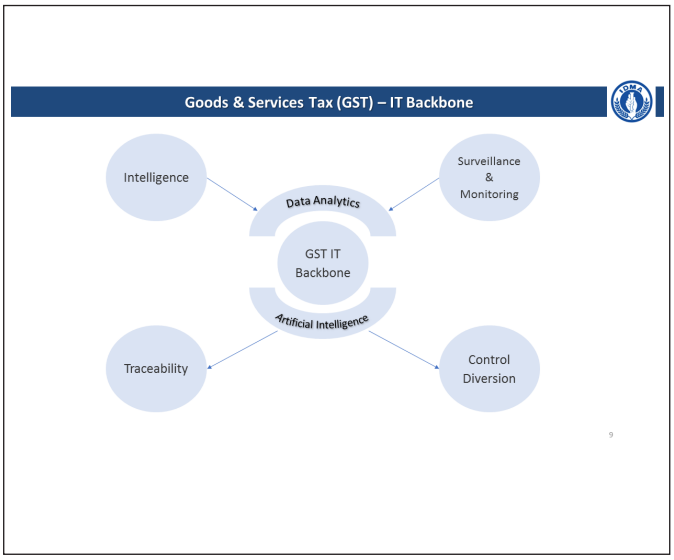
- Absence of a single nodal agency for licit industry/trade in India
- Lack of subject matter experts and periodic changes in personnel
- Lack of structured interaction with industry to disseminate information regarding the ISSL list of non-scheduled & designer precursor chemicals
- Trust deficit with industry & trade
- Multiple agencies have data but no coordinated effort to monitor & control - Track & trace mechanism

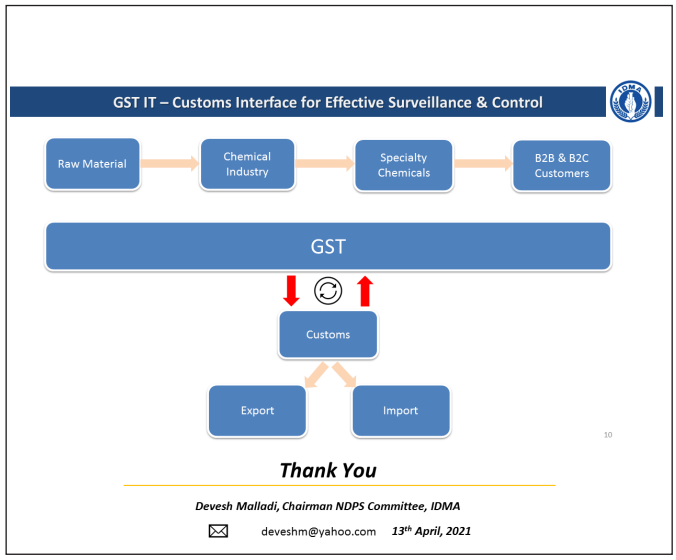
5

6









Most Urgent - Vehicle Sticker - Red Code Sticker For Pharmaceutical Sector In Maharashtra

ATTENTION MEMBERS

We attach herewith the letter no.CP/XI(6)/144/(Prohibitory Order)/2021 dated 17th April 2021 received from the Shri Chaitanya S., Depuy Commissioner of Police (Operations) & Executive Magistrate, Greater Mumbai wherein it has been insisted that those travelling in public using any vehicle should affix a sticker of circular shape of 6 inches diameter of the following description affixed visibly on the front screen & rear screen of the vehicle and in case of two-wheelers on a visible portion on the front & rear for the movement of the vehicle in lockdown areas.

The Pharmaceutical Sector comes under the **RED COLOUR STICKER** as mentioned below:

A. Red-colour sticker: For the vehicles related to doctors/medical staff, medical services, ambulances, hospitals, diagnostic centres, clinics, vaccination centres, medical insurance offices, pharmacies, pharmaceutical companies, other medical and health services including supporting, manufacturing and distribution units along with their dealers, transport and supply chain; manufacturing and distribution of vaccines, sanitizers, masks, medical equipment, their ancillaries, raw material units and support services, veterinary services/animal care shelters;

We request all our members having factories & offices in Maharashtra to diligently follow the above rule with immediate effect till 7 am on 1st May 2021. This will help us to continue our operations & keep serving the patients of our country.

Thanking you, With Warm Regards, ***Daara Patel,*** *Secretary – General*, IDMA

CP/XI(6)/144/(Prohibitory Order)/2021

THE COMMISSIONER OF POLICE, GREATER MUMBAI

ORDER

(UNDER SECTON 144 OF CRIMINAL PROCEDURE CODE, 1973)

1. WHEREAS, in exercise of powers, conferred under Section 2 of the Epidemic Diseases Act, 1897, read with all other enabling provisions of the National Disaster Management Act, 2005, the Government of Maharashtra, issued directions vide notification No. DMU/2020/CR.92/DisM-1, Dated : 13th April, 2021 (**"Break The Chain"**) to take certain emergency measures to prevent and contain the spread of COVID-19, and to enforce these measures throughout the state from 8 PM on 14th April, 2021 till 7 AM on 1st May, 2021,

2. Whereas, an order under section 144 of the CrPC has been issued dated 14th April 2021, by the undersigned, to observe the directions issued by the Government of Maharashtra in the above mentioned notification No. DMU/2020/CR.92/DisM-1, Dated : 13th April, 2021 ("Break The Chain"),

3. Whereas, in the notification No. DMU/2020/CR.92/DisM-1, Dated : 13th April, 2021 ("Break The Chain") issued by the Government of Maharashtra, movement of any person in public place without valid reasons has been prohibited, save for those services and activities that are exempted in that notification, in case of which movement is to be unrestricted,

4. THEREFORE, I, **Chaitanya. S., Dy. Commissioner of Police (Operations), Greater Mumbai,** and Executive Magistrate, vide powers conferred upon me u/sec 144 of the Criminal Procedure Code, 1973 (Act II of 1974) r/w the order of Commissioner of Police, Greater Mumbai, dated 23/12/1959 u/s 10 sub section (2) of the Maharashtra Police Act, 1951 (Mah. Act XXII of 1951), with a view to prevent danger to human life, health or safety, do hereby, promulgate an order under section 144 of the CrPC, in the areas under the control of Commissioner of Police, Greater Mumbai, prohibiting movement of any person in public using any vehicle, unless a sticker of circular shape of 6 inches diameter of the following description is affixed visibly on the front screen and rear screen of the vehicle, and in the case of two-wheelers on a visible portion on the front and rear, for the movement of the vehicle freely in the lockdown areas:

A. Red-colour sticker: For the vehicles related to doctors/medical staff, medical services, ambulances, hospitals, diagnostic centres, clinics, vaccination centres, medical insurance offices, pharmacies, pharmaceutical companies, other medical and health services including supporting, manufacturing and distribution units along with their dealers, transport and supply chain; manufacturing and distribution of vaccines, sanitizers, masks, medical equipment, their ancillaries, raw material units and support services, veterinary services/animal care shelters;

B. Green-colour sticker: For the vehicles related to transport of eatables/food items such as groceries, vegetables, fruits, dairy products, bakery products, confectionaries and all types of food items in raw or cooked form;

C. Yellow-colour sticker: For the vehicles related to transportation of officers and staff of central, state and local governments, including their statutory authorities and organizations, all public essential services by local authorities, public transport, press/media, water supply services, electric and gas supply services, municipal services, services required for restoration/maintenance of telecom services, e-commerce (only for the supply of essential goods and services), government and

on 1st May, 2021, unless withdrawn earlier.

7. Any person contravening this order or misusing the sticker by affixing the stickers of above description on a vehicle and moving in public in that vehicle for a reason/service/activity not exempted in paragraph 4(A), 4(B) and 4(C) above and the notification No. DMU/2020/CR.92/DisM-1, Dated : 13th April, 2021 ("Break The Chain"), shall be punishable under section 188 IPC and penal provisions under the Epidemic Diseases Act 1897 and National Disaster Management Act 2005 and with other legal provisions as applicable.

8. As the notice cannot be served individually on all concerned, the order is hereby passed ex-parte. It shall be published for the information of the Public, through the Press, or by affixing copies on the Notice Boards of the Police Stations and offices of the Divisional ACsP and Zonal DCsP.

Given under my hand and seal on this 17th day of April 2021 at Mumbai.

Office of the
Commissioner of Police,
Brihanmumbai.

DY. COMMISSIONER OF POLICE (OPERATIONS) BRIHAN MUMBAI

(Chaitanya. S.)
Dy. Commissioner of Police (Operations),
and Executive Magistrate
Greater Mumbai.

IPC NOTICE

Approach to Alternative Rapid Microbiological Methods - reg.

IPC Notice dated 16th April, 2021

To,
All Stakeholders of Indian Pharmacopoeia,

The Indian Pharmacopoeia Commission (IPC) has proposed a new General Chapter on 'Approach to Alternative Rapid Microbiological Methods' and the draft has been posted on the IPC website (www.ipc.gov.in) on 9th April 2021 for inviting comments, if any, from all the stakeholders (copy enclosed)*. The draft has been prepared after intense and in-depth consultation with relevant subject experts and approved by IPC's Expert Working Group- Microbiology. The best practices followed in other countries and the procedures and approaches provided under similar chapters in other Pharmacopoeias (like USP, BP etc) have also been taken into consideration while preparing this draft.

As we are aware that current pandemic due to COVID-19 has urgently warranted for making available quality medicines to the patients at the earliest. This includes, but not limited to, Remdesivir Injection which has been approved by the CDSCO for restricted emergency use for the treatment of patients with severe COVID-19 infection. Recently the healthcare system has faced challenges in maintaining continuous supply of COVID-19 related drugs, particularly Remdesivir Injection, and it emerged that application of rapid alternative methods to the official Indian Pharmacopoeia (IP) methods may help in tackling this challenge.

In view of the above, as an interim measure it is proposed that the stakeholders may follow the draft General Chapter on 'Approach to Alternative Rapid Microbiological Methods' available on IPC's website. The proposed draft Rapid Microbiological Methods would enable faster laboratory testing of the drug(s) thereby making them accessible to the patients at the earliest without compromising the quality of the product. This approach would be in line with the provisions of the

'Alternative Methods' already given in the General Notices of the IP (Volume I, Page 12) wherein it is mentioned that automated procedures utilising the same basic chemistry as the test procedures given in the monograph may also be used to determine compliance.

Accordingly, the manufacturers may submit validated data of the alternative Rapid Microbiological Methods and obtain the necessary approvals from appropriate Drug Regulatory Authorities under the provisions of the Drugs and Cosmetics Act 1940 and Rules 1945 there under.

Dr Rajeev Singh Raghuvanshi, Secretary-cum-Scientific Director, Indian Pharmacopoeia Commission, Ministry of Health & Family Welfare, Ghaziabad.

(*Not reproduced here. Members interested are requested to kindly download the same from IPC website: www.ipc.gov.in OR contact IDMA Secretariat at email: mail_idma@idmaindia.com for mailing a soft copy of the same).

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CDSCO MATTERS

Special Condition under which the permission for import of drug with residual shelf life less than 60% is allowed

DCG(I) Circular Ref.File No.DCGI/Misc/2020 (110), dated 13th April 2021

To
All Port Offices of CDSCO.

In light of representation received and Covid-19 pandemic situation the effective date of the circular of even no dated 17.04.2020, 10.07.2020 and 18.12.2020 issued on subject cited above is extended up to **31st October 2021** or till further order whichever is earlier.

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

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Exclusion of FDC of Tamsulosin and Deflazacort from ban - reg.

Gazette Notification No.G.S.R. 255(E), dated 7th April, 2021

Whereas the Central Government, on being satisfied that the Fixed Dose Combination (hereinafter referred as the FDC) of corticosteroid with any other drug for systemic use is likely to involve certain risk to human beings, vide its notification number G.S.R. 578(E), dated the 23rd July, 1983, inter alia prohibited the manufacture and sale of FDCs of Steroids for internal use except combination of Steroids with other drugs for the treatment of Asthma;

And whereas, the Central Government vide notification number G.S.R. 738(E), dated the 9th October, 2009 further amended the said notification number G.S.R. 578(E), dated the 23rd July, 1983 and substituted item 14 and the entries relating thereto with the entry "Fixed Dose combination of corticosteroid with any other drug for internal use except for preparations meant for meter dose inhalers and dry powder inhalers";

And whereas, FDC of Tamsulosin HCl 0.4 mg (as film coated modified release tablet) + Deflazacort 30 mg hard gelatin capsule was examined by Prof. Kokate Committee constituted by the Central Government for examining the safety and efficacy of FDCs which were licensed prior to 1st October, 2012 without prior approval of the Central Licensing Authority and therefore, Prof. Kokate committee examined the said FDC in current scenario based on the available documents and scientific literature and considered this FDC as rational and accordingly, the FDC of Tamsulosin HCl 0.4mg (as film coated modified release tablet) + Deflazacort 30 mg hard gelatin capsule was approved;

And whereas, FDC of Tamsulosin HCl 0.4 mg (as film coated modified release tablet) + Deflazacort 30 mg hard gelatin capsule was also referred to Drugs Technical Advisory Board and upon examination, the Drugs Technical Advisory Board had now recommended to exclude the FDC of Tamsulosin HCl 0.4 mg (as film coated modified release tablet) + Deflazacort 30 mg hard gelatin capsule from the prohibition made vide notification number G.S.R. 738(E), dated the 9th October, 2009.

Now therefore, in exercise of the powers conferred by section 26A of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, after consultation with the Drugs Technical Advisory Board, hereby makes the following amendments further to amend the notification number G.S.R. 578(E), dated the 23rd July, 1983, namely:—

In the notification, in the Table, for item 14 and the entries relating thereto, the following item and entries shall be substituted, namely:—

"14. Fixed Dose Combination of corticosteroid with any other drug [excluding Fixed Dose Combination of Tamsulosin HCl 0.4 mg (as film coated modified release tablet) + Deflazacort 30mg in hard gelatin capsule] for internal use except for preparations meant for meter dose inhalers and dry powder inhalers.".

F. No. X.11014/8/2020-DR

Dr Mandeep K Bhandari,
Joint Secretary,
Department of Health and Family Welfare,
Ministry of Health and Family Welfare,
New Delhi.

Note: The Principal Notification was published in the Gazette of India, Extraordinary, Part II, Section 3, Subsection (i) vide notification number G.S.R. 578(E), dated the 23rd July, 1983 and lastly amended vide Notification Number G.S.R. 738(E), dated the 9th October, 2009.

CBIC amends Notification No.14/2016-Customs (ADD), dated 21st April 2016, so as to extend the applicability of the said notification up to and inclusive of 20th October, 2021 - reg.

Notification No.22/2021-Customs (ADD), dated 15th April, 2021

Whereas, the designated authority vide initiation notification No.7/46/2020-DGTR, dated the 2nd March, 2021, published in the Gazette of India, Extraordinary, Part I, Section 1, dated the 2nd March, 2021, has initiated review in terms of sub-section (5) of section 9A of the Customs Tariff Act, 1975 (51 of 1975) (hereinafter referred to as the Customs Tariff Act) and in pursuance of rule 23 of the Customs Tariff (Identification, Assessment and Collection of Anti-dumping Duty on Dumped Articles and for Determination of Injury) Rules, 1995 (hereinafter referred to as the said rules), in the matter of continuation of anti-dumping duty on imports of **'Barium Carbonate'** falling under tariff item 2836 60 00 of the First Schedule to the Customs Tariff Act, originating in or exported from **People's Republic of China**, imposed vide notification of the Government of India, in the Ministry of Finance (Department of Revenue) No.14/2016-Customs (ADD), dated the 21st April, 2016, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), vide number G.S.R.434(E), dated the 21st April, 2016, and has requested for extension of the said anti-dumping duty in terms of sub-section (5) of section 9A of the Customs Tariff Act;

Now, therefore, in exercise of the powers conferred by sub-sections (1) and (5) of section 9A of the Customs Tariff Act, read with rules 18 and 23 of the said rules, the Central Government hereby makes the following amendment in the notification of the Government of India, in the Ministry of Finance (Department of Revenue), No.14/2016-Customs (ADD), dated the 21st April, 2016, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), vide number G.S.R.434(E), dated the 21st April, 2016, namely:-

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

"3. Notwithstanding anything contained in paragraph 2, the anti-dumping duty imposed under this notification shall remain in force up to and inclusive of the 20th October, 2021, unless revoked, superseded or amended earlier.".

F.No.354/21/2010-TRU (Pt-II)

Rajeev Ranjan, Under Secretary, Department of Revenue, Ministry of Finance, New Delhi.

Note: *The Principal Notification No.14/2016-Customs (ADD), dated the 21st April, 2016, was published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), vide number G.S.R.434(E), dated the 21st April, 2016*

● ● ●

The Sea Cargo Manifest and Transshipment Regulations, 2018 amended (2nd Amendment of 2021) - reg.

Notification No.44/2021-Customs (N.T.) dated 15th April, 2021

In exercise of the powers conferred by section 157, read with sections 30, 30A, 41, 41A, 53, 54, 56, sub-section (3) of section 98 and sub-section (2) of section 158 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 Sea Cargo Manifest and Transhipment Regulations, 2018, namely:-

1. Short title and commencement:

(1) These regulations may be called the **Sea Cargo Manifest and Transhipment (Second Amendment) Regulations, 2021.**

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

2. In the said regulations, in regulation 15,-

(a) in sub-regulation (2), for the words, figures and letters, "till 15th April, 2021", the words, figures and letters, "till 31st May, 2021" shall be substituted.

F.No.450/58/2015-Cus IV(Pt)

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

Note: *The Principal Regulations were published in the Gazette of India, Extraordinary, Part II, Section 3 Sub-section (i) vide number G.S.R.448(E), dated the 11th May, 2018 and were last amended vide Notification No.39/2021- Customs (N.T), dated the 31st March, 2021 vide number G.S.R. 238(E), dated the 31st March 2021.*

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CBIC MATTERS

CBIC notifies New Exchange Rates w.e.f. 16th April 2021 - reg.

Notification No.43/2021-Customs (N.T.), dated 15th April, 2021

In exercise of the powers conferred by section 14 of the Customs Act, 1962 (52 of 1962), and in supersession of the Notification No.40/2021-Customs(N.T.), dated 1st April, 2021 except as respects things done or omitted to be done before such supersession, the Central Board of Indirect Taxes and Customs hereby determines that the rate of exchange of conversion of each of the foreign currencies specified in column (2) of each of **Schedule I** and **Schedule II** annexed hereto, into Indian currency or vice versa, shall, **with effect from 16th April, 2021,** be the rate mentioned against it in the corresponding entry in column (3) thereof, for the purpose of the said section, relating to imported and export goods.

SCHEDULE-I

Sr. No.	Foreign Currency	Rate of exchange of one unit of foreign currency equivalent to Indian Rupees	
(1)	(2)	(3)	
		(a)	(b)
		(For Imported Goods)	(For Exported Goods)
1.	Australian Dollar	59.35	56.90
2.	Bahraini Dinar	206.15	193.55
3.	Canadian Dollar	61.20	59.05
4.	Chinese Yuan	11.70	11.35
5.	Danish Kroner	12.35	11.90
6.	EURO	91.75	88.60
7.	Hong Kong Dollar	9.85	9.50
8.	Kuwaiti Dinar	257.95	241.90
9.	New Zealand Dollar	55.20	52.80
10.	Norwegian Kroner	9.10	8.80
11.	Pound Sterling	105.45	101.95
12.	Qatari Riyal	21.35	20.05
13.	Saudi Arabian Riyal	20.70	19.45
14.	Singapore Dollar	57.30	55.35
15.	South African Rand	5.40	5.05
16.	Swedish Kroner	9.05	8.75
17.	Swiss Franc	83.15	79.90
18.	Turkish Lira	9.60	9.00
19.	UAE Dirham	21.15	19.85
20.	US Dollar	76.15	74.45

SCHEDULE-II

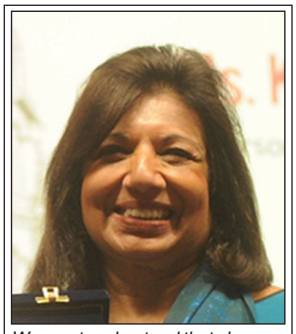
Sr. No.	Foreign Currency	Rate of exchange of 100 units of foreign currency equivalent to Indian Rupees	
1.	Japanese Yen	70.40	67.90
2.	Korean Won	6.95	6.55

F.No. 468/01/2021-Cus.V

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

● ● ●

Kiran Mazumdar-Shaw explains key issues like drug availability, vaccination and 2nd peak


We must understand that chances of re-infection are high for all viral diseases, says Mazumdar-Shaw.

Kiran Mazumdar-Shaw, Executive Chairman, Biocon, decodes the current Covid situation. Edited excerpts from her interview to ET Now:

What is your take on the Remdesivir situation, including the price drop?

This surge in demand was completely unexpected. The companies have rallied around, with everyone rapidly ramping up production. I think we will be able to put availability issues behind us in a few weeks' time. By early or mid May, we should be able to cater to all the demand.

As far as pricing is concerned, it's the market forces that have brought prices down substantially. This augurs well for patients who need it.

There is a shortage of other Covid drugs as well. When do you see the situation normalising?

*It is very difficult to predict how long the second wave will last. We are ramping up production of drugs like **Itolizumab** and **Tocilizumab** to meet surge demand.*

There is an acute shortage. This is a life saving drug. So there is a huge challenge, and we are all trying to address it.

What is your view on people catching Covid after the first vaccine shot, and some even after the second one?

We must understand that chances of re-infection are high for all viral diseases. What vaccination does is, it protects you from severe infection.

With one shot, your body is able to rapidly deploy its defensives against an invading virus. Therefore it is important to vaccinate as many people as possible at least with one shot.

Those getting re-infected after vaccination are only catching moderate or mild contractions. That is an important thing to take note of. That is why there is a need to double down on vaccine deployment.

When do you think the second surge will peak?

See, one must understand that the virus has mutated. You will now have mutant strains that will go on challenging us. But like I said, if a substantial percentage of the population can be vaccinated, that will enable us to keep our hospitals and medical resources from getting overwhelmed.

The second wave, in my opinion, will take a few more months to subside. I think we should be prepared for various types of possibilities.

Source: ET Now, The Economic Times, 19.04.2021

● ● ●

In Lok Sabha & In Rajya Sabha

In Lok Sabha

e-Commerce Companies

Lok Sabha Starred Question No: 311

Shri A Ganeshamurthi:

Q. Will the Minister of **COMMERCE AND INDUSTRY** be pleased to state;

(a): whether the All India Chamber of Commerce and Industry (AICCI) has demanded the Union Government that some big e-commerce companies be banned from operating in India due to excessive discounts, low pricing and restrictions on goods and if so, the details thereof;

(b): whether it is true that the said e-commerce companies have also exploited loopholes in the FDI policy and foreign exchange regulations;

(c): if so, the details thereof including the action taken/ being taken by the Government against these companies; and

(d): if no action has been taken/proposed to be taken, the reasons therefor?

Answered on 17th March 2021

A. (a) to (d): A Statement is laid on the Table of the House.

STATEMENT REFERRED TO IN REPLY TO PARTS (a) TO (d) OF THE LOK SABHA STARRED QUESTION NO. 311:

(a): No such representation from All India Chamber of Commerce and Industry (AICCI) has been received in this Department.

(b) & (c): The Government has received complaints against certain e-commerce companies alleging violation of FDI policy and necessary actions under the provisions of Foreign Exchange Management Act, 1999 have been taken for investigation by Enforcement Directorate.

(d): Does not arise.

The Minister of Commerce & Industry (Shri Piyush Goyal)

Lok Sabha Unstarred Question No: 3497

International Intellectual Property Index (IIPI)

Shri M K Vishnu Prasad:

Q. Will the Minister of **COMMERCE AND INDUSTRY** be pleased to state;

(a): whether International Intellectual Property Index (IIPI) has been released by the Global Innovation Policy Centre recently;

(b): if so, the details thereof including the criteria fixed for determining the rankings in IIPI;

(c): whether India's ranking has slipped in IIPI and if so, the details thereof and the reasons therefor;

(d): whether the Government has made any effort to support investments in innovation and creativity through increasingly robust Intellectual Property protection and enforcement and if so, the details thereof;

(e): the number of Intellectual Property Rights awareness workshops/seminars conducted by the Government during the last three years and the current year so far; and

(f): the other steps taken/being taken by the Government to improve the ranking in IIPI?

Answered on 17th March 2021

A. (a): No Sir. The VIII edition of the International Intellectual Property Index (IIPI) was released by U.S Chamber of Commerce Global innovation Policy Centre (GIPC), on February 5, 2020 subsequent to which no further edition has been released.

(b): As per the VIII Edition, the International Intellectual Property Index (IIPI) has mapped the Intellectual Property Ecosystem in 53 Global economies. The index evaluates the Intellectual Property framework in each economy across 50 indicators spread across 9 categories.

(c): As per the VIII edition India was ranked 40th out of a total of 53 countries, as against 36th in 50 countries assessed in 2019. While India ranked the very last out of all the countries initially in 2012, it has

improved its rank gradually, indicating a consistent improvement in India's IPR regime according to the report. Other rankings like global innovation index also showcase India's prowess in innovation and IP where India's rank improved to 48 in 2020 as against 81 in 2015.

India's ranking of IIPI for the last few years is as under:

Edition	Year	India's Rank	No. of Countries
VIII	2020	40	53
VII	2019	36	50
VI	2018	44	50
V	2017	43	45
IV	2016	37	38
III	2015	29	30
II	2014	25	25
I	2012	11	11

India's overall score has increased from 36.04 (16.22 out of 45) in the VII edition, to 38.46 (19.23 out of 50) in the VIII edition. India's score on IP indicators improved from 16.22 (36.04%) to 19.23 in existing indicators which indicates improvement in India's IP ecosystem. Three out of five indicators added recently are international treaties to which India has not become member; hence it has not been scored against them.

(d): Government of India has undertaken various steps to support investments in innovation and creativity through robust the IPR regime and enforcement in the country. Some of recent steps taken are:

- The facility of Expedited Examination has been provided for patent applications filed by Start-ups and for applications where the Applicant has selected Indian Patent office as ISA/IPEA for his PCT application. In the year 2019, Expedited Examination system has been extended for patent applications filed by small entities and other seven more categories of applicants.
- Design Amendment Rules, 2021 was notified in the Gazette of India on 25.01.2021 wherein provision has been made for 80% reduction in fee for startups and small entities/MSMEs to bring them at par with natural persons. This would incentivize MSMEs and startups to file for industrial designs.
- The scheme for facilitating Start-ups Intellectual Property Protection (SIPP) launched for encouraging innovation and creativity of start-ups wherein start-up entities can avail reimbursement for fee to be paid to facilitators while filing their patent applications, has been extended up to 31st March, 2023.
- Further, to simplify the patent prosecution process for the foreign and domestic companies who have filed their inventions in India, statement of working submitted in the Form 27 has been simplified whereby a single form can be filled for related patent applications.
- On enforcement front several initiatives have been taken to further strengthen the IPR regime in India. Apart from creating awareness among general public, more than hundred sensitization programs have been carried out with Police, Customs and Judiciary. DPIIT has developed various resources such as IPR Enforcement Toolkit for Police and a booklet on Frequently Asked Questions (FAQ)
- "A-Z of Intellectual Property Rights". Further to counter online piracy, CIPAM collaborated with National Internet Exchange of India (NIXI) and Maharashtra Cyber and Digital Crime Unit (MCDCU), to suspend over 380 infringing websites on the basis of incomplete KYC (or WHOIS norms).

(e): Awareness in IPR: Department for Promotion of Industry and Internal Trade (DPIIT) through Cell for IPR Promotion and Management (CIPAM) and in collaboration with the office of CGPDTM is regularly engaged in dissemination of information and knowledge to IP stakeholders by way of participation in awareness activities in IPR, conducted for schools, universities, industries, legal and enforcement agencies and other stakeholders in collaboration with industry Associations in the country. IPO officials regularly participate as resource persons in these programmes. The details of IPR Awareness workshops/ seminars conducted are as under:-

S. No.	Target Group	2017-2018	2018-2019	2019-2020	2020-2021 (till date)
1.	CIPAM - Academic Institutions (Schools, Colleges, Universities)	78	653	300	95
2.	IP training and sensitization programs for enforcement agencies and judiciary	13	19	42	29
3.	Ministry of Micro, Small & Medium Enterprises (MSME)	30	56	113	138

(f): In order to continuously improve & strengthen the IPR Regime in the country, Government of India

has taken multiple initiatives in the last few years. India has acceded to WIPO Copyright Treaty and WIPO Performers and Phonograms Treaty and Nice, Vienna and Locarno Agreements.

To clear the backlog created due to paper filing of the application and slow, tedious examination procedure in the past, government has taken several initiatives to modernize the IP offices as well as augmenting the manpower at the office of Controller General of patent designs and trademarks.

As a result of the steps taken by India to improve its IP regime:

- Period of examination of new Trademarks applications is reduced from 13 months in 2015-16 to less than 30 days presently. India now has among the fastest trademark examination globally.
- Trademark is registered in less than 7 months, if there are no office objections or opposition filed, as compared to 3-5 years required earlier.
- 11.25 lakh Trademark Registrations in just four and half years (2015 to 2019) as compared to 11 lakh Registrations during 75 Years (1940-2015).
- Patent Examination increased from 22631 in 2014-15 to 80088 by end of F.Y. 2019-20.
- Time taken in examination of patents from an average of 72 months in 2014-15 to 12 to 26 months at present.
- Grant of patents has increased from 5978 in 2014-15 to 24936 in 2019-20.

However, owing to several TRIPS plus provisions and the methodology followed by IIPI, Government of India does not consider these rankings as a true indicator of its performance and does not take any specific steps to improve its ranking therein.

The Minister of State in the Ministry of Commerce & Industry (Shri Som Parkash)

Impact of Coronavirus on Supply Chain

Lok Sabha Unstarred Question No: 3512

Shri Hemant Tukaram Godse:

Q. Will the Minister of**COMMERCE AND INDUSTRY** be pleased to state;

(a): whether there is disruption in the supply of raw materials from China due to Corona virus and if so, the details thereof;

(b): the steps taken by the Government to deal with its impact on several Indian industries, especially in Pharma Sector, wherein imbalance in demand and supply has resulted in price rise of items across the industries; and

(c): if so, the details thereof along with the precautionary measures taken by the Government to bridge the demand and supply gap and contain the rise in prices of items across the country?

Answered on 17th March 2021

A. (a) to (c): The Corona Virus outbreak in China initially impacted the supply chains of Indian industries which are dependent on China for import of components, intermediaries and raw materials. Thereafter, the Chinese production resumed during the year. However due to the global supply chain shocks on account of the pandemic, countries are seeking to build resilience in their supply chains to reduce over-concentration of import sources.

The Government engaged with the Export Promotion Councils and Trade Bodies to address potential disruptions in their supply chains, secure and transport inventories available with various suppliers, and accordingly put them in touch with our Missions abroad. The Missions facilitated several Business-to-Business virtual meetings to broaden the supply base of the domestic industry. The Government has also launched schemes such as Production Linked Incentive Schemes (PLIs) to promote domestic manufacturing capacities in critical sectors such as Key Starting Materials/Drug Intermediates, Active Pharmaceutical Ingredients apart from electronic components & mobiles etc. These would broaden the base of the supply chains and make products available at competitive prices.

The Minister of State in the Ministry of Commerce and Industry (Shri Hardeep Singh Puri)

Demand of Indian products in International Market

Lok Sabha Unstarred Question No: 3529

Shri Krishna Pal Singh Yadav:

Q. Will the Minister of**COMMERCE AND INDUSTRY** be pleased to state;

(a): whether the Government is aware that the credibility and demand of Indian products are increasing in the world market and if so, the details thereof;

(b): the steps taken by the Government to provide world market for industries and farmers including the schemes being considered;

(c): whether the efforts made by the Government to increase exports during last three years have been successful and if so, the details thereof; and

(d): whether the Government proposes to facilitate the provision of world market for domestic industries and agriculture and if so, the details thereof?

Answered on 17th March 2021

A. (a): India's share in world merchandise exports remained constant at 1.7% in 2017, 2018 and 2019 (Jan-Dec). However, India's rank as an exporter improved from 20th position in 2017 to 18th position in 2019 (as per latest available WTO press releases), indicating that the credibility and demand of Indian products are increasing in the world market.

(b): The following are some of the initiatives taken by Government to provide world market for industries and farmers, and the schemes being implemented:

(1): A comprehensive "Agriculture Export Policy" to provide an impetus to agricultural exports related to agriculture, horticulture, animal husbandry, fisheries and food processing sectors, is under implementation.

(2): A Central Sector Scheme 'Transport and Marketing Assistance for Specified Agriculture Products' for providing assistance for the international component of freight, to mitigate the freight disadvantage for the export of agriculture products, and marketing of agricultural products, is under implementation.

(3): The Department of Commerce has several schemes to promote exports, including exports of agricultural products, viz. Trade Infrastructure for Export Scheme (TIES), Market Access Initiatives (MAI) Scheme etc. In addition, assistance to the exporters of agricultural products is also available under the Export Promotion Schemes of Agricultural & Processed Food Products Export Development Authority (APEDA), Marine Products Export Development Authority (MPEDA), Tobacco Board, Tea Board, Coffee Board, Rubber Board and Spices Board.

(4): Promoting districts as export hubs by identifying products with export potential in each district, addressing bottlenecks for exporting these products and supporting local exporters/manufacturers to generate employment in the district.

(5): The Government has introduced the Remission of Duties and Taxes on Exported Products (RoDTEP). This scheme seeks remission of Central, State and Local duties/taxes/levies at different stages at the Central, State and local level, which are incurred in the process of manufacture and distribution of exported products, but are currently not being refunded under any other duty remission scheme. Besides, exports are zero rated through drawback of duties, GST refund as well as other export promotion schemes.

(6): Interest Equalization Scheme on pre and post shipment rupee export credit has been extended by one year i.e. upto 31-3-2021.

(7): Common Digital Platform for Certificate of Origin has been launched to facilitate trade and increase FTA utilization by exporters.

(8): Active role of Indian missions abroad towards promoting India's trade, tourism, technology and investment goals has been enhanced.

(c): India's Merchandise exports have risen from USD 275.85 Billion in 2016-17 to USD 313.36 Billion in 2019-20 which is an increase of USD 37.51 Billion in the past three years.

(d): The Union Budget for 2021-22 extensively and comprehensively envisages several initiatives aimed at enhancing India's overall competitiveness and manufacturing capacities, which would enable growth, diversification and technological enhancement of India's exports. These cover both ease of doing business in the area of approvals and procedures, and the physical environment for investment including the creation of robust infrastructure and logistics.

The Minister of State in the Ministry of Commerce and Industry (Shri Hardeep Singh Puri)

Promotion of Local manufacturing

Lok Sabha Unstarred Question No:3549

Shri Sanjay Kumar Bandi:

Q. Will the Minister of **COMMERCE AND INDUSTRY** be pleased to state;

(a): whether any tariff protection to promote local manufacturing in India will come with inbuilt sunset

clauses, if so, the details worked out/implemented so far;

(b): whether recommendations have been given by NITI Aayog, asserting that the country's self-reliance mission must not be equated to it becoming a 'protectionist' and closed economy and the Government propose to extend the production linked incentive (PLI) scheme for manufacturing pharmaceuticals, medical devices and electronics announced under the Atma Nirbhar Bharat package to six more sectors and want to give our domestic entrepreneurs the best situations to attract more FDI; and

(c): if so, the details thereof and the progress made so far in this regard?

Answered on 17th March 2021

A. (a) to (c): Keeping in view India's vision of becoming 'Atmanirbhar' and to enhance India's Manufacturing Capabilities and Exports, an outlay of INR 1.97 lakh crore has been announced in Union Budget 2021-22 for PLI schemes for 13 key sectors for a period of 5 years starting from fiscal year (FY) 2021- 22. These 13 sectors include already existing 3 sectors named (i) Mobile Manufacturing and Specified Electronic Components, (ii) Critical Key Starting materials/Drug Intermediaries & Active Pharmaceutical Ingredients, and (iii) Manufacturing of Medical Devices and 10 new key sectors which have been approved by the Union Cabinet recently in November 2020. These 10 key sectors are:

(i): Automobiles and Auto Components,

(ii): Pharmaceuticals Drugs,

(iii): Specialty Steel,

(iv): Telecom & Networking Products,

(v): Electronic/Technology Products,

(vi): White Goods (ACs and LEDs),

(vii): Food Products,

(viii): Textile Products: MMF segment and technical textiles,

(ix): High efficiency solar PV modules, and

(x): Advanced Chemistry Cell (ACC) Battery.

The PLI schemes will be implemented by the concerned Ministries/ Departments and will be within the overall financial limits prescribed. Domestic as well as foreign owned entities are eligible to be beneficiaries of these PLI schemes.

The PLI Schemes are expected to enable the setting up of a widespread supplier base for the global champions established under the scheme. It will help bring scale and size in key sectors and create and nurture global champions.

The Minister of State in the Ministry of Commerce & Industry (Shri Som Parkash)

India's Import

Lok Sabha Unstarred Question No: 3590

Shri Mala Roy:

Q. Will the Minister of **COMMERCE AND INDUSTRY** be pleased to state;

(a): the details of top five countries from where India imported goods in last one year including the amount of imports; and

(b): the reasons of import from China including the trade value of import from China in the last one year?

Answered on 17th March 2021

A. (a) & (b): The details of top five countries from where India has imported goods during 2020 (January-December) are as follows:

(Value in US$ billion)

S. No.	Country	2020* (January- December)
1	China	58.71
2	U S A	26.89
3	U Arab Emts	23.96
4	Saudi Arab	17.73
5	Iraq	16.26
	Total of Above	**143.55**
	% Share	**38.59**
	India's Total Import	**371.98**

Source; DGCI&S. * Provisional

*Provisional Imports take place to meet the gap between domestic production and supply, consumer demand and preferences for various items. The major items of import from China are products such as telecom instruments, computer hardware and peripherals, fertilizers, electronic components/ instruments, project goods, organic chemicals, drug intermediates, consumer electronics, electrical machinery etc.

The Minister of State in the Ministry of Commerce and Industry (Shri Hardeep Singh Puri)

Special Economic Zones (SEZs)

Lok Sabha Unstarred Question No:3605

Shri Vijay Baghel:

Q. Will the Minister of **COMMERCE AND INDUSTRY** be pleased to state;

(a): the main features and objectives of Special Economic Zones(SEZs) set up in the country;

(b): the details and the number of SEZs in the country;

(c): whether the agriculture and food processing sector of the country are getting the benefits of SEZs; and

(d): if so, the details thereof?

Answered on 17th March 2021

A. (a): The Special Economic Zones (SEZs) policy was launched in April, 2000. The Special Economic Zones Act, 2005, was passed by Parliament in May, 2005 which received Presidential assent on the 23rd of June, 2005. The SEZ Rules, 2006 came into effect on 10th February, 2006. The salient features of the SEZ scheme are:-

(i): A designated duty free enclave to be treated as a territory outside the customs territory of India for the purpose of authorised operations in the SEZ;

(ii): No licence required for import;

(iii): Manufacturing or service activities allowed;

(iv) : The Unit shall achieve Positive Net Foreign Exchange to be calculated cumulatively for a period of five years from the commencement of production;

(v): Domestic sales subject to full customs duty and import policy in force;

(vi): SEZ units will have freedom for subcontracting;

(vii): No routine examination by customs authorities of export/import cargo;

(viii): SEZ Developers /Co-Developers and Units enjoy tax benefits as prescribed in the SEZs Act, 2005.

The main objectives of Special Economic Zones (SEZs) in the country are the following:-

i. generation of additional economic activity

ii. promotion of exports of goods and services;

iii. promotion of investment from domestic and foreign sources;

iv. creation of employment opportunities;

v. development of infrastructure facilities

(b): There were 7 Central Government Special Economic Zones (SEZs) and 12 State/Private Sector SEZs prior to the enactment of the SEZs Act, 2005. In addition, 425 proposals for setting up of SEZs in the country have been accorded formal approval under the SEZ Act, 2005. Presently, 378 SEZs are notified, out of which 265 are operational. States/Union Territories-wise details of SEZs is at Annexure-I.

(c) and (d): Yes Sir, 8 Special Economic Zones (SEZs) have been approved for the Agro and Food Processing sector in India. Of these 8 SEZs, 7 have been notified and 4 are operational. A statement showing details of Agro and Food Processing SEZs in India is at Annexure-II. The exports from these SEZs during the last five years and current year 2020-21 (i.e. up to 31st December, 2020) is as under:

Years	Exports (Value in Rs. Crores)
2015-16	2365
2016-17	4061
2017-18	4117
2018-19	4405
2019-20	5219
2020-21 (up to 31.12.2020)	5456

The Minister of State in the Ministry of Commerce and Industry (Shri Hardeep Singh Puri)

Trade Policy

Lok Sabha Unstarred Question No: 3616

Shri Balashowry Vallabbhaneni:

Q. Will the Minister of **COMMERCE AND INDUSTRY** be pleased to state;

(a): whether the current trade policy is going to expire in March, 2021;

(b): if so, whether the Ministry has formulated a new Trade Policy and if so, the present status of the same;

(c): the details of consultations that have been held with various stakeholders and details of suggestions given and accepted by the Ministry?

A. (a) to (c) : The current Foreign Trade Policy (2015-2020) which was announced for a period for five years was extended by a year due to COVID-19 till 31st March, 2021. In order to prepare Foreign Trade Policy (2021-2026), Trade Notice No. 34 dated 12.11.2020 was issued inviting suggestions from Individuals, Export Promotion Councils, Industry Associations and other stake holders based on which a number of inputs/suggestions have been received. A Board of Trade meeting was held on 02.12.2020 with various stakeholders including State Governments. Meeting with Export Promotion Councils (EPCs) and Industry associations were held on 4.12.2020 and 7.12.2020 respectively. Another meeting with EPCs and Industry associations was held on 11.2.2021. As part of consultation, a meeting of the Parliamentary Consultative Committee of the Ministry of Commerce and Industry was held on the 'New Foreign Trade Policy' on 12th January, 2021. The work of preparation of new Foreign Trade Policy (2021-2026) is ongoing.

The Minister of State in the Ministry of Commerce and Industry (Shri Hardeep Singh Puri)

In Rajya Sabha

New Drug Policy

Rajya Sabha Unstarred Question No. 1969

Shri P Bhattacharya:

Q. Will the Minister of **CHEMICALS AND FERTILIZERS** be pleased to state;

(a): whether Government has formulated a new drug policy;

(b): if so, the details thereof;

(c): by when it is likely to be announced;

(d): from which date it is being implemented;

(e): the steps taken in that regard;

(f): whether any safeguards have been provided therein to control the rising prices of medicines and pharmaceutical products, particularly life-saving drugs; and

(g): if so, the details thereof and if not, the reasons therefor?

Answered on 12th March 2021

A. (a) : No, Sir.

(b) to (g): In view of the reply (a) above, the question does not arise.

Minister in the Ministry of Chemicals & Fertilizers (Shri D V Sadananda Gowda)

● ● ●

DPIIT notifies Calcium Carbide (Amendment) Rules, 2021

Industrial Policy Notification No.G.S.R.259(E), dated 26th March, 2021

(Published in the Gazette of India on 12th April, 2021)

The draft of the following rules to amend the Calcium Carbide Rules, 1987, which Central Government proposes to make in exercise of the powers conferred by sub-section (2), (3) of section 29 of the Petroleum Act, 1934 (30 of 1934) is hereby published as required by sub-section (4) of section 29 of the said Act for information of all persons likely to be affected thereby, and notice is hereby given that the said draft shall be taken into consideration after the expiry of a period of 30 days from the date on which the copies of the Gazette of India containing this notification are made available public.

Objections or suggestions if any, to these draft rules may be sent to the Shri Sushil Satpute, Director, Department for Promotion of Industry and Internal Trade, Ministry of Commerce and Industry, Room No.265, Udyog Bhavan, New Delhi–110 107 or Email: sushil.satpute@nic.in; within the period specified above;

The objections or suggestions which may be received from any person with respect to the said draft rules within the period above so specified will be taken into consideration by the Central Government.

Draft Rules

1. (1) These rules may be called the **Calcium Carbide (Amendment) Rules, 2021**

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

2. In the said rules, in Rule 31, sub-rule (1) the words “maximum of three years” shall be substituted with “maximum of ten years”.

3. In the said rules, in Rule 34, sub-rule (1)(b), the words and figure “a scrutiny fee of Rs 10” shall be substituted with “a scrutiny fee of Rs.100”

4. n the said rules, in Rule 35, sub-rule (2)(b), the words and figure “a fee of Rs 10” shall be substituted with “a fee of Rs.100”

5. In the said rules, in Rule 37, sub-rule (2), the words “for three calendar years” shall be substituted with “for ten calendar years”.

6. In the said rules, in Rule 42, sub-rule (2)(iii), the words and figure “a fee of Rs 10” shall be substituted with “a fee of Rs.100”.

7. In the said rules, in Rule 43, sub-rule (2), the words and figure “A fee of Rs. 10” shall be substituted with “A fee of Rs.100”.

8. In the said rules, in Rule 44, the words and figure “a fee of Rs. 10” shall be substituted with “a fee of Rs.100”.

9. In the said rules, in Rule 45 sub-rule (2), the words and figure “a fee of Rs. 10” shall be substituted with “a fee of Rs.100”.

10. In the said rules, the Rule 46 shall be deleted and substituted with;

(1) All fees payable under these rules to the Chief Controller or Controller shall be paid through epayment or through Non Tax Receipt Portal (Bharat Kosh)

(2) fees payable to District Authority or any other authority under these rules shall be paid in such a manner as may be specified by that authority”

11. In the said rules, in Chapter VII, sub-rule (1)(a), the words “by an express telegram (Telegraphic Address: Explosives, Nagpur) shall be substituted with “by an email: explosives@explosives.gov.in”

12. In the said rules, in the First Schedule, in Article No.1, in column 5 under the heading “Fees” the words and figures “Rs. 25” shall be substituted with “Rs.250”.

13. In the said rules, in the First Schedule, in Article No.2, in column 5 under the heading “Fees” the words and figures “Rs.25 for the first 500 Kgs. plus Rs.10 for additional 500 Kgs. or part thereof, subject

to maximum of Rs.1,500 per calendar year" shall be substituted with "Rs.250 for the first 500 Kgs. plus Rs.100 for additional 500 Kgs. or part thereof, subject to maximum of Rs.15,000 per calendar year"

14. In the said rules, in the Second Schedule, Form I in Rule 4 the words

"Telegraphic address,

Telex"

shall be replaced with

"Latitude & Longitude:

Email address:"

15. In the said rules, in the Form II after Condition 15, following shall be inserted namely:

Account of Receipt and Sale of Calcium Carbide License No

Note: This record should be kept up to date. Entries should be made daily and as and when Calcium Carbide is received or sold.

Date	Opening Balance Kgs.	Carbide received Kgs.	Type and No. of packages	Name, address & license No. of supplier	Carbide sold Kgs.	Types & No. of packages	Name, address & License No. of persons to whom Carbide was sold	Closing Balance	Sign of licensee	Remarks
1	2	3	4	5	6	7	8	9	10	11

16. In the said rules, in the Form III after Condition 15, following shall be inserted namely:

Account of Receipt and Sale of Calcium Carbide

License No

Note: This record should be kept up to date. Entries should be made daily and as and when Calcium Carbide is received or sold.

Date	Opening Balance Kgs.	Carbide received Kgs.	Type and No. of packages	Name, address & license No. of supplier	Carbide sold Kgs.	Types & No. of packages	Name, address & License No. of persons to whom Carbide was sold	Closing Balance	Sign of licensee	Remarks
1	2	3	4	5	6	7	8	9	10	11

F.No.P-13013/1/2021-EXPLOSIVE

Sumita Dawra,
Addl. Secretary,
Department for Promotion of Industry and Internal Trade,
Ministry of Commerce and Industry,
New Delhi.

Note: *The Principle Rule were published in Gazette of India, Extraordinary, Part II, Section 3, Sub section (i), vide Notification Number, G.S.R.105(E) dated the 18th February, 1987 and subsequently amended vide Notification Number G.S.R.109(E) dated the 28th February, 1990, Notification Number G.S.R.647(E) dated the 20th August, 2015 and notification number G.S.R.1094(E) dated the 8th November, 2018.*

Massive fragment screen points way to new SARS-CoV-2 inhibitors

New research published in Science Advances provides a template for how to develop directly-acting antivirals with novel modes of action, that would combat COVID-19 by suppressing the SARS-CoV-2 viral infection.

The study focused on the macrodomain part of the Nsp3 gene product that SARS-CoV-2 uses to suppress the host cell's natural antiviral response. This part of the virus's machinery, also known as Mac1, is essential for its reproduction: previous studies have shown that viruses that lack it cannot replicate in human cells, suggesting that blocking it with a drug would have the same effect.

The study involved a crystallographic fragment screen of the Nsp3 Mac1 protein by an open science collaboration between researchers from the University of Oxford, the XChem platform at Diamond Light Source, the UK's national synchrotron, and researchers from the QCRG Structural Biology Consortium at the University of California San Francisco. The international effort discovered 234 fragment compounds that directly bind to sites of interest on the surface of the protein, and map out chemical motifs and protein-compound interactions that researchers and pharmaceutical companies can draw on to design compounds that could be developed into antiviral drugs. This work is thus foundational for preparing for future pandemics.

"Robustly identifying this kind of chemical matter for promising and tractable targets like Nsp3 is a first step in rational drug discovery. This is always a long journey fraught with difficulty and failure, but the battery of new structural biology methods that we combined in this study, including fragment screening at Diamond and computational docking at UCSF, are helping to change drug discovery and make it easier to find effective drug candidates," comments Principal Beamline Scientist, Frank von Delft.

These fragments cover a wide range of chemical motifs, and the study lays out the next steps of designing more elaborate molecules that combine the observed themes, synthesizing them and confirming experimentally whether they strongly bind the protein and have a biological effect. The most promising compounds can then be progressed in fully-fledged drug discovery programmes, which includes not only improving the biological potency but also ensuring the final molecule has important drug properties such as easy absorption and minimal side effects.

Most drugs contain a few key components that cause the desired, effect while the rest of the molecule may be important for other reasons, such as solubility, uptake from the gut or how the drug is processed by our metabolism. Traditional high-throughput screening entails testing very large collections of bigger, generally sub-optimal molecules, which are experiment of great complexity.

Instead, fragment screening is an approach for identifying building blocks of the future drug molecule, observing how they interact with the protein under study, contextualizing those interactions, and providing starting points for molecules that directly influence the biology of the protein. This method significantly reduces the number of compounds that need to be screened to find one that really binds, while still informing a broad range of potential molecules. Doing the experiment by structural biology, as implemented at the XChem platform, yields this information directly in 3D, greatly accelerating up the design process and ensuring a far more cost-effective overall experiment.

The UCSF collaborators also used another innovative drug discovery technique, Computational Docking. This deploys computer models and simulations to assess the likely interactions of virtual molecules for favourable interactions with Mac1 and their promise as starting points for drug discovery. The team identified 60 candidates from a virtual library of 20 million molecules, which were then experimentally tested using X-ray crystallography, yielding 20 good hits.

"This is a significantly higher-than-random hit rate, validating the new specific docking methodologies developed by our UCSF colleagues. The high quality structural data of Mac1 that we obtained by X-ray crystallography was essential, but the validation of the approach means that in future, we have additional power for exploring compounds that are not physically available. Overall, this work not only accelerates our ability to validate whether targeting NSP3 Mac1 is an effective way to develop antivirals; it also is hugely valuable in improving the template of methodologies for future inhibitor discovery and development throughout the community of drug discovery," concludes Frank von Delft.

Source: World Pharma News, 14.04.2021 (Excerpts)

FICCI seeks incentives for COVID vaccine makers

Ficci seeks incentives for Covid vax makers

There is a need to roll out incentives for Covid-19 vaccine manufacturers to help them ramp up production in a bid to cater to the rising demand across the country, industry body Ficci said on Tuesday, 13.04.2021. The Government also needs to give provisions for immediate and sufficient grants and subsidies, through its Covid funds, for those manufacturers that are already developing or manufacturing Covid vaccines in the country, it noted.

"There is an urgent and critical need to encourage vaccine manufacturers to substantially augment their capacities for production. Since the cost of vaccines have been capped by the Government, the vaccine manufacturers need to be provided with appropriate incentives for ramping up the production," Ficci said in a statement.

The industry body has recommended financing under the PLI-type scheme to support vaccine manufacturers, it added. While welcoming approval of Sputnik V vaccine for emergency use, the industry body said that vaccines that are proven and successful in other markets should be encouraged to be brought into India at the earliest, in order to maintain supply chains.

"This should be considered for import and sale of international vaccines as well as initiate manufacturing of such vaccines in the country. Given that most of these vaccines have extensive dossiers and data on their safety and efficacy for large populations, including for Indians living abroad, we should waive off the need for Indian clinical trial data," it added.

FICCI noted that many States have been facing the shortage of Covid vaccines over the past few days, including locations in Punjab, Rajasthan, Uttarakhand, Uttar Pradesh, Jharkhand and Bihar, compelling State Governments to scale down their daily vaccination targets.

"India intends to vaccinate a priority population of 30 crore by August 2021. Given that 10.85 crore people have received at least the first dose of Covid vaccination and going with the current rate of 30 lakh vaccinations per day, we would need more than 38 crore doses (of two dose vaccines) to fully vaccinate this priority group," it said. According to reports, Indian Government has 2.04 crore doses in pipeline for next few days, FICCI stated.

Source: Hans News Service, Hans India, 14.04.2021

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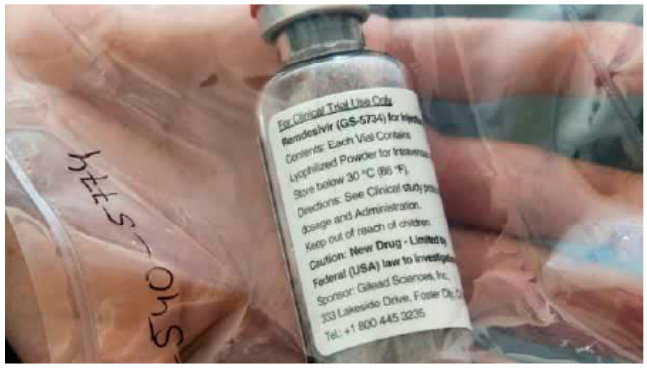
Cipla doubles Remdesivir production to meet 'unprecedented' demand



File Photo: One vial of the drug Remdesivir *(AFP)*

Pharma major Cipla Ltd has doubled production of COVID-19 medication Remdesivir to help meet "unprecedented demand" as the country battles a massive second wave of infections, the drug maker told *Reuters* on Tuesday, 13.04.2021.

On Sunday, 11.04.2021 India banned the export of anti-viral drug Remdesivir and its Active Pharmaceutical Ingredients to deal with crippling shortages of the medication in many parts.

"We have scaled up the production of Remdesivir by 2x from the last wave of the pandemic," Cipla said in a statement to *Reuters*. "Given the unprecedented demand for the drug, we have now further ramped up our capacities through our network."

The company is working with authorities to restrict Remdesivir supply just to hospitals and places with a high burden of severe COVID-19 cases, it added. Just two months ago, Cipla had projected falling demand for Remdesivir in India as Coronavirus infections were on a steady decline.

The World Health Organization in November issued a conditional recommendation against the use of Remdesivir in hospitalised patients, saying there was no evidence that the drug improved survival and other outcomes. Still, many countries, including India, have continued its use.

Cipla has a deal to make and supply US based Gilead's Remdesivir in more than 100 countries. Several other Indian drug producers also have similar agreements. Cipla also warned that it was facing a shortage of tocilizumab, an arthritis drug developed by Roche that has been shown in trials to reduce the risk of death in patients with severe COVID-19. "We expect intermittent supplies (of tocilizumab) as demand outstrips supply," Cipla said.

Source: (With inputs from Reuters), Mint, 14.04.2021

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Go all syringes blazing against this COVID wave

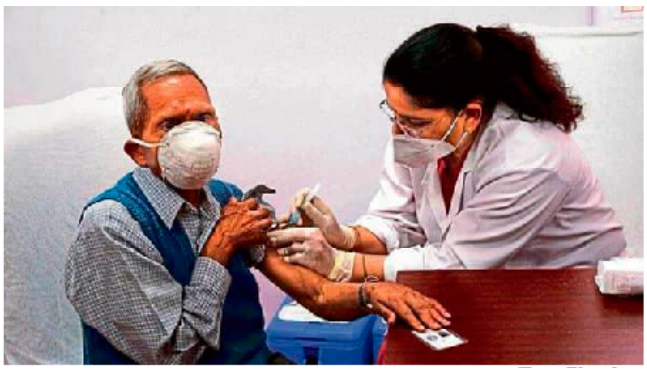

Photo: Bloomberg

At last, the Centre has given all vaccines okayed by major regulators abroad an in-principle go-ahead in India. This could've been done earlier. Let's lose no further time against Covid-19.

This is a big decision that could tilt the scales in India's favour in our battle against the deadly Coronavirus, whose resurgence has revived painful memories of last year's migrant crisis and raised the spectre of another suffocating lockdown.

On Tuesday, 13.04.2021 the Government fast-tracked approvals of all COVID vaccines that have received okays for emergency use from credible foreign regulators—such as those of the US, UK, EU and Japan—and also all jabs that feature on the World Health Organization's emergency-use list.

These vaccines need not be put through local Clinical Trials for efficacy and safety, having passed tests abroad, but will still be required to undergo post-approval 'bridging trials' designed to assess their effect on Indians. Moreover, the first 100 beneficiaries of each fast-track entrant shall be monitored for a week to gauge safety outcomes before it can be widely deployed.

This shift in stance, made just a day after Russia's Sputnik-V jab got an Indian go-ahead, should serve to widen our arsenal against COVID infections. So far, we have relied on Serum Institute of India's (SII's) *Covishield* and Bharat Biotech's indigenous *Covaxin* for our inoculation drive.

This effort can now be joined by Johnson & Johnson's single-dose vaccine (though, like SII's, it is under watch for a tiny risk of blood-clots) and a couple of mRNA jabs that represent a recent leap of technology: Moderna's and BioNTech-Pfizer's.

Source: Live Mint, 14.04.2021

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DGFT's Trade Facilitation Mobile App to improve efficiency of Importers, Exporters: Goyal

The new app provides features such as all services offered by DGFT, tracking IEC Portfolio – IEC, applications, authorizations; raise and track help requests in real-time and share trade and public notices.

Photo Credit :

The trade facilitation mobile app of the Directorate General of Foreign Trade (DGFT) is a state-of-the-art system and it will help improve the efficiency of both importers

and exporters, Commerce and Industry Minister Piyush Goyal said on Monday, 12.04.2021.

The app would provide real-time trade policy updates, notifications, applications, status alerts and real-time data, he said while launching the app.

It would also enable exporters and importers to explore item wise exim (export-import) data, policy, and statistics. Besides, it would provide artificial intelligence-based 24x7 assistance and all services of the DGFT.

'It will help improve the efficiency of both importers and exporters,' Goyal said adding that easy accessibility of information will also 'break the walls of traditional and opaque processes which often are not equally fair to all our participants'.

Further, the minister suggested to rechristian DGFT. 'I have suggested that we now move from the phrase 'Director General' and went into something more facilitative, something more collaborative.

'I would urge DGFT (Amit Yadav) to give a thought to it and we should rechristian our DGFT to really reflect our thinking and the role that we envisage for DGFT in the years to come,' he added.

He also said mobile governance will enable the creation of quality-conscious and cross competitive domestic industry and help significantly contribute to the export target of USD 1 trillion by 2025. The app will be available on Android and iOS platforms. It can also be downloaded from the DGFT website. It has been developed by Tata Consultancy Services (TCS), as per the directions of the DGFT.

The new app provides features such as all services offered by DGFT, tracking IEC Portfolio – IEC, applications, authorisations; raise and track help requests in real-time and share trade and public notices.

Source: BW online bureau, Business World, 17.04.2021

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Industry seeks 20% upward price revision for all non-scheduled drugs to offset rising input costs

Faced with rising input and transportation costs over the last more than one year, making it difficult for them to maintain viability of business, the drug manufacturers have urged the National Pharmaceutical Pricing Authority (NPPA) to allow a 20 percent upward price revision for all non-scheduled drugs for the current year over last year as well as allow prices of those scheduled drugs whose retail prices are below the ceiling price, to be raised up to the ceiling price.

This will help them offset high input costs. There has been an increase in prices of many raw materials over the last year giving industry sleepless nights.

The price of gliclazide, a hypoglycaemic sulphonylurea antidiabetic active substance increased from US$ 80 a kg to US$ 120 per kg. The price of DCDA intermediates used in metformin, the first-line oral antidiabetic drug has gone up from US$ 1.90 per kg to US$ 3 a kg and it is soon expected to touch US$ 4 per kg.

The price of para amino phenol (PAP), a key starting material to manufacture paracetamol, an essential antipyretic has doubled over the last year. PAP is imported from China. The price of a derivative of artemisinin, an anti-malarial drug, which is cultivated in China and Central Asia, has gone up over 3 times in a year. The price of propylene glycol, used as a drug solubilizer in topical, oral, and injectable medications, and as a stabilizer for vitamins, and as a water-miscible cosolvent in liquid formulations, has increased four times in the last one year, impacting the cost of manufacturing across every type of formulation.

There has been an unprecedented rise in the cost of packing material like PVC/PVDC blister foils and PET bottles to the tune of 40 percent in the last twelve months.

The cost of corrugated boxes and paper board, used for packing the formulations have gone up by 30 to 40 percent, due to a ban on the import of waste paper, leading to a shortage of pulp. Spiraling diesel prices have led to an increase of 20 percent in transportation costs.

The huge escalation in input and transportation costs and their cascading effect on the pharmaceutical value chain, has thrown up severe challenges to maintain the viability of the pharmaceutical business for a significant number of drug manufacturers.

Taking serious note of this, Indian Drug Manufacturers' Association (IDMA) has recently submitted a representation to NPPA and Department of Pharmaceuticals (DoP) outlining certain measures which can be taken within the framework of the existing price control mechanism to help industry partially tide over these extremely exigent circumstances.

The industry body requested for a 20 percent increase in prices of all non-scheduled formulations for the current

year over last year, under paragraph 19 of DPCO 2013 as the circumstances are indeed extraordinary.

Non-scheduled drugs are allowed an increase of up to 10 percent in prices every year.

It also urged NPPA to permit an increase in the prices of those scheduled formulations, selling below the ceiling price, up to the ceiling price. Many manufacturers of scheduled formulations are suffering on this count and para 13(2) of DPCO 2013 needs to be relaxed under the current circumstances, stated IDMA.

Besides this, the industry body also appealed to the apex drug price controller to revise the ceiling prices based on the Consumer Price Index (CPI) henceforth as against the current method of revising the ceiling prices as per the Wholesale Price Index (WPI) which are announced annually in April every year. CPI is a more realistic indicator of inflation, it added.

For instance the CPI was 6.7 percent in the calendar year 2020 as against only 0.54 percent WPI.

Source: Laxmi Yadav, Pharmabiz, 15.04.2021

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DCG(I) extends deadline to submit notarized documents for import and registration of cosmetics

As the situation arising out of the Covid-19 pandemic is worsening further in the country, the Drugs Controller General of India (DCGI) has further extended deadline by four months to submit notarized or apostilled regulatory documents for import and registration of cosmetics such as Power of Attorney (PoA), QMS certificate, free sale certificate (FSC) and manufacturing license with legal signatures.

The DCGI had earlier extended deadline by 4 months from December 2020 onwards to submit notarized or apostilled regulatory documents for import and registration of cosmetics such as PoA, QMS certificate, FSC and manufacturing license with legal signatures due to Covid-19 pandemic.

This is in continuation to the notices served on April 20, 2020, August 19, 2020 and December 18, 2020 towards DCGI giving extension on the same due to the pandemic.

The DCGI's action in this regard was due to the reason 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.

"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, August 19, 2020 and December 18, 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 there under 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," the DCGI Dr V G Somani in a notice stated.

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 earlier extended the deadline up till 4 months 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 PoA, QMS certificate, FSC etc for applications for import of medical devices and IVD kits under MDR-2017 due to Covid-19 pandemic.

Source: Shardul Nautiyal, Pharmabiz,15.04.2021

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My Diagnostics to expand to 100 cities by 2022

MyDiagostics, India's leading digital health clinic, which has currently presence in 14 cities across the country, is planning to expand through 100 cities by 2022. The company is planning to expand to tier-I and tier-II cities including Delhi, Mumbai, Bengaluru, Pune

and Ahmedabad, with the aim of providing access to nearly 60 million households. Besides, some of the products will be made available in all the pin codes in India.

The company's focus will be on both types of expansion, including digital and physical, creating awareness programmes, and providing a rapid test results cycle. It has partnered with Thyrocare Technologies, General Diagnostics, Medcis Pathlabs to provide diagnostics services.

"Covid has taught us the importance of strengthening the immune system to fight against the deadly virus. Though, this would not be the only pandemic that people would experience. With the globally connected world, always-on work culture, infinite notifications, risk of disease, and climate changes, people are looking for meaningful and sustainable ways to improve their health, performance, and longevity. The market will move towards continuous preventive healthcare focused on root-cause gut health, metabolic health, immune health, and nutrition," stated Vikas Gupta, Co-founder and Chief Product Officer at MyDiagnostics.

Gupta added, "Most of the healthcare services will be focused on delivering at home. This would improve the unit economics of hospitals/providers and enhance the patient's experience, cost, and outcomes. Digital systems powered by AI will become the defector delivery medium."

Founded in 2016, MyDiagnostics offers a range of health checkup packages and is renowned for its high-quality labs and easy sample collection services at home through online booking. The results are provided online, along with consultation from in-house medical experts. Known for offering excellent patient care, the platform also provides digital tools to track health parameters. With the help of the platform, individuals can book preventive health check test packages to improve health and longevity at affordable costs.

Source: Yash Ved, Pharmabiz, 15.04.2021

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'Extend interest subsidy scheme for exporters'

Commerce Ministry tells RBI to continue all the benefits under the scheme

To help Indian exporters struggling to conduct their business in the uncertain global market, the Commerce Ministry is trying to ensure that the interest equalisation scheme, which lapsed on March 31, is extended by the Reserve Bank of India (RBI) without curtailments.

"The Commerce Ministry is in touch with the RBI on the extension of the interest equalisation scheme for exporters. It is being hoped that the scheme will be extended to all beneficiary sectors without modifications soon," a source tracking the matter told.

The background:

The interest equalisation scheme, introduced on April 1, 2015, extends a subsidy on interest provided on pre- and post-shipment export credit ranging between 3 percent and 5 percent to exporters. The banks provide credit at the lower interest rate to exporters and the differential amount is later reimbursed by the Government. In addition to MSME exporters of all items, exporters of 416 identified products are eligible for the benefit.

"Exporters are hopeful that the benefits under the interest equalisation scheme will remain intact in the new fiscal and there will be no curtailment in the list of eligible items or a tinkering of rates," the source said.

Since the budgetary allocation for 2021-22 set aside by the Finance Ministry for the scheme at ₹1,900 crore is more than the revised estimates for last year, there is a general optimism that there will be no rude surprises in store for exporters.

"Although, there are indications that there will be continuity in the scheme, one can never be certain till it is notified by the RBI," the source added. Last year, following the one year extension of the old five-year Foreign Trade Policy till March 31, 2021, the RBI also issued a notification for a one-year extension of the interest equalisation scheme.

Scheme to be extended?

Now that the Government has given a second extension to the old FTP, this time by six months (till September 30, 2021), there are speculations about the period of extension of the scheme.

"There is uncertainty whether the Government wants the interest equalisation scheme to be part of the next five year FTP. As some experts feel the scheme has the potential of getting identified as an export subsidy at the WTO and, therefore, create possible conflict in the future, it may be better to extend it on a piece-meal basis," the official said.

India's goods exports in April-March 2020-21 were valued at an estimated $289.92 billion, which was 7.4 percent lower than exports worth $313.36 billion in April-March 2019-20. In March 2021, however, exports shot up by 58.23 percent to $34 billion, propelled by sectors such as engineering goods, gems & jewellery and pharmaceuticals.

Source: Amiti Sen, The Hindu Business Line, 12.04.2021

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16 Applications cleared under PLI for drug intermediates, APIs

Companies have committed investment of Rs.348.7 crore, seek to create 3,042 jobs

A total of 16 applications have been approved under the Production-Linked Incentive (PLI) scheme for promotion of domestic manufacturing of critical Key Starting Materials (KSMs)/drug intermediates and Active Pharmaceutical Ingredients (APIs) with a total committed investment of Rs.348.70 crore and employment generation of about 3,042 by the companies.

"The commercial production of these plants is projected to commence from April 1, 2023," per an official release from the Ministry of Chemicals and Fertiliser on Tuesday, 13.04.2021. Companies that received a nod for their proposals include Honour Lab, Anasia Lab, Hetero Drugs, Surya Life Sciences Andhra Organics, Sreepathi Pharmaceuticals, Global Pharma Healthcare, Kreative Actives, Amoli Organics and Vapi Care Pharma.

Green-field plants:

To attain self-reliance and reduce import dependence in these critical bulk drugs, the Department of Pharmaceuticals had launched the PLI scheme by setting up green-field plants with minimum domestic value-addition in four different target segments for 41 products with a total outlay of Rs.6,940 crore for the period 2020-21 to 2029-30.

A total of 215 applications were received for the 36 products spread across the four target segments. "With this, all the 215 applications received have been considered and 47 (excluding two successful applications withdrawn subsequently), with a committed investment of 5,366.35 crore, have been approved by the Government under the PLI scheme for APIs. "Setting up of these plants will make the country self-reliant to a large extent in respect of these bulk drugs," the release stated.

The disbursal of PLI by the Government over the six-year period would be up to a maximum of about Rs.6,000 crore against the budgetary outlay of Rs.6,940 crore.

Under the scheme, after considering all 28 applications, 14 applications have been approved with a committed investment of Rs.873.93 crore which will lead to utilisation of maximum incentive of about Rs.1,694 crore against a total budget outlay of Rs.3,420 crore.

"The Government has decided to re-invite applications for the uncovered/under-covered products in the PLI schemes for bulk drugs and medical devices for utilizing the approved outlay," the statement said.

Source: The Hindu Business Line, 14.04.2021

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Centre set to fast-tracks approvals for foreign-made COVID-19 vaccines

In a major decision that will pave the way for quicker access of a number of Covid-19 vaccines in the country, India has decided to fast track emergency approvals for foreign-produced Coronavirus vaccines that have been granted restricted use permission in other countries.

The decision comes amidst a massive surge of Covid-19 infections in the country that has now surpassed the first peak of the pandemic India witnessed last year.

The emergency decision by the Government however still maintained the fig leaf of bridging trial, as experts pointed out, by maintaining that the first 100 beneficiaries of such foreign vaccines shall be assessed for seven days for safety outcomes before it is rolled out for further immunisation programmes within the country.

Nonetheless, the relaxation in existing rules makes it easier for Covid-19 vaccines by Pfizer, Moderna, Johnson & Johnson and Novavax to apply for emergency use in

India even though those have not been tested in the Indian population.

The announcement on foreign-made vaccines comes after the National Expert Group on Vaccine Administration for COVID-19, recommended that vaccines, which have been developed & are being manufactured in foreign countries and which have been granted emergency approval for restricted use in the USA, UK, European Union or Japan or which are listed in World Health Agency emergency use listing may be granted emergency use approval in India.

The panel however also mandated the requirement of post-approval parallel bridging Clinical Trial in place of conduct of local Clinical Trial as per the provisions prescribed under the second schedule of the New Drugs & Clinical Trials Rules 2019.

The matter related to fast tracking the emergency approvals for foreign-produced Covid-19 was discussed in the 23rd NEGVAC meeting chaired by V K Paul, Member (Health), Niti Aayog, said the Union Health Ministry.

"This decision will facilitate quicker access to such foreign vaccines by India and would encourage imports including import of bulk drug material, optimal utilization of domestic fill and finish capacity," ministry added in a statement.

Authorities however maintained that it may be several weeks before any of the foreign-made vaccines are available for public use in the country and will also depend on interest shown by international vaccine makers.

Many experts have long been saying that Covid-19 vaccines being used by developed elsewhere that have completed efficacy trials should be included in the country's Covid immunisation drive.

"The Indian regulator should consider approving other vaccines that have finished efficacy trials elsewhere and have partnerships with Indian vaccine companies – for example, Johnson & Johnson, Sputnik V and Novavax," virologist Shahid Jameel had said a couple of weeks back.

Source: Sumi Sukanya Dutta , Express News Service, The New Indian Express, 14.04.2021

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INTERNATIONAL NEWS

Indian Pharma exports grow at 18% to 24.44 bn USD in FY 21

Pharma exports from India witnessed over 18 percent growth to USD 24.44 billion during the last financial year against USD 20.58 billion in FY20, Pharmaceuticals Export Promotion Council of India (Pharmexcil) said on Saturday, 17.04.2021.

'We have observed a big leap in our exports in the month of March 2021 which is USD 2.3 billion (figures for March are provisional) and is highest among the exports of all the months of this financial year, the growth rate for this month is 48.5 percent against the exports in March 2020 (USD 1.54 billion),' Udaya Bhaskar, Director General of Pharmexcil said in a release.

Growth rate seems relatively big as the exports of March 2020 was crunched due to lockdown across the world and supply chain disruption, he was quoted as saying.

When the global Pharma market is negatively grown by 1-2 percent in 2020, there is a big surge in demand for Indian made generics owing to its quality and affordability, the official said adding Drug formulations and Biologicals is the second largest Principal commodity being exported by India.

The Pharma exports body is expecting big growth in Indian vaccine exports in the coming years and the government policy on PLI (Production Linked Incentive) scheme will also help the domestic Pharma to grow by reducing import dependence and develop export potential in the days to come as most of the countries are looking at India for APIs (Active Pharmaceutical Ingredient) he said.

North America is the largest exporting region for Indian pharmaceuticals with more than 34 percent share. Country wise exports to the US, Canada and Mexico have recorded a growth of 12.6, 30 and 21.4 percent respectively.

South Africa being the second largest exporting country, recorded a big jump of 28 percent growth while Europe was the third largest exporting region which has recorded approximately 11 per cent growth over previous year.

Source: PTI, Yahoo Finance, 19.04.2021

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Pharmexcil sees Australia Good Potential Market for Indian Generic Medicines

The Pharmaceuticals Export Promotion Council of India (Pharmexcil) in its report has forecasted good potential for the Indian generic medicines in Australia in the therapeutic areas of central nervous systems and cardiovascular diseases.

According to Udaya Bhaskar, Director General of Pharmexcil, as more than 41 percent of Australian population is fast aging, the Government is looking to supply cost effective and high quality standard medicines to its population. It is expected that by 2026 the Australian Government apart from procuring standard branded medicines from its own domestic industry, it is also likely to depend on countries like India to meet its growing demand of medicines particularly needed for consumption of treatment of non communicable diseases relating to central nervous system and Cardiovascular diseases.

"In the year 2016, the total Australian Pharma market was at $10.3 billion and is expected to grow at a slow pace for branded medicines. However, for the generics the growth is going to double by 2026. And this is where the Indian Pharma companies can explore their chance of making presence in the Australian generic markets.

As Indian exporters excel in the manufacture of generics of central nervous system and Cardiovascular system, I expect, the coming 5 years are going to give great opportunity for the Indian players for grabbing the Australian generic markets," observed the Pharmexcil DG.

However, the Council report also cautioned that as the Australian market is a saturated market with very few sub-populations lacking access to medicines and thereby chances of its growth in volumes is very moderate. As per the latest updates, the Australian Government announced that it has covered list of 1,400 medicines which have been subjected to the price disclosure cycle and these medicines will receive extra subsidies under the Pharmaceutical Benefits System (PBS).

Further the Australian Government had also announced that more than $300 million worth of medicine to treat lung cancer, multiple myeloma and cystic fibrosis will be added to the Pharmaceutical Benefits Scheme.

As the Australian Government will continue to use drug price control as a means to reduce healthcare expenditure, it is most likely the Government will continue to do more spending on pharmaceuticals. As it is spending on patented drugs, which accounts for 66 percent of total pharmaceutical expenditure, in the coming days it is expected that their share will continue to be eroded by generic drugs.

The regulatory regime in Australia is also comparable to those in other developed states like USA, UK and EU and the pricing and reimbursement is also fairly generous to research-based drug makers. The Government also appreciates the industry's value-added benefits and provides tax incentives to start-up biopharmaceutical firms.

And moreover as 90 percent of the prescriptions generated are covered by the state run PBS and the market is dominated by incidences of non communicable diseases like neuropsychiatric conditions, cancer, respiratory diseases and Cardiovascular diseases. The competitive landscape is quite encouraging for Indian Pharma industry and definitely in the coming years, Pharmexcil sees Australia a great market for generic medicines in the non communicable disease segment.

Source: A Raju, Pharmabiz, 16.04.2021

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FEATURE

Repurposing vaccine production to meet immediate challenges is legitimate, says Jaishankar

India's ability to make Covid-19 vaccines is itself the result of international cooperation

Minister of External Affairs S Jaishankar - The Hindu

Minister of External Affairs S Jaishankar has said that if a country is under stress and the numbers of those infected are going up, like in India, it is legitimate to repurpose production to where the immediate challenge lay.

However, to the extent a country has margins, the ability and the obligation to help others, it would be a decent thing to do as doing good is also doing smart, the Minister added speaking at the curtain-raiser session of Raisina Dialogue on 'India, SDGs, Vaccines & Global Expectations' on Tuesday, 13.04.2021.

"Now, in our case, our vaccine producers had some contractual commitments. They had commitments to Covax as you know, where we actually helped health workers in a number of African countries, with some of our own neighbours in South Asia, with the CARICOM and with the FIPIC. Because with small countries, it isn't just the ability to buy, they don't have actually the wherewithal to really access the market," the Minister said.

International cooperation:

With the number of fresh Covid-19 cases touching new highs, India is, at present, focussed on meeting the domestic demand for vaccines instead of responding to global demand for exports. While some in India have criticised the Government for being generous with other countries earlier and exporting millions of doses of the vaccines instead of storing them from later use, many countries have expressed disappointment with the slowdown in supplies from India over the recent months.

Taking on those who have criticised India's exports of the vaccines, the Minister said that those who question international cooperation need to also understand this that India's ability to make vaccines is itself a result of international cooperation. "International cooperation is not a one way street where we are giving things to other people and somewhere short changing ourselves. People need to understand that," he said.

Part of India's rise would be really to demonstrate additional capabilities in terms of vaccine manufacture and distribution. "And I think the world would be better served by those additional capabilities. Capabilities, which are in the hands of a country, which embraces the world, which actually, as I said, believes in international cooperation and whose heritage is to do that...." he said.

Source: The Hindu Business Line, 14.04.2021 (Excerpts)

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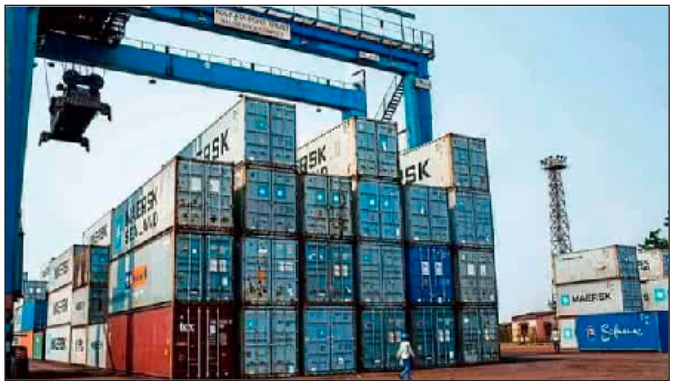
India's Merchandise Exports, Imports hit record in March

Asit Ranjan Mishra

- India's merchandise exports and imports surged to record levels in March even as global trade faced significant challenges following the blockage of the Suez channel by the Ever Given vessel for a week.
- Data released by the Union Commerce Ministry on Thursday,15.04.2021 showed that merchandise exports grew 60.3% to a record $34.45 billion, while imports rose 53.7% to $48.38 billion, leading to a trade deficit of $13.9 billion. Indian exporters and importers use the Suez channel for trade worth $200 billion with North America, South America and Europe every year.

Aditi Nayar, Chief Economist, ICRA Ratings, said the sharp expansion in merchandise exports and imports



Indian exporters and importers use the Suez channel for trade worth $200 billion annually with North America, South America and Europe. ***(Photo: Bloomberg)***

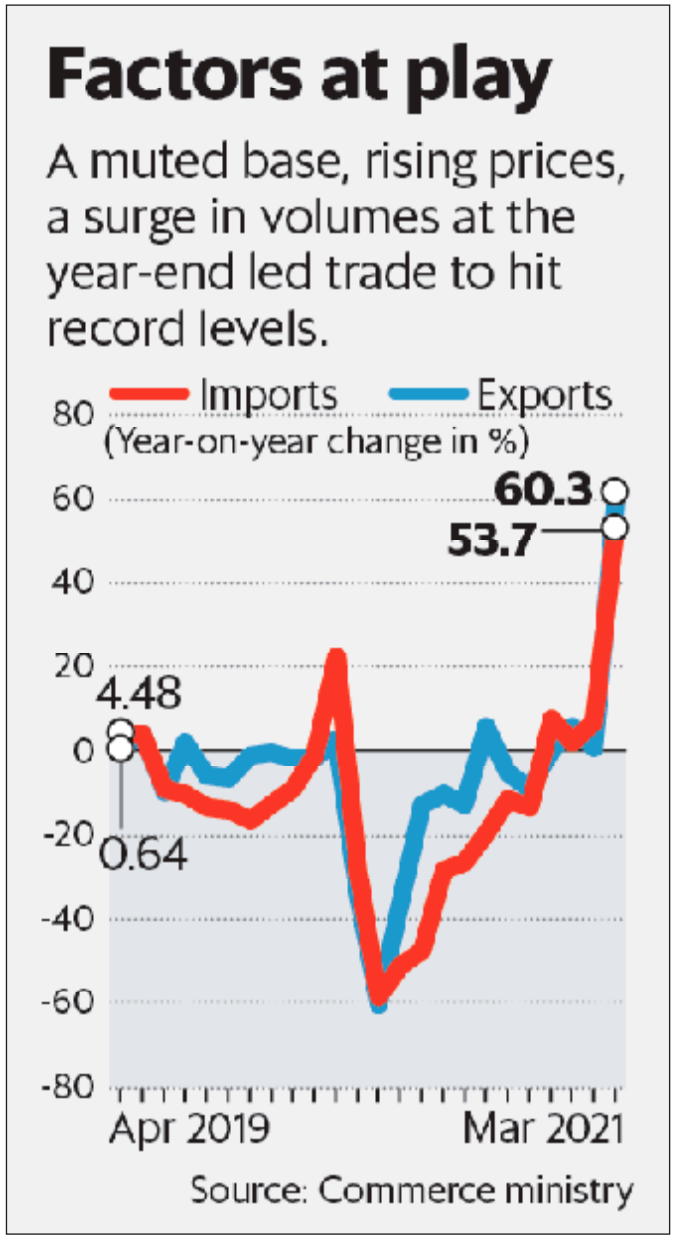
during March reflects a combination of factors, such as a muted base, rising commodity prices reflecting post-vaccine optimism, as well as a surge in volumes at the end of the year.

"If the localized restrictions proliferate, both exports and imports may be adversely impacted in the ongoing quarter in sequential terms. Given the surge in infections, we expect demand to get shifted from Q1FY22 to the later part of the year, which may temporarily dampen imports. For now, we expect India to record a current account deficit of $22-27 billion in FY22," she added.

Moody's Investors Services on Tuesday, 13.04.2021 said the escalating second wave of infections in India presents a risk to its growth forecast of 13.7% for FY22 as the re-imposition of virus management measures will curb activity and may dampen market sentiments. Daily Covid cases crossed the 200,000 mark in India for the first time on Wednesday, 14.04.2021 since the outbreak of the pandemic. Many states have imposed night curfews and mobility restrictions to curb the rapidly spreading viral infection.

The high growth came over the low base of March 2020, when exports collapsed 35% and imports plummeted 29% with countries imposing strict curbs to stem the spread of covid-19. However, in terms of value, both exports and imports improved significantly from February, at $28 billion and $41 billion, respectively.

In March, non-petroleum and non-jewellery exports grew 61.7% led by engineering goods (67.7%), drugs and pharmaceuticals (45.4%). Imports were led by a spurt in domestic demand for gold (591.7%) followed by electronic



goods (77%) and machinery (60%). Overall, exports in FY21 contracted by 7.3% to $290.6 billion, while imports fell 18% to $389.2 billion, leading to a trade deficit of $98.6 billion.

The WTO last month had said that prospects for a quick recovery in global trade have improved with merchandise trade expanding more rapidly than expected during the second half of FY21.

Source: Live Mint, 16.04.2021 (Excerpts)

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