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IDMA BULLETIN

VOL. NO. 53 | ISSUE NO. 06 (PAGES: 32) | 08 TO 14 FEBRUARY 2022 | ISSN 0970-6054 | WEEKLY PUBLICATION

Indian APIs & Formulations for Global Healthcare

INDIAN DRUG MANUFACTURERS' ASSOCIATION

REGISTER NOW

IDMA & APTAR PHARMA - Eye Care Webinar

on

"Ocular Drug Delivery, A Therapeutic Area with an Interesting Past and a Fascinating Future": to be held on 17th February 2022, Time: 4:00 PM - 5:30 PM

(Details on Page No. 4)

IDMA-CISCO Meraki Webinar

on

'Create the factory of future' to be held 24th February 2022
Time: 2.30 pm - 3.30 pm

(Details on Page No. 5)

HIGHLIGHTS

IDMA BULLETIN

Vol. No. 53 **Issue No. 06** **08 to 14 February 2022**

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NATIONAL NEWS:

INDIAN DRUG MANUFACTURERS' ASSOCIATION (IDMA)

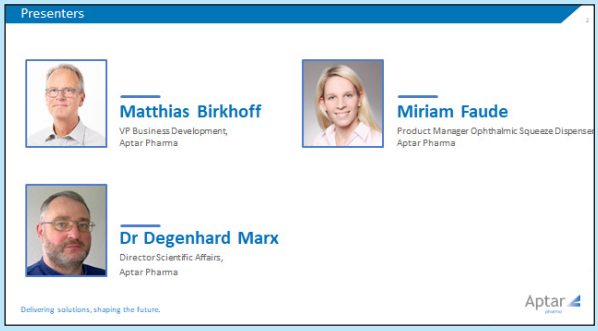
102, Poonam Chambers, A Wing, 1st Floor, Dr. Annie Besant Road, Worli, Mumbai - 400 018. Maharashtra, India.
Tel: +91-22-24974308 / 24944624 E-mail: actadm@idmaindia.com Website: www.idma-assn.org

Dear Member,

Aptar Pharma and Indian Drug Manufacturers Association (IDMA) is organizing an Eye Care Webinar on "Ocular Drug Delivery, A Therapeutic Area with an Interesting Past and a Fascinating Future" on the Thursday, 17th February 2022 from 4.00 pm to 5.30 p.m.

The Moderator of the Webinar : Mr. S R Vaidya, Chairman, MSME Committee, IDMA

The International Speakers for this webinar :



Abstract :

Ophthalmic diseases such as AMD and Glaucoma are potentially blinding chronic conditions, requiring life-long medical therapy. Failure to adhere to proper treatment may lead to disease progression and visual loss, not to speak of economic consequences.

Poor compliance is widespread. It is often a cocktail of many ingredients, including stinging drops and the difficulty of applying drops accurately, in particular for older patients. Preservatives play a prominent role in this unfavorable mixture.

However, nobody must accept any compromises when it comes to microbiological integrity.

This webinar presents available options and discusses future trends, in particular preservatives, debatable additives, but also novel ideas like "Connected Eye Care", an issue that gains even more attraction in the pandemic situation we are all in.

You will learn about strategies to address patient compliance in both clinical settings and in home care as well as limitations and regulatory hurdles.

Kindly note that there are no registration fees for this webinar but prior registration is compulsory.

REGISTRATION LINK : registration page

https://teams.microsoft.com/registration/PkrXX3rVDkGNfALE3wYiNA,M8Y2FUhaNEmpIW5AtPPojg,H699HZJvpke-twCuPK6LVQ,kS0JCOhubUGFfXDFqOhP7Q,06URgzC2y0mJE5u3A4NPtw,iJgaAMb71U2HM0vJSjBiLQ?mode=read&tenantId=5fd74a3e-d57a-410e-8d7c-02c4df062234&skipauthstrap=1

Looking forward to your support and participation in making this webinar a grand success.

Thanks & regards,

Daara B Patel
Secretary – General,
IDMA

cisco Meraki | IDMA

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IDMA representation to DoP on Lack of availability of Shipping Containers and the Impact on the Industry - reg.

IDMA have submitted the following representation on 27th January 2022 to Shri Sanjay Meena, Section Officer (Policy), DoP, Ministry of Chemicals and Fertilizers, Government of India with a copies to Ms Nidhi Mani Tripathi, Joint Secretary, Ministry of Commerce & Industry, Ms. Indu C. Nair, Director (FT(ASEAN), EP Pharma & UNESCAP), Department of Commerce, Ministry of Commerce and Industry, Dr. Sumit Garg, IRS, Deputy Secretary, DoP, Ministry of Chemicals and Fertilizers and Shri Venkat Hariharan Asha, Deputy Director, DoP, Ministry of Chemicals and Fertilizers on the above subject:

Dear Sir,

Thank you for your email dated 25th January 2022 regarding a very important subject for the Industry as stated above.

As you are aware, disruption in supply chain has been a major global concern, and it is very critical for the pharmaceutical sector as medicines are expected to be available at the right place at the right time at an affordable cost in order to save lives.

Please refer our letter dated 12th May 2021 (attached) addressed to Hon. Minister Dr Mansukhbhai L Mandaviyaji. The letter has carried our views on the matter, as on that time.

We thank the Government for taking up our issues, and we are happy to state that the general feeling is that the situation has improved considerably from what it was in the second half of year 2020 and in the first half of year 2021.

The availability of containers has considerably eased as compared to May-June 2021 levels, however there exists considerable constraints in availability of the containers at the ICDs. This also increases the transportation costs for inland manufacturers as in many cases, they have to catch the containers at the ports instead of ICDs. This impacts the supply chain of Indian Pharmaceutical products.

The sea freights levels have escalated several folds from what they used to be in 2019-2020 before the onset of the pandemic. The rates have now stabilized after intervention of the government, since last 4-5 months. However, since they are quite higher than previous levels, the elevated freight costs is seriously impacting the overall cost of goods exported by us. This impacts the cost efficiency of Indian Pharmaceutical products and affects our competitiveness.

We once again appreciate the government for its praiseworthy work in this matter, and sincerely urge to continue its efforts to engage with the shipping lines to address the above concerns, as freight has a direct impact on availability and cost of pharmaceuticals exported.

Thanking you,

Yours sincerely,
For Indian Drug Manufacturers' Association

Dr Viranchi Shah
National President

INDIAN DRUG MANUFACTURERS' ASSOCIATION

H.O.: 102-B, Poonam Chambers, A Wing, Dr. Annie Besant Road, Worli, Mumbai 400 018,
Tel: 022 – 24974308 E Mail: admin@idmaindia.com
B-4/115, Safdarjung Enclave, New Delhi 110 029, Tel: 011 – 26171367 Email: idmadelhi@gmail.com,
Indian APIs & Formulations for Global Healthcare

12th May 2021

Hon'ble Shri Mansukh L Mandaviya ji,
Minister of State for Ports, Shipping and Waterways and
Minister of State for Chemical and Fertilizers,
Government of India,
Transport Bhawan, New Delhi 110 001
E Mail: minister-shipping@gov.in

Respected Sir,

Sub: Current issues in exports of pharmaceutical goods

Ref: DGFT Trade Notice No.02/2021-22 dated 26/04/2021: (*Operationalisation of DGFT 'COVID-19 Helpdesk' for International Trade related Issues'*)

Greetings from Indian Drug Manufacturers' Association.

This has reference to the DGFT Trade Notice No.02/2021-22, dated 26th April 2021 for operationalization of DGFT 'COVID 19 Helpdesk' for International Trade related issues. We are hopeful that this initiative will surely help the pharmaceutical goods exporters significantly in the current awfully challenging time.

We would like to draw your kind attention towards some of the challenges that our members are facing in exporting the pharmaceutical goods.

(1) Steep increase in freight charges in the current Covid-19 scenario:

a) Air freight increased by 7 to 10 times during the Covid-19 period compared to pre-covid-19 rates due to the suspension of several international carriers. Conversely, sea freights during the Covid -19 period remained more or less the same as their pre-Covid-19 period level. This resulted in the shifting of transportation volume from air to sea modes, which caused a huge increase in sea freight rates. A comparison of sea freight rates data in Oct - Nov 2020 and March - April 2021 is shown below for your ready reference. *(Although this increase in freight has impacted all the major locations, we mention the most impacted destination*

Country	Port	Container type	% of increase in Sea Freight from Oct-Nov 2020 to March -April 2021
Nigeria	Apapa	40' reefer	25%
South Africa	Durban	40' reefer	20%
France	Rouen	40' reefer	67%
Russia	Kotka / Moscow	40' reefer	56%

Brazil	Rio de janerio	40' reefer	69%
Myanmar	Yangon	40' reefer	62%
Casablanca	Morocco	40' reefer	55%
Tanzania	Dar-es-salaam	40' reefer	28%
Belgium	Antwerp	40' reefer	105%
Australia	Sydney	40' reefer	67%
Canada	Toronto	40' reefer	55%
USA	New York/EWR	40' reefer	35%

b) We anticipated that air freights will be normalized after yearly closing (March 2021); however Airlines are cancelling their flights to India due to prevailing situation, resulting in scarcity of air space with increased air freight rates.

(2) Containers issue:

a) The free period for empty containers provided by shipping line(s) earlier used to be between 10-14 days. The current free period has been reduced to 7-8 days, further impacting the transaction cost.

b) Worthy containers for pharmaceutical products are still in short supply at many ports, hence shipping lines are taking shelter of such excuses to increase rates.

c) Many vessels are skipping JNPT /Main gate ports (Mumbai, Chennai, Mundra), leading to high detentions, increased lead time and high transit inventory

(3) Shipping lines issues / General issues at port:

a) During the Pre-Covid period, several shipping lines were available; however, in the covid-period, only limited options/shipping lines are available. Thus, rates and lead times have increased many fold.

b) Shipping lines have added many surcharges, and there is an increase in basic rates happening almost every month now. The increase is between US$ 1000 to US$1500 per container per month. The overall cost of shipping goods by air /sea modes have gone up by 52 to 55 %.

c) Limited services are available for some ports (such as Sydney, Toronto, Russia), creating a massive backlog at Transit ports. It results in a significant increase in overall lead time.

As we continue to export with above laid down constraints in the current challenging time, we request your kind intervention and issue directions to the concerned in keeping the freight cost under check, and resolution of containers & shipping lines issues. This will help in smoothen the export, which is currently getting hindered.

Thanking you.

Yours sincerely,

Mahesh H Doshi
National President

WHO request information about the manufacturers in India for the listed goods/items - reg.

Dear Members,

We have been given to understand from WHO that they are interested in finding out if the following goods/items are being manufactured in India :

S.No	Goods/ Items/Services
i.	Antithymocyte globulin 25 mg (Rabbit) Vial
ii.	Beractant 4 ml Vial
iii.	Beractant 8ml Vial
iv.	Bevacizumab 400 mg Amp/ Vial (Brand Name AVAST IN by ROCHE)
v.	Oesflurane Bottle
vi.	Fat emulsion 20% containing Soyabean oil, Egg phospho lipids 500 ml Bottle
vii.	Human cryoprecipitated anti-haemophilic Factor-VIII Vial
viii.	Iohexol 350 mg of Iodine/ml 100 ml Bottle
ix.	Growth Hormone 4 mg (Somatropin) Vial
x.	Sevoflurane Bottle
xi.	Continuous ambulatory dialysis fluid 1.5% Bag
xii.	Continuous ambulatory dialysis fluid 2.5% Bag
xiii.	Sterile perfusion fluid for organ preservation for transplantation Bag

In case you are manufacturing any of the above items, please inform the IDMA Secretariat at **admin@idmaindia.com** at the earliest.

Thanks and regards,

Daara B Patel
Secretary - General

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Register your Participation: Pharmexcil Business Delegation (physical) to Philippines, Vietnam and Indonesia during 21st -30th March 2022

Pharmaceuticals Export Promotion Council of India

(Set up by Ministry of Commerce & Industry, Govt. of India)

PXL/HO/Cir-136/2021-22 Date: 08.02.2022
Hyderabad

IDMA (Indian Drug Manufacturer'S Association)

Dear Sir/Madam,

Subject: Register your Participation: Pharmexcil Business Delegation (physical) to Philippines, Vietnam and Indonesia during 21st - 30th March 2022 (MAI assistance available)

We would like to bring to your kind notice that Pharmexcil with the support of the Ministry of Commerce & Industry, Government of India is organizing Business Delegation to Philippines, Vietnam and Indonesia during the week of March commencing from 21 March.2022 until 30.March.2022. The Missions in Philippines, Vietnam and Indonesia have given their acceptance for hosting the Business Delegation.

ASEAN is one of the major importers of Indian generic medicines with an approximately USD 13 BN generic market. The region offers great potential for India pharmaceutical products and our exports during the fy 2020-21 is USD 1462 mn contributing about 6 % of the total pharma exports from India, with a growth rate of 13.14% over previous year. During April-Jan (2021-22), the exports to ASEAN have touched USD 1461 mn with a growth rate of 18% over April-Jan (2020-21).

Considering the nature of the region falling into Focus area for pharmaceutical exports from India and the potential for Generics and APIs, Pharmexcil is organising a business delegation (physical) to **Philippines (Manila), Vietnam (Ho Chi Minh), and Indonesia (Jakarta).**

As part of the Business Delegation, Buyer Seller Meets will be organised at each country along with meetings with the Regulatory officials and prominent trade associations. The details of the BSM schedule and other meetings will be shared soon.

PARTICIPATION DETAILS:

- Participation fee is Rs.60,000/-for BSM in all three countries. Participation fee includes BSM set up at all Destinations.
- Members are required to submit a mandatory Registration form via google form **(link) with** complete details as per the provided format latest by **14th February, 2022.**
- On the submission of the Registration form, you are required to pay INR 60,000 in favor of "Pharmaceuticals Export Promotion Council of India" and share the payment details with accounts2@pharmexcil.com (Bank Details enclosed).
- Members may please note that confirmation of your participation is based on receipt of the payment.
- The suggested Flight itinerary, Hotel names and tariffs (in consultation with Indian Missions abroad) will be communicated in due course.
- Destination can undergo change/modifications/cancelled subject to our Embassy/Missions advice in view of unavoidable circumstances pertaining to the travel restrictions.
- Participation fee is non-refundable and can be refunded only if the event is cancelled due to unavoidable circumstances at the instance of our Mission/Council

LINK TO REGISTER: https://docs.google.com/forms/d/e/1FAIpQLSdf04tOrtYmtg5sKbu61Q5p78kq4pK5JZ-VwC6BwxyM3l2pwg/viewform

MAI ASSISTANCE:

Members whose export turnover during previous year are less than Rs.50.00 crores and are having minimum of one year (12 calendar months) membership with the council are eligible for MAI assistance subject to the other guidelines of MAI scheme. Under the scheme Director/Partner/ Proprietor/Senior Managers can avail reimbursement of economy class airfare subject to a maximum of **INR 75,000/- per company.**

We therefore request you to kindly register your participation to join the Business Delegation to enable Pharmexcil make necessary arrangements for Visa and travel for the Business Delegation.

For more information /further clarifications, members may write to us at **dd.smk@pharmexcil.com**

Thanking you,

With regards,

Uday Bhaskar
Director General

Ensuring Use of Indian Pharmacopoeia Reference Standards and Impurity Standards for Quality Testing of Drugs - reg.

No. T.11013/02/2018-AR&D, dated 4th February 2022

1. In order to fulfill the requirements of the Drugs and Cosmetics (D&C) Act, 1940 and Rules 1945 there under, Ministry of Health & Family Welfare, Government of India has entrusted Indian Pharmacopoeia Commission (IPC) with mandates of publishing the Indian Pharmacopoeia (IP) at regular intervals along with the certification and distribution of IP Reference Standards (IPRS) and Impurity Standards.
2. IPRS are specifically required for establishing conformance to the IP standards. An IPRS, being an integral and essential component of the IP standard, is an official standard that alone is authoritative in assessing the quality of drugs and use of any unauthorised Reference Standard is a noncompliance of the IP standards.
3. Moreover, as per the Schedule M of the D&C Act, Part I, Quality Control System (16.14) - "Pharmacopoeia reference standards, working standards, references, spectra, other reference materials and technical books, as required, shall be available in the Quality Control Laboratory of the licensee".
4. IPC has been making efforts to promote the use of IPRS and Impurity Standards by the manufacturers and testing laboratories and steps are being taken to stop the use of unauthorized standards in quality control testing.
5. However, despite all these efforts, the current trends of the sale of IPRS and Impurity Standards from IPC do not match with the number of pharmaceutical manufacturers and testing laboratories in India. Rather, it has been observed that there is a tendency among the stakeholders to procure unauthorised Reference Standards from dubious sources and to use them in routine drug analysis.
6. Using unauthorised Reference Standards is an illegal act in accordance with the provisions of the Drugs and Cosmetics Act 1940. Also, such malpractices could be the cause of manufacture and marketing of counterfeit/ spurious drugs in India which may have serious consequences on the health of its citizens.
7. In order to further ensure the use of authentic IPRS and Impurity Standards, IPC has taken an initiative to trace the details of the Reference Standards being used in quality control analysis by different stakeholders and to share with 1PC necessary information w.r.t. purchase of IPRS and Impurity Standards.
8. Stakeholders are encouraged to purchase authentic IPRS and Impurity Standards by visiting IPC website (www.ipc.gov.in).

Dr. Rajeev Singh Raghuvanshi, Secretary-cum-Scientific Director, Ministry of Health & Family Welfare, Government of India, Sector 23, Raj Nagar, Ghaziabad 201 002 (U.P.), INDIA.

● ● ●

Making available of suitable drugs to meet the requirements of emergency arising due to COVID-19 under section 26B of the Drugs and Cosmetics Act, 1940 (23 of 1940) - reg.

Health & Family Welfare Notification S.O.553(E), dated 09th February, 2022

1. Whereas, there is an outbreak of COVID-19 pandemic throughout India, resulting into dangerous and opportunist infections, disease like Mucormycosis, etc., due to which emergency has arisen to make available new drugs for treatment or management of COVID-19 and related diseases;

Whereas, the Central Government is satisfied that making available suitable new drugs is essential to meet the requirements of emergency arising due to pandemic COVID-19, and in public interest it is necessary and expedient to regulate the manufacture and stock for sale or distribution of such new drugs for prevention and treatment of COVID-19 and associated infection;

Now, therefore, notwithstanding anything contained in the Drugs Rules, 1945 and New Drugs and Clinical Trials Rules, 2019, for the purposes of making available suitable drugs to meet the requirements of emergency arising due to COVID-19, in exercise of the powers conferred by section 26B of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, hereby notifies the following, namely:-

(a) In case a person intends to manufacture and stock a new drug for COVID-19, which is under clinical trial for marketing authorisation for sale or distribution, then, such person shall have to obtain permission in Form CT-06 to conduct clinical trial of such drug and on successful completion of the clinical trial and after obtaining permission in Form CT-23 from the Central Licensing Authority under the New Drugs and Clinical Trials Rules, 2019, he shall make an application under rule 69 or rule 7 or rule 75 or rule 75A of the Drugs Rules, 1945, as the case may be, to the concerned Licensing Authority appointed by the State Government along with the permission obtained for conducting clinical trial in Form CT-06 under the New Drugs and Clinical Trials Rules, 2019, for grant of license to manufacture and stock the drug for sale or distribution under the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) (hereinafter referred to as the said Act) and the rules made thereunder:

Provided that the requirement of prior permission from the Central Licensing Authority under rule 81 of the New Drugs and Clinical Trials Rules, 2019 to manufacture the new drug as required under rule 83 of the said rules shall be deferred in public interest to meet the emergent situation arisen out of COVID-19 and such person shall obtain the said permission after successful completion of the clinical trial and submission of application along with fees, data and particulars in accordance with the provisions of the New Drugs and Clinical Trials Rules, 2019.

(b) The Central License Approving Authority or the State Licensing Authority, as the case may be, if satisfied that requirements under the provisions of the said Act and the Drugs Rules, 1945 and the New Drugs and Clinical Trials Rules, 2019 have been complied with, grant License in accordance with the provisions of the Drugs Rules, 1945 to manufacture and stock the new drug subject to the condition that the licensee shall sell or distribute the new drug only after obtaining permission for such new drug in Form CT-23 from the Central Licensing Authority under the New Drugs and Clinical Trials Rules, 2019.

2. In case of any inconsistency between this notification and any rule made under the said Act, the provisions of this notification shall prevail over such rule in public interest so as to meet the emergency which has arisen due to COVID-19 pandemic.

3. This order shall come into force on the date of its publication in the Official Gazette.

F.No.X.11014/02/2020-DRS

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

● ● ●

Draft rules to further amend the Medical Device Rules, 2017 published - reg.

Health & Family Welfare - Other Notification G.S.R.104(E), dated 09th February 2022

The following draft of certain rules further to amend Medical Device Rules, 2017, which the Central Government proposes to make, in exercise of the powers conferred by sub-section (1) of section 12 and sub section (1) of section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), is hereby published after consultation with the Drugs Technical Advisory Board for information of all persons likely to be affected thereby and notice is hereby given that the said draft rules shall be taken into consideration on or after the expiry of a period of forty-five days from the date on which copies of the Gazette of India containing these draft rules are made available to public;

Objections and suggestions which may be received from any person within the period specified above will be considered by the Central Government;

Objections and suggestions, if any, may be addressed to the Under Secretary (Drugs), Ministry of Health and Family Welfare, Government of India, Room No. 434, C Wing, Nirman Bhavan, New Delhi - 110011 or emailed at drugsdiv-mohfw@gov.in.

DRAFT RULES

1. (i) These rules may be called the **Medical Devices (.....Amendment) Rules, 2022.**

(ii) These rules shall, unless specified otherwise, come into force on the date of their final publication in the Official Gazette.

2. In the Medical Devices Rules, 2017(hereinafter to be referred as said rules), in rule 34, in sub-rule (1), after the words “wholesale licence for sale or distribution” and before the words “under these rules”, the following words and figure shall be inserted namely:—

“or registration certificate in Form-42”

3. In the said rules, in rule 87, at the end of sub-rule(1), the following sub-rule shall be inserted, namely:-

“(1)(A) Notwithstanding anything contained in sub-rule(1), any person intends to sale medical devices exclusively as referred in clause (zb) of rule 3 shall obtain registration certificate as provided hereinafter in these rules.”

4. In the said rules, after rule 87, the following rules shall be inserted, namely:-

“87(A) Registration Certificate to sell, stock, exhibit or offer for sale or distribute a medical device including *in vitro* diagnostic medical device.-

(1) The State Licencing Authority shall appoint Licensing Authorities for the purpose of issuing Registration Certificate in this Part for such areas as may be specified.

(2) Any person who intends to sell, stock, exhibit or offer for sale or distribute a medical device including *in vitro* diagnostic medical device shall make an application in Form MD-41 for grant of Registration Certificate to sell, stock, exhibit or offer for sale or distribution to the State Licensing Authority.

(3) The application made under sub-rule (2), shall be accompanied with

i. a fees prescribed in Second Schedule of the said rules;

ii. Self certificate of compliance with respect to Good Distribution Compliance;

iii. Details of the applicant/firm including its constitution, along with ID proof viz: Aadhar card, PAN card;

iv. Documentary evidence in respect of ownership or occupancy on rental of the premises;

v. Details of competent technical staff under whose direction and supervision the sales activity of medical device shall be undertaken and such staff shall possess the following educational qualification and experience,-

(a) holds a degree of a recognized University; or

(b) is a registered Pharmacist; or

(c) has passed intermediate examination or its equivalent examination from a recognized Board with the one-year experience in dealing with sale of Medical Devices.

vi. Brief description on other activities carried out by applicant, viz: storage of drugs, medical items, food products, stationeries etc or any other activities carried out by applicant in the said premises.

vii. The application made under sub-rule (2), shall be accompanied with an undertaking to the effect that the storage requirements to sell, stock, exhibit or offer for sale or distribute a medical device will be complied with.

(4) The State Licensing Authority shall, after scrutiny of documents and on being satisfied that the requirements of these rules have been complied with, grant a Registration Certificate in Form MD-42, or if not satisfied, reject the application for reasons to be recorded in writing, within ten days from the date, the application is made under sub-rule (2).

(5) If the application for grant of Registration Certificate to sell, stock, exhibit or offer for sale or distribute a medical device is rejected under sub-rule (4), the aggrieved person may prefer an appeal before the State Government within forty-five days from the date of receipt of such rejection, which may, after such enquiry and after giving an opportunity of being heard to the appellant, dispose it within a period of sixty days from the date of receipt of such appeal.

87(B) Conditions of registration certificate to sell, stock, exhibit or offer for sale or distribute a medical device including *in vitro* diagnostic medical device.—

i. The Registration Certificate shall be displayed at a prominent place in the premises visible to the public.

ii. The Registration Certificate holder shall provide adequate space, proper storage condition for storage of the Medical Devices.

iii. The Registration Certificate holder shall maintain required temperature and lighting as per requirements of such Medical Devices.

iv. The Medical Devices shall be purchased only from Importer or licensed manufacturer or registered/licenced entity under said rules.

v. Separate records, in form of invoice or register or electronic details including software of purchases and sales of Medical Devices showing the names and quantities of such Medical Devices, names and addresses of the manufacturers/importers, Batch Number/Lot Number, Expiry Date shall be maintained. Such records shall be open to inspection by a Medical Device Officer appointed under the sub-rule (2) of rule 18 of the said rules, who may, if necessary, make enquiries about purchases and sale of the Medical devices and may also take samples for testing.

vi. All registers and records mentioned under these rules, shall be preserved for a period of not less than two years from the last entry, therein.

vii. The Registration Certificate holder shall maintain an inspection book in Form MD-43 to enable the Medical Devices Officer to record his/her observations and defects noticed.

87(C) Validity of registration certificate.—

(1) A Registration Certificate issued in Form MD-42, shall remain valid in perpetuity, subject to payment of Registration Certificate retention fee as specified in the Second Schedule before completion of the period of five years from the date of its issue, unless, it is suspended or cancelled by State Licensing Authority.

Provided that, If the Registration certificate holder fails to pay the required Registration Certificate retention fee on or before due date as referred to in sub-rule(1), the Registration Certificate holder shall, in addition to the Registration Certificate retention fee, be liable to pay a late fee calculated at the rate of two percent. of the Registration Certificate retention fee for every month or part thereof within six months.

Provided further that, in the event of non-payment of such fee during that period, the Registration Certificate shall be deemed to have been cancelled.

87(D) Suspension and cancellation of Registration Certificate.—

(1) Where the Registration Certificate holder, contravenes any provision of the Act and the said rules, the State Licensing Authority, shall, after giving the Registration Certificate holder an opportunity to show cause as to why such an order should not be passed, shall by an order and for reasons to be recorded in writing, suspend it for such period as it considers necessary either wholly or in respect of any of the medical device or cancel the Registration Certificate.

(2) A Registration Certificate holder whose Registration Certificate has been suspended or cancelled by the State Licensing Authority under sub-rule (1), may within forty-five days of the receipt of a copy of the order by such authority, prefer an appeal to the State Government or Authority designated by the State Government, and the State Government or Authority designated by the State Government , shall after giving the Registration holder an opportunity of being heard, confirm, reverse or modify such order, with reasons to be recorded in writing."

5. In the said rules, in Appendix, after Form MD-40, the following Forms shall be inserted, namely:-

"Form MD-41

[See sub-rule (2) of rule 87(A)]

APPLICATION FOR GRANT OF REGISTRATION CERTIFICATE TO SELL, STOCK, EXHIBIT OR OFFER FOR SALE OR DISTRIBUTE A MEDICAL DEVICE INCLUDING *IN VITRO* DIAGNOSTIC MEDICAL DEVICE

1. Name of Applicant:
2. Address of the premises to be registered:
3. Contact details of applicant including telephone number, mobile number, fax number and email id:
4. Nature and constitution of applicant: (i.e. proprietorship, partnership including Limited Liability Partnership, private or public company, society, trust, other to be specified)
5. Name, Qualification and experience of competent person appointed:
6. Fee paid on _____ Rs_____ receipt/challan/transaction Id_____.
7. I have enclosed the documents as specified in the rule 87(A)(3) of Medical Devices Rules, 2017.

Place: _____

Date: _____

Name, Designation & Signature of Director/Proprietor/Partner

Form MD-42

[See sub-rule (4) of rule 87(A) and rule 87(C)]

REGISTRATION CERTIFICATE TO SELL, STOCK, EXHIBIT OR OFFER FOR SALE OR DISTRIBUTE A MEDICAL DEVICE INCLUDING *IN VITRO* DIAGNOSTIC MEDICAL DEVICE

Registration No.: ……..

1. M/s, ……(Name of the firm) situated at ……(full address with telephone and e-mail) has been registered to sell, stock, exhibit or offer for sale or distribute a medical device including in vitro diagnostic medical device under the Medical Devices Rules, 2017.
2. Name and Qualification of competent person:
3. This Registration is subject to the conditions as specified in the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Medical Devices Rules, 2017.

Place: _____

Date: _____

State Licensing Authority

Form MD-43

[See clause (vii) of rule 87(B)]

Form in which the Inspection Book shall be maintained

(A) The cover of the inspection book shall contain the following particulars, namely:—

1. The name and address of the Registration Certificate holder _____.
2. Registration Certificate Number _____

(B) (i) The pages of the inspection book shall be serially numbered and duly stamped by the State Licensing Authority*. The pages, other than the first and the last pages, shall have the following particulars:-

Name and designation of the medical device officer who inspected the premises:

Date of inspection _____

Observations of the medical device officer _____

Signature of the medical device officer

(ii) The first and last pages of the inspection book shall be endorsed by the State Licensing Authority with the following words, namely:—

Inspection book maintained by M/s _____situated at _____ for Registration number _____ in Form MD-43_____ under the Medical Devices Rules, 2017.

State Licensing Authority

Notes:

(i) Printed copy of the Inspection Book may be obtained by the licencee from the Licensing Authority on payment of fee as may be specified by the concerned Licensing Authority from time to time.

(ii) The inspection book shall be maintained at the premises of the licencee.

(iii) The original copy of observations made by the medical device officer shall be maintained in the premises of the licencee and duplicate copy shall be sent to the State Licensing Authority. The triplicate copy shall be taken as record by the medical device officer.

6. In the said rules,—

(i) in rule 88, in sub-rule (1), after the words "or wholesale" and before the words "may, supply", the following words and figure shall be inserted, namely:—

"or registration certificate in Form-42".

(ii) In Second Schedule, after the figures "64(1), 81(1), 84," and before the figure "91", the following figures and letters shall be inserted, namely:—

"87(A)(3) and 87(C)(1)".

(iii) In Second Schedule, in the table, after serial number 51 and the entries relating thereto, the following serial number and entries shall be inserted, namely:-

Sr. No.	Rule	Subject	In rupees (INR) except where specified in dollars ($)
(1)	(2)	(3)	(4)
52.	87(A)(3)	Registration Certificate for sale of Medical Devices	3000
53.	87(C)(1)	Retention fee for Registration certificate for sale of Medical Devices	3000

(iv) In Fourth Schedule, in Part I, after the words "manufacturing licence" and before the words "with telephone", the words "or registration certificate" shall be inserted.

(v) Under Appendix, in Form MD-14, in para 3, sub-para (ii), after the words "manufacturing licence" the words "or registration certificate" shall be inserted.

(vi) Under Appendix, in Form MD-15, in para 1, after the words "manufacturing licence" and before the words "of authorised agent" the words "or registration certificate" shall be inserted.

(vii) Under Appendix, in Form MD-26, in para 3, sub-para (ii), after the words "manufacturing licence" the words "or registration certificate" shall be inserted.

(viii) Under Appendix, in Form MD-28, in para 3, sub-para (ii), after the words "manufacturing licence" the words "or registration certificate" shall be inserted.".

F.No. X.11014/15/2021-DR

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

Note: *The principal rules were published in the Official Gazette vide notification number G.S.R. 78(E), dated the 31st January, 2017 and last amended vide notification number G.S.R. ..... (E), dated.....*

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Direction Under Section 5 of the Environment (Protection) Act, 1986 to Plastic raw material Manufacturers for phasing out of Single Use Plastic (SUP) - reg.

F.No.B.17011/7/UPC-II-PWM(SUP)/2022, dated 01st February 2022

To,
The. Manufacturers,
(As per list)

Whereas, the Ministry of Environment, Forest & Climate Change (MoEF&CC) notified the Plastic Waste Management (PWM) Rules, 2016, in exercise of the powers conferred under sections 3,6, & 25 of the Environmental (Protection) Act, 1986 vide Notification No. G.S.R. 320 (E) dated March 27, 2016; and

Whereas, MoEF&CC issued Notification,dated August 12, 2021 which mandated banning of identified Single Use Plastic (SUP) items and prescribed minimum thickness of carry bags with effect from July 01, 2022; and

Whereas, as per Rule 4(2) of PWM Rules, 2016 (as amended), *"The manufacture, import, stocking, distribution, sale and use of following SUP, including polystyrene and expanded polystyrene, commodities shall be prohibited with effect from the 1st July, 2022:*

(a) *ear buds with plastic sticks, plastic sticks for balloons, plastic flags, candy sticks, ice-cream sticks, polystyrene [Thermocol] for decoration.*

(b) *Plates, cups, glasses, cutlery such as forks, spoons, knives, straw, trays, wrapping or packing films around sweet boxes, invitation cards, and cigarette packets, plastic or PVC banners less than 100 micron, stirrers;* and

Whereas, as per Rules 4(1)(c) of PWM Rules, 2016 (as amended) "Carry bag made of virgin or recycled plastic shall not be less than seventy five microns in thickness with effect from the 30th September, 2021 and one hundred and twenty (120) microns in thickness with effect from 31st December, 2022"; and

Whereas, M/s (Name of Industry) is engaged in manufacturing plastic raw material which can be used for production of plastic items including banned SUP Items as per details given above.

Now, therefore, in compliance of above and in exercise of powers vested under Section 5 of Environment (Protection) Act, 1986 to the Chairman CPCB, following Directions are issued to your industry for compliance:

i. Not to supply plastic raw material to producers (in formal / informal sector) engaged in production of banned SUP items

ii. To ensure that suppliers/ stockists/ dealers and other entities engaged in the industry's supply chain do not supply plastic raw material to producers engaged in production of banned SUP items

iii. To provide monthly details (by 7th of every month) of material sold to suppliers/stockist/dealers/ producers including GST details to CPCB as per prescribed format (Annexure I). The soft copy of monthly report in excel format is to be emailed to pwm.cpcb@nic.in

Necessary action shall be taken by your firm to ensure compliance of aforesaid directions and Action Taken Report to be submitted to this office in the prescribed format by March 31, 2022, failing which appropriate action including levying of Environmental Compensation will be taken against your industry in accordance with the provisions under Environmental (Protection) Act, 1986.

Yours faithfully,

Tanmay Kumar, Chairman, Central Pollution Control Board, Ministry of Environment. Forest and Climate Change, Government of India

Annexure- I

Monthly report of Plastic flaw Material Manufacturers								
	Duration		Month		Year			
Sr. No.	Name & Contact details (Address, email id & Phone no.)	Category (Supplier/ producer stockist/retail)	GST No of the entity supplied to	Product manufactured (in case of producer	Type of plastic raw material supplied	Qty of raw material supplied (T)	Date of supply	GST paid

List of Raw Material Manufacturers for SUP

Sr. No.	Registered Address
1.	M/s. Reliance Industries Limited, 3rd Floor, Maker Chambers IV, 222, Nariman Point, Mumbai, Maharashtra - 400021
2.	M/s. Indian Oil Corp, Indian Oil Bhavan, G-9, Ali Yavar Jung Marg, Bandra (East), Mumbai -400051
3.	M/s. Haldia Petro Chemicals, Tower 1, Bengal Eco Intelligent Park (Techna) Block EM, Plot No 3, Sector V, Salt Lake PO: Bidhan Nagar, District: North 24 Paraganas, Kolkata 700091
4.	M/s. GAIL(INDIA) Limited, GAIL Bhawan, 16 Bhikaji Cama Place, R K Puram, New Delhi - 110066
5.	M/s. HPCL Mittal Energy, Phullokari Village, TalwandiSaboo Taluka, District Bathinda - 151301, Punjab
6.	M/s. IVL Dhunseri Petrochem, Dhunseri House', 4A, Woodburn Park, Kolkata 700020
7.	M/s. Supreme Petrochem Ltd., Solitaire Corporate Park, Building No. 11, 5th Floor, 167, Guru Hargovindji Marg, Chakala, Andheri (East), Mumbai - 400093,
8.	M/s. Finolex Industries, Gat No. 399, Village Urse, Taluka Maval, Pune District, Maharashtra - 410506
9.	M/s. Chemplast Sanmar Ltd., 9 Cathedral Rd Madras,Tamil Nadu 600086
10.	M/s. LG Polymers India Pvt Ltd., Quality Innovation & Solutions RR Venkatapuram, Visakhapatnam Andhra Pradesh - 530029
11.	M/s. INEOS Styrolution India Limited, 5th Floor, OHM House-2, OHM Business Park, Near Balaji Hospital, Subhanpura, Vadodara - 390007, Gujarat
12.	M/s. ONGC Petro Additions Ltd, 35, Nutan Bharat Co-operative Housing Society Limited, R.C. Dutt Road, Alkapuri, Vadodara-390007, Gujarat
13.	M/s. Mangalore Refinery & Petrochemicals Ltd., Kuthethoor P.O., Via Katipalla, Mangalore, - 575030
14.	M/s. Brahmaputra Cracker & Polymer Ltd., 1st Floor, House No 6, Bhuban Road, Uzanbazar Guwahati, Assam - 781001
15.	M/s. DCW Limited, Nirmal 3rd Floor, Nariman Point Mumbai-400021, India.
16.	M/s. DCM Shriram Ltd., 2nd Floor (West Wing), World Mark 1 Aerocity, Delhi - 110037
17.	M/s. Gujarat State Fertizliers Ltd., P.o. Fertilizernagar, Vadodara, Gujarat - 391750
18.	M/s. Bhansali Engineering Polymers, Unit No. 401, 4th Floor, Peninsula Heights, C.D., Barfiwala Road, Andheri (West), Mumbai 400058

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In Lok Sabha

In Lok Sabha

SEZ Policy

Lok Sabha Starred Question No. 11(H)

Shri Ajay Nishad:

Q. Will the Minister of **COMMERCE & INDUSTRY** be pleased to state:

(a) the main features of the present Special Economic Zone (SEZ) policy;

(b) whether shortcomings have been detected in the said policy which has caused huge revenue loss to the Government;

(c) if so, the details thereof;

(d) whether the Government has reviewed the SEZ policy and carried out or proposes to carry out any amendment in the rules, laws and procedures related to the said policy; and

(e) if so, the details thereof?

Answered on 02nd February 2021

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

STATEMENT REFERRED TO IN REPLY TO PARTS (a) to (e) OF LOK SABHA STARRED QUESTION NO. 11 FOR ANSWER ON 02nd FEBRUARY, 2022 REGARDING " SEZ POLICY".

(a): The Special Economic Zones (SEZs) policy was launched in April, 2000 as part of the extant Foreign Trade Policy, 2000-05 (FTP 2000-05). 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 Act, 2005 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 imports into SEZ;

(iii) Single Window Clearance at the level of Board of Approval (BOA) and Unit Approval Committee (UAC);

(iv) SEZ Units are required to achieve Positive Net Foreign Exchange (NFE) to be calculated cumulatively for a period of five years from the commencement of production;

(v) Supply of goods from SEZ units to Domestic Tariff Area (DTA) is allowed on payment of Customs duties including anti-dumping, countervailing and safeguard duties under the Customs Tariff Act, 1975, where applicable, as leviable on such goods when imported;

(vi) No routine examination by Customs authorities of export/import cargo;

(vii) Dedicated Customs wing for fast clearance.

(viii) SEZ Developers /Co-Developers and Units enjoy Direct Tax and Indirect Tax benefits as prescribed in the SEZ Act, 2005.

(b) and (c): No Sir.

(d) and (e): Review of SEZ policy is an on-going process and on the basis of inputs/suggestions received from stakeholders on the policy and operational framework of the SEZs, Government periodically takes necessary measures for facilitating smooth and effective implementation of the SEZ Act/Rules. Amendments carried out in the SEZ Act, 2005 and SEZ Rules, 2006 during the last three years are at Annexure.

Annexure to the Lok Sabha Starred Question No. 11 for 2nd February, 2022

Amendments carried out in the SEZ Act, 2005 and SEZ Rules, 2006 during the last three years:

1. Amendments carried out in the SEZ Act, 2005:

   Amendments carried on 8th July, 2019 for enabling Trusts and any other entity notified by the Central Government to set up units, definition of persons in Section 2(v) has been amended through the Special Economic Zones (Amendment) Bill, 2019. The bill got assent of President of India on 06.07.2019.

2. Amendments carried out in the SEZ Rules, 2006:

(a) Amendment carried out on 31st January, 2019:-

In Rule 42(1)(ii)(h) of the SEZs following amendment has been made:

Provided further that in case of a gems and jewellery unit, studded gold jewellery, silver jewellery and imitation jewellery, the finished goods requiring further processing or semi-finished goods, taken outside the Special Economic Zone for sub-contracting by the unit, shall be brought back into the unit within forty-five days.

(b) Amendment carried out on 7th March, 2019:-

In the backdrop of amendment carried on 19th September, 2018, suggestions from stakeholders were received to further amend the SEZ Rules and accordingly, the amendment were carried out including the amendment in rule 53 regarding method of calculation of Net Foreign Exchange (NFE) for the Units in SEZs.

(c) Amendment carried out on 17th December, 2019:

For utilization of the vacant spaces in SEZs, removal of distinction between sector specific and multi sector requirement, an amendment vide notification G.S.R. 940(E) dated 17th December, 2019 has been carried out for encouraging more investment and growth in exports.

(d) Amendment carried out on 31st December, 2019:

Rule 53A has been inserted to facilitate the calculation of net foreign exchange for a unit in an International Financial Service Center in view of its special nature.

(e) Amendment carried out on 23rd October, 2020:

In Rule 24(3) of the SEZs following proviso has been made:

Provided further that in case of supplies from Domestic Tariff Area to foreign suppliers in Free Trade and Warehousing Zone, the drawback or any other similar benefit Scheme shall be admissible where the payments are made in foreign currency by the foreign supplier to Domestic Tariff Area subject to sub-rule (5) of rule 18 of the said rules.

(f) Amendment carried out on 16th June, 2021:

After Rule 21 of the SEZs following rule has been inserted, namely:-

21A. Setting up of Unit by Multilateral or Unilateral or International agencies in International Financial Services Centre:-

(1) A Multilateral agency or Unilateral agency or International agency notified under the United Nations (Privileges and Immunities) Act, 1947 (46 of 1947) shall be allowed to set up their local or regional office in the International Financial Services Centre as an Unit.

(2) The application for setting up and operation of such Unit in the International Financial Services Centre shall be made before the Board of Approval through the concerned Development Commissioner.

(3) The terms and conditions for setting up and operations by such Units shall be laid down by the Board of Approval based on the recommendation of the Development Commissioner.

(4) Notwithstanding anything contained under these Rules, the Board of Approval may exempt such Units from any provisions of these Rules including provisions relating to positive Net Foreign Exchange earning or filing of Annual Performance Report or such other exemption, based on the recommendation of the Development Commissioner.

(5) The proposal for extension of the Letter of Approval of such Units shall be considered by the Board of Approval.

The Minister of Commerce And Industry (Shri Piyush Goyal)

Import/Export from China

Lok Sabha Starred Question No. 9

Shri Balubhau Alias Suresh Narayan Dhanorkar:

Q. Will the Minister of **COMMERCE & INDUSTRY** be pleased to state:

(a) whether the imports from China have increased during the last seven years;

(b) if so, the details and the reasons thereof;

(c) whether the exports to China have declined during the last seven years; and

(d) if so, the details and the reasons thereof?

Answered on 02nd February 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 LOK SABHA STARRED QUESTION NO. 9 FOR ANSWER ON 02nd FEBRUARY, 2022 REGARDING " IMPORT/EXPORT FROM CHINA".

(a) to (b): The trade data of India's imports from China from FY 2014-15 to FY 2021-22 is as under:

(Values in USD billion)

YEAR	2014-15	2015-16	2016-17	2017-18	2018-19	2019-20	2020-21	2021-22 (Till Nov,21)
Import	60.41	61.71	61.28	76.38	70.32	65.26	65.21	59.03

(Source: DGCIS)

The imports from China have increased from USD 60.41 billion in 2014-15 to USD 65.21 billion in 2020-21, exhibiting marginal increase of 7.94% over 2014-15. However, the imports were static between 2019-20 & 2020-21. For the 7 years period prior to 2014-15, the imports from China increased from USD 17.47 billion in 2006-07 to USD 51.03 billion in 2013-14 exhibiting an increase of 192%. 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. Some of our imports from China like the Active Pharmaceutical Ingredients (APIs) and drug formulations provide the Indian pharma industry raw material for producing finished goods which are also exported out of India.

(c) to (d): The trade data of India's exports to China from FY 2014-15 to FY 2021-22 is as under:

(Values in USD billion)

YEAR	2014-15	2015-16	2016-17	2017-18	2018-19	2019-20	2020-21	2021-22 (Till Nov,21)
Export	11.93	9.01	10.17	13.33	16.75	16.61	21.19	15.62

(Source: DGCIS)

India's exports to China are growing steadily. The exports to China increased from USD 11.93 billion in 2014-15 to USD 21.19 billion in 2020-21, exhibiting an increase of 77.6% over 2014-15. The commodities exhibiting increase in exports include engineering goods, petroleum products, organic and inorganic chemicals, electronic goods, cotton yarn, marine products, minerals and ores etc. The Government of India has made sustained efforts to achieve a more balanced trade with China, including bilateral engagements to address the trade issues with China.

The Minister of Commerce and Industry
(Shri Piyush Goyal)

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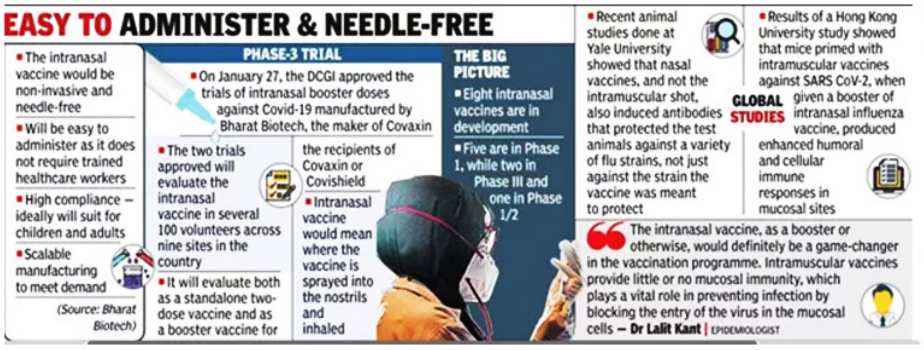
Nasal vaccine blocks virus at entry site, may be game-changer: Experts

PUNE: Health experts are betting big on drug maker Bharat Biotech's intranasal vaccine against Covid-19, which is expected to provide protection at entry point of virus. On January 27, the company got the regulatory approval for conducting Phase-3 clinical trials of its intranasal Covid-19 vaccine as a booster dose.



Virologist Dr Shahid Jameel told TOI that nasal vaccines for respiratory disease have the advantage of generating antibodies at mucosal surfaces — the first point of entry of these viruses. "They would be more effective in neutralising incoming viruses at the point of entry than injectable vaccines that give systematic immunity, which may help reduce transmission," he said.

He said though the data on under-development vaccines was awaited, the trick would be the right formulation to ensure effective vaccine antigen delivery to the mucosal immune system.

Another epidemiologist Dr Lalit Kant said the intranasal vaccine, as a booster or otherwise, would definitely be a game-changer in the vaccination programme. Intramuscular vaccines provide little or no mucosal immunity, which plays a vital role in preventing infection by blocking the entry of the virus in the mucosal cells, he said.

Dr Kant, who was the former head of the epidemiology and communicable diseases department at the Indian Council of Medical Research (ICMR), said mucous membranes contain their own immune defence system that combat pathogens transmitted by air, water or food. When challenged, these mucosal membranes produce B cells, which secrete immunoglobulin A (IgA) antibodies. "IgA antibodies work locally on mucosal surfaces found in the nose, stomach, and lungs," Dr Kant said.

He said polio vaccine worked this way, and has brought us nearer to eradication of poliomyelitis. Measles vaccine given as an aerosol has, however, not been as effective as the injectable one, he added.

Central health ministry officials and even national task force members did not wish to commit anything on the vaccine being used in the national immunization programme. "The trials are on and it would definitely be interesting to see the results," said a senior health official.

Dr Kant said it would be of special interest to see if the antibodies would be able to neutralize heterologous strains of the virus.

The Phase-3 randomized multi-centric clinical trials for the intranasal vaccine of Bharat Biotech will evaluate nasal vaccine for both the two-dose primary schedule and booster dose schedule. According to the company, the intranasal vaccine stimulates a broad immune response -- neutralizing IgG, mucosal IgA and T cell responses. Immune responses at the site of infection in the nasal mucosa are essential for blocking both infection and transmission. "The nasal route has excellent potential for vaccination due to the organized immune systems of the nasal mucosa," a company official said.

Source: TNN, 08.02.2022

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An R&D edge to the 'world's pharmacy'

Can India's formidable pharma sector — a global supplier of affordable drugs — innovate in time to stay ahead of the curve?

Last week's Union Budget had a hint of a suggestion on Government support for research initiatives in "sunrise" sectors, including pharmaceuticals.

For the pharmaceutical industry, which has showcased its manufacturing prowess to the world time and again, research offers the stepping stone to the next international trajectory. But unlike producing generics or branded

Pharmaceutical R&D is capital intensive and linked to unlimited risk | Photo Credit: yalax

formulations, research is a different ball game — capital-intensive and linked to unlimited risk.

In her budget address, Finance Minister Nirmala Sitharaman explained the government's intent to unlock newer opportunities for the pharmaceutical sector by fuelling research and development (R&D). "Supportive policies, light-touch regulations, facilitative actions to build domestic capacities, and promotion of research and development will guide the government's approach," she said.

The FM's statement was not isolated and follows a string of similar developments. Last October, the Department of Pharmaceuticals released a draft policy aimed at "catalysing research and development and innovation in the pharma- medtech sector in India".

A month later, addressing the Indian Pharmaceutical Alliance's global innovation conclave, Prime Minister Narendra Modi urged the industry to invest in becoming self-reliant in the production of key pharmaceutical raw materials.

Why innovate?

Known as a pharmacy to the world, India — thanks to its formidable pharmaceutical sector — has helped ease access to affordable drugs at home and abroad. Now, biopharmaceuticals is driving growth for global pharma with the emergence of biologics and biosimilars.

India's draft policy pegs the global biosimilar opportunity at $70 billion by 2027. Till October 2020, about 100 biosimilars were approved in India, with over 40 others under clinical development.

Lincoln Pharmaceuticals, which holds patents for some drug delivery processes, sees innovation being driven by market needs. Its Director, Munjal Patel, says, "We innovate on drug delivery systems. Our R&D is constantly on how to make drug delivery convenient for the patients. But in doing so, there are certain costly aspects such as bio-equivalence study of drugs that take away a lot of resources. Such R&D would get a boost if there is some recognition or special treatment for taking it up."

On the medical devices front, there are over 750 domestic manufacturers with an average investment of $2.3–2.7 million and turnover of $6.2-6.9 million, according to the policy draft.

The sector is heterogenous, consisting of large multinationals as well as small and medium enterprises (SMEs), and growing. Take medical ventilators maker Max Ventilator, which sees an enormous opportunity for designed and made-in-India patient-care devices including ventilators.

"We have enough talent in our country. But there is a lack of motivation to pursue R&D. It is good that the policymakers are addressing this. But this space will see growth only when companies are ready to invest and spend on R&D. Also, we need policies which encourage customers to prefer Indian products," said Ashok Patel, founder of Max Ventilator. The medical devices sector faces the challenge of cheap imports, with about 90 per cent of India's needs being imported from the US, Europe and China.

Challenges and enablers

The research draft addresses key challenges including an enabling regulatory framework and ecosystem that supports innovation and research, smoothening of processes for industry-academia linkages, and creation of infrastructure such as innovation hubs to foster R&D.

It points to fiscal support for innovation-focused companies, SMEs and start-ups. This includes tax exemptions and grant support, seed capital for start-ups in key emerging pharma and medical technologies, a special fund to promote medtech, a pharma-focused category-1 alternative investment fund, and equity funding as well as direct funding for late-stage clinical trials.

"Countries that have created such an ecosystem are reaping the market benefits and financial rewards of innovation," said the draft policy, holding out the promise of good global and local outcomes from robust initiatives in research.

Source: Rutam Vora, Business Line, 07.02.2022

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Surprise USFDA inspections to return

Demand for inspection at offshore facilities has been on the rise from some Republican senators

The US administration has decided to conduct surprise inspections of offshore manufacturing facilities reuters

US Food and Drug Administration will soon start unannounced onsite inspections of drug manufacturing facilities outside the US, including units in India. The USFDA had suspended most of its foreign inspections in March 2020 due to the covid-outbreak.

The US administration has decided to conduct surprise inspections of offshore manufacturing facilities to ensure quality products enter the US market. Besides, demand for surprise inspection at offshore facilities has also been on the rise from a section of Republican senators, who are seeking to offer a level-playing field to US manufacturers.

"Foreign pharmaceutical facilities are awarded significant lead time between the time they are notified of a facility inspection and the time the inspections take place. Domestic facilities do not receive the same treatment, receiving little to no advance notice prior to a facility inspection," wrote Joni Ernst, junior US senator from Iowa. On 13 January, she introduced a bill, Creating Efficiency in Foreign Inspections Act, which seeks to move pharma units back to the US to strengthen the supply chain. Over 40% of generic drugs for the US is imported from India and China, which is a also a major source of active pharmaceutical ingredients used in manufacturing drugs.

"We are getting inputs from companies on the USFDA move," said Sudarshan Jain, secretary general, Indian Pharmaceutical Alliance, a lobby group of large generic drug companies.

In 2014, the FDA ran similar surprise inspections that led to many companies being served warning letters and alerts.

Law firm Sidley Austin LLP said in research note that during the 2014 pilot programme regulatory action against Indian drug manufacturers had increased by 60%.

The bill proposes an amendment to Section 704 of the US Federal Drugs and Cosmetics Act to include an addendum saying that an officer conducting inspections on locations outside the US "shall not notify the owner or operator of such establishment of the planned inspection before the inspection occurs".

Exceptions will be made in case laws of a country where the facilities are located make it mandatory to issue advanced notice, but even then, it should be given "minimum" time.

India and the US have wrestled with the issue of generic drug exports in the past, while lobbying from both sides on supply chain diversification intensified when the Trump administration was in office.

The former US President's 'Make in America' pitch had targeted both Indian and Chinese drug manufacturers. But following the covid outbreak, Indian generic drug companies stepped up supply to meet increasing demand of medicines in the US market, including essential covid medications such as hydroxychloroquine. According to USFDA database, there is a shortage of over 164 drugs in the US.

Source: Divya Rajagopal, HT Mint, 07.02.2022

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Publishing details of export, import items may draw 6-month jail, 50k fine

NEW DELHI: Publishing of details linked to value, classification or quantity of individual export and import items could attract a jail term of up to six months or a fine of Rs 50,000 or both, the finance bill for 2022-23 has proposed.

The move is aimed at plugging the leak of such sensitive data and ensuring privacy of transactions entered into by exporters and importers. The bill makes it clear that nothing contained in this new section that has been proposed shall apply to any publication made by or on behalf of the central government.

The explanation in the bill said the expression "publishes" includes reproducing the information in printed or electronic form and making it available for the public.

Officials said the demand for stringent action had come from the trade bodies as commercially sensitive data was being published by some publications and websites hurting exporters and importers.

"The move is aimed at ensuring confidentiality and privacy of data of individual exporters and importers," said an official while making it clear that it does apply to any official trade data that is released by the government. The government publishes several data linked to exports and imports as part of overall trade data.

They said that the proposed changes were aimed at preventing hackers and publications publishing commercially sensitive data.

"The proposed clause will only criminalise the illicit publication of personalised, transaction level information by private entities, which affects the competitive position of Indian businesses in international trade and compromises their data privacy," the Central Board of Indirect Taxes and Customs (CBIC) said on Twitter.

Source: TOI, 06.02.2022

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First Nasal Spray For Treating Adult Covid Patients Launched In India

"FabiSpray is designed to kill the COVID-19 virus in the upper airways," reads the official statement.

Mumbai based innovation-driven global pharma company Glenmark has launched Nitric Oxide Nasal Spray (FabiSpray) in India, in partnership with SaNOtize, for treatment of adult patients suffering from COVID-19.

Glenmark received manufacturing and marketing approval from India's drug regulator, Drugs Controller General of India, for Nitric Oxide Nasal Spray as part of the accelerated approval process.

"Phase 3 trial in India met the key endpoints and demonstrated reduction of viral load of 94 per cent in 24 hours and 99 per cent in 48 hours. Nitric Oxide Nasal Spray (NONS) was safe and well-tolerated in COVID-19 patients. Glenmark to market NONS under the brand name FabiSpray," reads the official statement.

The company claims that when the Nitric Oxide Nasal is sprayed over nasal mucosa it acts as a physical and chemical barrier against the virus.

"FabiSpray is designed to kill the COVID-19 virus in the upper airways. It has proven anti-microbial properties with a direct virucidal effect on SARS-CoV-2. NONS when sprayed over nasal mucosa acts as a physical and chemical barrier against the virus, preventing it from incubating and spreading to the lungs," the statement reads.

Terming the spray an effective and safe antiviral treatment for COVID-19, Glenmark Pharmaceuticals Ltd's Chief Commercial Officer Robert Crockart said "we are confident it will offer patients a much needed and timely therapy option."

"As a leading pharmaceutical player, it is important that we are an integral part of India's fight against the COVID-19 pandemic. We are happy to receive regulatory approval for Nitric Oxide Nasal Spray (FabiSpray) and launch it in partnership with SaNOtize," he said.

Over the issue of clinical trials results, Dr. Monika Tandon, Senior VP and Head of Clinical Development in Glenmark Pharmaceuticals Ltd. said,"The results from this Phase 3, double blind, placebo controlled trial are encouraging. Demonstration of reduction in the viral load has significant positive impact from a patient and community perspective. In the current scenario, with new emerging variants exhibiting high transmissibility, NONS provides a useful option in India's fight against COVID-19." "As per studies conducted in the Utah State University USA, NONS is proven to kill 99.9 per cent of SARS-Cov-2 virus including Alpha, Beta, Gamma, Delta, and Epsilon variant within 2 minutes." She said.

Dr Srikanth Krishnamurthy one of the Principal Investigators of the study said, "I have had a chance to view the results of the study. Nitric Oxide Nasal Spray lowers the viral load and hastens RT-PCR negativity when used early in COVID 19 infection leading to recovery. Most importantly, viral load reduction with NONS has the potential to reduce the chain of transmission. Last but not the least, NONS being topical is safe and makes this therapeutic option very attractive".

Source : Statesman, 10.02.2022

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