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IDMA BULLETIN

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INDIAN DRUG MANUFACTURERS' ASSOCIATION

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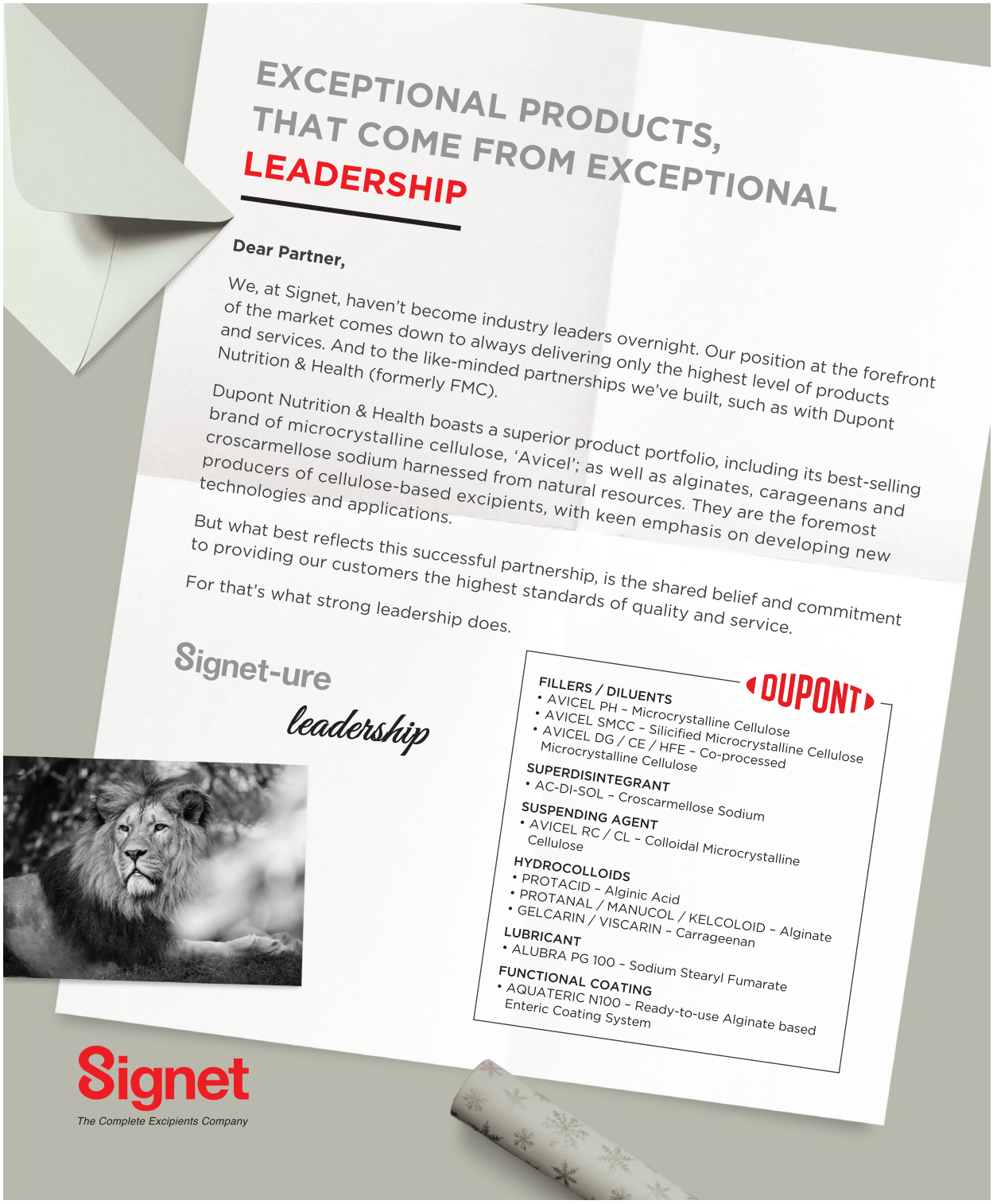
on

Generating global opportunities for a future-ready India
on Friday, 4th February, 2022 - | 3:00 PM - 4:00 PM IST

(Details on Page No. 4)

HIGHLIGHTS

- ★ **IDMA's persistent Representations on 'Route change' and 'Digitalisation of import/export permits' have been acknowledged - Two Public Notices issued by CBN** *(Page No. 7)*
- ★ **Do not assume COVID pandemic reaching 'end game', warns WHO** *(Page No. 30)*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IDMA BULLETIN

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Generating global opportunities for a future-ready India

Join us for an exclusive webinar

4th February, 2022 | 3:00 PM - 4:00 PM IST | Register now

Dear IDMA Member,

IIDMA & SAP are joining hands once again after the successful Global Bharat Webinar in 2021 for the IDMA - SAP WEBINAR on “Generating Global Opportunities for a Future-ready India on Friday, 4th February, 2022 from 3:00 PM to 4:00 PM IST. The information on the webinar and the Register link is **(https://growthmattersforum.com/webinar/generating-global-opportunities-for-a-future-ready-india?source=IDMA).**

The Registration is complimentary but necessary. Request members to REGISTER NOW and take benefit from the same.

As you aware, India's MSME segment is one of our economy's most potent growth engines. Now with the clarion call to Make in India and build an Atmanirbhar Bharat, today, the national expectations are pinned on the sector more than ever. So it is time for Leaders like you to embrace technology for sustainable growth and greater resilience.

We're proud to kickstart the 2022 edition of the Global Bharat Webinars with the 1st virtual session to help expand your business to global markets and scale new heights.

IDMA & SAP invite you to join us and discover how your business can access the right technology platforms and solutions to explore new global market opportunities and enable a digital-first company.

Request members to join this webinar to know more about the Global Bharat initiative & how technology will enable you to grow faster and help your companies and the Indian Pharma Industry!

Thanks & regards,

Daara B. Patel
Secretary - General

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We look forward to engaging and informative session with you.
Team CISCO Meraki

IDMA's persistent Representations on 'Route change' and 'Digitalisation of import/export permits' have been acknowledged - Two Public Notices issued by CBN - reg.

Dear Member,

We attach herewith two Public Notices issued by CBN. This is pursuant to IDMA's persistent Representations on 'Route change' and 'Digitalisation of import/export permits'.

We, at IDMA, thank the Central Bureau of Narcotics for the above two Public Notices which would accelerate progress in the Indian Pharmaceutical Industry. On behalf of our National President, Dr. Viranchi Shah, We would like to congratulate Mr. M Devesh, Chairman NDPS Committee for this excellent accomplishment.

Kindly note that the Public notice on 'Route Change' would give a big relief and flexibility to Industry and Trade whereas the Public notice on 'Modality on Submission of Applications' is only the first step towards digitalisation.

Thanks and regards,

Daara B Patel
Secretary – General

Change in modality for submission of applications of export authorization/ import certificate/ NOCs for export/ import of Narcotic Drugs/ Psychotropic Substances/ Controlled Substances - reg.

Public Notice F.No. XVI/ 13/ 04/Tech/Psy/2022, dated 13th January 2022

Based on the spirit of Government of India's initiative regarding ease of doing business, regular changes in business, social, health related activities due to COVID-19 Epidemic, considering the changing scenario of business and in order to facilitate the trade it has been decided that henceforth the exporter/importer of Narcotic Drugs/ Psychotropic Substances/ Controlled Substances can submit their applications online in the following manner:-

(i) Scanned copy of duly filled in Application Form alongwith copies of all the requisite documents (including the import certificate) duly self attested by the authorised signatory of the company should be sent on the following email id:-

For Narcotic Drugs	:	suptd-narco@cbn.nic.in
For Psychotropic substances	:	supdt-tech@cbn.nic.in
For Controlled substances	:	supdt-precursor@cbn.nic.in

NOTE:- For ease of understanding of the exporter/importer, the list of all the narcotic drugs/ psychotropic substances/ controlled substances given in various schedules/lists of NDPS Act/Rules, 1985 may be referred for this purpose. May also be viewed on our website www.cbn.nic.in under the heading manufacture / import/ export.

(ii) The application will be submitted only from the official email id of the firm.

(iii) In the subject heading of each application the phrase will be written as "Application for export or import of **the name of drug or substance".**

(iv) Application for export/import of narcotic drugs/psychotropic substances should invariably accompany with the receipt and challan of fee of Rs.1000/- paid through Govt. of India's Non-tax receipt portal (NTRP) www.bharatkosh.gov.in. (Detailed stepwise procedure for paying the fee through this portal is annexed with this notice)

(v) Before submitting application through email for export of narcotic drugs/ psychotropic substances/ controlled substances the company should ensure to send the original import certificate, issued by the Government of importing country, by post/courier to this office. The receipt of post/courier of sending original import certificate may be scanned and attached in mail. However, in such cases the export authorization will be issued only on receipt of original import certificate. (Rule 58(2)(b) of NDPS Rules, 1985)

(vi) The exporter/importer should ensure to submit single application for the intended export/import of Narcotic Drugs/ Psychotropic Substances/ Controlled Substances. They should also ensure to send their application on the respective email id as given above. In case of submission of multiple applications and other than specific email, all the application will not be considered.

(vii) The CBN will issue the export authorization/import certificate/ NOC after following the due procedure and the said export authorization/ import certificate/ NOC will be sent through speed post to the company.

(viii) The exporter/ importer should submit one pdf file for one application. Multiple applications in single pdf file shall not be entertained.

Narcotics Commissioner, Government of India , Central Bureau of Narcotics, Ministry of Finance, O/o the Narcotics Commissioner, 19, The Mall, Morar, Gwalior - 474 006

Route change for export consignment due to frequent change/cancellation/re-routing of international flights due to pandemic of COVID-19 - reg.

Public Notice F.No. XVI/ 13/04/Tech/ Psy/2022, dated 13th January 2022

It is in the notice of the department that there is worldwide logistic issue due to COVID-19 Epidemic. The cancellation and re-scheduling of schedules international flights is common now a days and the exporter of Narcotic Drugs, Psychotropic substances and Controlled Substances are facing difficulty in adhering to the routing for which export authorization/ NOC has been issued.

Therefore, in order to facilitate the trade, it has been decided that till **further orders,** the exporters in case of change in route (than that mentioned in the export authorization/ NOC issued by CBN) shall intimate on specific email id as given below:-

For Narcotic Drugs	suptd-narco@cbn.nic.in
For Psychotropic substances	supdt-tech@cbn.nic.in
For Controlled substances	supdt-precursor@cbn.nic.in

from the official email id of the firm, about the exact routing, at least 48 hours prior to the shipment of a consignment of Narcotic Drugs/ Psychotropic substances/ Controlled substances and proceed to export of the approved consignment with changed route without waiting for formal approval of CBN.

Narcotics Commissioner, Government of India, Central Bureau of Narcotics, Ministry of Finance, O/o the Narcotics Commissioner, 19, The Mall, Morar, Gwalior - 474 006.

● ● ●

Request for Suggestions : Recommendations in 161st Report of Department Related Parliamentary Standing Committee on "Review of the IPR Regime in India" – reg.

Dear Member,

This is with regards to the recommendations in 161st Report of Department Related Parliamentary Standing Committee on "Review of the IPR Regime in India" as shared by our IDMA, IPR Chairman, Dr. Gopakumar G Nair.

The entire report is available on **https://rajyasabha.nic.in**/ → committees → Department related (RS) → Commerce → Reports.

Also Press Release dated 23rd July 2021 relating to report of committees are available on **https://rajyasabha.nic.in/** → Press Release.

Interested members are requested to visit their website for detailed information.

For communicating to the Office of the Controller General of Patents, Designs and Trade Marks (CGPDTM), Mumbai. We hereby, request IDMA members to share their views, suggestions and proposals to IDMA, IPR, Chairman at gopanair@gnaipr.net with a copy to IDMA Secretariat at publications@idmaindia.com

Regards,

Daara B Patel

Secretary- General

IDMA

● ● ●

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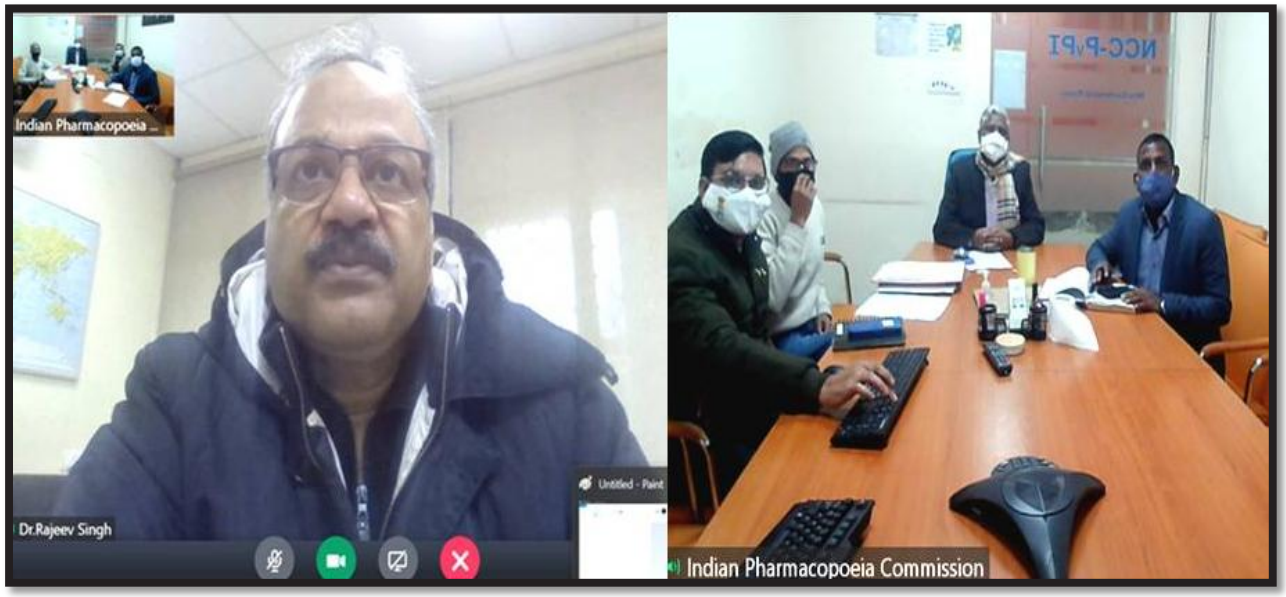
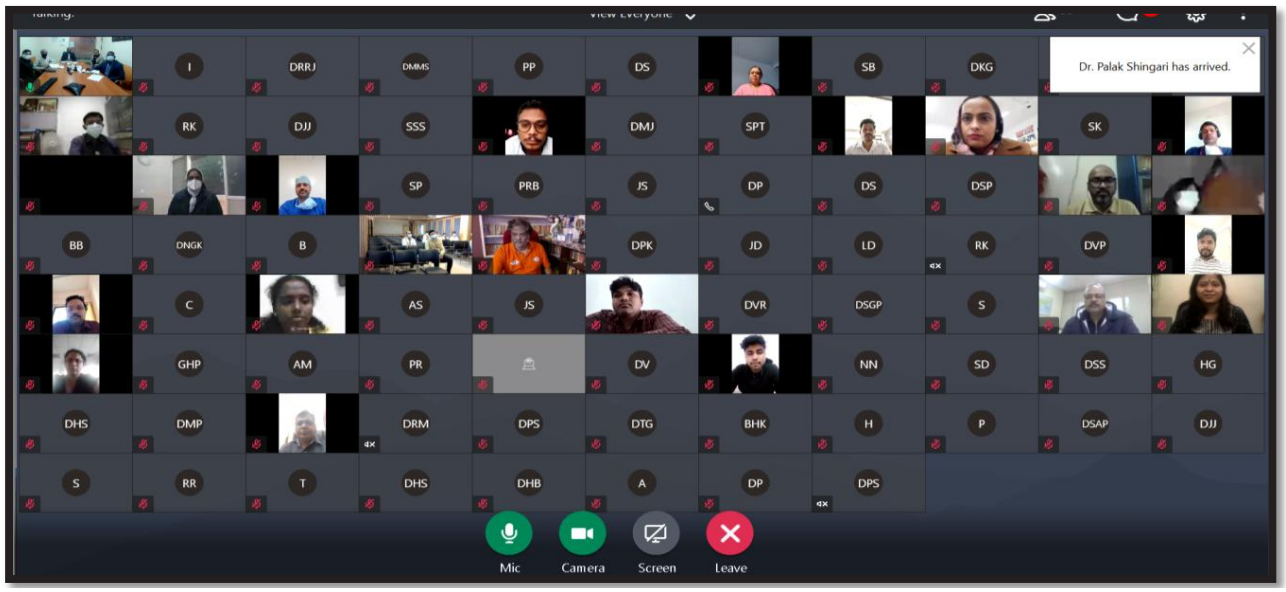
Virtual Worksop-cum-Training Programme on Pharmacovigilance for NABH Accredited Hospitals in India

Indian Pharmacopoeia Commission, National Coordination Centre for Pharmacovigilance Programme of India (NCC-PvPI), had signed a Memorandum of Understanding with National Accreditation Board for Hospitals and Healthcare Providers (NABH) for effective implementation of Pharmacovigilance system in the country.

NCC- PvPI successfully organised the Virtual Training on Pharmacovigilance for NABH Accredited Hospitals in India on 21st January 2022. The Training Programme was intended to provide a platform for the NABH-Accredited Hospitals to understand the systems and procedures involved in ADR-reporting and relevant practices. The training started with **welcome address by Dr. Jai**





Prakash, Officer-in-Charge, PvPI, followed by **Keynote address by Dr. Rajeev Singh Raghuvanshi**, Secretary-cum-Scientific Director IPC. Dr. Raghuvanshi extended his warm greetings and best wishes to all the participants on behalf of IPC. He also shared his expectation to further expand PvPI.

The resource persons for virtual Worksop-cum-training included experts from NABH representative, Indian Pharmacopoeia Commission, PvPI and ADR Monitoring Centre who trained the participants during the training. A total of **96 participants** from across the country attended the training programme. The training programme was aimed to enhance the involvement of NABH Hospitals in monitoring and reporting of ADRs to PvPI. The virtual training programme is expected to strengthen the Pharmacovigilance activity at their respective organizations in order to protect the safety and well-being of the patients. During the concluding remarks, **Dr. Jai Prakash**, Officer-in-Charge, PvPI, motivated the participants to report ADRs and enrol their organization as AMC under PvPI. He emphasized that Pharmacovigilance part of drug intervention is important not only during the drug development process but also after marketing authorization. Dr. Shashi Bhushan, Dr. R.S Ray, Mr. Akash Deep Rawat, Mr. Girjesh Vishwakarma, Mr. Omkar Mishra from NCC PvPI supported during the workshop.

Note: Please visit IPC website (www.ipc.gov.in) for regular updates.

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DGFT MATTERS

Procedures for application for Tariff Rate Quota (TRQ) under FTA/CECA for FY2022-23

Trade Notice No.33/2021-2022, dated 27th January, 2022

To,
Importers/Members of Trade and Commerce

1. Reference is invited to para 2.107 of the HBP, wherein the details of allocation of Tariff Rate Quota (TRQ) under various FTA/CECA are notified. The procedure for application of TRQ has been laid down in Annexure I, II and III of Appendix 2A of the Handbook of Procedures.
2. In this reference, kind attention is drawn to Trade Notice 40/2020-21 dated 04.02.2021 whereby the e-Tariff Rate Quota System for Imports was introduced. It is reiterated again that all applicants seeking Tariff Rate Quota (TRQ) for imports for the period FY2022-23 are to be submitted online using the "e-Tariff Rate Quota" system. The last date for e-TRQ applications for FY2022-23 is 28.02.2022. Please note that TRQ applications should not be submitted as 'Licence for Restricted Imports'.
3. The applicant may navigate to the DGFT Website to apply online as follows -- DGFT Website (https://dgft.gov.in) --> Services --> Import Management System --> Apply for TRQ
4. For guidance on these e- processes, the Help manual & FAQs may be accessed on the DGFT Website -- > Learn -- > 'Application Help & FAQs'. For any further assistance you may utilize any of the following channels –
   i. Raise a ticket through the DGFT Helpdesk service under Services -- > 'DGFT Helpdesk Service'
   ii. Call the toll-free Helpdesk number
   iii. Send an email to the Helpdesk on dgftedi@gov.in

This issues with the approval of Competent Authority.

File No. 01/53/8/AM22/Misc/I-1/IC[E-30586]

Md. Moin Afaque, Deputy Director General of Foreign Trade, Directorate General of Foreign Trade, Ministry of Commerce and Industry, Department of Commerce, New Delhi

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Draft rules to amend the New Drugs and Clinical Trials Rules, 2019 published - reg.

Drugs & Cosmetics Notification G.S.R.32(E), dated 21st January 2022

The following draft of certain rules further to amend the New Drugs and Clinical Trials Rules, 2019 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) in consultation with the Drugs Technical Advisory Board is hereby published 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 fifteen days from the date on which the 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, A Wing, Nirman Bhavan, New Delhi - 110011 or emailed at drugsdiv-mohfw@gov.in.

DRAFT RULES

1. (1) These rules may be called the **New Drugs and Clinical Trials (Amendment) Rules, 2022.**

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

2. In the New Drugs & Clinical Trials Rules, 2019 (hereinafter to be referred as principal rules), in rule 8, in sub rule 3(ii), at the end, the following Proviso shall be inserted, namely:-

"Provided that, where no communication has been received from the Central Licensing Authority to the applicant within the forty-five working days period, the registration of ethics committee shall be deemed to have been granted by the Central Licensing Authority and such registration shall be deemed to be legally valid for all purposes and the applicant shall be authorized to initiate clinical trial in accordance with these rules."

3. In the principal rules, in rule 8, after sub-rule 3, the following sub-rule shall be inserted, namely:-

"(3A) The applicant who has taken deemed approval under the Proviso to sub-rule 3(ii) shall before initiating the functions of the Ethics Committee, inform the Central Licensing Authority in Form CT-02A and the Central Licensing Authority shall on the basis of the said information, take on record the Form CT-02A which shall become part of the official record and shall be called deemed registration of the Central Licensing Authority."

4. In the principal rules, in rule 22, in sub-rule (2), the following proviso shall be inserted, namely:-

"Provided that, where no communication has been received from the Central Licensing Authority to the applicant within the ninety working days period, the permission to conduct all clinical trial shall be deemed to have been granted by the Central Licensing Authority and such permission shall be deemed to be legally valid for all purposes and the applicant shall be authorized to initiate clinical trial in accordance with these rules."

5. In the principal rules, in rule 22, after sub-rule (2), the following sub-rule shall be inserted, namely:-

"(2A) The applicant who has taken deemed approval under the proviso to sub-rule (2) shall before initiating the clinical trial, inform the Central Licensing Authority in Form CT-06A and the Central Licensing Authority shall on the basis of the said information, take on record the Form CT-06A which shall become part of the official record and shall be called deemed approval of the Central Licensing Authority."

6. In the principal rules, in rule 24, the following proviso shall be inserted, namely:—

"Provided that, where no communication has been received from the Central Licensing Authority to the applicant within the ninety working days period, the

permission to conduct all clinical trial shall be deemed to have been granted by the Central Licensing Authority and such permission shall be deemed to be legally valid for all purposes and the applicant shall be authorized to initiate clinical trial in accordance with these rules:

Provided further that the applicant who has taken deemed approval under this rule shall before initiating the clinical trial, inform the Central Licensing Authority in Form CT-06A and the Central Licensing Authority shall on the basis of the said information, take on record the Form CT-06A which shall become part of the official record and shall be called deemed approval of the Central Licensing Authority."

7. In the principal rules, in rule 34, in sub-rule (2), the following Proviso shall be inserted, namely:—

"Provided that, where no communication has been received from the Central Licensing Authority to the applicant within the ninety working days period, the permission to conduct bioavailability or bioequivalence study of the new drug or investigational new drug shall be deemed to have been granted by the Central Licensing Authority and such permission shall be deemed to be legally valid for all purposes and the applicant shall be authorized to initiate such study in accordance with these rules."

8. In the principal rules, in rule 34, after sub-rule (2), the following sub-rule shall be inserted, namely:—

" (2A) The applicant who has taken deemed approval under the proviso to sub-rule (2) shall before initiating bioavailability or bioequivalence study of the new drug or investigational new drug, inform the Central Licensing Authority in Form CT-07A and the Central Licensing Authority shall on the basis of the said information, take on record the Form CT-07A which shall become part of the official record and shall be called deemed approval of the Central Licensing Authority."

9. In the principal rules, in rule 53, in sub-rule(1) and sub-rule (2), the following Proviso shall be inserted, namely:—

"Provided that, where no communication has been received from the Central Licensing Authority to the applicant within the period of ninety working days, the permission to manufacture new drugs or investigational new drugs for clinical trial or bioavailability or bioequivalence study or test and analysis shall be deemed to have been granted by the Central Licensing Authority and such permission shall be deemed to be legally valid for all purposes and the applicant shall be authorized to manufacture the new drug or investigational new drug for said purposes in accordance with these rules."

10. In the principal rules, in rule 53, after sub-rule (2), the following sub-rule shall be inserted, namely:—

"(2A) The applicant who has taken deemed approval under the proviso to sub-rule (1) and sub-rule (2) shall before manufacturing the new drug or investigational new drugs for the said purposes inform the Central Licensing Authority in Form CT-11 A and the Central Licensing Authority shall on the basis of the said information, take on record the Form CT-11A which shall become part of the official record and shall be called deemed approval of the Central Licensing Authority."

11. In the principal rules, in rule 60, in sub-rule (1)(ii), following proviso shall be inserted, namely:—

"Provided that, where no communication has been received from the Central Licensing Authority to the applicant within the period, to manufacture unapproved active pharmaceutical ingredient for development of pharmaceutical formulation for test or analysis or clinical trial or bioavailability and bioequivalence study shall be deemed to have been granted by the Central Licensing Authority and such permission shall be deemed to be legally valid for all purposes and the applicant shall be authorized to manufacture the new drug or investigational new drug for said purposes in accordance with these rules."

12. In the principal rules, in rule 60, in sub-rule (2)(ii), for the proviso attached thereto, the following shall be substituted, namely:—

"Provided that, where no communication has been received from the Central Licensing Authority to the applicant within the period, to manufacture unapproved active pharmaceutical ingredient for development of pharmaceutical formulation for test or analysis or clinical trial or bioavailability and bioequivalence study shall be deemed to have been granted by the Central Licensing Authority and such permission shall be deemed to be legally valid for all purposes and the applicant shall be authorized

to manufacture the new drug or investigational new drug for said purposes in accordance with these rules.

Provided further that in case of rejection, the applicant may request the central Licencing Authority, to consider the application within a period of sixty days from the date of rejection of the application on payment of fee as specified in the Sixth Schedule and submission of required information and documents."

13. In the principal rules, in rule 60, after sub-rule (2), the following sub-rule shall be inserted, namely:—

"(2A) The applicant who has taken deemed approval under the proviso to sub-rule (1) shall before manufacturing the new drug or investigational new drugs for the said purposes inform the Central Licensing Authority in Form CT-15A and the Central Licensing Authority shall on the basis of the said information, take on record the Form CT-15A which shall become part of the official record and shall be called deemed approval of the Central Licensing Authority"

14. In the principal rules, in the Eighth Schedule,—

(i) after Form CT-02, the following Form shall be inserted, namely:—

"FORM CT-02A

(See rules 8, 9, 10 and 14)

INFORMATION TO INITIATE THE FUNCTIONING OF ETHICS COMMITTEE RELATING TO CLINICAL TRIAL OR BIOAVAILABILITY AND BIOEQUIVALNENCE STUDY

I ……. (Name and full address with contact details) hereby inform the Central Licensing Authority to initiate functioning of ethics committee as specified in the New Drugs and Clinical Trials Rules, 2019.

2. The ethics committee shall observe the conditions of registration specified in Chapter III of the New Drugs and Clinical Trials Rules, 2019 and the Drugs and Cosmetics Act, 1940.

Place: ……. Signature

Date: ……..... (Name and designation)"

(ii) after Form CT-06, the following Form shall be inserted, namely:—

"FORM CT-06A

(See rule 22)

INFORMATION TO INITIATE CLINICAL TRIAL OF NEW DRUG OR INVESTIGATIONAL NEW DRUG

I/We, ... (name and full postal address of the applicant) of..... hereby inform to initiate the conduct clinical trial on new drug or investigational new drug.

The details of the application areas under:

1. Name of Applicant:	
2. Nature and constitution: (proprietorship, partnership including limited liability partnership, company, society, trust, other to be specified)	
3. (i) Sponsor address, telephone number, mobile number, fax number and e-mail id:	

(ii) Clinical trials site address, telephone number, mobile number, fax number and e-mail id: (iii) Name and address of person responsible for payment of compensation, if any: (iv) Address for correspondence: [corporate or registered office or clinical trial site]	
4. Details of new drugs or investigational new drugs and clinical investigation site [As per Annexure].	
5. Phase of the Clinical Trial	
6. Clinical trial protocol number with date:	
8. I hereby declare that I have already submitted the application under rule 21 of these rules and have been granted deemed approval under rule 22(2) and enclosed the documents as specified in the Second Schedule ofthe New Drugs and Clinical Trials rules, 2019.	
9. I hereby state and undertake that: (i) I shall comply with all the provisions of the Drugs and Cosmetics Act,1940, and the New Drugs and Clinical Trials Rules, 2019.	

Place: …….

Date: …….....

Signature

(Name and designation)

Annexure:

Details of new drugs or investigational new drugs:

Names of the new drug or investigational new drug:	
Therapeutic class:	
Dosage form:	
Composition:	
Indications:	

Details of clinical trial site:

Names and address of clinical trial site:	
Ethics committee details:	
Name of investigator:	

”

(iii) after Form CT-07, the following Form shall be inserted, namely:—

“FORM CT-07A

(See Rules 34, 35, 36, 37 and 38)

INFORMATION TO INITIATE BIOAVAILABILITY OR BIOEQUIVALENCE STUDY OF NEW DRUG OR INVESTIGATIONAL NEW DRUG

I/We, ...(name and full postal address of the applicant) of ..... hereby inform to initiate to conduct bioavailability or bioequivalence study (*strike off whichever is not applicable*) of the new drug or investigational new drug as per protocol number_____dated_____in the below mentioned study centre.

2. Details of new drug or investigational new drug and study centre [As per Annexure].

3. This deemed approval is subject to the conditions prescribed in part B of Chapter V of the New Drugs and Clinical Trials Rules, 2019 under the Drugs and Cosmetics Act, 1940.

Place: ……. Signature

Date: ……..... (Name and designation)

Annexure:

Details of new drugs or investigational new drugs:

Names of the new drug or investigational new drug:	
Therapeutic class:	
Dosage form:	
Composition:	
Indications:	

Details of clinical trial site:

Names and address of clinical trial site:	
Ethics committee details:	
Name of investigator:	

”

(iv) after Form CT-11, the following Form shall be inserted, namely:—

“FORM CT-11A

(See rules 53, 54, 55, 56, 57 and 58)

INFORMATION TO MANUFACTURE NEW DRUG OR INVESTIGATIONAL NEW DRUG FOR CLINICAL TRIAL, BIOAVAILABILITY OR BIOEQUIVALENCE STUDY OR FOR EXAMINATION, TEST AND ANALYSIS

I/We, ...(name and full postal address of the applicant) of..... hereby inform to initiate the manufacturing of the new drug or investigational new drug for conduct of clinical trial or bioavailability or bioequivalence study as per protocol number__dated__inthebelow mentioned clinical trial sites or bioavailability and bioequivalence study centre [As per Annexure] or for examination, test and analysis.

Serial Number	Name of the new drug or investigational new drug to be manufactured.	Class of new drug or investigational new drug.	Quantity to be manufactured.

2. This deemed approval is subject to the conditions specified in the Chapter VIII of New Drugs and Clinical Trials Rules, 2019 under the Drugs and Cosmetics Act, 1940.

3. Details of manufacturer and manufacturing site under this licence.

Serial Number	Name and address of manufacturer (full address with telephone, fax and e-mail address of the manufacturer).	Name and address of manufacturing site (full address with telephone, fax and e-mail address of the manufacturing site).

Place: …….

Date: …….....

Signature

(Name and designation)

Annexure:

Details of clinical trial site:

Names and address of clinical trial site:	
Ethics committee details:	
Name of investigator:	

”

(v) after Form CT-15, the following Form shall be inserted, namely:—

“FORM CT-15A

(See rules 60, 61, 62, 63 and 64)

INFORMATION TO MANUFACTURE UNAPPROVED ACTIVE PHARMACEUTICAL INGREDIENT FOR THE DEVELOPEMNT OF FORMULATION FOR TEST OR ANALYSIS OR CLINICAL TRIAL OR BIOAVAILABILITY OR BIOEQUIVALENCE STUDY

I/We, ... (name and full postal address of the applicant) of ..... hereby inform to manufacture the unapproved active pharmaceutical ingredient specified below to manufacture its formulation for test or analysis or for conduct of clinical trials or bioavailability or bioequivalence study.

Name of the unapproved active pharmaceutical ingredient (API) to be manufactured	Quantity

2. Details of Manufacturer, Manufacturing site of active pharmaceutical ingredient.

Serial number	Name and address of manufacturer (full address with telephone, fax and e-mail address of the manufacturer)	Name and address of manufacturing site (full address with telephone, fax and e-mail address of the manufacturing site)

3. Details of Manufacturer, Manufacturing site of formulation manufacturer to be supplied.

Serial number	Name and address of formulator (full address with telephone, fax and e-mail address of the manufacturer)	Name and address of site where the manufactured unapproved active pharmaceutical ingredient to be used (full address with telephone, fax and e-mail address of the manufacturing site)

4. This deemed approval is subject to the conditions specified in Chapter VIII of the New Drugs and Clinical Trials Rules, 2019 under the Drugs and Cosmetics Act, 1940.

Place: …….

Date: …….....

Signature

(Name and designation)

Annexure

Details of record of unapproved active pharmaceutical ingredient manufactured:

Serial number	Date of manufacture	Licence number	Name of the unapproved active pharmaceutical ingredient	Quantity manufactured	Manufactured for

Details of reconciliation of unapproved active pharmaceutical ingredient manufactured:

Date	Name of the unapproved active pharmaceutical ingredient	Licence number	Quantity manufactured	Quantity supplied	Quantity remained	Supplied to	Quantity – left over or remain unused or got damaged or expired or found of sub-standard quality	Action taken

*** Write NA where not applicable.** ".

F.No. X.11014/29/2021-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 Gazette of India vide notification number G.S.R. 227(E), dated the 19th March, 2019 and last amended vide notification No. G.S.R. … (E), dated the*

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Gas Cylinder Rules, 2016 amended (1st Amendment of 2022) - reg.

Industrial Policy Notification G.S.R.44(E), dated 20th January 2022

(Published in the Gazette of India on 25th January, 2022)

WHEREAS the draft of certain rules further to amend the Gas Cylinder Rules, 2016 was published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-Section (i), dated the 25th June, 2021, vide number G.S.R.462 (E), dated the 25th June, 2021, inviting objections and suggestions from all persons likely to be affected thereby, before the expiry of a period of thirty days from the date on which the copies of the Official Gazette containing the said notification were made Available to the public;

AND WHEREAS, the copies of the said Gazette were made available to the public on 25th June, 2021;

AND WHEREAS, objections and suggestions received from the public on the said draft rules were considered;

NOW, THEREFORE, in exercise of the powers conferred by sections 5 and 7 of the Explosives Act, 1884 (4 of 1884), the Central Government hereby makes the

following rules further to amend the Gas Cylinder Rules, 2016, namely:-

1. Short title and commencement

(1) These rules may be called the **Gas Cylinders (Amendment) Rules, 2022.**

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

2. In the Gas Cylinders Rules, 2016 in rule 6, in Sub-rule (2) after clause (b), the following clause shall be inserted, namely:-

"(c) All the high pressure cylinders and Cryogenic containers used for filling of Non-Toxic, Non-Flammable Gases and Liquids shall have permanent and tamper proof marking in form of Bar Code or RFID or QR code or any means of electronic identification number at conspicuous place on cylinders and containers.

Provided that for the cylinders manufactured before the publication of these rules shall have above said permanent and tamper proof marking, before expiry of six months in case of oxygen cylinders and one year in case of other non-toxic and non-flammable gas cylinders from the date of publication of these rules."

F.No.P-13033/32/2021-EXPLOSIVE-Part(1)

Sumita Dawra, Additional Secretary, Department of Industrial Policy and Promotion, Ministry of Commerce and Industry, New Delhi

Note: *The principal rules were published in the official Gazette of India vide notification number G.S.R. number 1081(E) dated 22nd November, 2016 and subsequently amended as follows:*

(1) G.S.R. 189(E) dated 27th February, 2018

(2) G.S.R. 44(E) dated 23rd January, 2019.

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DoP invites application under PLI Scheme for the left over slots/quantity for Promotion of Domestic Manufacturing of critical Key Starting Materials (KSMs)/Drug Intermediates and APIs - reg.

No. 31026/16/2020-Policy/Scheme, dated: 27th January, 2022

1. Department of Pharmaceuticals had issued guidelines for the Production Linked Incentive (PLI) Scheme for Promotion of Domestic Manufacturing of critical Key Starting Materials (KSMs)/Drug Intermediates and Active Pharmaceuticals Ingredients (APIs) in the Country on 29th October 2020. Applications were invited under the Scheme which have already been appraised and selected.

The Department further invites applications from eligible applicants under the Scheme for the left over slots/quantity for the following eligible products:-

Sr. No.	Target Segment	Name of Eligible Product	Minimum Annual Production Capacity as per Scheme Guidelines (in MT)	Shortfall in Minimum Annual Production Capacity (in MT)	Maximum no. of applicants to be selected
1.	Key Fermentation based KSMs/Drug Intermediates	Erythromycin Thiocynate (TIOC)	800	1,600 MT	2
		7 - ACA	1000	1,000 MT	1

2.	Fermentation based niche KSMs/Drug Intermediates /APIs	Neomycin	80	160 MT	2
		Gentamycin	40	80 MT	2
		Vitamin B1	200	200 MT	1
		Clindamycin Base	60	120 MT	2
		Streptomycin	50	100 MT	2
		Tetracycline	200	400 MT	2
3.	Key Chemical Synthesis based KSMs/Drug Intermediates	Dicyandiamide (DCDA)	8000	32,000 MT	4
		2-MNI	800	3200 MT	4

2. The eligible applicants may apply through online only. The link is https://plibulkdrugs.ifciltd.com/. The detailed guidelines of the Scheme is available at https://pharmaceuticals.gov.in/sites/default/files/REVISED%20 GUIDELINES%20FOR %20BULK%20DRUGS-29-10-2020_1.pdf.

3. The last date for filing of the application is 45 days from the issuance of the Notice.

N. K. Joshi, Under Secretary, Ministry of Chemicals & Fertilizers, Department of Pharmaceuticals, Shastri Bhawan, New Delhi.

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GOVERNMENT PRESS RELEASE

Dr Mansukh Mandaviya launches NIPER Research Portal

Research and Innovation is a necessity for the sustained growth of the pharmaceuticals sector - Dr Mansukh Mandaviya

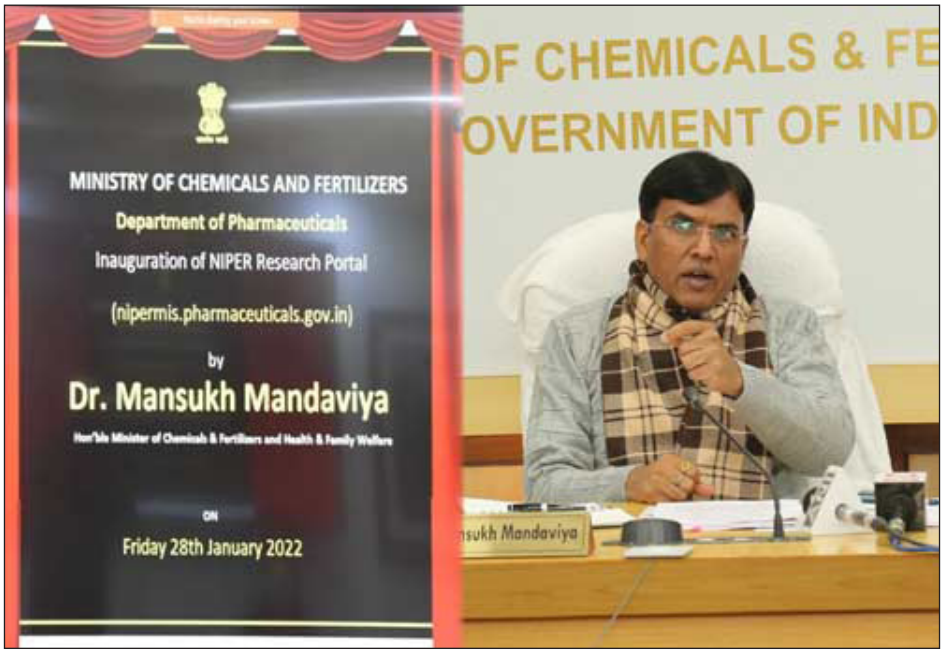
Industry-Academia Cooperation is crucial to channelize the young talent and human resources– Dr Mansukh Mandaviya

Union Minister for Chemicals and Fertilizers Shri Mansukh Mandaviya today launched NIPER Research Portal along with Shri Bhagwanth Khuba, Minister of State for Chemicals and Fertilizers in presence of Dr V. K Paul, Member (Health), Niti Aayog. National Institute of Pharmaceutical Education and Research (NIPER) Research Portal has been created with the aim to disseminate the information about all the NIPERs and their research activities, patents filed and Publication information at one place so that a industry and other stakeholders know about them.

Reiterating the vision of the Prime Minister Shri Narendra of Jai Jawan, Jai Kisan, Jai Vigyan and Jai Anusandhaan, Dr Mansukh Mandaviya said that Research & Development is one of the crucial pillars for a country's economy. He said that we need to harness this energy of aspirations of all stakeholders and create a holistic ecosystem. Our expertise in generics can also be further expanded to other sectors, he added.

Pointing towards the importance of healthy competition both in Industry and Academia, the Union Minister noted that competition and demand is a necessity of research and innovation as this promotes quality ideas and solutions for our citizens. He stressed that Research and Innovation is a necessity for the sustained growth of pharmaceuticals sector.

The Minister stated that the country already has young talent and human resources, but we need to channelize them effectively through Industry-Academia cooperation. *To enhance this industry–Academia collaboration, the Department of Pharmaceuticals has created this*



Research Portal to capture the research activities of all seven NIPERs, he informed. He said that that the platform inaugurated today would help us in promoting this synergy and would be a boon for our industries, especially the MSME sector.

Shri Bhagwanth Khuba said India is the third-largest pharmaceutical manufacturing country and our vaccine development story is an example of effective cooperation among stakeholders. He said that the platform will track the research and tasks of all NIPERS. He further said that the Government is committed to promote research and innovation and this portal is a step in that direction.

Dr VK Paul recollected the key role played by NIPERs in India's health ecosystem. He requested the government to streamline the funding pipeline and expedite the budgets allocated. He urged the industry to provide support like the NIPERs research fund for priority areas. He also encouraged NIPERs to create a vibrant scientific community by engaging with stakeholders and mobilizing ideas of the young generation, promoting academic autonomy and delivering on their research goals.

Accentuating the importance of NIPER's Research Program, which focuses on the needs of the hour, the Secretary, Department of Pharmaceuticals, Ms S. Aparna said that the importance of Research and Innovation has never been more important and more apparent than in the last two years of the global pandemic. We have seen the need for new drugs, re-purposed drugs, safer drugs, more efficacious drugs and the most affordable drugs to help mankind, she added. Shri highlighted that the portal will promote research work that is more relevant to the current evolving need of the sector and the requirements of the patient community.

The purpose of this portal is to authenticate availability of the research work that is ongoing. It will help other researchers and especially the industry to get in touch with the relevant organization so that they can work together and make the research more purposeful and meaningful. For long, research institutes have been working in silos or isolation. The research portal will try to bring together research institutions spread across different departments within government and also these institutions with industries. The Ministry of Chemicals and Fertilizers also requested all relevant research institutions like the Department of Biotechnology, Department of Scientific and Industrial Research, Ministry of AYUSH, ICMR etc., and even DRDO, where a lot of pharmaceuticals sector-related research takes place to join this portal.

Kindly click the link below to see the portal:

http://nipermis.pharmaceuticals.gov.in

Source: PIB Delhi, 28.01.2022

Innovation in R & D top focus

Living with the pandemic for two years has caused strategic shifts in business models that are here to stay. In an emailed interview with Sohini Das, chairman of Hyderabad based Dr Reddy's Laboratories ***Satish Reddy*** *outlines how the pharma industry came together globally to produce essential Covid-19 drugs, vaccines, sanitisers and other items. Moreover, ahead of the Union Budget, the industry has already made representations for creating a policy environment to encourage innovation. Edited excerpts:*

The pandemic has caused significant shifts in the dynamics of the pharma industry. Your comments.

I think that after two years of living with the pandemic, these are some very important points to reflect on. And all the points that you mention – shifts in focus areas, agility in R&D and supply, and collaborations – I see them as interconnected. Our way of working as an industry, for instance, has become far more collaborative. At the start of the pandemic, for almost two months, there were daily calls between industry leaders.

I would like to speak from our own experience at Dr Reddy's. When the pandemic started, vaccines and anti-virals or even sanitisers were not core to our business model and therapy choices. We went from that position to successfully being able to offer treatment options for the entire spectrum of Covid-19 indications—vaccine, mild, moderate, severe and more—in quick time. To achieve this, several components had to come together well.

Next, we had to progress towards creating or facilitating those required capabilities very quickly. In some areas, we invested in developing capabilities in-house. For many others, we opted for a model based on partnerships because we realised that this approach would best serve the urgent healthcare needs of the day.

You ventured into new areas like antivirals. Will there be a strategic shift in your business model?

Apart from venturing into antivirals and other spaces during the pandemic as Covid therapeutics that I mentioned earlier, with regard to long horizon shifts in focus areas, yes definitely our experiences during the pandemic may very well lead us to explore some long-term business shifts. For example, we have said earlier that based on our learnings from the Sputnik V vaccine, we may consider the viral vaccines and viral vector platforms space as a new investment and growth area in the long term.

What kind of changes or reforms does the Industry want at the policy level?

Yes, like I was saying earlier, we have had the opportunity to meet with the highest levels of the Government of India during the last two years of the pandemic, particularly as part of efforts by the Indian Pharmaceutical Alliance (IPA). Apart from taking stock of COVID therapeutics in the pandemic, we have also had opportunities to make representations on policy matters.

I think innovation in R&D is a big focus area for us as a company and indeed the pharma industry in India. Innovation needs long-term vision, planning and investment in capabilities and talent. It also needs to factor in the cost of risk, long gestation periods and even the cost of failure. So some of our most passionate policy representations to the Government have centred on creating an enabling ecosystem for innovative R&D in pharma.

What kind of representations have you made to the Centre?

Funding for R&D would be one of the biggest components of such an ecosystem. Here, along with

the pharma industry, I think key players would be the Government obviously, and also regulators, academic institutions, start-up and tech entrepreneurs, as well as private funding from venture capitalists or private equity. Policy incentives such as restoration of weighted deduction in R&D expenditure, expansion of the scope of the patent box, special innovation funds, and other measures would be important.

Besides funding, clear policies to support and spur innovation; a regulatory landscape that offers clear timelines, accountabilities and support to clinical trials in India; industry-academia collaboration; cultivating the right talent and skills; and creation of innovation hubs would be other components of such an enabling ecosystem.

What is your opinion on the draft R&D policy?

I do want to highlight two developments that I thought were steps in the right direction. One is the draft R&D policy that is currently under consideration. The policy appears to be inclusive and comprehensive, and also mindful of realistic requirements of innovative R&D. The other is the first-ever Global Innovation Summit of the pharma industry held in November 2021 and inaugurated by the Prime Minister of India himself. The Summit saw participation from the Government, industry and other stakeholders and lively discussions on all of the above matters. Our close consultation and meetings with the Government continues, and the industry will look forward to implementation and progress on these issues whilst playing its part in making quality innovative medicines available to patients in need.

Source: Business Standard, 24.01.2022

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In Lok Sabha & In Rajya Sabha

In Rajya Sabha

Stringent law against manufacturers of spurious drugs

Rajya Sabha Unstarred Question No. 1780

Shri Satish Chandra Dubey:

Q. Will the Minister of **Chemicals and Fertilizers** be pleased to state:

(a) whether Government has any proposal to enact a stringent law against manufacturers of spurious drugs, as spurious drugs were found at many places during the COVID-19 situation;

(b) if so, the details thereof, if not, the reasons therefor; and

(c) the details of its impact on pharmaceutical sector?

Answered on 14th December 2021

A. (a), (b) & (c): The manufacture, sale and distribution of drugs are primarily regulated in the country under the provisions of Drugs & Cosmetics Act & Rules 1945 made thereunder through a system of licensing and inspection by State Licensing Authorities appointed by respective State Governments. Licensee is required to comply with all the condition of license as prescribed under Drugs & Cosmetics Rules, 1945 and State Licensing Authorities are empowered to take action on violation of any conditions of such licenses including prosecution in appropriate Court of law. The Drugs and Cosmetics Act, 1940 was amended under Drugs & Cosmetics (Amendment) Act 2008 to provide stringent penalties for manufacture of spurious and adulterated drugs. Certain offences have also been made cognizable and non-bailable.

Minister of State for Chemicals & Fertilizers and New & Renewable Energy (Shri Bhagwanth Khuba)

Benefits of Janaushadhi Kendras

Rajya Sabha Unstarred Question No. 1784

Shri Prakash Javadekar:

Q. Will the Minister of **Chemicals and Fertilizers** be pleased to state:

(a) the number of Janaushadhi Kendras operative in the country;

(b) the details of cost differential in the medicines provided through Janaushadhi Kendras;

(c) whether it has come to the notice of Government that many doctors do not prescribe or write in their prescription the generic name of the medicine; and

(d) the steps Government intends to take in this regard?

Answered on 14th December 2021

A. (a): As on 07.12.2021, about 8,560 Pradhan Mantri Bhartiya Janaushadhi Kendras (PMBJKs) are functional under the Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) covering all the districts of the country. State/Union Territory-wise list of PMBJKs is enclosed as **Annexure.**

(b): A medicine under PMBJP is priced on the principle of a maximum of 50% of average price of the top three brands of that medicine. Thus, the price of Jan Aushadhi Medicines is cheaper at least by 50% and in some cases, by 80% to 90% of the market price of the branded medicines. The availability of quality generic medicines at affordable prices to all through PMBJKs has resulted in substantial savings to the patients. An illustrative list comparing the prices of generic medicines under PMBJP and non-generic branded medicines available in the market is as under:

Sr. No.	Name of Medicine	PMBJP Price (in Rs.)	Avg. MRP of branded Medicines (in Rs.)	Savings
1	Atorvastatin Tablets IP 10mg	8	58	86%
2	Amlodipine Tablets IP 5mg	5	27	81%
3	Glimepiride Tablets IP 2mg	5	62	92%

4	Metformin Hydrochloride 500mg (Prolonged release) and Glimepiride 1mg Tablets IP	16	69	77%
5	Paracetamol Tablets IP 650 mg	12	28	57%
6	Levocetirizine Tablets IP 5 mg	7	59	88%
7	Gemcitabine Injection IP 200mg	240	1,303	82%
8	Docetaxel Injection IP 80 mg	1,800	15,123	88%

(c)& (d): The erstwhile Medical Council of India vide its Circular No.-MCI- 211(2)(Gen.)/2017-Ethics/104728 dated 21.04.2017 has advised all doctors for prescription of Drugs with a generic name. Department has also requested the State Governments time to time for advising the Government Doctors to prescribe generic medicines only.

Annexure

Statement referred to in part (a) of Rajya Sabha Unstarred Question No. 1784 for 14.12.2021 raised by Shri Prakash Javadekar regarding Benefits of Janaushadhi Kendras

State/UT-wise list of PMBJK's functional across the country as on 07.12.2021		
Sr. No.	**Name of the State/UT**	**Number of PMBJK functional**
1	Andaman and Nicobar Islands	3
2	Andhra Pradesh	183
3	Arunachal Pradesh	28
4	Assam	87
5	Bihar	271
6	Chandigarh	7
7	Chhattisgarh	241
8	Delhi	375
9	Goa	10
10	Gujarat	551
11	Haryana	232
12	Himachal Pradesh	63
13	Jammu And Kashmir	119
14	Jharkhand	75
15	Karnataka	955
16	Kerala	950
17	Ladakh	2
18	Lakshadweep*	0
19	Madhya Pradesh	240
20	Maharashtra	623
21	Manipur	33
22	Meghalaya	15
23	Mizoram	22
24	Nagaland	16
25	Odisha	344
26	Puducherry	18
27	Punjab	304
28	Rajasthan	137
29	Sikkim	3
30	Tamil Nadu	861
31	Telangana	158
32	Dadra And Nagar Haveli & Daman And Diu	36
33	Tripura	24
34	Uttar Pradesh	1177
35	Uttarakhand	215
36	West Bengal	182
Grand Total		8,560

** Medicines are directly supplied to the administration of the Union Territory of Lakshadweep.*

Manufacturing Capacity of Covid- 19 Vaccine Making Companies

Rajya Sabha Unstarred Question No. 1845

Dr. Kanimozhi Nvn Somu:

Shri M. Mohamed Abdulla:

Q. Will the Minister of **HEALTH AND FAMILY WELFARE** be pleased to state:

(a) the total capacity of manufacture of COVID-19 vaccines by M/s Serum Institute of India and M/s

Bharat Biotech and whether they have achieved production to their full capacity;

(b) whether the Ministry or ICMR has approved any other companies to manufacture and produce COVID-19 vaccines in India;

(c) whether the Central Drugs Standard Control Organisation has granted import permission for importing and manufacturing of COVID-19 vaccines to meet the demand in the country; and

(d) if so, the details of the permission granted and the total number of vaccines expected?

Answered on 14th December 2021

A. (a): ChAdOx1 nCoV- 19 Corona Virus Vaccine (Recombinant) (COVISHIELD) is manufactured by M/s Serum Institute of India Pvt., Ltd., Pune, while the Whole Virion Inactivated Corona Virus Vaccine (COVAXIN) is manufactured by M/s Bharat Biotech International Limited, Hyderabad.

As communicated by the M/s Serum Institute of India, the current monthly vaccine production capacity of Covishield is approx. 250-275 Million doses per month.

Further, as communicated by M/s Bharat Biotech International Limited, Hyderabad, the current monthly vaccine production capacity of Covaxin is approx. 50-60 Million doses/month. Both companies have achieved close to 90% of present production capacity.

(b)to (d): As per the provisions of New Drugs and Clinical Trials Rules, 2019 under Drugs and Cosmetics Act, 1940 and in light of urgent need due to COVID pandemic in the country, CDSCO has granted permissions to following COVID-19 vaccines other than COVAXIN & COVISHIELD for prevention of COVID-19 for restricted use in emergency situation:

Permission For Manufacture of COVID-19 vaccines:

1. Gam-COVID-Vac Combined vector vaccine [SPUTNIK-V] manufactured by M/s Ra (biologicals), Panacea Biotec Ltd., New Delhi using imported Ready to Fill (RTF) bulk from M/s Generium JSC, Russia on 02.07.2021.
2. Novel Corona Virus 2019-nCoV vaccine [ZyCoV-D] manufactured by M/s Cadila Healthcare Limited, Ahmedabad on 20.08.2021.
3. Ad26.COV2-S (recombinant) COVID-19 Vaccine manufactured by M/s Biological E limited, Hyderabad using imported bulk of M/s Johnson & Johnson Pvt. Ltd on 18.08.2021.
4. Gam-COVID-Vac Combined vector vaccine [Sputnik–V] manufactured under technology transfer from M/s RDIF, Russia by M/s Hetero Biopharma Limited, Hyderabad on 07.10.2021.

Permission For Import of COVID-19 Vaccines:

1. Gam-COVID-Vac Combined vector vaccine [SPUTNIK-V] to M/s Dr. Reddy's Laboratories Ltd, Hyderabad on 12.04.2021.
2. mRNA-1273 COVID-19 vaccine (Moderna) to M/s Cipla Limited, Mumbai on 29.06.2021.
3. Ad26.COV2-S (recombinant) COVID-19 Vaccine to M/s Johnson & Johnson Pvt. Ltd., Mumbai on 07.08.2021.

The Minister of State in the Ministry of Health and Family Welfare (Dr. Bharati Pravin Pawar)

Empanelment of Suppliers of Generic Medicines

Rajya Sabha Unstarred Question No. 1852

Shri B. Lingaiah Yadav

Q. Will the Minister of **HEALTH AND FAMILY WELFARE** be pleased to state:-

(a) whether Government has issued guidelines for empanelment of suppliers of generic medicines, if so, the details thereof and, if not, the reasons therefor; and

(b) the checks and balances that exist in the absence of guidelines, for ensuring that spurious medicines do not enter CGHS and other Government medicine supply chain in the name of generic medicines?

Answered on 14th December 2021

A. (a) and (b) Medical Store Organisation (MSO) under the Ministry of Health and Family Welfare procures medicines including generic medicines from the manufacturers registered with them and supplies the medicines to CGHS and other registered indenters such as Central/ State Government hospitals, dispensaries etc. The registration of manufacturing units of the manufacturers/ suppliers is done as per the procedure laid down in the "Procurement and

Operational Manual for Medical Store Organisation and Government Medical Store Depots". Before registering the firms, MSO obtains a report from the licensing authority with regard to standing and performance of the manufacturing unit, availability of necessary facilities to carry out necessary tests for the drugs, past history about cancellation of license or conviction of the firm etc. and decides on their registration.

MSO ensures physical inspection and analytical testing of coded samples of each and every batch from two different approved testing laboratories selected randomly by the computer software before acceptance for supply to CGHS and other indentors. In case of failure of drugs in laboratory test, deregistration/debarment action is taken as per terms and conditions of supply.

The Minister of State in the Ministry of Health and Family Welfare (Dr. Bharati Pravin Pawar)

In Lok Sabha

Share of Exports in GDP

Lok Sabha Unstarred Question No. 2839

Shri S. Jagathrakshakan:

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

(a) whether the Government has drawn any action plan to raise the share of exports in the country's GDP from the current 10.2 percent to 15 percent by 2030 for both merchandise and services;

(b) if so, the details thereof; and

(c) if not, the reasons therefor?

Answered on 15th December 2021

A. (a): Government has been facilitating, monitoring, assisting and channelizing efforts to increase the exports and thereby its share in GDP through a target-driven approach by engaging all stakeholders, across states and districts. Despite the pandemic, the share of India's total exports (Good & Services) to GDP was 18.7% in 2020-21, which is already above 15 percent. Exports have performed remarkably well in the current financial year with the share of exports to GDP at 21.7 percent in the first half (April to September) of 2021-22.

(b) & (c): The following are some of the steps taken by Department of Commerce to increase exports and thereby its share in GDP:

1) 'Districts as Export Hubs'(DEH) Initiative under which products and services with export potential have been identified in all districts of the country. An institutional mechanism has been set up in each District in the form of District Export Promotion Committees (DEPCs). The primary function of the DEPC is to prepare and act on District Specific Export Action Plans in collaboration with all the relevant stakeholders from the Centre, State and District levels.

2) A Central Sector Scheme 'Transport and Marketing Assistance (TMA) 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) Market Access Initiative (MAI) Scheme is an Export Promotion Scheme envisaged to act as a catalyst to promote India's exports on a sustained basis. The scheme is formulated on focus product-focus country approach to evolve specific market and specific product through market studies/survey. Assistance would be provided to Export Promotion Organizations/ Trade Promotion Organizations/National Level Institutions/ Research Institutions/Universities/ Laboratories, Exporters etc., for enhancement of exports through accessing new markets or through increasing the share in the existing markets.

4) 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.

5) Trade Infrastructure for Export Scheme (TIES) is operational from FY 2017-18 with the objective of assisting Central and State Government agencies for creation of appropriate infrastructure for growth of exports.

6) 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.

7) Common Digital Platform for Certificate of Origin to facilitate trade and increase FTA utilization by exporters.

8) EPCs, Commodity Boards and India's mission abroad are actively promoting India's trade, tourism, technology and investment goals.

The Minister of State in the Ministry of Commerce and Industry (Smt. Anupriya Patel)

Import data

Lok Sabha Unstarred Question No. 2860

Shri Balubhau Alias Suresh Narayan Dhanorkar:

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

(a) the year-wise details of import from FY 2009-10 to FY 2021-22;

(b) whether rate of import growth has increased in the last six years;

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

(d) the steps being taken by the Government to reduce imports?

Answered on 15th December 2021

A. (a) to (d) The details of India's overall (merchandise and services) imports along with percentage change from 2009-10 to 2021-22 are:

Years	Value of Overall Imports (in US$ Billion)
2009-10	348.40
2010-11	450.32
2011-12	567.55
2012-13	571.50
2013-14	528.95
2014-15	529.61
2015-16	465.64
2016-17	480.21
2017-18	583.11
2018-19	640.14
2019-20	602.98
2020-21	511.96
April-October, 2020	250.44
April-October, 2021 *	405.31

Source: DGCI&S, Kolkata and RBI (: Provisional)*

The data reveals that India's import declined during 2015-16, 2019-20 and 2020-21 by 12.08, 5.80% and 15.09% respectively.

Imports take place to meet the gap between domestic production and supply, consumer demand and preferences for various products. The Government has taken several steps to create/enhance domestic capacity, incentivise domestic manufacturing through Production Linked Incentive Schemes (PLI), phased manufacturing plans, timely use of trade remedy options, adoption of mandatory technical standards, enforcement of Free Trade Agreement (FTA) Rules of Origin (RoO) and development of import monitoring system.

The Minister of State in the Ministry of Commerce and Industry (Smt. Anupriya Patel)

Import of API

Lok Sabha Unstarred Question No. 2866

SHRI ASADUDDIN OWAISI:

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

(a) whether the Government has imposed any restriction on import Activated Pharmaceutical Ingredient (API) from certain countries;

(b) if so, the details of the countries on which such restrictions have been imposed and volumes of API that was being imported from them prior to such restriction;

(c) the details of the quantity and nature of API being exported by India in the last three years;

(d) whether the Government has taken steps to increase the production of API in India to prevent supply shock that was witnessed during the initial period of COVID-19; and

(e) if so, the details thereof?

Answered on 15th December 2021

A. (a)&(b) : No country-wise restrictions have been imposed on import of Active Pharmaceutical Ingredients (API).

(c): APIs such as Diloxanide furoate, cimetidine, famotidine, heterocyclic compounds, other antibiotics and erythromycin and its derivatives, together account for approximately 50% share in the total value of India's API exports.

The details of API exports for the last three years are tabled below:

India's API Exports (in USD Millions)				
Category	2018-19	2019-20	2020-21	2021-22 (April-Oct 2021)
API (Bulk Drugs & Drug Intermediates)	3895.38	3867.77	4405.36	2469.84

(d)&(e) : To increase the domestic production of Active Pharmaceutical Ingredients (APIs), Intermediates and Key Starting Materials (KSMs), and also to reduce India's dependency on other countries for critical inputs and bulk drugs in the long run, the Government has approved the following schemes :-

i. Scheme on Promotion of Bulk Drug Parks for financing Common Infrastructure Facilities in 3 Bulk Drug Parks with financial implication of Rs. 3,000 crores for next five years;

ii. Production Linked Incentive (PLI) Scheme for promotion of domestic manufacturing of critical KSMs/Drug Intermediates and APIs and for domestic manufacturing of pharmaceuticals.

The Minister of State in the Ministry of Commerce and Industry (Smt. Anupriya Patel)

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NATIONAL NEWS

Do not assume COVID pandemic reaching 'end game', warns WHO

GENEVA, Jan 24 (Reuters) - The head of the World Health Organization (WHO) warned on Monday that it was dangerous to assume the Omicron variant would herald the end of COVID-19's acutest phase, exhorting nations to stay focused to beat the pandemic.

"It's dangerous to assume that Omicron will be the last variant and that we are in the end game," Tedros Adhanom Ghebreyesus told a WHO executive board meeting of the two-year pandemic that has killed nearly 6 million people.

"On the contrary, globally the conditions are ideal for more variants to emerge."

Though Omicron has sent total cases soaring to nearly 350 million, its less lethal impact and the increasing prevalence of vaccines has led to optimism in some parts that the worst of the pandemic may have passed.

Tedros, the WHO's first African head who is running unopposed for a second term, urged discipline and unity in combatting the coronavirus.

The COVID-19 pandemic is now entering its third year and we are at a critical juncture," he told a news conference earlier. "We must work together to bring the acute phase of this pandemic to an end. We cannot let it continue to drag on, lurching between panic and neglect."

Source: Economic Times, 25.01.2022

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Pharma of the future

Gearing up to fight the diseases of tomorrow

Simon Gallagher

As we begin another year, the world remains under the shadow of the Covid-19 pandemic with the emergence of another new variant. Covid-19 has impacted how we interact with people, how companies in general and pharmaceutical, in particular, are perceived, and how they function and innovate. Through collective efforts, the pharmaceutical industry is working to turn around the course of human diseases.

The foremost commitment for the pharmaceutical industry is to ramp up research in finding effective treatments for not just Covid-19 but also other diseases that continue to impact people's lives. Companies will invest in short- and medium-term cell and gene therapy and biologics.

In the coming times, we will see the industry actively advocating multi-stakeholder collaboration to create a mindset for research, innovation, and skill augmentation; aligning academia with industry needs; ramping up research infrastructure; negotiating regulatory changes; and making research lucrative and rewarding.

Precision medicines

By far, medicine has primarily followed the 'one-size-fits-all' mechanism. The future will see an increased effort to bring in precision medicines through artificial intelligence and machine learning. For this, we need to improve procedures for genetic testing and integrate the study of genetic and metabolic makeup and function into the traditional healthcare processes.

We will see digital solutions paving way for this change. Digital solutions are being used for monitoring not just patients but also clinical trials and managing the supply chain for efficient delivery. We experienced a rise in the uptake of digital solutions last year, and this is only going to grow hereon.

Covid-19 has shown us the power of collective action on multiple levels: global, national, local, and individual. It has shown the disruptive power of a healthcare crisis that can bring down the most vibrant economy. This pandemic is transforming each of us, every company, every industry, and testing the capabilities of entire nations. Billions of people across the globe placed their trust in the pharmaceutical industry. Our priority must be to honour this trust, find the solutions, not give up and ensure we provide greater value to patients, people, and the community.

Simon Gallagher is General Manager (Interim) India, Takeda. Views are personal

Source: Business Line, 24.01.2022

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Priorities for global trade in 2022

Easing Covid-19 vaccine access for all—so far determined by bilateral deals and producer companies and facilities like Covax—must be the primary goal

What are the key developments to watch out for in global trade in 2022 Managing the pandemic will remain a global priority. It will not be any different for the WTO. Within this priority, the most important goal for the WTO will be to ensure effective distribution of vaccines to various parts of the world.

The WTO hasn't yet been able to play a facilitating role in distribution of vaccines. Till December 31, 2021, 71% of the total vaccines exported worldwide have moved through various bilateral supply arrangement deals. Around 21% from the remaining share have been exported through COVAX, either through donations to the facility, or through supplies contracted by it. There have been quality issues with the COVAX vaccines with several recipient countries having had to reject the supplies received as they had come close to the expiry dates.

It is thus clear that vaccine trade has continued to be a 'managed' one. Recipient countries are working out supply arrangements with vaccine producers on pre-agreed terms for vaccine sale and delivery. This is hardly the uninhibited, cross-border flows of vaccines that should occur.

The ostensible reason behind vaccine exports (and imports) continuing to remain managed is pre-determination of vaccine prices. Vaccine producers are able to negotiate pre-determined prices with the buyers depending on the requirements of the latter as well as their abilities to pay. In this respect, vaccine export deals are resembling forward contracts executed for various commodities by different countries on pre-decided terms.

The WTO was expected to bring vaccine exports out of the pre-determined supply agreements and make them move freely. The fact that it hasn't happened that way till now, in spite of the Omicron variant sweeping across the world, shows that producers are able to dictate prices and terms of sale. As more and more vaccines become available and overall global supplies increase, individual producers are likely to lose their command over setting prices. Much would also depend on whether the WTO is able to reach a decision on not letting intellectual property (i.e. patents) become a factor in movement of vaccines. A multilateral consensus on this subject is extremely important.

India recently asked for a virtual Ministerial meeting of the WTO for working out a plan on the WTO's pandemic response with specific focus on the issue of waiving intellectual property rules for vaccines and other pandemic therapeutics. However, till now, there hasn't been any noticeable movement on the issue. Matters haven't been helped by the fact that the WTO has had to postpone its Ministerial Conferences twice, once in June 2020, and then again in November 2021.

While the Ministerial Conference is certainly important in taking a decision on waiving intellectual property rules and pushing the cause for global equity in vaccines, the difficulty of holding it face-to-face is not a good enough reason for the WTO not being able to decide on waivers. It must work out a way of progressing on the subject under these exceptional circumstances, whether it be through informal consultations among some key members, or speeding up text-based negotiations.

Production and distribution of vaccines will also feature prominently in the trade discourse outside the WTO in the coming year. Major global groupings like the G7 and G20 will continue to work on ensuring smooth flow of vaccines among their members. To some extent, vaccines will continue to figure in various FTA talks as well.

Along with a decision on intellectual property waivers on vaccines, the postponed Ministerial Conference of the WTO was also expected to work out an action plan for aligning global trade rules to climate action goals. This was imperative after the COP26 achieved tangible outcomes in its meeting last year.

Considerable movement on this subject is expected within the various FTA discussions that are taking place around the world. These include the FTAs that India is negotiating with the UAE, UK, Australia, Canada and the EU, some of which are expected to conclude towards the end of the year. In all these agreements, climate-friendly trade policies are expected to be drafted.

For this year, and also much of the foreseeable future, global and regional trade agendas are expected to stay focused on welfare-centric goals, most notably in public health and sustainable development. The focus has clearly been hastened by the pandemic and the fact that it has proved stubborn and refused to go away. At the same time, however, the focus has come from the realization among trade policy makers that trade needs to be seen as standing up and delivering.

The current global context offers trade a great opportunity for refurbishing its tarnished image of having delivered benefits from globalisation in a discriminatory fashion. There is no better way of correcting the impression than contributing decisively to global public health and sustainable development goals. However, the structural and procedural obstacles for doing so, visible most prominently within the WTO, and to some extent in regional and bilateral FTA spaces, can deny trade the opportunity to restore its benign image. The will to obtain good outcomes must be matched by efforts and results.

The author is Senior research fellow and research lead (trade and economics) at the Institute of South Asian Studies, NUS Views are personal

Source: Amitendu Palit, Financial Express, 27.01.2022

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Each dose of Covishield, Covaxin likely to be capped at Rs 275 after getting regular market approval

According to them, the National Pharmaceutical Pricing Authority (NPPA) has been directed to start working towards capping the price to make the vaccines affordable.

The price of Covishield and Covaxin, the Covid vaccines which are expected to soon get regular market approval from India's drug regulator, is likely to be capped at Rs 275 per dose plus an additional service charge of Rs 150, official sources said. According to them, the National Pharmaceutical Pricing Authority (NPPA) has been directed to start working towards capping the price to make the vaccines affordable.

As of now, Covaxin is priced at Rs 1,200 per dose while Covishield costs Rs 780 in private facilities. The prices include Rs 150 service charge. Both the vaccines are only authorised for emergency use in the country. An Subject Expert Committee on COVID-19 of the Central Drugs Standard Control Organisation on January 19 recommended granting regular market approval to Covid vaccines Covishield and Covaxin for use in the adult population subject to certain conditions.

"The NPPA has been asked to work towards capping the price of the vaccines. The price is likely to be capped at Rs 275 per dose along with an additional service charge of Rs 150," an official source said. Prakash Kumar Singh,

the director (government and regulatory affairs) at Serum Institue of India, had submitted an application to the Drugs Controller General of India on October 25 seeking regular market approval for its Covishield vaccine.

A couple of weeks ago, V Krishna Mohan, the whole-time director at Bharat Biotech, submitted complete information on the chemistry, manufacturing and controls, along with the pre-clinical and clinical data while seeking regular market authorisation for Covaxin. Covaxin and Covishield were granted Emergency Use Authorisation (EUA) on January 3 last year.

Source: Financial Express, 26.01.2022

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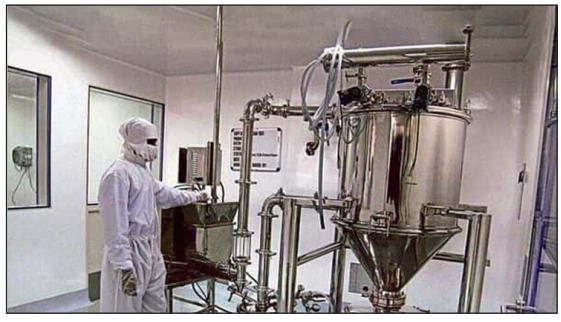
Budget should support innovation in pharma sector, say experts

The experts also called for expanding the ongoing production-linked incentive (PLI) programme to include manufacturing of active pharmaceutical ingredients (API) so that the pharmaceutical sector can make a stronger push to achieve self-reliance in raw material production.

The budget should offer incentives for innovation in the pharmaceutical sector to encourage new drug discovery and enable local drugmakers to tap more developed markets, industry experts said at Mint Budget Conversations recently.



The panellists called for expanding the ongoing PLI scheme to include manufacturing of active pharmaceutical ingredients.

The experts also called for expanding the ongoing production-linked incentive (PLI) programme to include manufacturing of active pharmaceutical ingredients (API) so that the pharmaceutical sector can make a stronger push to achieve self-reliance in raw material production.

India is a major generic drug producer globally though it lacks in new drug discovery. "The pharma sector no longer requires crutches but needs a competitive edge," said C.K. Mishra, adviser, Serum Institute of India. "How do you become the best in the world? And two critical things I would like to mention. One is (being) competitive in terms of production, competitive in terms of price, and the second is quality. And we need to work very strongly on this," he added.

He further said that the pharmaceutical industry needs to sharpen its competitiveness to capture more markets overseas. "I think we are reaching a situation in India where the pharma sector thinks that we've done enough right. So, we need to inject that additional incentive into the pharma sector to grow further," Mishra said. "This is the sunrise sector of India and we must focus on it, even if it means some budget outgo, because ultimately it will bring in revenues to compensate for what you spend right now. One of the requirements is the understanding that pharma is a sensitive sector and we are talking about drug and health security. It's not just production and commerce; it's drug security, certainly. We need to be looking at institution building," Mishra said.

He said India's pharmaceutical sector needs to further enhance its capabilities in research and development.

"As far as fiscal incentives are concerned, the pharmaceutical sector can do well on its own if we are able to push them with R&D and human resources in a big way. Science must come in from the government. And then new molecules will come, new drugs will come in. India will be a big player," Mishra said. The fertilizer and agrochemical sector is also struggling with insufficient innovation and technological progress, said Chhabilendra Roul, former secretary, department of fertilizers. For instance, he said that the technology used for ammonia and urea processing is old.

"But we have now new frontiers of technology coming up, particularly, green ammonia and green hydrogen. But for that you need a lot of technological push, a lot of incentive from the government," he said.

"The gestation period for repaying the benefits from R&D is quite long and you need deep pockets for that. Most of the fertilizer or agrochemical companies in India don't have that," Roul said. "There are very small and marginal players in the sector. There are large players but still they don't have the deep pockets to spend on R&D," he said. Mishra said with the ongoing climate crisis, any sector that wants to progress needs to have strong foundation in going green.

"We need to invest in green technology," he said.

Source: Swati Luthra, HT Mint, 25.01.2022

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