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IDMA BULLETIN

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Indian APIs & Formulations for Global Healthcare

INDIAN DRUG MANUFACTURERS' ASSOCIATION

No Spot Registration

IDMA 60TH YEAR CELEBRATIONS 2022

Friday, 7th & Saturday, 8th January 2022,
Hotel Sahara Star, Mumbai

(Details on Pages: 4)

Register Now

HIGHLIGHTS

- ★ **Virtual meeting convened under the Chairmanship of Executive Director (CS), FSSAI to discuss the concerns related to Nutraceutical, Health Supplement manufacturers, with specific reference to Licensing and Audits** *(Page No. 9)*
- ★ **Parliamentary panel asks DoP to conduct in depth study on concessions given by China to its bulk drug industry** *(Page No. 24)*
- ★ **PM's vision brought health, pharma under single minister: Mansukh Mandaviya** *(Page No. 26)*

A Publication of
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IDMA BULLETIN

Vol. No. 52 **Issue No. 47** **15 to 21 December 2021**

IDMA ACTIVITIES:

DoP MATTERS:

GOVERNMENT COMMUNICATIONS:

PARLIAMENT NEWS:

NATIONAL NEWS:

INDIAN DRUG MANUFACTURERS' ASSOCIATION (IDMA)

1961 – 2021 (60 Glorious Years)

102, Poonam Chambers, A Wing, 1st Floor, Dr. Annie Besant Road, Worli,
Mumbai - 400 018. Maharashtra, India.
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No Spot Registration

IDMA 60TH YEAR CELEBRATIONS 2022

Friday, 7th & Saturday, 8th January 2022

Hotel Sahara Star, Mumbai

Register Now

Dear Member,

Greetings from Indian Drug Manufacturers' Association (IDMA).

We, at IDMA, humbly request our Members to whole-heartedly participate in the IDMA 60th Year Celebrations by way of **Registrations, Advertisements & Sponsorships.** Your support is very much desirable and necessary in strengthening your Association as well as for the success of any initiatives taken up by your Association. We are sure that with your support the 60th Year Celebrations is going to be a massive and glorious success story in the history of your Association.

The 60th Year Celebrations will be organized on 7th & 8th January 2022 in Mumbai. We intend to commemorate this historic occasion of the completion of 60 years of our Association, with a two day long celebration consisting of Panel Discussions, Technical Sessions and Entertainment Program to boost the image of our Association as the Premier Association of the Indian Pharmaceutical Industry.

The main objectives of the celebrations are:

- **Showcasing Pharmaceutical and Allied Industries across the Globe**
- **Disseminating knowledge on various subjects**
- **Highlighting the achievements of IDMA**

This year at the 60th Year Celebrations, we have invited Eminent National and International personalities to address our members over two days. We will also be recognizing Top Achievers in the Indian Pharmaceutical Industry, who have made India Proud and respected world over as providers of affordable quality medicines.

As part of the Celebrations, the winners of the:

1. **IDMA Margi Memorial Best Patent Awards**
2. **IDMA ACG-SCITECH Research Paper Awards**
3. **IDMA Corporate Citizen Awards**
4. **IDMA - N. I. Gandhi Chief Mentor Award**

would be announced and the Awards would be presented.

Your Association has come a long way and many milestones have been achieved in the last 60 Years and specially the last two years which have been different, difficult and trying times. You would be pleased to note that during Covid-19 Pandemic, IDMA Secretariat has played an important role in facilitating uninterrupted supply of quality medicines with excellent coordination between the Industry, Government, Regulators and other Associations. Nevertheless, it is due to your untiring efforts and commitment to the wellbeing and prosperity of our Association that we will be completing 60 years of glorious service to our Pharma Industry and to our great Nation.

We are sure you will be an integral part of the Grand Celebrations.

IDMA 60th ANNUAL PUBLICATION 2022

The IDMA 60th Annual Publication 2022, an up-to-date and most informative compendium will be released at the Annual Celebrations. This Annual Publication will present statistics, vital data and information on the Pharmaceutical industry. This Publication has also come to be recognized as the indispensable reference book of the Indian Pharmaceutical Industry.

AN OFFER NOT TO BE MISSED

Advertisers can, through this single medium, reach their target audience such as Bulk Drug Manufacturers, Formulators, Researchers, Analysts, Traders, Scientists, Students, Consultants, various Government Officials etc. and leave an enduring impression on everyone connected with the Industry.

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OPPORTUNITIES FOR SPONSORSHIPS:

We would be extremely pleased if you would accept one of the below Sponsorship for this celebrations :-

PLATINUM SPONSOR : Rs. 25 Lakh		**GOLD SPONSOR : Rs. 10 Lakh**	
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Sponsors will be provided special benefits & privileges as per the copy attached: For details please contact IDMA Secretariat.

REGISTRATION FEES:

To participate in the 60th Year Celebrations, the registration fee would be as under:

Reception Committee Member	Rs.7,500/- plus GST @ 18%
Delegate	Rs.6,000/- plus GST @ 18%
(For more than 4 registrations from one Company, the 5th registration will be complimentary)	

For further details, please contact:

Mr. Melvin	Ms. Geeta	Ms. Batul	Ms. Parivaz
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actadm@idmaindia.com	publications@idmaindia.com	technical@idmaindia.com	idma2@idmaindia.com

ROOM RATES :

We have negotiated special room rates for our members. **The special room rate would be Rs.6,000/- per night for a Single Occupancy and Rs.7,000/- per night for a Double Occupancy.** The room rate includes complimentary breakfast and internet facilities.

Kindly note that those members who desire to stay at Hotel Sahara Star, please forward their details to the IDMA Secretariat.

Your active participation & interaction with the cream of the Pharmaceutical Industry as well as Ministry Officials and Bureaucrats, from the Centre as well as States, will not only add value to your business but also ensure that the flag of our Association continues to fly higher in the Global Pharmaceutical Industry.

Looking forward to your usual fine cooperation in making this historic event a 'सुपर से भी ऊपर' Success.

Thanking you,

With best regards,

Bharat Shah
Chairman, Organizing Committee, IDMA
60th Year Celebrations

Mahesh H Doshi
National President

Daara B Patel
Secretary - General

KNOWLEDGE-BASED VS EVIDENCE-BASED – COULD SPELL THE DIFFERENCE BETWEEN HEALTH & ILL-HEALTH!

Dr R K Sanghavi, *Consultant - NeuroMarketing & TechnoRegulatory (Pharma & Nutra)*
Chairman – Nutraceutical Committee (IDMA)

Dear Reader,

It has been so truly said by Otto von Bismarck [former President of Prussia (German State) in 19th century] — 'Only a fool learns from his own mistakes. The wise man learns from the mistakes of others.' It is the 10% existent wise men that lead - 90% trudge behind as followers – be it the political scenario, spiritual realm or world of science. Wise men become powerful and in the current Forbes list of such top 10 are 6 politicians, 1 religious head & 3 mega global entrepreneurs. In enterprises, when it comes to science and discovery, only 3 out of the top 10 have excelled in contributing to the world of medicine! Leaders are rare & leaders in medical domain are even rarer!

A normal I.Q. (Intelligence Quotient) is considered as between 90-110. A genius has an I.Q. above 140 but most famed political, spiritual and science leaders measure 160 to 200! It is the I.Q. that determines the ability to be knowledgeable it is their knowledge on a particular subject that determines one's status as an acknowledged leader in this world!

Knowledge is familiarity, awareness or understanding of something or someone. It may have been acquired by any means be it perception and reasoning, testimony and scientific inquiry, education and practice. Socrates, the Greek Philosopher said, dissemination of knowledge is different from mere opinion. Plato (another Greek Philosopher of same era of 300-400 BC) and George Eliot (famed English novelist of 19th century) have written: "Opinion is really the lowest form of human knowledge; it requires no accountability, no understanding." Opinion is based on belief and belief is the mental acceptance of an evidence that one has merely accepted blindly sans any relevant background education and thorough research.

Dr R K Sanghavi is Mumbai-*based privately Consulting Physician since 40 years, who served in Ramakrishna Mission Hospital and many other charitable institutions. He has consulted Ethical & OTC verticals of the Healthcare Industry in domains of Medico-Marketing, Training & Dr-lecturing, Techno-Legal & Regulatory, and is a member of the Subject Review Committee of NFI. Dr Sanghavi has near 200 company-years of exposure, experience and expertise by virtue of advising over 80 small, medium and large Pharma companies, including MNCs. He takes credit in pioneering the Nutraceutical vertical of Healthcare in India and was associated since early 1990s with fi rst launch of most nutraceutical ingredients (antioxidants, glucosamine-chondroitin, omega-3 fatty acids, evening primrose oil, CoQ10, phytoestrogens, phospholipids, soluble fi ber, St John's Wort, etc.) which have wide acceptance - having delivered near 300 lectures in India including overseas for specialist Drs. As Chairman of IDMA's Medical Committee for 15 years Dr Sanghavi had organized 20 conferences; he is currently chairing the Nutraceutical Committee since last one decade. Dr Sanghavi has successfully represented IDMA on all six occasions in various High Courts, and in Supreme Court, pertaining to banning of irrational FDCs (CDSCO) and implementation of an unjustifi able system of Product Approval for nutraceuticals (FSSAI).*

It would be interesting to understand the ramifications in various spheres of our interactive world-space the implications of following those who are knowledge-based versus the evidence-based.

POLITICS: A country needs a visionary to carve a new path of glory based on knowledge and not someone who trudges upon a trodden path that is evidence-based and a survival strategy. How many of the family, friends and colleagues opine upon policies but having neither background of political sciences nor experience of being a politician? These are all mere evidence-based opinionators.

SPIRITUALISM: Why do millions of commoners flock to hear a preacher? The self-professed God man gives discourses based on knowledge. The followers listening in rapt attention are ordinary evidence-based believers, who being devoid of knowledge, greedily imbibe the words of wisdom flowing from the minds of the knowledge-based and otherwise genuine spiritual 'gurus'.

CORPORATE: Either the Corporate opts for a Captain who intends the organization to prosper by paying attention to cutting corners, or zooms in on a visionary whose mission is to shift the Company's gears by organic growth and diversification. The easiest path to show growth in profit is to cut costs. It is but evident and a no-brainier that this is the mechanism adopted by all managers who have a hardened evidence-based mind that is strongly set on the basis of similar prior experience. In reality it is the recruiter, who determines whether the company blooms by recruiting knowledge-based leaders, or the company dooms because of opting for managers who swear by adopting evidence-based practices!

HEALTH: The word evidence-based is the pet of 'academic' Medical Professionals! Most can never see beyond evidence because reasoning is by-far an alien art for them. The patient seals his / her fate depending upon the choice of health - provider. All evidence-based Drs advise patients for bypass surgery if there are more than 3 blocks! However, the current leader of Maharashtra is hale-n-hearty even after 8 stents, one of my patients after 5 stents, and my doctor friend (post-Covid-19) after 9 stents! They all had reposed faith in knowledgeable doctors who had guided them in avoiding a major bypass surgery and getting away with a simple angioplasty and were back to their routine lives in 48 hours! All at same cost and prognosis.

*The COVID-19 pandemic has made many literate Indians aware of viruses, vaccines and therapies thanks to print and A-V media! So much so, they advise otherwise ordinary citizens, discuss at parties, get togethers, and across conversations in everyday life, when & what vaccine to take, what preventive & curative treatment and investigations are best! As a qualified medical doctor, engaging in even speaking at webinars for COVID-19 related topics, including once for an international platform, it amazes me that my kith and kin even try imposing their opinions regarding vaccines and therapies for the coronavirus on the basis of evidences googled! Such goggling facts leads to an evidence-based mind-set, BUT educational background backed by extensive data assimilation is the secret of a knowledge-based doctor. With a mere medical qualification sans knowledge, the evidence-based doctor will merely swear by ALREADY **set** 'Treatment Guidelines' but a knowledge-based therapist will **set his OWN guidelines.***

*The difference in evidence-based versus knowledge-based is also the determinant of why some doctors treat coronavirus infections, heart disease and diabetes aggressively or otherwise. There is one quick clue to judge whether one has followed the right knowledge-based health adviser or otherwise. If a diabetic has co-existing leg pain (neuropathy), heart disease or eye complication, the treating doctor is definitely a mere evidence-based practitioner. The **knowledge-based** scores over **evidence-based** opinionated individuals but the latter being in 90% majority, whether common man, 'fake' gurus or evidence-based doctors, there is a real grave threat to progress in the world of politics, peace in spiritualism and well-being in the health arena! In fostering positive health by nutraceuticals the proclaimed negativity regarding these supplements, including the current widely prevalent falsification of facts in social & digital media, by evidence-based opinionators has been counter-productive!*

Courtesy: Indian Drugs, Editorial, 58 (09), September, 2021

Report on "An Interactive Meeting with Uzbekistan Delegation" Hotel Crowne Plaza @ Ahmedabad on 22nd November 2021

A delegation of The Republic of Uzbekistan visited Ahmedabad on 22.11.2021 (Monday). An interactive Session was organised with IDMA-GSB Members at Hotel Crowne Plaza Ahmedabad. 02 members were present in the Uzbekistan delegation led by Mr. Alisher Temirov, Dy. Director, Ministry of Health of the Republic of Uzbekistan Agency on Development of the Pharmaceutical Industry & Mr. Botir Khudoyberdiev, International Department of Uzbekistan. IDMA - GSB was represented by 18 members led by Dr. Shrenik Shah, Sr. Vice Chairman, Mr. Sanchit Chaturvedi, Vice Chairman & Mr. Sumit Agrawal, Hon. Secretary.

Programme started with a welcome speech delivered by Mr. Sumit Agrawal, Hon. Secretary, IDMA GSB. Dr. Shrenik Shah presented flower bouquet to Mr. A. Temirov and Mr. Ramesh Chokshi, Project Head Cadila Pharmaceutical presented flower bouquet to Mr. Botir Khudoyberdiev. Mr. A. Temirov & Mr. Botir Khudoyberdiev gifted memento to IDMA GSB.

A power point presentation was given by Mr. Alisher Temirov on topic "Investment Attractiveness and Economic Potential of the Pharmaceutical Industry of the Republic of Uzbekistan". Mr. Botir Khudoyberdiev also gave presentation on "Prospects for the Development of the Pharmaceutical Industry" He elaborated about Trade & Investment Opportunities in Uzbekistan. A small video presentation about the Economic and Investment Potential of the Pharmaceuticals Industry of Republic of Uzbekistan was also there.

The meeting ended with lunch. It was a very successful meeting wherein MOU was signed between Mr. Alisher Temirov, Dy. Director, from Uzbek side and Dr. Shrenik Shah, Sr. Vice Chairman, & Mr. Sumit Agrawal, Hon. Secretary, IDMA-GSB from India side on creating joint "Uzbek-Indian further develop investment cooperation in the field of Pharmaceutical industry in Uzbekistan".

Virtual meeting convened under the Chairmanship of Executive Director (CS), FSSAI to discuss the concerns related to Nutraceutical, Health Supplement manufacturers, with specific reference to Licensing and Audits

(Held on 17th December 2021: 11.00 - 12.30 hours)

The FBOs –whether Manufacturers, marketeers (now to be designated as 'Relabellers') and Re-packers, will henceforth all require to procure Central FSSAI license, including migration from their already possessed State License before 31st December 2021. The same, including the mechanics and the implicated steps were explained during the meeting by Mr Akhilesh Gupta, Asst Director FSSAI.

Representatives from various associations like IDMA, FICCI, CII and others were present in the meeting. The Q & A was kickstarted by the Executive Director (SBCD & Regulatory Compliance) Ms Inoshi Sharma by asking IDMA to put forth the clarification points. Dr R K Sanghavi, Chairman of Nutraceutical Committee elaborated on certain grey areas likely to be encountered whilst shifting to Central Licensing by the FBOs.

- Why re-Christian the marketeer as a Relabeller?
- Why link products manufactured and marketed with procuring of licenses?
- Do the distribution channel – depots, warehouses, etc. also need independent Central License?

Seemingly the FSSAI is not amiable to de-linking product listing with licensing. Against this the authorities were asked as to how the FBOs IPR with respect to product mfg. details would be held sacred and a secret (by Mr Ganesh Kamath of Vital Neutraceuticals, Mumbai) for which the Mr Akhilesh Gupta would be according reverting for according steps taken. Also, the FSSAI was requested to upload all the new ingredients approved names and Ms Kriti Chugh (Asst Director, Regulatory Compliances) opined that the same was already evident under the tab wherein the Scientific Committee deliberations have been captured in the FSSAI's website.

Ms Rini Sanyal, Director – Regulatory & Government Affairs (from Herbalife) also emphasized that re-designating marketers as Relabellers would tantamount to disregarding their contribution to the product's availability in terms of conceptualization, facilitating procuring of sensitive raw materials and supervising development and processing of the product. But the FSSAI seems intent in going ahead with deleting the option of marketeer from its licensing portal.

Dr R K Sanghavi
Chairman, Nutraceutical Committee, IDMA

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Information about Exports to various countries - reg.

Dear Member,

IDMA has been given to understand that there are some important meetings being organized by the Government and Other concerned authorities/departments with regards to exports, we, therefore, kindly request our members to update us with information on exports to various countries. This would be of great help to your organization.

We have been continuously receiving queries/emails from Department of Pharmaceuticals (DoP), Govt. of India requesting information on exports by our members to various countries and the problems faced / support required from the Government.

In order to enable us to provide the required information to the Government and also to support you in your export activities. We request members to provide the following information to the Secretariat at the earliest :

1. Names of Countries to which you export regularly
2. Issues faced / Support Required
3. Name of contact person / Export Head of your Organization and his / her Co-ordinates

Members requested to share details to IDMA Secretariat at idma1@idmaindia.com

Looking forward to your prompt positive response.

Thanks & regards,

Daara B Patel
Secretary – General

Release of Phytopharmaceutical Monograph Development Guidelines by Secretary, Ministry of Health and Family Welfare, Govt of India Mr Rajesh Bhushan

Details of approved applications for PLI- reg.

Dear Member,

Please find below the Details of applications approved under PLI for Promotion of domestic manufacturing of KSMs/DIs/APIs in India and Details of applications approved under PLI for Pharmaceuticals.This has been placed on DoP website (https://pharmaceuticals.gov.in).

Details of Applications approved under Production Linked Incentive (PLI) Scheme for Pharmaceuticals

Group A

S. No.	Name of the applicant	Applicant Category
1	Sun Pharmaceutical Industries Limited	Domestic
2	Aurobindo Pharma Limited	Domestic
3	Dr. Reddy's Laoratories Limited	Domestic
4	Lupin Limited	Domestic
5	Mylan Laboratories Limited	Foreign MNC
6	Cadila Healthcare Limited	Domestic
7	Cipla Limited	Domestic
8	Amneal Pharmaceuticals Private Limited	Foreign MNC
9	Glenmark Pharmaceuticals Limited	Domestic
10	Intas Pharmaceuticals Limited	Domestic
11	Torrent Pharmaceuticals Limited	Domestic

Group B

S. No.	Name of the applicant	Applicant Category
1	Biocon Limited	Domestic
2	MSN Laboratories Private Limited	Domestic
3	Wockhardt Limited	Domestic
4	Alembic Pharmaceuticals Limited	Domestic
5	Emcure Pharmaceuticals Limited	Domestic
6	Macleods Pharmaceuticals Limited	Domestic
7	Biological E Limited	Domestic
8	Natco Pharma Limited	Domestic
9	Strides Pharma Science Limited	Domestic

Group C

S. No.	Name of Applicant	Applicant Category	Type of Product Applied For
1	Vindhya Pharma (India) Private Limited	MSME	Pharmaceuticals
2	Aarti Industries Limited	Non-MSME	Pharmaceuticals
3	Symbiotec Pharmalab Private Limited	Non-MSME	Pharmaceuticals

4	Transasia Bio-Medicals Limited	MSME	IVD
5	Sai Life Sciences Limited	Non-MSME	Pharmaceuticals
6	Poly Medicure Limited	Non-MSME	IVD
7	Concord Biotech Limited	Non-MSME	Pharmaceuticals
8	Amoli Organics Private Limited	Non-MSME	Pharmaceuticals
9	BDR Pharmaceuticals International Private Limited	Non-MSME	Pharmaceuticals
10	Malladi Drugs & Pharmaceuticals Limited	Non-MSME	Pharmaceuticals
11	Symed Labs Limited	Non-MSME	Pharmaceuticals
12	BalPharma Limited	MSME	Pharmaceuticals
13	Acme Formulation Private Limited	MSME	Pharmaceuticals
14	Panacea Biotec Limited	Non-MSME	Pharmaceuticals
15	Abhilash Life Sciences LLP	MSME	Pharmaceuticals
16	Neogen Chemicals Limited	MSME	Pharmaceuticals
17	Biophore India Pharmaceuticals Private Limited	MSME	Pharmaceuticals
18	Nosch Labs Private Limited	Non-MSME	Pharmaceuticals
19	Aragen Life Sciences Private Limited	Non-MSME	Pharmaceuticals
20	Sri Krishna Pharmaceuticals Limited	Non-MSME	Pharmaceuticals
21	Optimus Drugs Private Limited	MSME	Pharmaceuticals
22	Venus Remedies Limited	Non-MSME	Pharmaceuticals
23	Psychotropics India Limited	MSME	Pharmaceuticals
24	Steril-Gene Life Sciences Private Limited	Non-MSME	Pharmaceuticals
25	Aurore Life Sciences Private Limited	MSME	Pharmaceuticals
26	Milan Laboratories India Private Limited	MSME	Pharmaceuticals
27	Vandana Life Science Private Limited	MSME	Pharmaceuticals
28	Nitika Pharmaceutical Specialities Private Limited	MSME	Pharmaceuticals
29	Hy-Gro Chemicals Pharmtek Private Limited	MSME	Pharmaceuticals
30	Mendas Pharma Private Limited	MSME	Pharmaceuticals
31	Optimus Pharma Private Limited	MSME	Pharmaceuticals
32	Maiva Pharma Private Limited	MSME	Pharmaceuticals
33	Trivitron Healthcare Private Limited	MSME	IVD
34	Agappe Diagnostics Limited	MSME	IVD
35	Premier Medical Corporation Private Limited	MSME	IVD

Details of applications approved under the Production Linked Incentive (PLI) scheme for promotion of domestic manufacturing of critical Key Starting Materials (KSMs)/ Drug Intermediates (DIs)/ Active Pharmaceutical Ingredients (APIs) in India

Sr. No.	Name of the Applicant	Name of the Eligible Product
Target Segment I – Key Fermentation Based KSMs/Drug Intermediates		
1	M/s Aurobindo Pharma Limited (through Lyfius Pharma Pvt. Ltd.)	Penicillin G
2	M/s Karnataka Antibiotics & Pharmaceuticals Ltd.	7 - ACA
3	M/s Aurobindo Pharma Limited (through Lyfius Pharma Pvt. Ltd.)	
4	M/s Kinvan Pvt. Ltd.	Clavulanic Acid

Target Segment II – Fermentation Based Niche KSMs/Drug Intermediates/APIs		
1	M/s Natural Biogenex Private Limited	Betamethasone
2	M/s Natural Biogenex Private Limited	Dexamethasone
3	M/s Natural Biogenex Private Limited	Prednisolone
4	M/s Symbiotec Pharmalab Private Limited	
5	M/s Macleods Pharmaceutical Limited	Rifampicin
6	M/s Sudarshan Pharma Industries Limited	Vitamin B1

Target Segment III – Key Chemical Synthesis Based KSMs/Drug Intermediates		
1	M/s Emmennar Pharma Private Limited	1,1 Cyclohexane Diacetic Acid (CDA)
2	M/s Hindys Lab Private Limited	
3	M/s Alkimia Pharma-Chem Pvt. Ltd. (APCPL)	
4	M/s Meghmani LLP	Para amino phenol
5	M/s Sadhana Nitro Chem Limited	
Target Segment IV – Other Chemical Synthesis Based KSMs/Drug Intermediates/APIs		
1	Rajasthan Antibiotics Limited	Meropenem
2	Centrient Pharmaceuticals India Private Limited	Atorvastatin
3	Anasia Lab Private Limited	Olmesartan
4	Andhra Organics Limited	
5	RMC Performance Chemicals Private Limited	Aspirin
6	M/s Alta Laboratories Limited (ALL)	
7	Lifetech Sciences	Ritonavir
8	Honour Lab Limited	Lopinavir
9	Hindys Lab Private Limited	Acyclovir
10	Dasami Lab Private Limited	Carbamazepine
11	Dasami Lab Private Limited	Oxcarbazepine
12	Hetero Drugs Limited	
13	Hazelo Lab Private Limited	Vitamin B6
14	M/s Sudarshan Pharma Industries Ltd. (SPIL)	
15	M/s Honour Lab Ltd. (HLL)	
16	Honour Lab Limited	Valsartan
17	Anasia Lab Pvt Ltd	Losartan
18	Hetero Drugs Ltd.	Levofloxacin
19	MSN Life Sciences Pvt. Ltd.	
20	Vital Laboratories Pvt. Ltd.	

21	Vital Laboratories Pvt. Ltd.	Ofloxacin
22	Global Pharma Healthcare Pvt Ltd	
23	M/s Globela Industries Pvt. Ltd.	
24	Kreative Actives Pvt Ltd	Diclofenac Sodium
25	Amoli Organics Pvt Ltd	
26	Vapi Care Pharma Private Ltd	
27	Hetero Drugs Ltd.	Carbidopa
28	Hetero Drugs Ltd.	Levodopa
29	Andhra Organics Ltd	Sulfadiazine
30	Sreepathi Pharmaceuticals Ltd.	Ciprofloxacin
31	Andhra Organics Ltd	Telmisartan
32	Honour Lab Limited	Levetiracetam
33	M/s Globela Industries Pvt. Limited	Norfloxacin
34	M/s Aviran Pharmachem Private Limited	Artesunate
35	M/s K P Manish Global Ingredients Pvt. Ltd.	

Felicitated Mr D. Chandrasekhar, Addl Development commissioner, MSME ,beside are Mr Sudheer Reddy, president TIF and IDMA TSB

Emerging favorable investment climate in the pharma sector of UAE – reg.

IDMA have received communication from Ms. Indu C. Nair, Director (FT(ASEAN), EP Pharma & UNESCAP), Department of Commerce, Ministry of Commerce and Industry, Udyog Bhavan, New Delhi dated 17th December 2021 on the above subject as reproduced below. Members are requested to reap the benefit of the favourable investment conditions.

This is in continuation of the ongoing discussion regarding the emerging favourable investment climate in the pharma sector of UAE. The UAE is currently focusing on cost containment and localized production Keeping in view of the above priorities, the UAE is offering incentives including customs exemptions, industrial license exemption fees and reductions on electricity tariffs to industrial companies to reduce operational costs. In May 2021, the UAE announced that it is seeking investment from Indian-based pharmaceutical companies, offering incentives (including financial contributions) to support manufacturing firms with strong R&D facilities to set up local production plants in the UAE.

The industry is requested to disseminate the information regarding the emerging favourable investment climate for the pharma industry in UAE among industry members to encourage investment of Indian Industry in UAE to reap the benefit of the favourable investment conditions.

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Request for comments on the list of items received from M/o Railways seeking exemption from revised Public Procurement Order, 2017 - reg.

IDMA have received an email communication from Mr Arvind Kumar, Under Secretary, Department of Pharmaceuticals dated 21st December 2021 on the above subject. Members are requested to provide the details at IDMA Secretariat at publications@idmaindia.com

Reference is invited to the OM dt.14.9.2021 of DoP. The information is awaited. In this regard, you are requested to provide the following details of domestic manufacturers of the drugs as mentioned in Annexure-A.

a. Name of the manufacturing entity

b. Address of the Registered Office and Manufacturing location (complete postal address)

c. Contact Details email id and phone numbers (Mobile and Office)

d. Local Content percentage .

e. Whether registered with GeM portal.

Sl No	Name of Medicine	Primary molecule/(s)	Manufactured & Marketed by	Percentage of Local Content	Detailed Remarks of PCMD/PCMO
1	ABEMACICLIB 150MG TABLET.	ABEMACICLIB 150MG TABLET.	ELI LILLY AND COMPANY INDIA PRIVATE LIMITED	20%	IMPORTED PRODUCT
2	Actemra	Tocilizumab 80 mg Inj.	Mfg. By Roche Japan and Mkt. By Roche India Distributed by Cipla Ltd.	Less than 20%	For COVID Management
3	AFATINIB 20 MG TAB 30 mg	AFATINIB 20 MG TAB	Mfg by BOEHRINGER INGELHEIM PHARMA GmBH & CO. KG and Mktd by Boehringer Ingelheim India Pvt Ltd	0	Medicine required for disease specific and patient specific cases
4	AFLIBERCEPT 40 MG	AFLIBERCEPT INJ 40MG VIAL	Mfd by BAYER AG, MULLERSTRASSE 178, D-13353, BERLIN, GERMANY and Mktd by Bayer Zydus Pharma Pvt. Ltd.	0	Medicine required for disease specific and patient specific cases
5	Alecensa 150 mg	Alectinib 150 mg tablet (Ph No-25163)	Mfg by: Excella GmbH, Germany. Mktd by: Roche Products India Pvt Ltd, Mumbai (RB Sl No.86, Product at Sl No.17)	0%	Protein Kinase inhibitor used in the treatment of non-small cell Lung cancer
6	Alteplase 50mg	Alteplase 50mg	Mfd by M/s Boehringer Ingelheim Pharma GmbH & Co. KG Birkendorfer str.65.88397 Biberach an der Riss. Germany. Imported & Mkt By: M/s Boehringer Ingelheim India Pvt Ltd.	Less than 20%	Imported product, not manufacturing in India. For Stroke and heart attack.
7	ATEZOLIZUMAB 840 MG/ 1.2MG	ATEZOLIZUMAB INJ 840 MG VIAL	ROCHE PRODUCTS INDIA PVT LTD	Less than 20%	THIS MOLECULE IS NOT AVAILABLE WITH ANY OF THE INDIAN MANUFACTURER
8	BASILIXIMAB 20 MG	BASILIXIMAB INJ 20 MG VIAL	NOVARTIS HEALTHCARE PRIVATE LIMITED	Less than 20%	THIS MOLECULE IS NOT AVAILABLE WITH ANY OF THE INDIAN MANUFACTURER
9	Brolucizumab solution for injection 120 mg/ml(vial + filter needle)	Brolucizumab	Novartis Pharmaceuticals corporation,(M/s Novartis healthcare Pvt LTD),M/s Sandoz Private Limited	0%	completely imported from switzerland
10	PALBOCICLIB 125 MG	CAP.PALBOCICLIB 125 MG	M/s Pfizer Manufacturing deutschland GmbH ,Germany		
11	CEFTAROLINE 600MG/VIAL	CEFTAROLINE 600MG/VIAL	PFIZER	Less than 20%	THIS MOLECULE IS NOT AVAILABLE WITH ANY OF THE INDIAN MANUFACTURER
12	Ceftazidim 2 gm + Avibactam 500mg Inj.	Ceftazidim 2 gm + Avibactam 500mg Inj.	Mfd & Mktd by M/s Pfizer Ltd.	0%	Imported product, not manufacturing in India.
13	CETUXIMAB 100 MG	CETUXIMAB INJ 100 MG VIAL	MERCK SPECIALITIES LIMITED	Less than 20%	THIS MOLECULE IS NOT AVAILABLE WITH ANY OF THE INDIAN MANUFACTURER
14	Creon 10000	Pancreatin Mini Microspheres equivalent to Pancreatin 150 mg with declared enzyme activity Amylase 8000 PEU/U, Lipase 10000 PEU/U & Protease 600 PEU/U	Minimicrospheres mfg. By abbott Products GmbH Germany and Product Mfg. By Abbott Indore	Less than 20%	For Renal Transplant patients as per recommendation of Nephrologist

Note : First page of Annexure A reproduce for the member reference.

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In Lok Sabha & In Rajya Sabha

In Lok Sabha

Manufacturing of Covid-19 Vaccines

Lok Sabha Unstarred Question No. 1111

Dr. T. Sumathy

(A) Thamizhachi Thangapandian:

Shri D.M. Kathir Anand:

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

(a) whether the Government has ascertained that the two approved COVID-19 vaccine manufacturers of Covishield and Covaxin have achieved the optimum production capacity, if so, the details thereof;

(b) whether the Government or Indian Council of Medical Research has approved any other companies other than the said two companies to manufacture and produce COVID-19 vaccines in India;

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

(d) whether the Central Drugs Standard Control Organisation (CDSCO) has granted import permission/ license for importing and manufacturing of COVID-19 Vaccines to meet the demand in the country; and

(e) if so, the details of the permission granted and the total number and quantum of vaccines expected through this arrangement?

Answered on 03rd 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 (e): 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)

Imports of Raw Materials of Drugs

Lok Sabha Unstarred Question No. 1128

Shri Parvesh Sahib Singh Verma:

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

(a) whether India is dependent on import of many key Chinese raw materials or intermediates and active pharmaceutical ingredients of various essential drugs;

(b) if so, the details of such materials imported during the last three years;

(c) the reasons for the dependence on China for API imports;

(d) the schemes in place to reduce these imports and empower local producers; and

(e) whether India is also completely dependent on Chinese import of any specific drugs and if so, the details thereof?

Answered on 03rd December 2021

A. (a) & (b): Many raw materials are imported from China for manufacturing of medicines. The details of imports of raw materials for the last three years is shown in the table below:

Year	Total value of import	Value of imports from China	Percentage import from China
2018-19	24850.07 Cr	16777.43 Cr	67.5%
2019-20	24171.78 Cr	16443.10 Cr	68.02%
2020-21	28528.97 Cr	19402.60 Cr	68.01%

Source: DGCIS, Ministry of Commerce and Industry.

(c): Most of the imports of the Bulk Drug/APIs being done in the country are because of economic considerations.

(d): The Department of Pharmaceuticals has launched following three schemes for promoting domestic manufacturing of Pharmaceutical drugs including APIs by attracting large investments in the sector to ensure their sustainable domestic supply and thereby reduce India's import dependence on other countries:-

(I) **Production Linked Incentive (PLI) Scheme for promotion of domestic manufacturing of critical Key Starting Materials (KSMs)/ Drug Intermediates (DIs) and Active Pharmaceutical Ingredients (APIs) In India:** The scheme provides for financial incentives will be provided to manufacturers selected under the scheme for manufacturing of 41 Key Starting Materials (KSMs)/ Drug Intermediates (DIs) and Active Pharmaceutical Ingredients (APIs).The scheme provides for incentives on incremental sales to selected participants for a period of 6 years. The total financial outlay of the scheme is Rs. 6,940 crore and the tenure of the scheme is from FY 2020- 2021 to 2029-30.

(II) **Scheme for Promotion of Bulk Drug Parks:** This scheme provides for grant- in-aid to 3 Bulk Drug Parks for creation of Common Infrastructure Facilities (CIF) with a maximum limit of Rs.1000 crore per park or 70% of the project cost of CIF, whichever is less. In case of North Eastern States and Hilly States (Himachal Pradesh, Uttarakhand, Union Territory of Jammu & Kashmir and Union Territory of Ladakh) financial assistance would be 90% of the project cost. The total financial outlay of the Scheme is Rs. 3000 crore and the tenure of the Scheme is from FY 2020-21 to 2024-25.

(III) **Production Linked Incentive Scheme for Pharmaceuticals**: The objective of the scheme is to enhance India's manufacturing capabilities by increasing investment and production in the sector and contributing to product diversification to high value goods in the pharmaceutical sector. One of the further objectives of the scheme is to create global champions out of India who have the potential to grow in size and scale using cutting edge technology and thereby penetrate the global value chains. Under this scheme, financial incentives will be provided to participants selected under the scheme for their incremental sales of eligible drugs manufactured in India. Eligible drugs under the scheme include Active Pharmaceutical Ingredients among other categories of pharmaceutical products. The scheme

provides for incentives on incremental sales to selected participants for a period of 6 years. The total financial outlay of the scheme is Rs. 15,000 crore and the tenure of the scheme is from FY 2020-2021 to 2028-29.

(e): The Indian pharmaceutical industry is the world's 3rd largest by volume, providing 20-22 per cent of generic drugs globally and is one of the biggest supplier of low cost vaccines. In 2020-21, imports of medicines worth Rs. 49,436 crores against export of Rs. 1,80,551 crores indicate the strong capacity of domestic manufacturing. As per the data available from port offices of CDSCO, the imports from China include Antibiotics, Vitamins, Hormones, Antiviral, Anti-TB, Anticonvulsant, Analgesic, Antipyretic, Antidiabetic, Cardiovascular etc.

Minister in the Ministry of Chemicals & Fertilizers (Dr. Mansukh Mandaviya)

FDI

Lok Sabha Unstarred Question No. 1630.

Shri Manoj Kotak:

Shrimati Raksha Nikhil Khadse:

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

(a) whether it is a fact that Government is considering foreign investment as one of the most important drivers of economic growth;

(b) if so, the details of the FDI and portfolio investments in the last five year;

(c) whether the Government plans to attract foreign investment and if so, the details thereof; and

(d) whether the Government plans for effective management for ease of doing business and investment in India?

Answered on 08th December 2021

A. (a): Foreign Direct Investment (FDI) is one of the important drivers of economic growth and a source of non-debt finance for the economic development of India. FDI complements and supplements domestic investment. Domestic companies are benefited through FDI by way of enhanced access to supplementary capital and state-of-art-technologies, as also exposure to global managerial practices resulting into employment generation and accelerated growth of the sectors.

(b): The details of foreign investment reported through routes of Foreign Direct Investment (FDI) inflow and Foreign Portfolio Investment (FPI) inflows (net) during the last five financial years are as under:

(Amount in USD Million)

S. No.	Financial Year	Total FDI Inflow	FPI inflows (net)
1.	2016-17	60,220	7,735
2.	2017-18	60,974	22,165
3.	2018-19	62,001	(-) 2,225
4.	2019-20	74,390	552
5.	2020-21	81,973	38,725

Source: Reserve Bank of India.

(c)**:** To promote FDI, the Government has put in place an investor-friendly policy, wherein except for a small negative list, most sectors are open for 100% FDI under the Automatic route. Further, the policy on FDI is reviewed on an ongoing basis, to ensure that India remains attractive & investor friendly destination. Changes are made in the policy after having intensive consultations with stakeholders including apex industry chambers, Associations, representatives of industries/groups and other organizations taking into consideration their views/comments.

(d) **:** Government has also taken various steps to improve the overall business regulatory environment in the country and create a conducive business environment by streamlining the existing regulations and processes and eliminating unnecessary requirements and procedures.

Recently, Government has taken various steps in addition to ongoing schemes to boost domestic investments in India. These include the National Infrastructure Pipeline, Reduction in Corporate Tax, easing liquidity problems of NBFCs and Banks, trade policy measures to boost domestic manufacturing. Government of India has also promoted domestic manufacturing of goods through the public procurement order, Phased Manufacturing Programme (PMP), Schemes for Production Linked Incentives of various Ministries.

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

PLI SCHEME

Lok Sabha Unstarred Question No. 1675.

Ms. Diya Kumari:

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

(a) whether the Government has devised a plan to promote sectors currently functioning under the Production Linked Incentives Scheme (PLI);

(b) if so, the details thereof;

(c) whether the Government plans to expand the sectors covered under the PLI scheme; and

(d) if so, the details thereof?

Answered on 08th December 2021

A. (a) & (b): Keeping in view India's vision of becoming 'Atmanirbhar' and to enhance India's Manufacturing capabilities and Exports, an outlay of INR 1.97 lakh crore (over US$ 26 billion) has been announced in Union Budget 2021-22 for PLI schemes for 13 key sectors of manufacturing starting from fiscal year (FY) 2021-22.

The 13 key sectors include already existing 3 sectors namely (i) Mobile Manufacturing and Specified Electronic Components, (ii) Critical Key Starting materials/Drug Intermediaries & Active Pharmaceutical Ingredients, (iii) Manufacturing of Medical Devices and 10 new key sectors which have been approved by the Union Cabinet in November 2020. These 10 key sectors are:

(i) Automobiles and Auto Components,

(ii) Pharmaceuticals Drugs,

(iii) Specialty Steel,

(iv) Telecom & Networking Products,

(v) Electronic/Technology Products,

(vi) White Goods (ACs and LEDs),

(vii) Food Products,

(viii) Textile Products: MMF segment and technical textiles, (ix) High efficiency solar PV modules, and (x) Advanced Chemistry Cell (ACC) Battery.

PLI Scheme for an additional sector, Drones and Drone Components, has also been approved by the Union Cabinet in September 2021. With the announcement of PLI Schemes, significant creation of production, employment, and economic growth is expected over the next 5 years and more.

The schemes have been specifically designed to attract investments in sectors of core competency and cutting edge technology; ensure efficiency and bring economies of size and scale in the manufacturing sector and make Indian manufacturers globally competitive so that they can integrate with global value chains.

The PLI schemes are being implemented by the concerned Ministries/ Departments. There are targeted promotion activities being taken up by concerned Ministries/ Departments for identification of potential global and domestic investors by way of organizing investor networking events, investor roundtables, seminars and one-on-one meetings with potential investors.

(c) & (d): All the approved sectors identified under PLI Schemes follow the broad framework of new and emerging technologies where India can leapfrog, overall economic gain accruing to the economy and export potential of the sectors. These sectors were recommended by NITI Aayog after detailed deliberations with concerned Ministries/ Departments followed by approval of the Union Cabinet. Any new sector for PLI will require fresh approval of the Cabinet. There is no proposal by NITI Aayog to expand scheme to other sectors.

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

Foreign Assistance

Lok Sabha Unstarred Question No.1696

Shri G.M. Siddeshwar:

Q. Will the Minister of **SCIENCE AND TECHNOLOGY** be pleased to state:

(a) whether the Government has received foreign assistance through international agreements for carrying out research programmes/ project in the country?

(b) if so, the details of the foreign assistance received during each of the last three years and the current year; and

(c) the details of the direct and indirect conditions imposed on recipient institutions/ bodies by the donors?

Answered on 08th December 2021

A. (a) & (b): No foreign assistance has been received through international agreements for carrying out research programmes/projects by the Department of Science and Technology and Council of Scientific and Industrial Research in the Ministry of Science and Technology.

The details of foreign assistance received by the Department of Biotechnology (DBT), Ministry of Science and Technology during each of the last three years and the current year is given at Annexure.

(c): The details of the direct and indirect conditions imposed on recipient institutions/bodies under DBT by the donors are as under:

Mostly, foreign assistance is governed by program/project specific collaboration agreements, which includes the following;

(i) Various terms & conditions with respect to the modalities of the funding, duration of the program, project implementation activities, milestones, data access/contribution framework(s), reports, project monitoring activities etc.

(ii) The recipient institutions are required to be not-for-profit and located in India.

(iii) All findings are to be submitted to the Funding Agency

(iv) Funding should be duly acknowledged in the publications and patents.

Annexure to part (a) & (b) of the Lok Sabha Unstarred Question No.1696 for 08.12.2021

The details of the foreign assistance received during each of the last three years and the current year is as under:

(i) The department partnered with Wellcome Trust, UK in 2008 to establish Biomedical Research Career Programme (BRCP). The program is administered by the trust "DBT/Wellcome Trust-India Alliance". The program provides opportunities to early, intermediate and senior level researchers to establish their research & academic career in Basic biomedical or Clinical & Public Health in India.

The assistance provided to the DBT/Wellcome Trust-India Alliance from Wellcome Trust, UK during last three years and the current year are placed below:

Amount *(INR in Lakhs)*			
2018-19	**2019-20**	**2020-21**	**2021-22 (Till Date)**
5,000	5,987	6,587	--

(ii) The National Biopharma Mission was approved by the Cabinet for implementation in May 2017 with a total cost US$ 250 million with 50% co-funding by the World Bank. The mission of the programme is to enable and nurture an ecosystem for preparing India's technological and product development capabilities in biopharmaceuticals to a level that will be globally competitive over the next decade, and transform the health standards of India's population through affordable product development.

The total assistance provided to the Biotechnology Industry Research Assistance Council (BIRAC), for implementation of the National Biopharma Mission in last 3 years and current year is as follows, 50% of which is reimbursed by the World Bank:

Amount *(INR in Lakhs)*			
2018-19	**2019-20**	**2020-21**	**2021-22 (Till Date)**
14,500	15,000	30,000	--

(iii) The Department and the Bill & Melinda Gates Foundation (BMGF), came together in 2012 to collaborate on supporting scientific and technological research for the benefit of the people of India and rest of the world. The programme being managed by BIRAC and receives equal contribution from the Department of Biotechnology (DBT), Bill & Melinda Gates Foundation (BMGF), USA. In 2016, Wellcome Trust also entered into partnership with PMU-BIRAC to provide translational research thrust into the programs.

The details of the foreign assistance during each of the last three years and the current year is as follows:

Amount *(INR in Lakhs)*			
2018-19	2019-20	2020-21	2021-22 (Till Date)
39.82	39.67	37.06	0.73

(iv) The foreign assistance received by Autonomous Institutes of the Department of Biotechnology through various International programs/projects is placed below:

Autonomous Institute	Amount *(INR in Lakhs)*			
	2018-19	2019-20	2020-21	2021-22 (Till Date)
DBT-National Institute of Plant Genome Research (NIPGR), New Delhi	55.83	15.26	38.80	Nil
DBT-Translational Health Science And Technology Institute (THSTI), Faridabad	1707.22	1285.43	301.57	67.61
DBT-Rajiv Gandhi Centre for Biotechnology (RGCB), Thiruvananthapuram	168	150	167	194
DBT-Centre for DNA Fingerprinting and Diagnostics (CDFD), Hyderabad	79.36	Nil	Nil	Nil

Minister of State (Independent Charge) of the Ministry of Science and Technology and Earth Sciences (Dr. Jitendra Singh)

Quality of Packaged/Processed Foods

Lok Sabha Unstarred Question No.1142

Shri Brijendra Singh:

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

(a) whether the majority of packaged/processed foods are unhealthy by nutritional standards, carrying long-term risks of chronic illnesses;

(b) if so, the details thereof;

(c) whether the Government intends to set a minimum nutritional standard for said food products to reduce the induced burden on health facilities and enhance diet quality of consumers; and

(d) if so, the details thereof?

Answered on 03rd December 2021

A. (a to d): Food Safety and Standards Authority of India (FSSAI) has informed that all packaged/processed foods have to conform to prescribed standards as in Food Safety and Standards Act, 2006 and Rules & Regulations made thereunder.

FSSAI has set up internationally benchmarked standards for various categories of food products under various Regulations which are largely harmonised with the Codex. FSSAI has also prescribed maximum limits of heavy metals, residues of pesticides and antibiotics/veterinary drugs etc. The standards provide scientific basis for ensuring safety, quality and integrity of food products. These are available at https://www.fssai.gov.in/ The standards are reviewed and updated periodically.

Majority of packaged/processed foods are having minimum standards and these are mandatory. Every FBO has to meet the minimum required standards set for the particular food product. Detailed nutritional information has to be declared on the back of pack of such food products. FSSAI has also notified that trans-fat in oils and fats shall not be more than 2% by weight and in respect of food products, not more than 2% by weight of oil and fat present in the food product. This limit is applicable from 1.1.2022. FSSAI has also nudged food businesses by encouraging them to reformulate packaged foods into healthier options. There are notable social behavioural change initiatives taken by FSSAI promote safe, healthy and sustainable diets. To improve nutritional quotient and fight malnutrition, FSSAI promotes food fortification through notification of regulations and undertakes advocacy for promotion of fortified food in Govt. food safety net programmes and in open market.

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

In Rajya Sabha

Pendency of MEIS and RoDTEP Issues in the Ministry

Rajya Sabha Unstarred Question No. 679

Shri Syed Zafar Islam:

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

(a) whether Merchandise Exports from India Scheme (MEIS) claims for 2020-21 and Remission of Duties and Taxes on Exported Products (RoDTEP) issues related to fixing price, refund are pending in the Ministry;

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

(c) the details of steps taken/being taken by the Ministry to expedite these issues?

Answered on 03rd December 2021

A. (a) & (b) : In September 2021, Government has released requisite funds for settling claims under Merchandise Exports from India Scheme (MEIS). As on 25.11.2021, out of all MEIS claims applied for period 2020-21, duty credit scrips have been issued for 97.3% of claims and 2.7% claims are under various stages of approval process. Completed MEIS applications are largely system driven except for certain applications which require manual examination such as for exports from non-EDI (Electronic Data Interchange) ports. Disposal of pending applications is also dependent on compliance of deficiencies by the applicant exporters.

A new Scheme, Remission of Duties and Taxes on Exported Products (RoDTEP) has been introduced for exports from 01.01.2021. RoDTEP Scheme guidelines and rates of remission were notified on 17.08.2021. After the notification representations have been received by members of trade and industry raising concerns about the notified rates and exclusion of exports under Advance Authorization (AA)/ Special Economic Zones (SEZ) and Export Oriented Units (EOUs).

Government has set up a Committee in the Department of Revenue, Ministry of Finance in October 2021, for determination of RoDTEP rates for AA/EoU/SEZ exports and to give supplementary report/ recommendations on issues or representations relating to errors or anomalies arising from the report of the earlier RoDTEP Committee, as well as the report of the incumbent RoDTEP Committee.

(c) : In order to liquidate the pendency under MEIS, regular follow up and monitoring is done with all the regional offices of Directorate General of Foreign Trade (DGFT).

The Minister of State In The Ministry of Commerce And Industry (Smt. Anupriya Patel)

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Delhi High Court orders complete disclosure of veg, non-veg ingredients of food items

The court said that the failure on the part of the Food Business Operators to comply with the requirements would expose them to class action for violation of the fundamental rights of the consuming public and invite punitive damages, apart from prosecution.

The Delhi High Court has said that all food business operators should make a full and complete disclosure of all the ingredients in any food article. (Representational image)

Ruling that everyone has a right to know what they are consuming, the Delhi High Court has said that it is mandatory for all food business operators to make a "full and complete disclosure" of all the ingredients that go into the making of any food item.

The disclosure should not only be by their code names but also by disclosing as to whether they originate from plant or animal source, or whether they are manufactured in a laboratory, irrespective of their percentage in the food article, said the court.

"It should also be fairly disclosed as to what is the plant source, or animal source — as the case may be, in respect of all the ingredients in whatever measure they are used," said the Division Bench of Justice Vipin Sanghi and Justice Jasmeet Singh.

The court said that the failure on part of Food Business Operators to comply with the requirements would expose them to class action for violation of the fundamental rights of the consuming public, and invite punitive damages, apart from prosecution.

"Food Safety and Standards Authority of India should verify all such claims made by the Food Business Operators, and the connivance or failure on the part of the FSSAI or its officers to perform their duties shall expose all such officers to claims by the aggrieved parties, and prosecution under the law," said the court.

The order has been passed in a petition filed by Ram Gaua Raksha Dal, a non-governmental trust, which has argued that they want their 'right to know' to be respected. The trust wanted the authorities to strictly implement the existing rules on labelling of food products and cosmetics. It also argued that these rules should be made mandatory for all other items.

The members of the Trust are followers of Namdhari sect of Sikhism and they profess strict vegetarianism, the court was told. "The members do not know which of the products available in the market are fit for consumption by those professing strict vegetarianism because a lot of products, including eatables, are either having either non-vegetarian ingredients or undergo processing in such a way that they cannot be described as strictly vegetarian," the petitioner told the court.

The court said failure of the authorities in checking such lapses is leading to not only non-compliance of the Food Safety and Standards Act and the Regulations but also leading to deceit by such Food Business Operators of the public at large, particularly those who wish to profess strict vegetarianism.

"It matters not as to what is the percentage of such like ingredients (which are sourced from animals), which are used in the manufacture of food article. Even though their usage may constitute a miniscule percentage, the use of non-vegetarian ingredients would render such food articles non-vegetarian, and would offend the religious and cultural sensibilities/ sentiments of strict vegetarians, and would interfere in their right to freely profess, practice and propagate their religion and belief," said the court.

It also said that the Act very clearly intends and expressly provides for declaration on all food items being made. But some food business operators are taking advantage by misreading the regulations, it added.

Source: Sofi Ahsan, Indian Express, 14.12.2021

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Parliamentary panel asks DoP to conduct in depth study on concessions given by China to its bulk drug industry

The Department related standing Committee for the Ministry of Chemicals and Fertilisers has once again asked

the Department of Pharmaceuticals (DoP) to conduct an in depth study of various concessions being provided by China to its bulk drug industry and to initiate further measures on war footing to address the drug security issues related to overdependence on imported raw materials for pharmaceutical industry in the country. It has also called for an action taken report from the NITI Aayog on various recommendations it has submitted earlier in this regard.

The Committee, in its Action Taken report on its earlier report on Demands for Grants 2021-22 of the DoP, noted that the Department, in consultation with the NITI Aayog, has launched the Production Linked Incentive (PLI) Schemes for Key Starting Materials (KSM)/Drug Intermediates/Active Pharmaceutical Ingredients (APIs) in India; bulk drug parks; and PLI for pharmaceuticals.

While appreciating these steps, the Committee headed by Member of Parliament Kanimozhi Karunandhi, said it "feel that it is necessary to make an in depth study of various concessions being provided by China to its bulk drug industry and to initiate further measures in a war footing manner so as to make the country a viable competitor to China in the field of production of API/bulk drug/KSMs". It has in an earlier report, recommended various steps including the in depth study to improve availability of local raw materials for the sector.

"The Committee hopes that immediate steps will be taken in this regard. An action taken reply may be furnished to the Committee in the matter," it said in the report submitted to the Parliament recently.

Further, it noted that the API/KSM/DI manufacturing sector requires robust infrastructural support and subsidised utilities such as electricity, water, steam, brine, effluent treatment plant etc. to help create economies of scale for fermentation based bulk drug industry clusters.

The Schemes launched by the Government would have addressed these necessities for creation of a strong fermentation based bulk drug industry in the country. It asked the DoP to intimate about the extent of infrastructural and utilities support being provided under the new schemes.

While the Committee has earlier recommended a reclassification of suppliers into three categories - Class 1 with 100 per cent local content, Class II with 80 per cent local content and Class III with 60 percent local content - in order to improve availability of local products, and to provide progressive incentives like zero duty on 100 per cent local content suppliers and rationally increasing duty on other two categories of suppliers both for public and private procurements done in pharma sector, the Department was silent on the latter recommendation, it said.

It has also sought the government to enhance the budget allocation for scheme Promotion of Bulk Drugs during the revised estimation stage for the year 2021-22 to make effective strides in establishing three bulk drug parks and expand the scheme to establish more bulk drug parks in future. The DoP should also frame a comprehensive incentive policy for domestic bulk drugs producers, it added.

"The Committee hopes that this Scheme will get adequate and timely financial support from the Ministry of Finance and the progress made in this regard may be intimated to the Committee. Moreover, along with the establishment of three bulk drug parks, the Committee recommends that the work to establish more such parks should also start at the right earnest so as to create a strong base for the manufacturing of bulk drugs in the country," it added. It also sought specific action taken replies from NITI Aayog to be furnished to the Committee along with the action taken replies of the Department on the report.

Source: Gireesh Babu, Pharmabiz, 08.12.2021

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Vaccinate all, sequence genes

Synopsis

Indian vaccine makers, Bharat Biotech and Zydus Cadila, must publish studies on the efficacy of their vaccines in relation to the Omicron variant

As the cases of Omicron variant rise, the government must redouble its vaccination efforts. Even as a decision on the need for a booster is discussed, it is critical to complete the first round of vaccination. This will require addressing issue of hesitancy and anti-vaxerism, accounting for sizeable population groups. An aggressive outreach campaign to ensure that everyone takes the full dose of the vaccine is vital. Some experts warn that an Omicron wave is likely to hit India early next year. This gives the government a small window in which to complete the vaccination drive.

Indian vaccine makers, Bharat Biotech and Zydus Cadila, must publish studies on the efficacy of their vaccines in relation to the Omicron variant. Alongside, there has to be a push to develop new drugs for Covid, apart from

to licence the production of promising candidates from MSD and Pfizer, in addition to the monoclonal antibody treatment from Regeneron. Another area that India must augment is genome sequencing, given the population size. Early warning system for such diseases is critical, especially given that zoonotic diseases are likely to be more prevalent than less. India has the capacity but the will has been lacking, so far. Clear policy guidance and investment into these areas will help buttress the health system, which has many gaps.

A little over 50% of the adult population is fully vaccinated and 80% have been vaccinated at least once.

A little over 50% of the adult population is fully vaccinated and 80% have been vaccinated at least once. Public data demonstrate that in many states, rural areas are lagging urban areas. In some states - Uttar Pradesh, West Bengal, Bihar, Maharashtra - the gap between the fully and partially vaccinated is around 50%, in some others, it is about 30%. This gap must be closed. A decision regarding a third dose must be taken soon, as well. Omicron is an extremely infectious variant. Safeguarding the population will require taking the difficult decision on mandating vaccination or negative test reports as a precondition for accessing public spaces, such as transport, government offices and educational institutions.

Source: ET Bureau, 19.12.2021

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PM's vision brought health, pharma under single minister: Mansukh Mandaviya

The minister elaborated that the regulatory body, Drugs Controller General of India, is under the health ministry although its work comes under pharma.

Union Health Minister Mansukh Mandaviya Saturday credited Prime Minister Narendra Modi for bringing the

Health Minister Mansukh Mandaviya speaks in the Lok Sabha during ongoing Winter Session of Parliament, in New Delhi, Friday, Dec 10, 2021

health and pharmaceutical ministries under a single minister. "Modiji, for the first time, entrusted health as well as pharma ministries in one person. This is so beneficial because all policy (niti) of health is dependent on pharma and vice versa," Mandaviya said addressing an inaugural programme on holistic healthcare with a focus on pharmaceuticals and medical devices at a pre-Vibrant Gujarat Summit.

The minister elaborated that the regulatory body, Drugs Controller General of India, is under the health ministry although its work comes under pharma. "So, when I was the pharma minister (chemicals minister), if I would put forth a proposal (before the DCGI), I would have again to go to the health minister for approval. With both combined, it has become holistic because Modiji saw everything in totality," he said.

The Union Minister further said health was never seen as a factor of development. "Health was always perceived as treatment. Modiji has linked development to the health sector. He started Ayushman Bharat, and health and wellness centres. Modiji thought comprehensively and increased MBBS seats that will go up to one lakh so as to strengthen the tertiary health system at the district level. When he became the PM, there were 6 AIIMS, now the 12th has started," Mandviya said at the event held at Pandit Deendayal Energy University at Gandhinagar.

In July, as the country was easing out of the second wave of the pandemic and entering the mucormycosis epidemic, the portfolio of health and family welfare was handed over to Mandaviya following Harsh Vardhan's resignation ahead of the cabinet shuffle. Prior to it, Mandaviya held the independent charge as Minister of State for chemicals and fertilizers from 2019, which he continues to hold.

Mandaviya also pitched for Gujarat and India as investment destinations, especially in the pharma sector. "The number of people in the middle-class bracket is increasing rapidly and the Union government is introducing schemes for healthcare accessibility. Due to Ayushman Bharat, 10 crore families, or 50 crore people, can access affordable healthcare facilities. I've seen it myself how poor families forego treatment because of cost so that their kids' education is not stopped or their daughters' weddings are not hindered or delayed. With Ayushman Bharat, people are buying medicines, which is an opportunity for the pharma sector," he said.

Mandaviya said there were two opportunities for the sector. "One is to scale-up in India and second, exports. After Covid-19, everyone wants to invest in India as their first priority."

Acknowledging the delay faced by industries in securing approvals for conducting the necessary research, Mandaviya said, "When Modiji called for a meeting with industrialists, many industries said they want to do research but they don't get the necessary permissions for up to three years in India. DCGI ensured to remedy this and make approvals simpler. Owing to this, in nine months, research was done and the production of the Covid vaccine was also done," he said referring to Covaxin jointly developed by Bharat Biotech and the Indian Council of Medical Research (ICMR).

At the event, DCGI VG Somani lauded Gujarat's machinery that was rolling out a "very well-structured innovation pipeline". "The entire machinery, be it politicking, bureaucracy or FDCA (Food and Drugs Control Administration) Gujarat, they value time, quality and demands — local, national and global. The way shown by Gujarat to access affordable medicines is being keenly watched by the whole world. Gujarat has the potential to meet 50 per cent of the demand of India and 20 per cent of the world, provided they take steps to reduce dependency on APIs (active pharmaceutical ingredient) and KSMs (key starting materials). It needs to take further steps to innovate and other issues such as pollution-related matters, which does not get fast-tracked," he said.

Source: Indian Express, 19.12.2021

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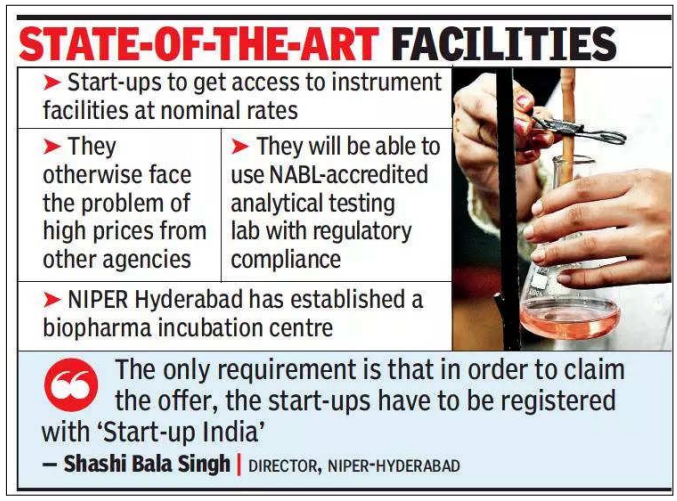
NIPER to open its doors for start-ups in biopharma

Hyderabad: In a first such move, the National Institute of Pharmaceutical Education and Research (NIPER) will open its doors for start-ups, offering its premier laboratory and other facilities for biopharma research and development. Shashi Bala Singh, director, NIPER-Hyderabad, said the institution will provide access to its instrument facilities at nominal rates to all start-ups working in biopharma sector. "The instrument facilities include state-of-the-art NABL-accredited analytical testing laboratory with regulatory compliance. To encourage entrepreneurship and innovation in biopharma sector, NIPER Hyderabad has established a biopharma incubation centre as a non-profit organisation named Aishkaran - Foundation for Pharma Innovation," she said.



The incubation centre was established under the prestigious Bio-NEST (Bio-incubators Nurturing Entrepreneurship for Scaling Technologies) scheme sponsored by Department of Biotechnology, Government of India.

She said as NIPER is situated in pharma capital of India, the institution aspires to build the spirit of entrepreneurship. The initiative is in sync with the Centre's 'Startup India' scheme, which promotes the cause of entrepreneurship in all aspects.

"The nominal prices of using instruments comes as a great advantage as the MSMEs and new start-ups face the problem of high prices from other agencies. The only requirement is that in order to claim the offer the start-ups have to be registered with Startup India," she added.

Dr Shashi Bala Singh said it is the right time for biopharma sector to grow, as the government is determined to assist the sector.

NIPER was recently accorded status of Institute of National Importance. The institute is giving a major thrust

in development of the biopharma sector for the benefit of entrepreneurs.

Source: Syed Akbar TNN, 23.12.2021

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Zydus's needle-free Covid vaccine may be introduced next week

According to the company, the Centre has placed an order of 10 million vaccine doses, at Rs 265 per dose

Beneficiaries receive Covid-19 vaccine shots at a vaccination centre in Thane on Thursday. The Centre announced that Zydus Cadila's Covid-19 vaccine ZyCoV-D will initially be used in districts in seven states.

The Zydus Healthcare's anti-coronavirus disease vaccine, ZyCoV-D, could be introduced in the national vaccination programme by next week, according to people familiar with the development.

"The training of vaccinators who would be administering the shots is nearly complete and the vaccine could be introduced very soon; likely by next week," said a person aware of the matter on condition of anonymity.

ZyCoV-D, which is world's first DNA-based and needle-free Covid-19 vaccine, has been approved for emergency use in people 12 years of age and above. However, in the absence of any policies in place on vaccinating children, the Union government has decided to first use the vaccine in adults.

According to the company, the Centre has placed an order of 10 million vaccine doses, at ₹265 per dose. Additionally, ₹93 will be charged as the cost of the needle-free intradermal applicator, which is required to administer the shot. The supplies are being released in a phased manner, according to people familiar with the matter.

ZyCoV-D, which is only the second indigenously developed Covid-19 vaccine besides Covaxin, will be initially used in districts of seven states that have low first dose coverage before being rolled out nationwide, one of the people cited above said. The seven states are Bihar, Jharkhand, Maharashtra, Punjab, Tamil Nadu, Uttar Pradesh and West Bengal.

The Central Drugs Laboratory in Kasauli, Himachal Pradesh, has cleared for market release close to 250,000 doses of the Zydus vaccine after putting the vials through stringent quality tests.

On August 20, the Drugs Controller General of India granted emergency use authorisation to ZyCoV-D but it is yet to be included in the vaccination drive.

Once rolled out, ZyCoV-D will become the third vaccine being used in the national vaccination programme, along with Covishield and Covaxin.

As on December 16, 87.5% of the eligible population has received at least one dose of the Covid-19 vaccine while 57.1% has been fully vaccinated.

Source: Rhythma Kaul, Hindustan Times, 17.12.2021

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SII Executive Director Dr Suresh Jadhav dies at 72

Dr Cyrus Poonawalla, chairman and managing director of Serum Institute of India, expressed sadness at the loss and said Jadhav was the international face of SII.

He was instrumental in the devpt of Covishield'

Dr Suresh Jadhav, one of the executive directors of Serum Institute of India, passed away late Tuesday night at Sahyadri Hospital due to renal failure and related complications. He was 72.

Dr Cyrus Poonawalla, Chairman and Managing Director of Serum Institute of India, expressed sadness at the loss and said Jadhav was the international face of SII. Jadhav is survived by his wife and two children. Adar Poonawalla, CEO of SII and other officials, visited Jadhav's residence to pay their last respects.

"Dr Jadhav was instrumental in setting up the Developing Countries Vaccine Manufacturing Network. He represented Serum Institute of India on the GAVI board and was also instrumental in liasioning with national and international regulatory authorities. He played a pivotal role in getting WHO pre-qualifications for several products," Poonawalla said. "Besides his role in quality control and regulatory affairs, he was the international face of Serum Institute of India," Poonawalla said.

Jadhav was instrumental in the development of Covishield vaccine.

Dr Soumya Swaminathan, chief scientist at WHO, tweeted, "Very Sad news. Exceptional lifetime contributions to vaccine development with huge impact on lives saved."

Prashant Yadav, a globally recognised scholar in the area of healthcare supply chains, also tweeted that he was a stalwart of vaccine manufacturing in India and built the technical capabilities of Serum Institute of India. "His passing away is a sad day for all in the vaccine industry, especially the DCVMN," he tweeted.

Source: Express News Service, 09.12.2021

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Mahima Datla: Scale Matters

Mahima Datla is leading Biological E into the Covid-19 vaccine market, and way beyond

Mahima Datla, 44, Managing Director, Biological E

For nearly two years, MahimaDatla and her team have been working relentlessly behind the screen to enter the Covid-19 vaccine market at the right time, with the right product. In her own words, the team crammed in 5-10 years of work into a single year. And the results are beginning to show.

Biological E, which has been manufacturing vaccines for over six decades, is weeks away from launching its Covid-19 vaccine Corbevax—developed in partnership with Baylor College of Medicine in Houston and California-based biopharmaceutical firm Dynavax Technologies.

Biological E targets to produce one billion Corbevax doses annually, including a mandate to supply 300 million doses to the Indian government. Meanwhile, Biological E's clinical trials for a Covid-19 vaccine for children are in the final phases.

India's first private sector biological products manufacturer, Biological E is aiming to make the most affordable vaccine at one of the highest scales globally.

"We decided early on that if we want to be meaningful, we don't have to be the first, but we need to be in many ways the largest to achieve economies of scale to produce the most affordable product. So from day one, we chose scaleable technologies to make the end cost affordable for the customer," says Datla.

Despite severe supply chain disruptions in the past two years, Datla says the company made great strides in Covid-19 vaccine development and, most importantly, did not miss any of its supplies for regular vaccines.

And that's no mean feat. Biological E provides a number of vaccines including hepatitis B, DPT, influenza, Japanese encephalitis, measles and rubella to close to 150 countries.

"Fifty per cent of our business comes from the Government of India and 50 per cent [from the] rest of the world. Despite the lockdown, we ensured every single customer of ours was serviced for all of the routine vaccines," she adds.

Source: Binu Paul, BuinessToday.In, 23.12.2021

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