

# IDMA BULLETIN

VOL. NO. 53

ISSUE NO. 17 (PAGES: 48)

01 TO 07 MAY 2022

ISSN 0970-6054

WEEKLY PUBLICATION



## INDIAN PHARMA - GLOBAL HEALTH CARE

INDIAN DRUG MANUFACTURERS' ASSOCIATION

### HIGHLIGHTS

- ★ **IDMA and US FDA Meeting at IDMA Office on 20<sup>th</sup> April 2022** (Page No. 4)
- ★ **Indian Pharmaceuticals clock best export performance ever in FY22** (Page No. 44)
- ★ **Smriti Irani hails Gujarat contribution in Pharmaceutical exports** (Page No. 44)

WE DO WHAT WE SAY.  
AND SAY WHAT WE DO.  
THAT'S OUR **RELIABILITY**  
YOU CAN RELY ON.



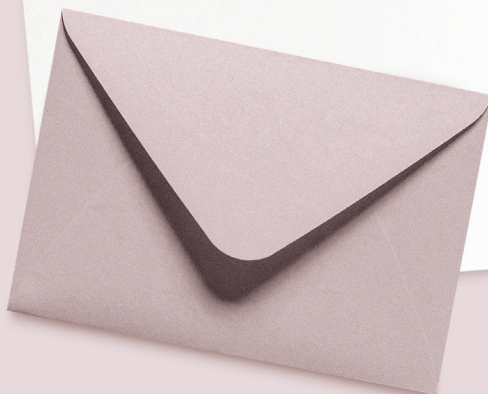
**Dear Partner,**

Consistency is one of the key factors of our success in the pharmaceutical excipients industry. It is why our customers have been able to trust and depend on us. And esteemed partnerships with the likes of CP Kelco and Nouryon, have only reinforced our adherence to these principles.

CP Kelco is backed by over 200 years of successful operational experience in globally diverse markets. They are trusted the world-over, for their efforts toward responsible business, ethics and environmental practices. Nouryon, formed in 2018, has swiftly become one of the world's top producers of specialty chemicals, with a keen focus on safety and sustainability in all their processes.

Signet takes immense pride in partnering with CP Kelco and Nouryon, the most reliable experts in Hydrocolloid manufacturing, modification and application, as well as Sodium CMC. They provide countless useful products such as Xanthan Gum, Gellan Gum, Pectin and Sodium CMC, that each serve a variety of functions - from viscosity modification to suspension stabilisation, as a thickening agent or gelation.

Signet-ure  
*reliability*



A HUBER COMPANY

**XANTURAL - Xanthan Gum**

- Xantural 75 - Fine Particle Size
- Xantural 180 - Coarse Particle Size
- Xantural 11K - Agglomerated Type

**KELCOGEL - Gellan Gum**

- Kelcogel CG LA - Low Acyl Type
- Kelcogel CG HA - High Acyl Type

**GENU PECTIN - Pectin (Citrus)**

**Nouryon**

**CEKOL - Carboxymethylcellulose Sodium**

- Cekol 30 / 700 P / 2000 P / 4000 P / 10000 P
- Cekol 20000 P / 30000 P / 40000 / 50000 P / 100000
- Majol 25000 S

**CHELATES**

- Dissolvine Na<sub>2</sub>-P - Disodium EDTA

**Signet**

The Complete Excipients Company



**Founder Editor:**  
Dr. A. Patani

**Editor:**  
Dr. Gopakumar G. Nair

**Associate Editors:**  
Mr. J. L. Sipahimalani  
Dr. Nagaraj Rao  
Dr. George Patani

**National President**  
Dr. Viranchi Shah

**Immediate Past National President**  
Mr. Mahesh Doshi

**Senior Vice-President**  
Mr. Bharat N Shah

**Vice-Presidents:**  
Dr. George Patani  
(Western Region)

Mr. Asheesh Roy  
(Eastern Region)

Mr. B K Gupta  
(Northern Region)

Mr. T Ravichandiran  
(Southern Region)

**Hon General Secretary**  
Mr. Mehul Shah

**Hon Joint Secretaries**  
Mr. Kamlesh C Patel  
Mr. Pranav Choksi

**Hon Treasurer**  
Mr. Vinay Pinto

**For information contact :**  
IDMA Secretariat: (H.O.)

Daara B Patel  
Secretary-General

Melvin Rodrigues  
Sr Manager (Commercial & Administration)

IDMA State Boards	Chairman
▶ Gujarat State Board	: Dr. Shrenik K Shah
▶ Haryana State Board	: P K Gupta
▶ Himachal Pradesh & Uttarakhand State Board	: R C Juneja
▶ Karnataka State Board	: S M Mudda
▶ Madhya Pradesh State Board	: Paresh Chawla
▶ Tamil Nadu, Puducherry & Kerala State Board	: J Jayaseelan
▶ Telangana State Board	: Shaik Janimiya
▶ West Bengal State Board	: Shiv Sagar Tewari
IDMA Delhi Office	: Ashok Kumar Madan Executive Director S. Ranganathan Asst. Manager (Administration)

A Publication of  
**Indian Drug Manufacturers' Association**  
102-B, 'A-Wing', Poonam Chambers,  
Dr. A.B. Road, Worli, Mumbai - 400 018  
Tel : 022-2494 4624 / 2497 4308 Fax: 022-2495 0723  
e-mail: publications@idmaindia.com/  
actadm@idmaindia.com/ website: www.idma-assn.org

**Published on 7<sup>th</sup>, 14<sup>th</sup>, 21<sup>st</sup> and 30<sup>th</sup> of every month**

**Annual Subscription**  
₹ 1000/- (for IDMA members)  
₹ 2000/- (for Government Research/Educational Institutions)  
₹ 4000/- (for non-members) US\$ 400 (Overseas)  
Please send your payment in favour of  
**Indian Drug Manufacturers' Association**

OPINIONS EXPRESSED BY THE AUTHORS OF INDIVIDUAL ARTICLES  
DO NOT NECESSARILY REPRESENT THE OFFICIAL VIEW OF IDMA.

# IDMA BULLETIN

Vol. No. 53

Issue No. 17

01 to 07 May 2022

## IDMA ACTIVITIES:

IDMA and US FDA Meeting at IDMA Office on 20th April 2022 ..... 4

Report on India Pharmaceutical and Medical Device  
International Conference 2022 ..... 8

IDMA Congratulates Mr Daara B Patel, Secretary – General,  
on his 20<sup>th</sup> year work Anniversary ..... 10

## GOVERNMENT NOTIFICATIONS:

Notification on Constitution of Central Council of  
Health and Family welfare ..... 12

Palm Fatty Acids (Quality Control) Order, 2022 published ..... 14

Rice Bran Fatty Acids (Quality Control) Order, 2022 published ..... 15

Coconut Fatty Acids (Quality Control) Order, 2022 published ..... 16

## GOVERNMENT COMMUNICATIONS:

India Pavilion at Africa Health Excon, Cairo, Egypt 5-7 June 2022  
Egypt International Exhibition Center (Eiec) : Hall 1 ..... 17

Business Delegation to LATAM: Colombia, Bolivia,  
Peru & Brazil (23<sup>rd</sup> July – 6<sup>th</sup> August 2022) ..... 19

Register your Participation: Pharmexcil Business Delegation  
(physical) to Indonesia, Philippines and Vietnam during 27<sup>th</sup>  
June 2022 until 6<sup>th</sup> July 2022 (MAI assistance available) ..... 21

Salient features of Pharma Annexure under  
"India-UAE CEPA" & "India-Australia ECTA"? ..... 23

Information sought from Exporters/Importers to Russia ..... 24

## DGFT MATTERS:

Amendment of Appendix 2B [List of Agencies Authorised  
to issue Certificate of Origin (Preferential)] of Foreign  
Trade Policy, 2015-2020 ..... 25

Amendment in Para 2.107 (TRQ under FTA/CECA)  
of Handbook of Procedure 2015-2020 ..... 26

## PARLIAMENT NEWS:

In Rajya Sabha & In Lok Sabha ..... 38

## NATIONAL NEWS:

Indian Pharmaceuticals clock best export  
performance ever in FY22 ..... 44

Smriti Irani hails Gujarat contribution in pharmaceutical exports ..... 44

*Blue Ocean of Compliance* by Dr. Rupali  
*Paranjape # 1 Best Sellers book on Amazon* ..... 37

**Book Reviews:** 4 Volumes on "Reviews on Indian  
Medicinal Plants" Released - Dr DB Anantha Narayana ..... 43

Advertisements ..... 2, 47 & 48



## Meeting at IDMA Office on 20<sup>th</sup> April 2022

IDMA had a meeting with US FDA Officials at IDMA office on the 20th April 2022. The US FDA was represented by Dr. Sarah McMullen, Dr. Sudheendra Kulkarni and Mr. Dhruv Shah. IDMA was represented by 20 IDMA members from different companies.

Mr. Daara Patel, Secretary General welcomed the Dignitaries and IDMA members & briefed them about the meeting.

Mr. Mehul Shah, Hon. General Secretary, Mr. S M Mudda, Chairman Regulatory Affairs Committee and Mr. Daara B Patel Secretary General presented the US FDA officials with Bouquets and Mementos.

Mr. Mehul Shah chaired the meeting and set the tone with his opening remarks which is reproduced below:

*Good Afternoon, Ladies and Gentlemen:*

*On behalf of our National President Dr. Viranchi Shah & Members of Indian Drug Manufacturers' Association (IDMA), I welcome all of you for the meeting with US FDA leaders. I am grateful to industry representatives and US FDA leaders for this interactive meeting.*

*I personally thank you all for your presence and special thanks to Dr. Sarah Mc Mullen, Dr. Sudheendra Kulkarni and Mr. Dhruv Shah from US FDA for their august presence.*

Mr. Mehul Shah briefed the US FDA Officials about Indian Drug Manufacturers' Association (IDMA) and said that it was established in 1961. He further added that IDMA is the industry association of leading pharmaceutical companies based throughout India. IDMA works with the

Government of India on industry's development plans, represents the industry on prominent issues such as pricing, regulatory affairs, and other policy matters, and plays a crucial role in keeping business leaders, media, and public informed about the industry. IDMA has more than 1,000 companies as members. It regularly organizes seminars, training programs and workshops for the benefit of members and the industry at large. We work closely with the Indian Pharmacopoeia Commission in compiling and bringing out the Indian Pharmacopoeia and wholeheartedly supports them in all their activities. We have also contributed to guiding industry in constantly improving quality and efficacy through our highly regarded "Annual Pharmaceutical Analyst Conventions" held since 1997.

The Indian Pharmaceutical industry is committed to manufacturing and supplying, innovative, cost-effective and efficacious medicines to patients and consumers in the US and rest of the world. The objective of today's discussion is to convey our expectations to the US FDA and receive their kind guidance on how we can together continue to develop and deliver high-quality medicines within a robust and forward looking regulatory framework. I trust we all can do very well, like we have done in the past. The future holds a bright promise for us "good health for everyone".

Mr. S M Mudda briefed the august gathering on various quality initiatives, APPQM, QMM draft etc. It was basically communicated to the USFDA officials that members are having compliance mind set and they all are very committed to get the approvals within stringent time frame. The points which were discussed in meeting were as follows

Sr. No	Agenda Points discussed with US FDA officials	Response from US FDA officials
1.	Restructuring of GDUFA fees-The GDUFA and facility maintenance fees are very high.	The officials replied that the Fees cannot be changed as GUDUFA 3 is fixed for period from Oct 2023 to Sept 2027. They have asked us to engage later for GDUFA 4 at an appropriate time.
2.	The inspection conducted are very stringent and the expected time for submission for the responses to the FDA is within 15 days, this time is not sufficient to check the impact assessment and remedial action plan with the subject matter experts as the time frame for submission is very small.	<p>The officials replied to this query that the Agency doesn't expect all the response and actions within 15 days. They mentioned that the organisation needs give an action plan which meaningful and sustainable within 15 days timeframe, some of the actions like training or SOP can be completed within 15 days.</p> <p>Further in the response they told that the timelines can be mentioned for the activities which will take more than 15 days to complete and implement.</p> <p>Although inspector indicates recommended classification, it is the centre that will finally assign the category (OAI, VAI or NAI).</p>
3.	The frequency for FDA inspection can be reduced for the organisations which are already approved by other regulatory bodies like EDQM, MHRA, PIC and TGA based on their GMP certificates and QMS data.	To this query they have mentioned as it is not possible.
4.	The time required for Transfer of Technique, applying for DMF for many important generic medicines is more than two years due to which there is shortage of generic medicines.	The officials said that the FDA Agency is trying to harmonise and make the FDA approval procedures (for ANDA, DMF) transparent so as to bring the approval time from 22 months to 18 months, for this the agency excepts the completeness of the documents. The approval takes time due the major or minor deficiencies in the approval documents due to which the Agency requires more data such as B.E studies, stability.
5.	There should be provision for supplying the Emergency and SOS medicines on priority in cases of situations such as Pandemic which will help to save lives of many patients.	The officials responded that during Emergency and SOS the Agency takes the call based on priorities and shortages.
6.	After an unsuccessful FDA inspection companies have to wait for nearly 1 to 5 years for next inspection for getting the approval, here IDMA can play an important role of bridging FDA inspection findings by monitoring progress through FDA nominated and recognised experts who will give diligent feedback on the remedial actions taken on the FDA observations.	They replied that time frame for inspection is challenge for both industry and Agency, but priorities are decided by the Agency Seniors in US.

7.	A harmonised procedure to be developed for procurement of Quality Reference standards for generic products on priority, also to facilitate early distribution of standards Indian reference standards can also to be considered.	They have agreed to revert.
----	--	-----------------------------

The following points were also discussed at the meeting:

Sr. No	Other Points discussed with US FDA officials	Response from US FDA officials
1.	The QMM point which is draft stage.	The response is that there is no firm plan as of yet
2.	Can ICH Q 12 be properly followed by US FDA for improving agility of suppliers, API, Packing materials etc.	The official responded that the organisation should bring case to case issues and to be pursued with US FDA.
3.	Is there any way to improve or minimise the Review cycle for CR /IR/DRL	The officials said it is not possible.
4.	Reviewers harmonisation	The officials said it is not possible.
5.	For Topical products a more product specific guidance's to be provided on fast track	FDA is working with various Institutions, R & D on the same. They have issued 79 guidance's in past 2 years.  The Agency requests to the industry that prior to designing of product where there is no guidance available, the industry can get in touch with Agency for prior guidance.
6.	IVRT/IVPT training	The officials said they are ready to conduct trainings overall as per topics suggested by IDMA like for e.g. IVRT/IVPT, Nitrosamine impurities, Filing of DMF & ANDA.

We give below the brief summary of the meeting was:

1. The members are requested to fill and give basic details in the survey provided by the USFDA which will help us to identify the gaps.
2. List of topics for the trainings which will be conducted by USFDA officials to be provided for example. IVRT/IVPT for topical products, Filing of DMF and ANDA.
3. Members should proactively connect with FDA on any specific issues if required.
4. The FDA Agency is transparent for their ANDA programme/product review, members should be in touch with Agency for review update, so that upfront information can be obtained

5. USFDA officials want to conduct programme for IDMA members in Mumbai or Gujarat where maximum members there, it can be a hybrid program, so that members from other States can join and things can hasten up. IDMA has the capability to host such hybrid event on large scale.
6. As intimated by the FDA officials the frequency of inspection will increase from next month so members are requested to focus on that and overall compliance

The interactive meeting was very vibrant and informative and appreciated by all present specially the efforts made by the US FDA to bridge the gap for the Regulatory compliance issues.

## Glimpses of meeting



# Report on India Pharmaceutical and Medical Device International Conference 2022

India Pharmaceutical and Medical Device International Conference 2022 was held on 25<sup>th</sup> to 27<sup>th</sup> April 2022 at Dr Ambedkar International Centre, New Delhi.

Dr Mansukh Mandaviya, Union Minister for Chemicals & Fertilizers and Health & Family Welfare, inaugurated the Conference. The inauguration took place in the presence of Mr. Bhagwanth Khuba, Minister of State for Chemicals and Fertilisers and Ms S Aparna, Secretary, Department of Pharmaceuticals.

Addressing the event, Dr Mansukh Mandaviya said that the Indian healthcare sector is becoming affordable and accessible for everyone due to the relentless efforts and leadership of Prime Minister Narendra Modi. "The government has been working relentlessly to increase the number of doctors, medical institutions, and health infrastructure including hospital, tertiary care centres, health and wellness centres in the country. "Conferences like India Pharma and India Medical Device 2022 provide a platform for industry, academia and policymakers to brainstorm and draft a plan for the next 25 years for the sector," the Minister said. The Union Minister also said that under the leadership of Prime Minister Modi, the youth's energy and brain power have been channelised.

In the conference, the Union Minister assured full support of the Government to the Pharma and medical devices sector and sought their feedback and support in preparing a roadmap for the next 25 years. Meanwhile,

various issues pertaining to the Pharma and medical devices sector were discussed at the conference.

IDMA President Dr Viranchi Shah attended the conference. He raised some of the issues with DCGI, CDSCO & state regulators as follows,

- Industry needs a hand holding to move ahead instead of focusing on failures.
- Focus should be on improvements based on failures but not on the statistics.
- Focus be more on CAPA than prosecution and prosecution should be the last resort while admitting that strictest action must always be taken on the culprits.
- Harmonisation, uniform approval systems, maintaining time lines are some other points need to be focused, he said

Meanwhile, various issues pertaining to the Pharma and medical devices sector were discussed at the conference.

According to the Ministry's press statement, Dr V.K. Paul, Member, NITI Aayog, Dr. Balram Bhargava, Director General, ICMR, senior officials from FICCI and Invest India and CEOs of various Pharma and medical devices companies were also present at the conference.

## Glimpses of conference







# IDMA Congratulates Mr Daara B Patel, Secretary – General, on his 20<sup>th</sup> year work Anniversary



Mr Daara B Patel, Secretary- General of IDMA completed 20 years of service with IDMA on 3<sup>rd</sup> May 2022. IDMA Staff organized a get together and congratulated him. They thanked him for his continuous support and excellent guidance always. Mr. Daara Patel appreciated and thanked everyone. He briefed them about his journey of 20 years in IDMA and said that each new day brought a different challenge and learning experience. He said every National President has contributed towards his growth and development.

## National President Dr. Viranchi Shah's Message

Dear Daara,

On behalf of our National Executive Committee and all the IDMA Members, we congratulate you on completing 20 Years with IDMA.

Thank you for being such a valuable asset for IDMA. Your contribution has immensely helped making IDMA the most respected voice of the Pharma industry. On this day we proudly acknowledge your contribution and commitment towards IDMA, and I wish you best luck for a great future.

Once again Happy 20th Anniversary.

Thanks and regards,

**Dr. Viranchi Shah**, National President



*On behalf of our National President, Dr. Viranchi Shah, a bouquet was presented by Mr. Melvin Rodrigues*



*IDMA Staff members greeting the Secretary-General, Mr. Daara Patel*



## IDMA PUBLICATIONS RATE CARD

Sr. No.	Name of Publications	Cost in ₹
1.	<b>IDMA BULLETIN (Annual Subscription – 48 Issues)</b> ( <i>Published on 7<sup>th</sup>, 14<sup>th</sup>, 21<sup>st</sup> and 30<sup>th</sup> of every month</i> )	
	• Members	1000/- p.a.
	• Government Research / Educational Institutions	2000/- p.a.
	• Non-Members	4000/- p.a.
2.	<b>INDIAN DRUGS (Annual Subscription – 12 Issues)</b> ( <i>Published on 28<sup>th</sup> of every month</i> )	
	• Members	1000/- p.a.
	• Students	1000/- p.a.
	• Government Research / Educational Institutions	2000/- p.a.
	• Non-Members	4000/- p.a.
3.	<b>IDMA APA Forum</b>	
	• Annual Membership	500/-
	• Life Membership	5000/-
4.	<b>TECHNICAL MONOGRAPHS</b>	
	NO. 1: STABILITY TESTING OF EXISTING DRUG SUBSTANCES AND PRODUCTS	400/-
	NO. 2: PRIMARY & SECONDARY CHEMICAL REFERENCE SUBSTANCES	400/-
	NO. 3: INVESTIGATION OF OUT OF SPECIFICATION (OOS) TEST RESULTS	400/-
	NO. 4: PHARMACEUTICAL PREFORMULATION ANALYTICAL STUDIES	400/-
	NO. 5: ENVIRONMENTAL MONITORING IN CLEANROOMS	400/-
	NO. 6: CORRECTIVE/PREVENTIVE ACTIONS (CAPA) GUIDELINE	400/-
	NO. 7: DATA INTEGRITY GOVERNANCE	400/-
5.	<b>TECHNICAL DOCUMENT</b> QUALITY 4.0 DIGITAL TECHNOLOGY OF THE FUTURE	500/-
6.	<b>IDMA MEMBERSHIP DIRECTORY</b>	1,500/-
7.	<b>IDMA ANNUAL PUBLICATION</b>	1,500/-

### KINDLY NOTE:

- Mailing of IDMA Bulletin and Indian Drugs by Post will commence prospectively only after receipt of payment.
- All payments may be made in advance by Cheque / DD / RTGS / NEFT only in favour of: **“Indian Drug Manufacturers’ Association”**.  
**For RTGS/NEFT: Name:** BANK OF BARODA, **Branch:** Worli, **Name of Account Holder:** INDIAN DRUG MANUFACTURERS’ ASSOCIATION, **Account No.** Current A/c 76080200000242, **IFSC :** BARB0DBWORLD **MICR CODE :** 400012332
- Courier charges for Publications under Serial Nos. 4 to 7 will be extra as applicable.
- Please intimate us details through email immediately after making the remittance through RTGS/NEFT, so as to enable us to do the needful promptly.
- GST will be charged extra, as applicable.

### INDIAN DRUG MANUFACTURERS’ ASSOCIATION

102-B, “A”-Wing, Poonam Chambers, Dr A B Road, Worli, Mumbai 400 018. Tel: 2494 4624 / 2497 4308 Fax: 022- 2495 0723  
E-mail: [admin@idmaindia.com](mailto:admin@idmaindia.com)/[publications@idmaindia.com](mailto:publications@idmaindia.com), Website: [www.idma-assn.org](http://www.idma-assn.org) / [www.indiandrugsonline.org](http://www.indiandrugsonline.org)

# **Notification on Constitution of Central Council of Health and Family welfare**

**Notification No.S.O. 1916(E), dated 22<sup>nd</sup> April 2022**

In exercise of the powers conferred by the Article 263 of the Constitution, the President hereby reconstitutes the Central Council of Health and Family Welfare and defines the nature of duties to be performed by it and its organization and procedure as follows, namely: -

**1. Organization of the Council:**

(l) The Council shall consist of: -

- |   |   |   |
|---|---|---|
| (a) The Union Minister for Health and Family Welfare  | : | Chairman                                    |
| (b) The Union Minister of State in the Ministry of Health and Family Welfare  | : | Vice Chairman                               |
| (c) Member (Full time), NITI Aayog  | : | Member                                      |
| (d) Minister in charge of the Ministries of the Health and Family Welfare, Medical Education and Public Health in the States/Union Territories with Legislatures            | : | Members                                     |
| (e) A representative each of the Union Territories Dadra & Nagar Haveli and Daman and Diu, Chandigarh, Andaman and Nicobar Islands, Lakshadweep, Jammu & Kashmir and Ladakh | : | Members                                     |
| (f) Member of Parliament  | : | Members                                     |
| 1. Dr. Subhash Ramrao Bhamre  | : | Lok Sabha                                   |
| 2. Dr. Arvind Kumar Sharma  | : | Lok Sabha                                   |
| 3. Dr. Sumer Singh Solanki  | : | Rajya Sabha                                 |
| 4. Shri Dineshchandra Jemalbai Anavadiya  | : | Rajya Sabha                                 |
| (g) Non-Officials   |   |   |
| (i) Representatives from Health and Family Welfare Sector   |   |   |
| 1. President, Indian Medical Association  | : | Member (Ex-officio)                         |
| 2. President, Family Planning Association of India,   | : | Member Mumbai (Ex-officio)                  |
| 3. President, Indian Council of Child Welfare, New Delhi  | : | Member (Ex-officio)                         |
| 4. Chairperson, Central Social Welfare Board, New Delhi   | : | Member (Ex-officio)                         |
| 5. President, Federation of Indian Chambers of Commerce   | : | Member and Industry, New Delhi (Ex-officio) |

6. President, All India Organisations of Employers, : Member New Delhi  
(Ex-officio)
- (h) Officials:
1. Secretary, Department of Health and Family Welfare : Member
  2. Secretary, Department of Health Research and : Member  
Director General (ICMR)
  3. Secretary, Ministry of Ayurveda, Yoga & : Member  
Naturopathy, Unani, Siddha and Homoeopathy (AYUSH)
  4. Secretary, Department of Higher Education, : Member  
Ministry of Human Resource Development
  5. Secretary, Ministry of Women and Child Development : Member
  6. Director General of Health Services : Member
  7. Economic Adviser : Member-Secretary
- (II) The Members of Lok Sabha shall be Members of the Council so long as they are members of Lok Sabha or for two years, whichever is earlier.
- (III) The Members of Rajya Sabha shall be Members of the Council so long as they are members of Rajya Sabha or for two years, whichever is earlier.
- (IV) The travelling and daily allowances of the non-official members for attending the meetings of the Council shall be regulated in accordance with the provision of Supplementary Rule 190 and orders of the Government of India there-under as issued from time to time.
- (V) The expenditure involved will be met from within the sanctioned budget grant for the purpose.
- (VI) Experts and technical advisers to the Central Government and State Governments shall not be members of the Council and shall not have any right to vote when any decision is taken by it but shall, if so required by the Council, be in attendance at its meetings.
- (VII) The Council shall have a Secretarial staff consisting of a Secretary and such officers and officials as the Chairman may, with the approval of the Central Government, think fit to appoint.

**2. Nature of the duties to be performed by the Council:**

The Council shall be an advisory body and in that capacity shall perform the following duties, namely: -

- (a) To consider and recommend broad lines of policy in regard to matters concerning Health and Family Welfare in all its aspects, such as the provision of remedial, promotive and preventive care, environmental hygiene, nutrition, health education and the promotion of facilities for training and research;
- (b) To make proposal for legislation in fields of activity relating to medical and public health and Family Welfare matters, laying down the pattern of development for the country as a whole;
- (c) To examine the whole field of possible co-operation on a wide basis in regard to inter- State quarantine during time of festivals, out-break of epidemics and serious calamities such as earth-quakes and famines and to draw up a common programme of action;
- (d) To make recommendations to the Central Government regarding distribution of available grants-in-aid for Health and Family Welfare purposes to the States and to review periodically the work accomplished in different areas through the utilization of these grants-in-aid; and

- (e) To establish any organization or organizations invested with appropriate functions for promoting and maintaining co-operation between the Central and State Health and Family Welfare administration.

**3. Procedure of the Council:**

The Council shall in its conduct of business observe following procedures, namely: -

- (a) The Council shall meet once or more each year;
- (b) It shall meet at such time and place as the Chairman may appoint in this behalf;
- (c) Five members (including the Chairman) shall form the quorum for a meeting of the Council;
- (d) The Chairman and, in his absence Vice-Chairman or such member as may be designated by the Chairman in this behalf from among the members referred to in clause (d) of sub- paragraph (I) of paragraph 1 shall preside at the meeting;
- (e) All questions which may come up before the Council at the meeting shall be decided by a majority of vote of the members (including the Chairman) present at the meeting;
- (f) In case of equality of votes, the person presiding shall have a second or casting vote;
- (g) The Council shall observe in the conduct of its business such other procedure as it may, with the approval of the Central Government, lay down from time to time.

**F.No.Z-16011/02/2021-BP**

*Rajesh Bhushan, Secretary, Ministry of Health and Family Welfare Notification, Constitution of Central Council of Health and Family Welfare, New Delhi.*



## **Palm Fatty Acids (Quality Control) Order, 2022 published**

**Chemicals & Fertilizers Order S.O.1963(E), dated 27<sup>th</sup> April 2022**

In exercise of the powers conferred by section 16 of the Bureau of Indian Standards Act, 2016 (11 of 2016) (hereinafter referred to as the said Act), the Central Government being of the opinion that it is necessary or expedient so to do in the public interest and after consultation with the Bureau of Indian Standards, hereby makes the following order, namely:-

**1. Short title, commencement and application:**

- (1) This order may be called the **Palm Fatty Acids (Quality Control) Order, 2022.**
- (2) It shall come into force on the one hundred and eighty- first day from the date of its publication in the Official Gazette.
- (3) It shall apply to goods or articles specified in column (1) of the Table below, but shall not apply to such good or articles meant for export.

**2. Conformity to standard and compulsory use of Standard Mark:**

Goods or articles specified in column (1) of the said Table shall conform to the corresponding Indian Standard specified in column (2) of the said Table and shall bear the Standard Mark under a licence from the Bureau of Indian Standard as per Scheme-I of Schedule-II of the Bureau of Indian Standards (Conformity Assessment) Regulations, 2018.

**3. Certification and enforcement authority:**

The Bureau of Indian Standards shall be the certifying and enforcing authority in respect of the goods or articles specified column (1) of the said Table.

**4. Penalty for contravention:**

Any person who contravenes the provisions of this order shall be punishable under the provisions of the said Act.

Goods or articles	Indian Standard	Title of Indian Standard
(1)	(2)	(3)
Palm Fatty Acids	IS 12067:1987	Palm Fatty Acids - Specification

F.No.C-II-13012/01/2021-Chem.II

*N K Santoshi,  
Deputy Director General,  
Ministry of Chemicals and Fertilizers,  
Department of Chemicals and Petrochemicals,  
New Delhi.*



## Rice Bran Fatty Acids (Quality Control) Order, 2022 published

**Chemicals & Fertilizers Order S.O.1964(E), dated 27<sup>th</sup> April 2022**

In exercise of the powers conferred by section 16 of the Bureau of Indian Standards Act, 2016 (11 of 2016) (hereinafter referred to as the said Act), the Central Government being of the opinion that it is necessary or expedient so to do in the public interest and after consultation with the Bureau of Indian Standards, hereby makes the following order, namely:-

### 1. Short title, commencement and application

- (1) This order may be called the **Rice Bran Fatty Acids (Quality Control) Order, 2022**.
- (2) It shall come into force on the one hundred and eighty- first day from the date of its publication in the Official Gazette.
- (3) It shall apply to goods or articles specified in column (1) of the Table below, but shall not apply to such good or articles meant for export.

### 2. Conformity to standard and compulsory use of Standard Mark

Goods or articles specified in column (1) of the said Table shall conform to the corresponding Indian Standard specified in column (2) of the said Table and shall bear the Standard Mark under a licence

from the Bureau of Indian Standard as per Scheme-I of Schedule-II of the Bureau of Indian Standards (Conformity Assessment) Regulations, 2018.

### 3. Certification and enforcement authority

The Bureau of Indian Standards shall be the certifying and enforcing authority in respect of the goods or articles specified column (1) of the said Table.

### 4. Penalty for contravention

Any person who contravenes the provisions of this order shall be punishable under the provisions of the said Act.

Goods or articles	Indian Standard	Title of Indian Standard
(1)	(2)	(3)
Rice Bran Fatty Acids	IS 12068:1987	Rice Bran Fatty Acids - Specification

F.No.C-II-13012/01/2021-Chem.II

*N K Santoshi,  
Deputy Director General,  
Ministry of Chemicals and Fertilizers,  
Department of Chemicals and Petrochemicals,  
New Delhi.*



# Coconut Fatty Acids (Quality Control) Order, 2022 published

Chemicals & Fertilizers Order S.O.1965(E), dated 27<sup>th</sup> April 2022

In exercise of the powers conferred by section 16 of the Bureau of Indian Standards Act, 2016 (11 of 2016) (hereinafter referred to as the said Act), the Central Government being of the opinion that it is necessary or expedient so to do in the public interest and after consultation with the Bureau of Indian Standards, hereby makes the following order, namely:-

**1. Short title, commencement and application:**

- (1) This order may be called the **Coconut Fatty Acids (Quality Control) Order, 2022**.
- (2) It shall come into force on the one hundred and eighty- first day from the date of its publication in the Official Gazette.
- (3) It shall apply to goods or articles specified in column (1) of the Table below, but shall not apply to such good or articles meant for export.

**2. Conformity to standard and compulsory use of Standard Mark:**

Goods or articles specified in column (1) of the said Table shall conform to the corresponding Indian Standard specified in column (2) of the said Table and shall bear the Standard Mark under a licence

from the Bureau of Indian Standard as per Scheme-I of Schedule-II of the Bureau of Indian Standards (Conformity Assessment) Regulations, 2018.

**3. Certification and enforcement authority:**

The Bureau of Indian Standards shall be the certifying and enforcing authority in respect of the goods or articles specified column (1) of the said Table.

**4. Penalty for contravention:**

Any person who contravenes the provisions of this order shall be punishable under the provisions of the said Act.

**TABLE**

<b>Goods or articles</b>	<b>Indian Standard</b>	<b>Title of Indian Standard</b>
(1)	(2)	(3)
Coconut Fatty Acids	IS 12069:1987	Coconut Fatty Acids - Specification

**F.No.C-II-13012/01/2021-Chem.II**

*N K Santoshi, Deputy Director General, Ministry of Chemicals and Fertilizers, Department of Chemicals and Petrochemicals, New Delhi.*



Have you renewed your **Membership** for the years

**2021-2022 & 2022-2023**

If not, please do so; kindly contact IDMA Secretariat at:

Email: [actadm@idmaindia.com](mailto:actadm@idmaindia.com) / [accounts@idmaindia.com](mailto:accounts@idmaindia.com)

Tel.: 022 - 2494 4624 / 2497 4308 / Fax: 022 - 2495 0723





**India Pavilion at  
AFRICA HEALTH ExCon, Cairo, Egypt  
5-7 June 2022  
Egypt International Exhibition Center (EIEC) : Hall 1**

Dear Sir/Madam,

We are pleased to inform that Council as an official International Partner for the event “**Africa Health ExCon**”, (first important trade fair), an initiative of the **Egyptian Authority for Unified Procurement, Medical supply and the Management of Medical Technology (UPA)**, under the auspices of **H.E. President Abdel Fattah El-Sisi** with an objective to

- Refocusing the minds of health & pharma business to Africa’s investment potential.
- Connecting the health care value chain to a fast developing market.
- Driving the healthcare industry to Africa through the right sourcing of products and an equitable distribution.

The Egyptian Authority for Unified Procurement, Medical Supply and the Management of Medical Technology (UPA) is endorsing Africa Health ExCon Exhibition and Conferences to be the continental hub of health innovation and trade in Egypt as well as in Africa.

It seeks to refocus the minds of all those operating in the Health and Pharma business to Africa’s investment potential and thrive the healthcare industry in Africa through the right sourcing of products and equitable distribution to contribute to the continent’s Health Agenda in ensuring equitable access of quality health technology products and services to all African Countries.

This ExCon will take place annually to create a sustainable platform connecting the world healthcare buyers and suppliers under one common roof, giving the chance for All healthcare partners to interact together as well as supporting the flow of trade business intra/extra in the mother continent as it offers numerous opportunities to discover products across several diversified categories, targeting the following sectors:

- |                                  |                                      |
|----------------------------------|--------------------------------------|
| • Medical Supplies & Consumables | • Medical Equipment                  |
| • Pharmaceuticals                | • Laboratory Consumables & Chemicals |
| • Dental Equipment & Supplies    | • Dermal Products                    |
| • Nutrition & Vitamins           | • Healthcare Providers               |
| • Pharmacies                     | • Medical Insurance                  |
| • Feeding Industries             | • Packaging                          |

In this exhibition many national and international companies are exhibiting their products and services. It will provide platform for better network, strengthen business relations and create new businesses opportunities. In addition, there will be an opportunity to attend numerous conferences on trending medical topics in Africa.

The Egyptian Authority for Unified Procurement, Medical Supply and the Management of Medical Technology (UPA) have offered a special discount of 50% to all the Indian companies who are going to participate under India Pavilion

in this Mega Trade Fair “Africa Health ExCon”. For more details about the event, please visit [www.africahealthexcon.com](http://www.africahealthexcon.com)

The council will be organizing India Pavilion by taking 264 sq. meter space, which is divided into 9 and 12 sq. meter stalls which will be furnished with minimum furniture and the costs of which are as follows:

**12 sq. meter stall (4 stalls) : Rs. 2.75 lakhs**

**9 sq. meter stall (24 stalls) : Rs. 2.00 lakhs**

All the Stalls will be furnished with minimum furniture

#### **Allotment of Stalls:**

Members may please click on the following links to see the Overall Floor plan of Africa Health ExCon and also India Pavilion.

### **OVERALL FLOOR PLAN of Africa Health ExCon**

With a view to make the allotment procedure easy and transparent, we made the reservation of stalls online. Interested members may please click on the following link reserve as per your choice.

### **INDIA PAVILION at Africa Health ExCon**

Members are required to make the full payment within a week of making a reservation, failing which their reservation automatically gets cancelled. Cancellation is not allowed once the stall is allotted. Amount paid will be forfeited.

#### **Assistance to the participants:**

Subject to the release of finances by Ministry of Commerce, Govt. of India and also other rules of MAI scheme (latest guidelines) (via LOGIN) members whose export turnover for the previous year is less than Rs.50 crores and has one year membership with the Council, will be eligible for financial assistance to the extent of Rs.75,000 towards travel expenses.

#### **Location of Pavilion:**

Pavilion is located in the middle of Hall 1, surrounded by big exhibitors like Bayer, Pfizer, Novartis, Sanofi, Roche, GSK, Astrazeneca, etc.

Since this is a good opportunity to increase exports in Africa and the Middle-East, we advise the members to take part in the event.

For further information about the event, members may contact us at [webdesk@pharmexcil.com](mailto:webdesk@pharmexcil.com)

With regards,

**Udaya Bhaskar**  
Director General



# Business Delegation to LATAM: Colombia, Bolivia, Peru & Brazil (23<sup>rd</sup> July – 6<sup>th</sup> August 2022)

PXL/HO/Cir-008/2022-23, dated 04<sup>th</sup> May 2022

We have pleasure in informing you that Pharmexcil proposes to organize a **Business Delegation to Colombia, Bolivia, Peru & Brazil during 23<sup>rd</sup> July – 7<sup>th</sup> August, 2022** with support of the Ministry of Commerce and Industry, Government of India.

The tentative program schedule proposed for the delegation as below:

S.NO	COUNTRY	DATE	DAY	PARTICULARS
1	COLOMBIA (BOGOTA)	23 <sup>rd</sup> /24 <sup>th</sup> July	Saturday/Sunday	Arrival in Bogota, Colombia
		25 <sup>th</sup> July	Monday	Inaugural Program & Conference with Ministry of Health, Drug Regulatory (INVIMA) & Procurement Agencies & Trade Associations etc. followed by Buyer Seller Meet
		26 <sup>th</sup> July	Tuesday	Buyer Seller Meet
		26 <sup>th</sup> July	Tuesday (Night)	Departure to Santa Cruz, Bolivia
2	BOLIVIA (SANTA CRUZ)	27 <sup>th</sup> July	Wednesday (early morning)	Arrival in Santa Cruz, Bolivia
		28 <sup>th</sup> July	Thursday	Inaugural Program & Conference with Ministry of Health, Drug Regulatory & Procurement Agencies & Trade Associations etc. followed by Buyer Seller Meet
		29 <sup>th</sup> July	Friday	Buyer Seller Meet
		30 <sup>th</sup> /31 <sup>st</sup> July	Saturday/Sunday	Departure to Lima, Peru
3	PERU (LIMA)	30 <sup>th</sup> /31 <sup>st</sup> July	Saturday/Sunday	Arrival in Lima, Peru
		1 <sup>st</sup> August	Monday	Inaugural Program & Conference with Ministry of Health, Drug Regulatory Officials & Trade Associations etc. followed by Buyer Seller Meet.
		2 <sup>nd</sup> August	Tuesday	Buyer Seller Meet
		3 <sup>rd</sup> August	Wednesday	Departure to Sao Paulo, Brazil
4	BRAZIL (SAO PAULO)	3 <sup>rd</sup> August	Wednesday	Arrival in Sao Paulo, Brazil
		4 <sup>th</sup> August	Thursday	Inaugural Program & Conference with Ministry of Health, Drug Regulatory Officials & Trade Associations etc. followed by Buyer Seller Meet.
		5 <sup>th</sup> August	Friday	Buyer Seller Meet
		6 <sup>th</sup> August	Saturday	Departure to India

*(The final dates are subject to confirmation from our respective missions and may change, as required)*

## Exports to proposed Destinations:

An overview of India's pharmaceuticals export to destination countries during the last three years in million USD is as below for your ready reference:

COUNTRY	FY-20	FY-21	FY-22	Growth rate %
Colombia	96.34	106.32	150.42	41.48
Bolivia	26.17	31.00	48.82	57.53
Peru	83.16	140.53	118.97	-15.31
Brazil	473.10	525.28	580.78	10.57

## **PARTICIPATION DETAILS:**

### **Registration:**

Members are requested to submit the mandatory Registration form via google form( <https://forms.gle/882ZDRReYpfNcg5LHA> ).

### **Participation Fee (Non-Refundable)**

Post submission of the Registration form, you are required to pay the participation fee of **INR 2,00,000/-** in favor of “**Pharmaceuticals Export Promotion Council of India**” and share the payment details with **accounts2@pharmexcil.com** . (Bank details enclosed).

Participation fee includes BSM set up at all Destinations, local transfers, Translation of your company profiles & Common 2 or 3 interpreters wherever required for Government meetings, Regulatory meetings, presentations etc.

Participation fee is Non-refundable. The amount is refunded only if the event is canceled due to unavoidable circumstances at the instance of our Mission/Council.

### **Timeline:**

**Deadline for payment is 13<sup>th</sup> May 2022.** Members may please note that confirmation of your participation is based on receipt of the payment only.

### **Travel & Logistics:**

The suggested Flight itinerary, Hotel names and tariffs (in consultation with Indian Missions abroad) will be communicated in due course.

Member companies are required to secure their business visas and make their reservations directly. The council will arrange required visa invitations from destination countries and issue visa recommendation letters for the participating Indian delegates.

### **MAI ASSISTANCE:**

Members whose export turnover during previous year are less than Rs.50.00 crores and are having minimum of one year (12 calendar months) membership with the council are eligible for MAI assistance subject to the other guidelines of MAI scheme.

Under the MAI scheme **Director/Partner/Proprietor/Senior Managers can avail reimbursement of economy class airfare subject to a maximum of INR 1, 25,000/- per company.**

### **Note:**

- Participation at 3 destinations is mandatory to claim MAI assistance.
- Destination can undergo change/modifications/canceled subject to our Embassy/Missions advice in view of unavoidable circumstances.
- For any further clarifications, members may contact us at **rodelhi@pharmexcil.com; 011-41536658, 9654438137**

Regards

**Uday Bhaskar**, Director General

.....  
**Bank Details - The payment may be made by NEFT/RTGS as per details below:**

Beneficiary name : **Pharmaceuticals Export Promotion Council of India**,  
Bank Name : **Union Bank of India**, Current A/c. No : **510131000001693**, IFSC Code : **UBIN0805220**,



# Register your Participation: Pharmexcil Business Delegation (physical) to Indonesia, Philippines and Vietnam during 27<sup>th</sup> June 2022 until 6<sup>th</sup> July 2022 (MAI assistance available)

PXL/HO/Cir-010/2022-23, dated 05<sup>th</sup> May 2022

We would like to bring to your kind notice that Pharmexcil with the support of the Ministry of Commerce & Industry, Government of India is organizing Business Delegation to Philippines, Vietnam and Indonesia during the week of June commencing from 27<sup>th</sup> June 2022 until 6<sup>th</sup> July.2022. The Delegation visit and its dates have been confirmed by the India Mission in Vietnam, Philippines and Indonesia.

The delegation is planned to visit these countries as an approved activity under the MAI activity of the Council. ASEAN is one of the major importers of Indian generic medicines with an approximately USD 13 BN generic market. ASEAN region offers great potential for India pharmaceutical products and our exports during the fy 2021-22 is 1760 USD mn contributing about 7.15 % of the total pharma exports from India, with a growth rate of 18 % over previous year.

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

Sr. No.	Country & City of Visit.	Proposed date	Programme
1.	Jakarta, Indonesia	26.June.2022 (Sunday)	Arrival of the delegation
		27.June.2022 (Monday)	Inaugural of Pharma Meet followed by Buyer Seller Meetings
		28.June.2022 (Tuesday)	Meetings with Trade Associations and the Ministry of Health/FDA etc
2.	Manila, Philippines	29.June.2022 (Wednesday)	Arrival of the delegation to Manila
		30 June.2022 (Thursday)	Inaugural of Pharma Meet followed by Buyer Seller Meetings
		01 July.2022 (Friday)	Meetings with Trade Associations and the Ministry of Health/FDA etc.
3.	Vietnam, Ho Chi Minh City	02 July.2022 (Saturday)	Arrival of the delegation to Ho Chi Minh City- Weekend Weekend
		03 July.2022 (Sunday)	
		04 July.2022 (Monday)	Inaugural of Pharma Meet followed by Buyer Seller Meetings
		05 July.2022 (Tuesday)	Meetings with Trade Associations and the Ministry of Health/FDA etc.
		06 July.2022 (Wednesday)	Departure to India

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

## **PARTICIPATION DETAILS:**

- Participation fee is Rs.60,000/-for BSM in all three countries. Participation fee includes BSM set up at all Destinations.
- Members are required to submit a mandatory Registration form via google form ([link](#)) with complete details as per the provided format latest by 13th May, 2022.
- On the submission of the Registration form, you are required to pay INR 60,000 in favor of “Pharmaceuticals Export Promotion Council of India” and share the payment details with accounts2@pharmexcil.com (Bank Details given below).
- Members may please note that confirmation of your participation is based on receipt of the payment.
- The suggested Flight itinerary, Hotel names and tariffs (in consultation with Indian Missions abroad) will be communicated in due course.
- Destination can undergo change/modifications/cancelled subject to our Embassy/Missions advice in view of unavoidable circumstances pertaining to the travel restrictions.
- Participation fee is non-refundable and can be refunded only if the event is cancelled due to unavoidable circumstances at the instance of our Mission/Council
- Kindly note that the companies who have already registered their participation through google form during March for ASEAN delegation are also requested to register again. Those who have made the payment of Rs.60,000/- to Pharmexcil during the month of March will be considered for the scheduled delegation.

## **MAI ASSISTANCE:**

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

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

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

Thanking you,

With regards,

**Uday Bhaskar**, Director General

---

### **NEFT/RTGS details**

Name : **Pharmaceuticals Export Promotion Council of India**

Bank Name: **Union Bank of India**

A/c.No. **510131000001693** , A/c. type: Current Account IFSC: UBIN0805220

Note : For GST tax invoice please contact accounts2@pharmexcil.com



# Salient features of Pharma Annexure under "India-UAE CEPA" & "India-Australia ECTA"?

PXL/HO/Cir-009/2022-23, dated 04<sup>th</sup> May 2022

Pharmexcil is pleased to inform members that India and the United Arab Emirates (UAE) have signed the Comprehensive Economic Partnership Agreement (CEPA) on 18 February 2022 and entered into force from 1st May 2022. The India-UAE CEPA is expected to boost the bilateral merchandise trade from US\$ 60 billion to US\$ 100 billion in 5 years, For the first time in a Trade Agreement, a separate Annexure on "Bilateral Cooperation on Pharmaceutical Products" has been incorporated to facilitate access of Indian pharmaceuticals products having regulatory approvals from reference countries namely Australia, Canada, European Union, Japan, the United States of America, or the United Kingdom.

Salient features of Pharma Annexure under INDIA-UAE CEPA are as follows:

- **Recognition of GMP certificates issued by Stringent Regulatory Authorities:** UAE will be accepting Pharmaceutical products of Indian origin without the need for prior inspection, provided that these products are approved by the Regulatory Authorities of reference countries
- **Fast Track Approval for Product Registration:** UAE does not need to carry out a full assessment or inspect its manufacturing sites for the products already approved by reference countries and fast-track the procedures for Pharmaceutical Products having approvals from at least one of the reference countries
- a) Marketing authorisation shall be provided within ninety (90) days without any inspections by for Pharmaceutical Products of the approved by the relevant Regulatory Authorities of reference countries.
- b) For all other Pharmaceutical Products where inspections are required, UAE shall, to the extent possible, and only as practicably possible, grant marketing authorisation within two hundred and seventy (270) days of application.

Further, India and Australia have also signed the Economic Cooperation and Trade Agreement (Ind-Aus ECTA) on 2 April 2022. It is anticipated that the IndAus ECTA will enhance the bilateral trade from US\$ 27.5 bn to about \$ 45 to \$ 50 Billion in next 5 years.

- Australia has agreed for an **Annex on Pharmaceutical products** under this agreement, which will enable **fast track approval for patented, generic and biosimilar medicines** using the Comparable Overseas Regulator Pathway. It will also enable **fast track quality assessment of manufacturing facilities** using, as appropriate, the inspection reports of the comparable overseas regulators. This is expected to be a significant trade facilitation measure for India's pharma sector which will enable Indian Pharma companies to access the Australian market and aid in boosting India's pharma exports.

**Please find the India-Australia ECTA.**

To create awareness among members, Pharmexcil is sharing the Copy of the Annex on Pharmaceutical products under both agreements along with the FAQs on both the agreements.

With Regards,

**Udaya Bhaskar**, Director General



# Information sought from Exporters/Importers to Russia

PXL/HO/Cir-006/2022-23, dated 2<sup>nd</sup> May 2022

This is in continuation to the circular “PXL/HO/Cir-150/2021-22” dated 16.03.2022 on the subject “Seeking details of pending payments with Russia & Ukraine”.

In context of the ongoing international conflict, the Department of Commerce(DoC) is aware that Indian pharmaceutical companies are facing various impediments to trade. The Foreign Trade Division (CIS), Department of Commerce would therefore like to understand and track the concerns and the difficulties that stakeholders are encountering while trading with Russia. This would help Pharmexcil and the Ministry to prioritize the issues raised and work towards clearing bottlenecks to trade with Russia.

Member companies having business operations in Russia should use the enclosed questionnaire to answer the questions sought by FT(CIS), DoC. Given the urgent nature of the request, member companies are requested to submit the response form latest by EOD 5<sup>th</sup> May 2022.

[https://docs.google.com/forms/d/e/1FAIpQLSeemdgLpyN\\_srtbP8JqdEOUMsEp1g0qAOaOiELHKBHQzGEHQ/viewform](https://docs.google.com/forms/d/e/1FAIpQLSeemdgLpyN_srtbP8JqdEOUMsEp1g0qAOaOiELHKBHQzGEHQ/viewform)

For any further information/clarification in this regard, please write to [rollins@pharmexcil.com](mailto:rollins@pharmexcil.com) / [rodelhi@pharmexcil.com](mailto:rodelhi@pharmexcil.com).

With regards,

Uday Bhaskar, Director General



## INDIAN DRUGS ONLINE

PUBLISHED ON 28<sup>th</sup> OF EVERY MONTH

ADVERTISEMENT BANNER RATES FOR INDIAN DRUGS WEBSITE (Rates in Rupees per insertion)

Position	Size	RATE	VALIDITY
Right Side Banner	180 X 150 Pixel	25,000	3 MONTHS
Left Side Banner	180 X 150 Pixel	25,000	3 MONTHS

### Terms and Conditions

- All payments by DD in advance only to be made in favour of **Indian Drug Manufacturers' Association**, payable at Mumbai
- 25% discount applicable only for IDMA members
- 15% discount is applicable on Annual Contract for Non IDMA Members
- Please provide Banner Artwork as per the size for advertisements before the deadline
- **Advertisement material must reach us 10 days before the date of release**

For more details please contact: **Publications Department**

### Indian Drug Manufacturers' Association

102-B, Poonam Chambers, Dr A B Road Worli, Mumbai 400 018. Tel: 24944624/24974308 Fax: 24950723  
Email: [publications@idmaindia.com](mailto:publications@idmaindia.com)/[actadm@idmaindia.com](mailto:actadm@idmaindia.com) /Website: [www.idma-assn.org](http://www.idma-assn.org) / [www.indiandrugsonline.org](http://www.indiandrugsonline.org)



## Amendment of Appendix 2B [List of Agencies Authorised to issue Certificate of Origin (Preferential)] of Foreign Trade Policy, 2015-2020

**Public Notice No. 05/2015-20-DGFT, dated 29<sup>th</sup> April, 2022**

In exercise of powers conferred under paragraph 1.03 and 2.04 of the Foreign Trade Policy (FTP) 2015-2020, the Director General of Foreign Trade hereby amends Appendix 2B [List of Agencies Authorised to issue Certificate of Origin (CoO) (Preferential)] of the FTP by including the list of authorised agencies allowed to issue CoO for India-UAE Comprehensive Economic Partnership Agreement (CEPA), as under:

S. No.	Name of the Agreement	Authorized Agencies	Product Assigned to each agency
17.	India - UAE Comprehensive Economic Partnership Agreement (CEPA)	Export Inspection Council and All Export Inspection Agencies	products
		Marine Products Export Development Authority and regional offices	Marine products
		Development Commissioner, Handicraft and regional offices	Handicraft
		Spices Board	Spices and Cashew nuts
		Coir Board	Coir and Coir products
		Textile Committee and regional offices	Textiles and Clothing
		Central Silk Board and regional offices	Silk products
		MEPZ special Economic Zone	All products by Units in Madras SEZ and EOUs located within the jurisdiction.
		Kandla Special Economic zone	All products manufactured by Units in Kandla and Surat SEZs and EOUs located within the respective jurisdiction
		SEEPZ Special Economic Zone	All products manufactured by Units in SEEPZ SEZ and EOUs located within the respective jurisdiction.
		Cochin Special Economic Zone	All products manufactured by Units in Cochin SEZ and EOUs located within the respective jurisdiction

	NOIDA Special Economic Zone	All products manufactured by Units in Noida SEZ and EOUs located within the respective jurisdiction
	Vishakhapatnam Special Economic Zone	All products manufactured by Units in Vishakhapatnam SEZ and EOUs located within the respective jurisdiction
	Falta Special Economic Zone	All products manufactured by Units in Falta SEZ and EOUs located within the respective jurisdiction
	Directorate General of Foreign Trade and regional offices	All products
	Tobacco Board	Tobacco and tobacco products
	Agricultural and Processed Food Products Export Development Authority (APEDA)	Agricultural Products

2. Effect of the Public Notice: List of authorised agencies allowed to issue Certificate of Origin (Preferential) for India-UAE CEPA is notified.

**File No. 01/93/180/57/AM-21/PC-2[B]/e- 26550**

*Santosh Kumar Sarangi, Director General of Foreign Trade & Ex-officio Addl. Secretary to the Govt. of India, Ministry of Commerce & Industry, Department of Commerce, New Delhi.*



## **Amendment in Para 2.107 (TRQ under FTA/CECA) of Handbook of Procedure 2015-2020**

**DGFT Public Notice No.06/2015-2020, dated 01<sup>st</sup> May 2022**

1. In exercise of powers conferred under paragraph 1.03 and 2.04 of the Foreign Trade Policy, 2015-20, the Directorate General of Foreign Trade hereby revises Para 2.107 of Handbook of Procedure 2015-2020 and Appendix 2A of FTP, 2015-20 to incorporate the items mentioned under Tariff Rate Quota (TRQ) under India -UAE Comprehensive Economic Partnership Agreement (CEPA), besides laying down the procedure for import of the items under TRQ as Annexure IV of Appendix 2A in accordance with Notification No.22/2022-Customs dated 30th April 2022.
2. Annexure IV of Appendix 2A enclosed may please be seen.
3. **Effect of this Public Notice:** The Tariff Rate Quotas (TRQ) as mentioned in Notification No.22/2022-Customs dated 30<sup>th</sup> April 2022 under India-UAE CEPA and procedure for allocation and import under given TRQs is notified.

**File No.01/89/180/01/AM-22/PC-2(B)/E-31419**

*Santosh Kumar Sarangi  
Director General of Foreign Trade &  
Ex-officio Addl. Secretary to the Govt. of India,  
Ministry of Commerce & Industry,  
Department of Commerce,  
New Delhi.*

## Imports of Items under the TRQ of the India- UAE CEPA

		Schedule of Tariff Rate Concessions (%)										
HS 8 Code	Description	Effective Rate (%)	Tariff Modality Offered	7.0 (TRQ - 45,000 MT)	6.5 (TRQ - 50,500 MT)	6.0 (TRQ - 56,000 MT)	5.0 (TRQ - 61,500 MT)	3.75 (TRQ - 67,500 MT)	3.75 (TRQ - 86,300 MT)	3.75 (TRQ - 105,00 0 MT)	3.75 (TRQ - 105,00 0 MT)	3.75 (TRQ - 105,00 0 MT)
390110 10	Linear low-density polyethylene (LLDPE), in which ethylene monomer unit contributes 95% or more by weight of the total polymer content	7.5	TR of 50% in 5 years with specified year-wise TRQs									
390110 20	Low density polyethylene (LDPE)	7.5										
390110 90	Other Polyethylene having a specific gravity of less than	7.5										

39012000	Polyethylene having a specific gravity of 0.94 or more	7.5	TR of 50% in 5 years with specified year-wise TRQs	7.0 (TRQ - 150,000 MT)	6.5 (TRQ - 168,000 MT)	6.0 (TRQ - 186,000 MT)	5.0 (TRQ - 204,000 MT)	3.75 (TRQ - 222,000 MT)	3.75 (TRQ - 252,000 MT)	3.75 (TRQ - 285,000 MT)	3.75 (TRQ - 285,000 MT)	3.75 (TRQ - 285,000 MT)
39014010	Linear low-density polyethylene (LLDPE), in which ethylene monomer unit contributes less than 95 % by weight of the total polymer content	7.5	TR of 50% in 5 years with specified year-wise TRQs	7.0 (TRQ - 45,000 MT)	6.5 (TRQ - 50,500 MT)	6.0 (TRQ - 56,000 MT)	5.0 (TRQ - 61,500 MT)	3.75 (TRQ - 67,500 MT)	3.75 (TRQ - 86,300 MT)	3.75 (TRQ - 105,000 MT)	3.75 (TRQ - 105,000 MT)	3.75 (TRQ - 105,000 MT)
39014090	Other Ethylene-alpha-olefin copolymers, having a specific gravity of less than 0.94	7.5										

39019000	Other polymers of ethylene, in primary sources	7.5		7.0 (TRQ - 11,000 MT)	6.5 (TRQ - 12,000 MT)	6.0 (TRQ - 13,000 MT)	5.0 (TRQ - 14,000 MT)	3.75 (TRQ - 16,000 MT)	3.75 (TRQ - 20,600 MT)	3.75 (TRQ - 25,000 MT)	3.75 (TRQ - 25,000 MT)	3.75 (TRQ - 25,000 MT)
39021000	Polypropylene	7.5		7.0 (TRQ - 70,000 MT)	6.5 (TRQ - 77,500 MT)	6.0 (TRQ - 85,000 MT)	5.0 (TRQ - 92,500 MT)	3.75 (TRQ - 100,000 MT)	3.75 (TRQ - 129,200 MT)	3.75 (TRQ - 158,500 MT)	3.75 (TRQ - 158,500 MT)	3.75 (TRQ - 158,500 MT)
39023000	Propylene copolymers	7.5		7.0 (TRQ - 50,000 MT)	6.5 (TRQ - 55,000 MT)	6.0 (TRQ - 60,000 MT)	5.0 (TRQ - 65,000 MT)	3.75 (TRQ - 70,000 MT)	3.75 (TRQ - 90,900 MT)	3.75 (TRQ - 112,000 MT)	3.75 (TRQ - 112,000 MT)	3.75 (TRQ - 112,000 MT)
39029000	Other polymers of propylene or of other olefins, in primary forms	7.5		7.0 (TRQ - 4,000 MT)	6.5 (TRQ - 4,500 MT)	6.0 (TRQ - 5,000 MT)	5.0 (TRQ - 5,500 MT)	3.75 (TRQ - 6,000 MT)	3.75 (TRQ - 7,700 MT)	3.75 (TRQ - 9,500 MT)	3.75 (TRQ - 9,500 MT)	3.75 (TRQ - 9,500 MT)
39041010	Emulsion grade PVC resin / PVC Pasteresin/ PVC dispersion resin	10	Tariff Reduction of 50% in 5 years with specified year-wise TRQs	9	8	7	6	5	5	5	5	5
39041020	Suspension grade PVC resin	10	(Cumulative Annual TRQ of 60,000 MT)	9	8	7	6	5	5	5	5	5
39041090	Other Poly (vinyl chloride),	10		9	8	7	6	5	5	5	5	5











- d. All applications for grant of TRQ authorizations shall be submitted online through the DGFT website (<https://dgft.gov.in>) → Import Management System → Tariff Rate Quota (TRQ)
- e. **TRQ limit to be proportioned annually. However, in case of Gold under tariff head 7108, allocation shall be proportioned on a quarterly basis.** The application along with the requisite fee is required to be filed online. The last date for applications for annual allocation for FY 2023-24 and onwards shall be 28<sup>th</sup> February of the previous financial year. For Gold TRQs under 7108, the last date for applications for annual allocation for FY 2023-24 and onwards, shall be as follows –

Application period	TRQ Import Period
1 <sup>st</sup> January to 28 <sup>th</sup> February	Q1- Apr to June
1 <sup>st</sup> May to 31 <sup>st</sup> May	Q2 - July to September
1 <sup>st</sup> August to 31 <sup>st</sup> August	Q3 - October to December
1 <sup>st</sup> November to 30 <sup>th</sup> November	Q4 – January to March

- f. **For the current FY 2022-23, applications are invited from 5<sup>th</sup> May 2022 to 18<sup>th</sup> May 2022. For Gold TRQ under 7108, the applications for the first two Quarters of the FY2022-23 i.e., till 30<sup>th</sup>September 2022, are invited from 5<sup>th</sup> May 2022 to 18<sup>th</sup> May 2022. Subsequently, for Gold TRQs for the third Quarter applications shall be invited from 1<sup>st</sup>August 2022 to 31<sup>st</sup> August2022, and for the fourth Quarter, applications shall be invited from 1<sup>st</sup>November 2022 to 30<sup>th</sup> November2022.**
- g. For Gold TRQ under 7108, the following conditions shall be considered additionally:
- i. Eligible Applicant must be a jewellery manufacturer.
  - ii. Eligible Applicant must be engaged in the business of goods falling under ITC(HS) codes 7108, 7113, 7114 and 7118 in Chapter 71 of ITC(HS).

- iii. Such Jewellery manufacturer should have an average annual turnover of Rs. 25 crores over the last 3 financial years.
- iv. The turnover of such Jewellery manufacturer should either:
- comprise of 90% of items manufactured/sold under HS code 7113, or
  - comprise of a quantity of items manufactured/sold under HS code 7113 which is at least equal to the TRQ quantity bid by the respective jewellery manufacturer (capped to the maximum TRQ allocation permissible per annum) under HS code 7113.
- v. Such Jewellery manufacturer should have a GST number and should have filed GST returns up to the applicable preceding GST return filing period.
- vi. Financial statements containing annual turnovers of the eligible applicant should be duly certified/audited by a Chartered Accountant, on the basis of the jewellers GST declarations.
- vii. Import of Gold Dore under TRQ shall not be considered.
- h. Reference Notification No. 22/2022-Customs dated 30th April 2022, for Gold TRQ imports under 7108, may be affected by the TRQ holder through Nominated Agencies as notified by RBI (in case of banks), nominated agencies notified by DGFT or Qualified Jewellers as notified by International Financial Services Centres Authority (IFSCA).
- i. For TRQ imports under 39041010, 39041020, 39041090, 39042100, 39043010, 39043090, 39046910, 39049010 and 39049090, the applicant must be an importer of the specified item during the last 2 years and must be a processor/manufacturer consuming the given inputs. The applicant must furnish self-certified copy of the document issued by Central/State/District Authorities indicating processing capacity.

- j. For all other tariff lines except under tariff head 7113, applicant must be a processor/manufacturer consuming the given inputs. GST returns or Udyam Registration or IEM registration may be accepted for qualifying as an eligible applicant as a proof of manufacturer.
- k. All allocations/TRQ licenses are valid only for that specific TRQ allocation period/ specific Quarter – TRQ license holders cannot carry over an allocation from one TRQ allocation period to another.
- l. The TRQ authorisation shall contain the name and address of the importer, Importer -Exporter Code (IEC), Customs notification number, tariff item as applicable, quantity and validity period of the certificate.
- m. The TRQ authorisation shall be issued electronically by the Directorate General of Foreign Trade and transmitted to Indian Customs EDI System (ICES). However, for non-EDI Ports not integrated with ICES, the TRQ shall also be issued on Security Paper.
- n. Imports made against the TRQ shall be allowed only upon debiting electronically in the ICES system or on debit as endorsed.
- o. In addition to the requirements as above, the TRQ authorization for items under Tariff head 7108, shall also contain Importer-Exporter Code (IEC) of the nominated agency/IFSCA, GST Identification Number (GSTIN) of the jewellery manufacturer to whom TRQ is being issued. The said TRQ importer shall follow the procedure set out in the Customs (Import of Goods at Concessional Rate of Duty) Rules, 2017.

\*\*\*\*\*

# Blue Ocean of Compliance by Dr. Rupali Paranjape

## # 1 Best Sellers book on Amazon

### Blue Ocean of Compliance

*Holistic Approach Towards Achieving Regulatory Compliance for Pharmaceutical Industries with No-Observation*

Are you struggling to solve the problems of non-compliances on your site?

Even with putting your best technologies, Knowledge, and efforts do you feel clueless?

If you want to protect your site from risks & huge losses due to non-compliances,

If you want to know the thought process & path which would lead you to qualifying a Regulatory Inspection with no-observation in cost effective way,

Then do not miss “Blue Ocean of Compliance” #1 Best Seller book on Amazon by Dr. Rupali Paranjape.

### About the Book

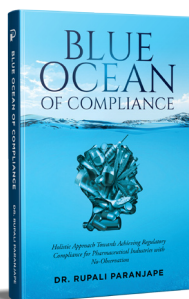
“Blue Ocean of Compliance” is a book employing a one-of-a-kind thought process for achieving compliance with no-observation.

It takes you through a guide of Regulatory Inspections elaborated with the US Regulatory Market regard.

This book will not only equip you with regulatory knowledge but will also empower you to solve complicated non-compliances, in the context of factors that we do not even think of. The ideas in this book are very simple to understand.

They will imbibe in you the seeds of “acting to win” instead of only being good enough to survive.

If you are a Founder, a CEO, an entrepreneur, or anyone in the pharmaceutical industry really: if you are a part of the pharmaceutical industry or even are just starting out, this book is a treasure for you.



### Why you must read this

- By reading & implementing this you will be able to avoid more than 492, 483s on your site.
- You will be able to avoid many circumstances that lead to Warning letters.
- You will become more familiar with the enforcement actions, reasons of non-compliances & ways to overcome them in cost-effective ways.
- You will come to know many factors which might not be discussed before to solve the non-compliance issues on the site.
- You will know one new thought process “Blue Ocean of Compliance”

The beautiful part of the book is, that it is written by an experienced doer that has spent years on shopfloor in a very simple manner, in easily understandable language with examples, case studies, 492 FDA 483 observations, and many Warning Letter Case studies and much more.

To book your copy click the below link; For India; <https://www.amazon.in/Blue-Ocean-Compliance-Rupali-Paranjape/dp/9390617014/>

For Abroad; <https://www.amazon.com/Blue-Ocean-Compliance-Rupali-Paranjape-ebook/dp/B09XMLFK7B>

### Contact details of Author Dr. Rupali Paranjape

**Mail:** [mail@drrupaliparanjape.com](mailto:mail@drrupaliparanjape.com)

**Website:** [www.drrupaliparanjape.com](http://www.drrupaliparanjape.com)

Catch her on

**LinkedIn:**

<https://www.linkedin.com/in/dr-rupali-paranjape/>

**YouTube Channel:**

<https://www.youtube.com/channel/UC7BZ0Scd3LjccScLipUVUVQ>

## In Rajya Sabha & In Lok Sabha

### In Rajya Sabha

#### **Anti Dumping Duty on Chinese Products**

#### **Rajya Sabha Unstarred Question No. 2592**

**Shri V. Vijayasai Reddy:**

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

- whether it is a fact that Government has imposed anti dumping duty on five Chinese products recently for five years on aluminium, chemicals, etc.;
- whether Directorate General of Trade Remedies (DGTR) has recommended imposition of duty on more products apart from above products; and
- if so, the details thereof?

#### **Answered on 25<sup>th</sup> March, 2022**

**A.** (a) : Yes, Sir. The Central Government (Department of Revenue, Ministry of Finance), on the basis of the recommendations of the Directorate General of Trade Remedies (DGTR), Department of Commerce, has imposed anti-dumping duty for five years on five Chinese products recently namely certain flat rolled products of aluminium, sodium hydrosulphite, silicone sealant, hydrofluorocarbon (HFC) component R-32 and hydrofluorocarbon blends.

(b) and (c): Yes, Sir. Apart from the above five products, the DGTR has recommended imposition of anti-dumping duty on other products originating in or exported from China PR in 2021-22. The details of these products are attached as Annexure-I.

#### **Annexure-I**

**The List of other Products Originating in or Exported from China PR on which the Anti Dumping Duty is Recommended by DGTR in 2021-22**

S.No.	Product
1.	Methyl Acetoacetate
2.	Phthalic Anhydride
3.	Aluminium foil 80 micron and below

4.	Seamless Tubes and Pipes
5.	Certain aceto-acetyl derivatives
6.	Axle for Trailers
7.	Untreated Fumed Silica
8.	Decor Paper
9.	Axle for Trailers
10.	Porcelain Vitrified Tiles
11.	Copper and Alloy FRP
12.	Acrylonitrile Butadiene Rubber (NBR)
13.	Rubber Chemical PX-13
14.	Polyester Spun Yarn
15.	Melamine
16.	Glass fibre
17.	Vitamin-C
18.	Cold Rolled Flat Product of alloy or Non-Alloy Steel
19.	Hot Rolled Flat Products of alloy or Non-alloy Steel
20.	Ceftriaxone Sodium Sterile
21.	Persulphates
22.	1,1,1, Tetrafluroethane or 134a of all types
23.	Colour coated / pre-painted flat products of alloy or non-alloy steel
24.	Wire Rod
25.	Elastomeric filament yarn
26.	Amoxycillin Trihydrate
27.	Plastic processing machinery
28.	PU Leather
29.	N, N'-Dicyclohexyl Carbodiimide (DCC)
30.	Ceramic Tableware and kitchenware

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

### **Surge in Imports**

#### **Rajya Sabha Unstarred Question No. 2594**

**Shri Sanjay Raut:**

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

- (a) whether it is a fact that many industries and their associations have expressed concerns at surge in imports, especially of metals and capital goods, from countries including Korea, Indonesia, Malaysia and Japan with whom India has signed Free Trade Agreements (FTAs);
- (b) if so, the details thereof and Government's response thereto;
- (c) whether it is also a fact that domestic manufactures have been adversely affected and derailing 'Make in India' programme due to mis-using of bilateral FTAs; and
- (d) if so, Government's response thereto and the steps taken by Government to check unlawful imports for survival of domestic industry?

**Answered on 25<sup>th</sup> March, 2022**

- A.** (a) to (d): Representations from industry and their associations are received from time to time on surge in imports from ASEAN countries, Japan and Korea, which are examined in consultation with the concerned administrative Ministries/ Departments and other stakeholders and taken up with the respective trading partners under the existing institutional mechanism enshrined in the respective FTAs. FTAs have inbuilt provisions to check any misuse of the FTA concessions, which inter-alia include strict compliance of the Rules of Origin, checking mis-declaration, if any, and taking trade remedial actions. The Government also reviews the provisions of the FTAs and their implications from time to time. Some of these actions taken by the Government include measures related to trade remedies such as Safeguards Duties, Anti-dumping Duties and Countervailing Duties, in case of sufficient grounds of misuse and surge in imports causing serious injury to domestic producers. Moreover, the Government has also restricted imports of certain products.

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

---

**Rise in Imports from China**

---

**Rajya Sabha Unstarred Question No. 2598**

**Shri Ripun Bora:**

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

- (a) whether it is a fact that the ongoing standoff with China is affecting bilateral trade and India's reliance on Chinese imports, including various raw materials;
- (b) if so, how does Government intend to address India's rising trade deficit with China therefor;
- (c) the reasons for 46.1 per cent rise in Indian imports from China in 2021 despite 'Make in India' initiatives thereof; and
- (d) the reasons for decline in the domestic manufacturing sector in the last three years, despite Government's highly publicised 'Make in India' scheme thereto?

**Answered on 25<sup>th</sup> March, 2022**

- A.** (a) to (d): The imports from China have exhibited a declining trend from USD 70.31 billion in 2018-19 to USD 65.21 billion in 2020-21, a decline of 7.2 per cent. On the other hand, India's exports to China have increased from USD 16.75 billion in 2018-19 to USD 21.18 billion in 2020-21, a rise of 26%. The Government of India has made sustained efforts to achieve a more balanced trade with China, including bilateral engagements to address the non-tariff barriers on Indian exports to China and measures against unfair trade practices. The Government has also launched Production Linked Incentive schemes (PLIs) in 14 sectors to promote domestic manufacturing capacities and attract investment and reduce dependency on imports. Efforts have also been made to source critical supplies from alternate sources and sensitize the concerned ministries/ departments to ramp up domestic capacities.

"Make in India" initiative was launched by Government on 25th September, 2014 to facilitate investment, foster innovation, build best in class infrastructure, and make India a hub for manufacturing, design, and innovation. "Make in India" initiative has significant achievements and presently focuses on 27 sectors under Make in India 2.0. The activities under the Make in India initiative are also being undertaken by several Central Government Ministries/ Departments and various State Governments. Ministries formulate action plans, programmes, schemes and policies for the sectors being dealt by them, while States also have their own Schemes for attracting investments.

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

**In Lok Sabha**

**Promotion of Domestic Medical Devices**

**Lok Sabha Unstarred Question No. 3769**

**Shri N. Reddeppa:**

**Dr. Sanjeev Kumar Singari:**

**Shri Kuruva Gorantla Madhav:**

**Shri Adala Prabhakara Reddy:**

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

- (a) the steps undertaken by the Government to reduce dependence on imports of medical devices; and
- (b) the current status of implementation of Production Linked Incentive (PLI) Scheme for Promoting Domestic Manufacturing of Medical Devices?

**Answered on 25<sup>th</sup> March, 2022**

- A.** (a) and (b): Department of Pharmaceuticals has launched a 'Production Linked Incentive (PLI) Scheme for Promoting Domestic Manufacturing of Medical Devices' with total financial outlay of Rs. 3,420 crore. In total 21 applicants with committed investment of Rs 1058.97 cr have been approved under the scheme. Further, the Department has launched another Scheme for 'Promotion of Medical Devices Parks' with a total financial outlay of Rs. 400 crore for setting up common infrastructural facilities in medical devices parks to be set up in four States/UTs. The proposals from the states of Uttar Pradesh, Tamil Nadu, Madhya Pradesh and Himachal Pradesh have been approved under the scheme.

**Minister of State in the Ministry of Chemicals and Fertilizers (Shri Bhagwanth Khuba)**

**Labelling of Packaged Foods**

**Lok Sabha Unstarred Question No. 3775**

**Shri Hemant Sriram Patil:**

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

- (a) whether any steps have been taken to make the nutrition facts label/ food package label compulsory so that the consumers can be guided for purchasing healthy alternative, if so, the details thereof;

- (b) whether the Government has evaluated the global best practices and the trends becoming most effective in informing about the health related damages caused due to packaged food products and if so, the details thereof;
- (c) the manner in which the Government is likely to ensure that the Indian food industry complies with the global norms and motivated to work on improving the unhealthy food items in the interest of public health; and
- (d) whether the Government/FSSAI has got any study conducted for evaluating people's perception regarding the warning signs on the labels of packaged food, if so, the details thereof and the outcome thereon?

**Answered on 25<sup>th</sup> March, 2022**

- A.** (a) to (d): Food Safety and Standards Authority of India (FSSAI) has informed that it has notified Food Safety and Standards (Labelling and Display) Regulations, 2020 regarding requirements for labelling of packaged food. Section related to nutritional information requires display of nutrients and their contribution to Recommended Daily Allowance (RDA) in percentage to enable consumers to make informed choice. It is mandatory for Food Business Operators (FBOs) to label the food package in accordance with these Regulations.

Department of Health Research has informed that National Institute of Nutrition, Hyderabad took up a study to assess the effectiveness of different formats of front-of-pack labelling (FOPL) on packaged food product and its effectiveness in communicating the unhealthiness of certain foods.

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

**Availability of Drugs at Janaushadi Kendras**

**Lok Sabha Unstarred Question No. 3694**

**Shri Suresh Kumar Kashyap:**

**Shri Ravindra Kushwaha:**

**Shri Ravi Kishan:**

**Shri Prataprao Jadhav:**

**Shri Basanta Kumar Panda:**



**Ms. Debasree Chaudhuri:**  
**Shri Anumula Revanth Reddy:**  
**Shrimati Queen Oja:**  
**Shri Shrirang Appa Barne:**  
**Shri Nalin Kumar Kateel:**  
**Shri Sanjay Seth:**  
**Shri Dhairyasheel Sambhajirao Mane:**  
**Shri Shankar Lalwani:**  
**Dr. Bharatiben Dhirubhai Shiyal:**  
**Shri Bidyut Baran Mahato:**  
**Shri Sanjay Sadashivrao Mandlik:**  
**Shri Sudheer Gupta:**

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

- the details of availability and consumption of various types of drugs/generic medicine available at the Janaushadhi Kendras and the difference in their price compared to that of other chemist shops;
- the number of beneficiaries under the Pradhan Mantri Bhartiya Janaushadhi Pariyojna (PMBJP) in the country, State/UT-wise;
- whether the Government has achieved its set target in opening Janaushadhi Kendras in the country and if so, the details thereof;
- the details of funds allocated and utilised under the PMBJP across the country during each of the last three years, State/UT-wise;
- the details of various events and activities conducted on the occasion of fourth Janaushadi Diwas; and
- whether more Janaushadhi Kendras are proposed to be opened to cater to the need of cheap and affordable medicines to the poor people in the country, if so, the details thereof, State/UT-wise?

**Answered on 25<sup>th</sup> March, 2022**

- A.** (a): The product basket of Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) comprises of about 1,616 medicines and 250 surgical devices, which are available for sale through more than 8,600 Pradhan Mantri Bhartiya Janaushadhi Kendras (PMBJKs) functional across the country. The product

basket covers all major therapeutic groups such as cardiovascular, anti-cancers, anti-diabetics, anti-infectives, anti-allergic, gastro-intestinal medicines, nutraceuticals, etc. A medicine under the Scheme is priced on principle of a maximum of 50% of the average price of the top three branded medicines. Therefore, 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 branded medicines.

(b) and (c): In a month, around 1.25 to 1.50 crore people on an average purchase medicine from more than 8,600 PMBJKs across the country. The annual targets of opening of PMBJKs under the scheme have been achieved within prescribed timelines. The target of having 8,300 PMBJKs by the end of the current financial year, i.e., 2021-22 has already been achieved in the month of September, 2021. As on 28.02.2022, about 8,689 PMBJKs have been opened, covering all districts of the country. State/UT-wise list of PMBJKs is attached as Annexure.

(d): The details of the funds sanctioned, allocated and utilized under the scheme for the financial years 2019-20 to 2021-22 are as under:

(Rs. In cr.)

Financial Year	Funds Allocated	Funds Utilized
2019-20	35.51	35.51
2020-21	65.00	65.00
2021-22 (as on 28.02.2022)	68.50	64.65

No State/UT-wise specific budget allocation made under the Scheme

(e): The 4<sup>th</sup> Jan Aushadhi Diwas was celebrated from 1<sup>st</sup> March, 2022 to 7<sup>th</sup> March, 2022. During the week-long celebration, various events were organized in coordination with PMBJKs owners, Beneficiaries, States/UTs officials, Public Representatives, Doctors, Health Workers, Nurses, Pharmacists, Jan Aushadhi Mitras and other stakeholders. The day wise activities organized across the country are as under:

Date	Activity
01.03.2022	Jan Aushadhi Sankalp Padyatra
02.03.2022	Matri Shakti Samman / Swabhimani
03.03.2022	Jan Aushadhi Bal Mitra
04.03.2022	Jan Aushadhi Jan Jagran Abhiyan

05.03.2022	Aao Jan Aushadhi Mitra Bane
06.03.2022	Jan Aushadhi Jan Arogya Mela (Health Checkup camps)
07.03.2022	Jan Aushadhi Diwas

The main event of 'Jan Aushadhi Diwas' was held on 7th March, 2022, wherein the Hon'ble Prime

Minister interacted through video conferencing with beneficiaries and kendra owners at various locations as well as addressed the citizens.

(f): The Government has set a target to open 10,500 PMBJKs by March 2025, across the country.

**Minister of State in the Ministry of Chemicals and Fertilizers (Shri Bhagwanth Khuba)**

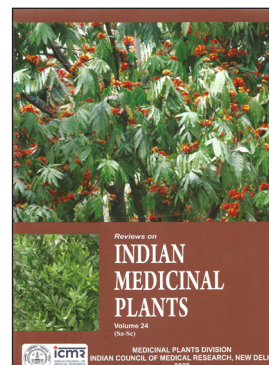
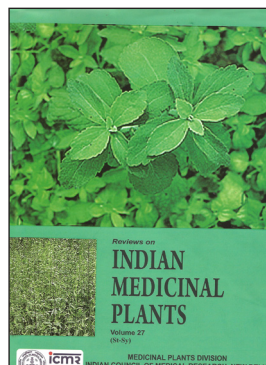
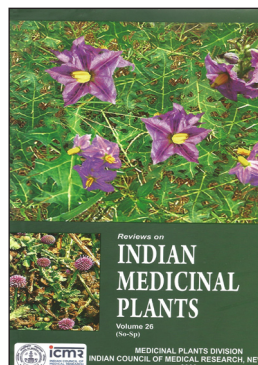
**Annexure**

**Statement referred to in parts (b) and (c) of the Lok Sabha Unstarred Q. No. 3694 for answer on 25.03.2022 regarding Availability of Drugs at Janaushadhi Kendras**

<b>State/UT-wise list of PMBJK's opened across the country till 28.02.2022</b>		
<b>Sl. No.</b>	<b>Name of the State/UT</b>	<b>Number of PMBJK opened</b>
1	Andaman & Nicobar	9
2	Andhra Pradesh	168
3	Arunachal Pradesh	28
4	Assam	89
5	Bihar	286
6	Chandigarh	7
7	Chhattisgarh	241
8	Delhi	383
9	Goa	10
10	Gujarat	522
11	Haryana	239
12	Himachal Pradesh	64
13	Jammu And Kashmir	126
14	Jharkhand	78
15	Karnataka	967
16	Kerala	986
17	Ladakh	2
18	Lakshadweep *	0
19	Madhya Pradesh	244
20	Maharashtra	630
21	Manipur	35
22	Meghalaya	15
23	Mizoram	22
24	Nagaland	16
25	Odisha	354
26	Puducherry	19
27	Punjab	306
28	Rajasthan	143
29	Sikkim	3
30	Tamil Nadu	869
31	Telangana	163
32	DNH & D&D	37
33	Tripura	24
34	Uttar Pradesh	1193
35	Uttarakhand	217
36	West Bengal	194
<b>Grand Total</b>		<b>8,689</b>

\* Medicines are directly supplied to the administration of UT of Lakshadweep

## 4 Volumes on “Reviews on Indian Medicinal Plants” Released



1. **Reviews on INDIAN MEDICINAL PLANTS, Volume 24 (Sa-Sc):** Medicinal Plants Division, Indian Council of Medical Research, NEW DELHI, 2022: ISSN: 0972-7957, Pages 1008; Price 1950.00 (US\$78.00)
2. **Reviews on INDIAN MEDICINAL PLANTS, Volume 25 (Se-Sm):** Medicinal Plants Division, Indian Council of Medical Research, NEW DELHI, 2022: ISSN: 0972-7957, Pages 833; Price 1620.00 (US\$ 64.00)
3. **Reviews on INDIAN MEDICINAL PLANTS, Volume 25 (So-Sp):** Medicinal Plants Division, Indian Council of Medical Research, NEW DELHI, 2022: ISSN: 0972-7957, Pages 716; Price 1648.00 (US\$ 66.00)
4. **Reviews on INDIAN MEDICINAL PLANTS, Volume 25 (St-Sy):** Medicinal Plants Division, Indian Council of Medical Research, NEW DELHI, 2022: ISSN: 0972-7957, Pages 859; Price 1967.00 (US\$ 79.00)

It appears that the medicinal plants division at ICMR worked even during the pandemic period and published the above 4 scientific review books which got released this year. These books comprise of detailed scientific review with relevant literature references, coloured photographs of the plant and exhaustive review information on each of the plant. The information is given under the headings of general information, botanical description, habitat, regional & other names, Ayurvedic description, therapeutic uses in Ayurveda, Properties & uses ascribed, Ethnobotanical reports, Pharmacognosy, Chemical studies, Pharmacological and biological studies, Clinical studies, Toxicological studies. Wherever available number of additional references have also been provided.

Volume 24 covers 63 plant genera and 211 species, Volume 25 covers 37 plant genera and 185 species, Volume 26 covers 34 plant genera and 130 species and Volume 27 covers 35 plant genera and 201 species.

Each monograph reviewed in these books is a treat to any scientist as it provides comprehensive information including structure of chemical compounds isolated and characterised in them, useful citation of human studies and their summary, useful citation of safety information and history of use documented in the traditional books. In fact, any researcher either in industry or otherwise can directly make use of these reviews as a base for project funding, planning research, and even for regulatory filing purposes. Pharmacy and Medical colleges should consider and procure the entire series for their libraries.

This reviewer had suggested earlier, that in this age of online accessing and difficulties to refer printed copies of books, ICMR may consider making contents of their publication available online even on a chargeable basis. It is not known what is the status of such a project, if it has been taken up. ICMR should also consider these publications procurable online as e-books in 'Kindle' compatible forms, so that revenue to ICMR is not lost.

As a Scientist, I thoroughly enjoyed reading these books and complement the scientists of ICMR, Medicinal Plants Division and the leadership of Technical Review Committee.

Reviewed by: DB Anantha Narayana  
CSO, Ayurvidye Trust, Bangalore.

## Indian Pharmaceuticals clock best export performance ever in FY22



*Credit rating agency ICRA has revised its outlook for the Indian pharmaceutical industry to 'stable' now from an earlier 'negative' rating at the start of the year.*

India's pharmaceutical industry had its best-ever export performance in 2021-22 as the sector registered a growth of 103% since 2013-14. The pharma sector has achieved an exceptional growth of almost \$10 billion in 8 years, as they grew from Rs 90,415 Cr in 2013 to Rs 1,83,422 Cr in 2021.

Indian pharmaceutical companies have created a global impression by virtue of their price competitiveness and good quality, which became a reality with 60% of the world's vaccines and 20% of generic medicines coming from India. Another noteworthy fact is that around 55% of India's pharma exports caters to highly regulated markets. Indian pharma companies also enjoy a good share in the prescription market in the United States and European Union.

The jump in the growth of pharma exports has been witnessed despite the global trade disruptions and drop in demand for COVID-19 related medicines. The trade balance continues to be in India's favour, with a surplus of USD 15175.81 million. India stands on 3rd position in terms of production and acquires rank 14th in terms of value. Presently, the size of Indian pharmaceutical industry is around USD 50 billion.

The share of pharmaceuticals and drugs in global exports of the country stands at 5.92%. Formulations and Biologicals hold a major share of around 73.31% in our

total exports, followed by bulk drugs and drug intermediates with exports of USD 4437.64 million. India's top 5 pharma export destinations are USA, United Kingdom, South Africa, Russia and Nigeria.

Indian pharmaceuticals and drugs industry attained sharp growth amid the COVID despair, with exports figure touching USD 24.4 Billion mark with a YoY growth of 18%. The remarkable exports growth feat in 2020-21 was achieved amidst the frequent lock downs, global supply chain disruptions and the depressed manufacturing sector. As part of the trade agreements, India also signed a cooperation agreement with UAE and Australia which will give enhanced access to Indian pharma products to these markets.

*Source: News on Air, 04.05.2022*



## Smriti Irani hails Gujarat contribution in pharmaceutical exports



AHMEDABAD: Hailing the state's contribution in the pharma sector, Union minister of women and child development Smriti Irani on Sunday said that of the \$24 billion exports achieved by India, Gujarat accounts for nearly 25 per cent. She was inaugurating the national conference on "Soaring Heights of Empowerment in Pharma & Healthcare Industry" here. The minister also launched a knowledge report on "Future Impact on Pharma & Healthcare with Diversity & Inclusivity: Vision 2030".

Extending her wishes on the state's Formation Day, she highlighted the contribution of Gujarat in the pharma sector stating that out of 24 billion USD exports achieved by India, the state accounts for nearly 25 per cent.

She expressed concern over lack of opportunities for women in the pharma and healthcare sectors and hoped that the conference would help to generate dialogue, discussion and drive outcomes towards the goal of more women in these sectors.

“Now tell me ladies and gentlemen, do we have that many female specialists only in this one particular sector?” she asked. “Look at us (women) as consumers, who want to ensure that we have the best of medical practices by women who lead out of sheer competence,” she said.

Irani also raised the issue of bias against women workers in the pharma and healthcare industry, and said that only 11 per cent of the workforce in the sector comprises women.

Five per cent women are in sales and marketing, 12 per cent in manufacturing, and 25 per cent in corporate functions, she said. “If we, the best and the brightest of minds, do not acknowledge the problem and do not address

the elephant in the room, how are we then, irrespective of our gender, going to find the solution?” she asked. The sheer number of women beneficiaries under the Ayushman Bharat scheme shows why it is “profitable to enhance the role of women in pharmacology and healthcare”, she said. “Breast screening under Ayushman Bharat - especially remember this is for the poorest of the poor in our country - has been over four crore seven lakh. For screening of the cancer of the cervix, the number of women who get themselves screened under the Ayushman Bharat Yojana is 3.16 crore,” she said.

In another function, the minister also distributed kits to beneficiaries under the state BJP’s ongoing ‘Suposhan Abhiyan’ scheme. Speaking at the function held at Dholakuva in Gandhinagar district, Irani said that this is perhaps the first time in India’s political history that a party has taken up the task of ensuring that children get nutritious food.

Source: *The Times of India*, 02.05.2022



## NOW AVAILABLE ! IDMA-APA GUIDELINES / TECHNICAL MONOGRAPHS

TECHNICAL MONOGRAPH NO. 1  
**STABILITY TESTING OF EXISTING  
DRUGS SUBSTANCES AND PRODUCTS**

TECHNICAL MONOGRAPH NO. 3  
**INVESTIGATION OF OUT OF  
SPECIFICATION (OOS) TEST RESULTS**

TECHNICAL MONOGRAPH NO. 5  
**ENVIRONMENTAL MONITORING  
IN CLEANROOMS**

TECHNICAL MONOGRAPH NO. 7  
**DATA INTEGRITY GOVERNANCE**

TECHNICAL MONOGRAPH NO. 2  
**PRIMARY & SECONDARY CHEMICAL  
REFERENCE SUBSTANCES**

TECHNICAL MONOGRAPH NO. 4  
**PHARMACEUTICAL PREFORMULATION  
ANALYTICAL STUDIES**

TECHNICAL MONOGRAPH NO. 6  
**CORRECTIVE/PREVENTIVE ACTIONS  
(CAPA) GUIDELINE**

TECHNICAL DOCUMENT NO. 8  
**QUALITY 4.0 DIGITAL TECHNOLOGY  
OF THE FUTURE**

Copies are available at IDMA Office, Mumbai. We do not mail any publications against VPP payment. All payments to be made in advance as Cheque/DD/RTGS/NEFT in favour of “**INDIAN DRUG MANUFACTURERS’ ASSOCIATION**” at Mumbai.

For more details please contact: **PUBLICATIONS DEPARTMENT** Tel.: 022 - 2494 4624 / 2497 4308 Fax: 022 - 2495 0723  
E-mail: [publications@idmaindia.com](mailto:publications@idmaindia.com), Website: [www.idma-assn.org/www.indiandrugsonline.org](http://www.idma-assn.org/www.indiandrugsonline.org)



# IDMA BULLETIN

PUBLISHED ON 7<sup>th</sup>, 14<sup>th</sup>, 21<sup>st</sup> and 30<sup>th</sup> of Every Month

## ADVERTISEMENT TARIFF

(Effective from 01.11.2017)

Magazine Size: 21.5 cm x 27.5 cm / Print Area: 18.5 cm x 23.5 cm

Position		Rate per Insertion ₹	
		B/W	Colour
Full Page (18 cm wd x 23.5 cm ht)	:	9,000	12,500
Half Page (18 cm wd x 11.5 cm ht) (Horizontal)		5,000	8,500
Half Page (8.5 cm x 23.5 cm) (Vertical)	:	5,000	8,500
Quarter Page (8.5 cm wd x 11.5 cm ht)	:	2,500	6,000
Strips Advts (4 cm ht x 18 cm wd)	:	2,500	-
Inside Cover Pages	:	-	18,000
Back Cover	:		25,000
Centre Spread (double spread) Print area (40cm wd x 27cm ht)	:	25,000	30,000

### Terms and Conditions:

- All payments by **Cheque/ Demand Draft/RTGS** in advance only to be made in favour of “**Indian Drug Manufacturers’ Association**”, Payable at Mumbai

**The RTGS details are as follows:- BANK: BANK OF BARODA**

Account Name : **Indian Drug Manufacturers’ Association**, Bank A/c No. : Current A/c **76080200000242**

Bank : **BANK OF BARODA**, Branch Address : Worli Branch, Mumbai-18, **IFSC : BARB0DBWORL**

**MICR CODE : 400012332**

- GST will be charged extra, as applicable. (Current Rate is @5%)
- SPECIAL DISCOUNTS for Series Advertisements
- For colour advertisements, positives to be supplied otherwise processing charges to be paid.
- Advertisement material must reach us 7 days before the date of publication.**
- Positioning of the Advt other than Cover Positions will be at our discretion.
- Only Colour Advts will be entertained on Cover Positions.

### Classified Advertisements

- Upto 80 words — ₹2,000/-
- 50% extra for Advt Box Number
- 50% extra for indent/layout spacing, bold captions, etc.
- ₹50/- extra for voucher copy
- Series discount not applicable for classifieds

**For further details such as series discounts etc, please contact:**

**Melvin Rodrigues — Cell: +9821868758 (Email: actadm@idmaindia.com)/**

**Geeta Suvarna — Cell: +9820161419 (Email: publications@idmaindia.com)**

**PUBLICATIONS DIVISION**

## INDIAN DRUG MANUFACTURERS’ ASSOCIATION

102-B, Poonam Chambers, Dr. A. B. Road, Worli, Mumbai 400 018. Tel: 022-2494 4624/2497 4308 Fax: 022-2495 0723

Website: [www.idma-assn.org](http://www.idma-assn.org)/[www.indiandrugsonline.org](http://www.indiandrugsonline.org)

# INFINITE APPLICATIONS. **ONE IDENTITY.**

Dear Partner,

For over three decades, we have been dedicating ourselves to the pharmaceutical excipients industry in India. Three decades of relentless effort that has become our identity.

Today, that effort is evident in hundreds of applications across the arena of pharma, nutra and biopharma. And we are renewing our pledge to further enforce our efforts by focusing on one area - excipients. So we can continue to serve the industry and our partners even better, with greater efficiency and deeper integration.

Because while what we do leads to infinite ends, our identity remains uniquely unchanged - excipients.

Signet-ure

*Identity*

**Signet**

The Complete Excipients Company





## Introducing PureHale From Aptar Pharma

PureHale is an industry first, a portable and ready-to-use nebulizer-like device designed to deliver natural care to upper airways.

When used in combination with saline water and other natural ingredient formulations, PureHale helps to relieve symptoms for upper airway conditions such as coughs, colds, allergies, respiratory problems, dry nose and throat and other irritations.

To find out more about how PureHale can make better breathing easy, contact **Guenter Nadler**, Business Development Director at Aptar Pharma on **+49 7732 801 536** or email **guenter.nadler@aptar.com**



**Aptar**   
pharma

Delivering solutions, shaping the future.