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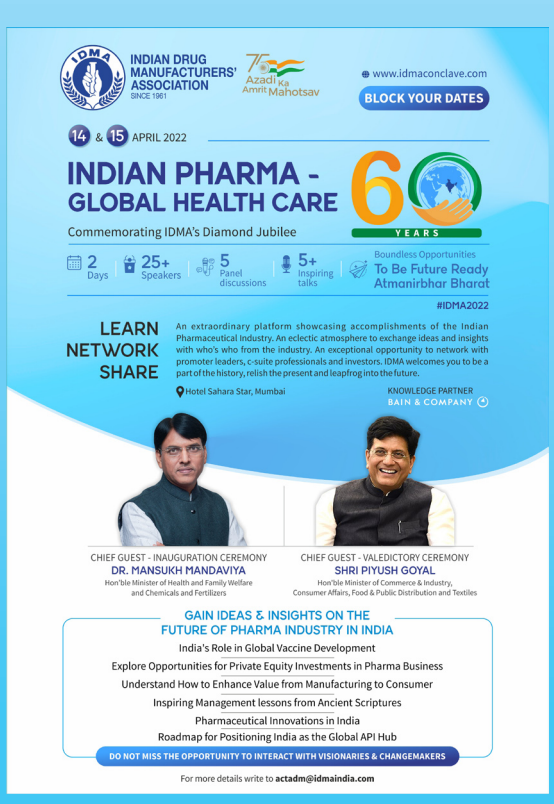
IDMA BULLETIN

VOL. NO. 53 | ISSUE NO. 13 (PAGES: 48) | 01 TO 07 APRIL 2022 | ISSN 0970-6054 | WEEKLY PUBLICATION

Indian APIs & Formulations for Global Healthcare

INDIAN DRUG MANUFACTURERS' ASSOCIATION



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HIGHLIGHTS

- ★ **Implementation of the Track and Trace system for export of Pharmaceuticals and drug consignments along with maintaining the Parent-Child relationship in the levels of packaging and their movement in supply chain - Extension of date of implementation** *(Page No. 11)*
- ★ **NPPA revises the ceiling prices (Wholesale Price Index) of various Scheduled formulations of Schedule-I under Drugs (Prices Control) order, 2013** *(Page No. 12-22)*
- ★ **Costlier APIs hurting pharma manufacturers: IDMA** *(Page No. 42)*

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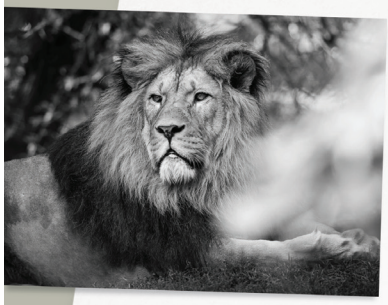

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FILLERS / DILUENTS
- AVICEL PH – Microcrystalline Cellulose
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- AC-DI-SOL – Croscarmellose Sodium

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- AVICEL RC / CL – Colloidal Microcrystalline Cellulose

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- PROTACID – Alginic Acid
- PROTANAL / MANUCOL – Alginate
- GELCARIN / VISCARIN – Carrageenan

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- ALUBRA PG 100 – Sodium Stearyl Fumarate

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- AQUATERIC N100 – Ready-to-use Alginate based Enteric Coating System

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e-mail: publications@idmaindia.com/
actadm@idmaindia.com/ website: www.idma-assn.org

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IDMA BULLETIN

Vol. No. 53 **Issue No. 13** **01 to 07 April 2022**

IDMA ACTIVITIES:

DGFT MATTERS:

NPPA MATTERS:

GOVERNMENT NOTIFICATIONS:

GOVERNMENT COMMUNICATIONS:

PARLIAMENT NEWS:

INTERVIEW:

NATIONAL NEWS:

INDIAN DRUG MANUFACTURERS' ASSOCIATION (IDMA)
1961 – 2021 (60 Glorious Years)

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

IDMA 60TH YEAR CELEBRATIONS 2022

Thursday, 14th & Friday, 15th April, 2022

Hotel Sahara Star, Mumbai

No Spot Registration
Register Now

Dear Member,

We are extremely happy to inform you that the arrangements for the 60th Year Celebrations has progressed **extremely well and we have an excellent line up of speakers, panellists and motivators who will leave you spellbound.**

We are pleased to inform you that our **Hon'ble Dr. Mansukh Mandaviya,** Minister of Health & Family Welfare and Chemicals & Fertilizers has confirmed to be the Chief Guest at the Inaugural ceremony on 14th April 2022 and our **Hon'ble Shri Piyush Goyal**, Minister for Commerce & Industry, Consumer Affairs, Food & Public Distribution and Textiles has confirmed to be the Chief Guest at the Valedictory ceremony on 15th April 2022. **Dr. Gnanvatsal Swami Ji** will deliver a Spiritual Address on the 2nd Day.

We have Industry Stalwarts who have confirmed their presence for various panel discussions scheduled over the two days, such as **Mr. Dilip Shanghvi** (Sun Pharmaceutical Industries), **Mr. Pankaj Patel** (Zydus LifeSciences Ltd), **Mr. Satish Reddy** (Dr. Reddy's Laboratories), **Mr. Vallabh Bhanshali** (ENAM Holdings), **Dr. Amit Varma** (Quadria Capital), **Mr. Utpal Sheth** (Rare Enterprises), **Mr. Dhaval Shah** (PharmEasy), **Mr. Rajkiran C** (PTC), **Mr. Ajith Pai** (Delhivery), **Dr. Pravin Iyer** (Glenmark Pharmaceuticals), **Dr. Premnath V** (NCL Innovations), **Dr. Dhananjay Bakhle** (Lupin), **Dr. Satyanarayana Chava** (Laurus Lab), **Mr. Premchand Godha** (IPCA Laboratories) and Mr. Rajeev Nanapanenni (Natco Pharma).

We are pleased to inform you that **Bain & Co is our knowledge partner** for this event. *We attach herewith the agenda for your kind perusal and information.*

There is a very interesting Fireside Chats on 14th April 2022 :-

Dr. Mansukh Mandaviya, Minister of Health & Family Welfare and Chemicals & Fertilizers, Government of India with **Parijat Ghosh**, Partner - Bain & Co.

There are two very interesting Fireside Chats on 15th April 2022 :-

1. **Mr. Natarajan Chandrasekaran,** Chairperson, Tata Group - by **Mehul Shah**, MD - Encube Ethicals
2. **Hon'ble Shri Piyush Goyal,** Minister for Commerce & Industry, Consumer Affairs, Food & Public Distribution and Textiles- by **Dr. Viranchi Shah**, MD – Saga Laboratories

We are pleased to inform you that we are having an excellent Entertainment program on 14th April in the evening from 7.00 p.m. onwards. Playback Singer Javed Ali & Stand-up Comedian Atul Khatri would be performing.

Request your best support for this once in a lifetime event of IDMA.

Kindly register yourself and senior executives of your esteemed organization at the earliest.

Please note that non-members who are known to you / your associates may also register.

Looking forward to welcoming you all.

For further details, please contact:

Mr. Melvin	Ms. Geeta	Ms. Batul	Ms. Parivaz
9821868758	9820161419	9920045226	9830081744
actadm@idmaindia.com	publications@idmaindia.com	technical@idmaindia.com	idma2@idmaindia.com

Best Wishes

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

Dr. Viranchi Shah
National President

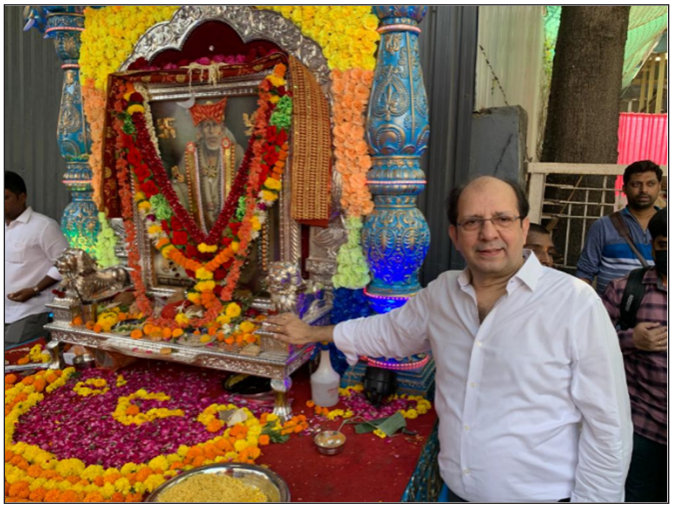
Daara B Patel
Secretary - General

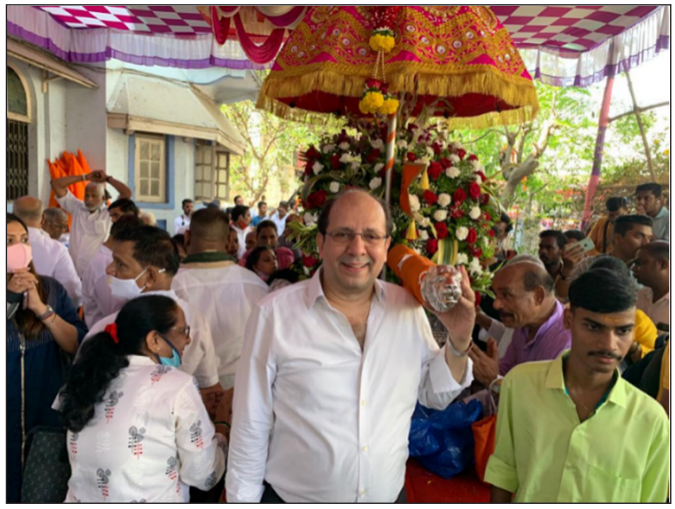
AGENDA		
Day 1: Thu, Apr 14, 2022		
09:00 - 10:00	Registration, High Tea and Networking	60
10:00 - 10:10	National Anthem, IDMA Anthem, and Lighting of the Lamp	10
	Welcome Address	
10:10 - 10:15	Daara Patel, Secretary General - IDMA	5
10:15 - 10:20	Bharat Shah, Chairman - IDMA Diamond Jubilee Organising Committee	5
10:20 - 10:25	Mahesh Doshi, Immediate Past National President - IDMA	5
10:25 - 10:30	Dr. Viranchi Shah, National President - IDMA	5
	Address by Guests of Honour	
10:30 - 10:40	Dr. V G Somani, Drugs Controller General of India	10
10:40 - 10:50	Kamlesh Kumar Pant, IAS, Chairman - National Pharmaceuticals Pricing Authority	10
10:50 - 11:00	S Aparna, IAS, Secretary - Department of Pharmaceuticals	10
11:00 - 11:10	Rajendra Shingne, Minister of Food and Drug Administration (FDA), Government of Maharashtra	10
11:10 - 11:15	**Release of IDMA 60th Year Annual Publication 2022**	5
	Address by Chief Guest	
11:15 - 11:30	**Dr. Mansukh Mandaviya**, Minister of Health & Family Welfare and Chemicals & Fertilizers, Government of India	15
11:30 - 11:45	**Honourable Prime Minister Shri Narendra Modi's Video Message**	15
	(pre-recorded)	
11:45 - 12:05	**Honouring Past IDMA National Presidents and Industry Veterans**	20
12:05 - 12:10	Vote of Thanks by Mehul Shah, Hon. General Secretary - IDMA	5
12:10 - 12:30	*Tea and Coffee Break*	20
	Fireside Chat	
12:30 - 13:00	Dr. Mansukh Mandaviya, Minister of Health & Family Welfare and Chemicals & Fertilizers, Government of India with Parijat Ghosh, Partner - Bain & Co.	30
13:00 - 14:00	*Lunch*	60
14:00 - 15:00	**Panel Discussion 1 - The Pharma Industry: Pivoting for Tomorrow**	
	Dilip Shanghvi, Managing Director - Sun Pharmaceutical Industries	
	Pankaj Patel , Chairman - Zydus Lifesciences	60
	Satish Reddy, Chairman - Dr. Reddy's Laboratories	
	Moderated by: Utkarsh Palnitkar, Founder - Aarna Corporate Advisors	
15:00 - 15:10	**IDMA N I Gandhi Chief Mentor Award**	10
15:10 - 16:10	**Panel Discussion 2 - Private Equity: Fueling Growth in Pharma SMEs**	
	Vallabh Bhanshali, Co-Founder & Chairman - ENAM Holdings	
	Dr. Amit Varma, Managing Partner - Quadria Capital	60
	Utpal Sheth, CEO - Rare Enterprises	
	Moderated by: Ramesh Damani, Member - BSE & Chairman - DMart	
16:10 - 16:25	**IDMA Corporate Citizen Awards 2021**	15
16:25 - 16:45	*Tea and Coffee Break*	20

16:45 - 17:45	**Panel Discussion 3 - Disruption:** Enhancing Value from Manufacturing to Consumer	
	Dr. Dhaval Shah, Co-Founder - PharmEasy	
	Rajkiran C, Senior Director - PTC	60
	Ajith Pai, COO - Delhivery	
	Moderated by: Parijat Ghosh, Partner - Bain & Co.	
17:45 - 17:55	**IDMA - Aptar Innovation of the Year Award**	10
17:55 - 18:00	**Summary and Closing Remarks by** Dr. George Patani, Vice President (Western Region) - IDMA	5
18:00 - 19:30	High Tea and Networking	90
19:30 - 21:30	**Entertainment Program and Dinner**	
	Javed Ali, Playback Singer Atul Khatri, Stand-up Comedian RJ Dilip, Host for the Entertainment Program	120

Day 2: Fri, Apr 15, 2022		
		Minutes
09:00 - 09:50	High Tea and Networking	50
09:50 - 10:00	**Welcome Address by Dr. Viranchi Shah**, National President - IDMA	10
10:00 - 10:40	**Fireside Chat** **Mr. Natarajan Chandrasekaran**, Chairman - Tata Sons with Mehul Shah, Hon. General Secretary - IDMA	40
	Management Tips for Entrepreneurs - Inspiration from Ancient Scriptures	
10:40 - 11:10	by **Dr. Gnanvatsal Swami**, Life Coach & Eminent Speaker	30
11:10 - 11:30	**Valedictory Address by Chief Guest** **Shri Piyush Goyal**, Minister of Commerce & Industry, Consumer Affairs, Food & Public Distribution and Textiles, Government of India *followed by* **Fireside Chat** with Dr. Viranchi Shah, National President - IDMA	20
11:30 - 12:00	**IDMA Margi Patel Choksi Memorial Best Patent Awards**	30
12:00 - 12:10	*Tea and Coffee Break*	10
12:10 - 12:55	**R&D Session - Innovation-in-India: In Purusit of R&D Excellence** Address by: Dr. Pravin S Iyer, Senior Vice President & Head NCE Research - Glenmark Pharmaceuticals Dr. Premnath V, Head - NCL Innovations Dr. Dhananjay Bakhle, Executive Vice President - Medical Research, Lupin	45
12:55 - 13:10	**IDMA ACG-SCITECH Best Research Paper Awards**	15
13:10 - 14:10	**Panel Discussion 4 - Inflection Point: Positioning India as the Global API Hub**	60
	Dr. Satyanarayana Chava, Founder and CEO - Laurus Labs	
	Premchand Godha, Chairman and Managing Director - Ipca Laboratories	
	Rajeev Nannapaneni, Vice-Chairman and CEO - Natco Pharma	
	Moderated by: Utkarsh Palnitkar, Founder - Aarna Corporate Advisors	
14:10 - 14:25	**Felicitation of IDMA Diamond Jubilee Core Team**	15
14:25 - 14:30	Vote of Thanks by Mehul Shah, Hon. General Secretary - IDMA	5
14:30	*Lunch*	

IDMA & Sai Seva Mandal thank IDMA members for donating free medicines for the Walking Pilgrimage (PADYATRA) from Mumbai to Shirdi





Mr Daara B Patel, Secretary General, IDMA at the inaugural function of the walking pilgrimage

Sai Seva Mandal organizes a walking pilgrimage (Padyatra) for the Sai Baba Devotees from Mumbai to Shirdi every year. This event was cancelled last two years due to the covid-19 pandemic. IDMA member companies contribute free medicines to the devotees every year.

This year the registrations for the Padyatra was overwhelming, approx. 3000+ devotees. There were many Ambulances, Doctors and Nurses organized to travel with the devotees. IDMA had requested its members for medicines for symptoms like fever, cold & cough, vitamins, tetanus injections, acidity problems, pain killers – roll-ons, gels, tablets, sprays & most importantly sanitizers.

IDMA & Sai Seva Mandal profusely thank the following members for providing the above medicines in large numbers for the devotees:-

1. Fourrts (India) Laboratories Pvt. Ltd.
2. Somatico Pharmacal Pvt. Ltd.
3. Cipco Pharmaceuticals
4. NuLife Pharmaceuticals
5. Alkem Laboratories Ltd.
6. Mova Pharmaceuticals Pvt. Ltd.
7. SaiMirra Innopharm Pvt. Ltd.
8. Micro Labs Ltd.
9. Bharat Parenterals Ltd.

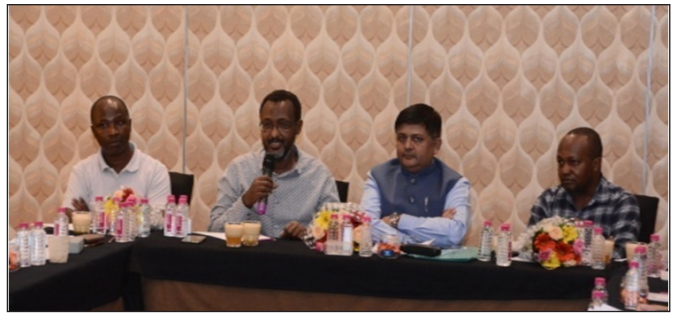
IDMA and Sai Seva Mandal pray to Shri Sai Baba to bless our members abundantly and be with them during these difficult & trying times.

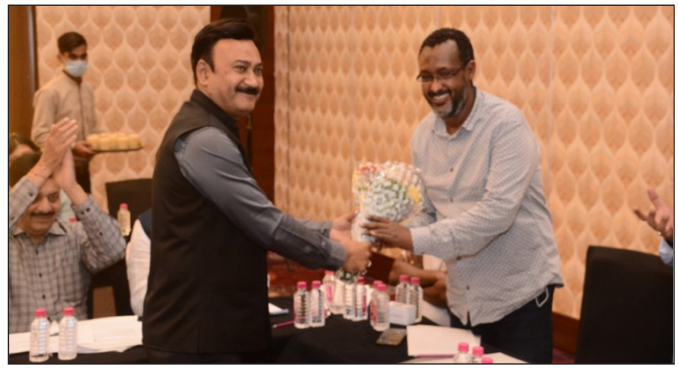
Report on "An Interactive Meeting of IDMA- GSB with Kenya Regulatory Authorities" at Crowne Plaza Ahmedabad City Centre, Ahmedabad, On 28th March 2022

An interactive meeting was organized by IDMA - GSB at Crowne Plaza Ahmedabad city Centre, Ahmedabad on 28th March 2022 with the delegation of Regulatory Authorities from Kenya. The delegation was led by Dr. Ahmed Ibrahim Mohamed – Director, Health Products & Technology (Pharmacy and Poisons Board), Kenya. Dr. Job Kandie and Dr. Allan Kyalo,Senior Principal, Regulatory Officer, Trade Dept., Pharmacy & Poisons Board, MoH, Kenya were also present.

IDMA -GSB was represented by Dr. Shrenik Shah, Chairman, other office bearers and Executive Committee members. Dr. Viranchi Shah, National President, IDMA also graced the occasion. The meeting had nearly 52 attendees including co-opted EC members, special invitees and past chairmen.

Mr. Sanchit Chaturvedi, Sr. Vice Chairman, IDMA - GSB informed that Shri Arvindbhai Shah, Father of Dr. Viranchi Shah, National President, IDMA and Smt. Nirmalaben Shah, Mother of Mr. Vijay Shah, Vice Chairman IDMA - GSB passed away in the third week of March 2022. Members observed Two minutes of silence as a mark of respect to the departed souls.





Programme started with a welcome speech delivered by Dr. Shrenik Shah, Chairman, IDMA-GSB.

Dr. Allan Kyalo, Senior Principal Regulatory Officer, Trade Dept., Pharmacy & Poisons Board, MoH, Kenya made a video presentation on "Kenya Pharmaceutical Sector Regulatory Framework". This was followed by a Q&A session, which was nicely handled by Ms. Jinkal Patel, Jt. Secretary, IDMA-GSB.

The Kenyan officials were felicitated with a Mementos (Statue of Unity - Sardar Vallabhbhai Patel – The World Tallest Statue).

The meeting ended with vote of thanks speech delivered by Ms. Jinkal Patel, Jt. Secretary, IDMA-GSB and followed by Dinner.

The interactive meeting was very meaningful and included a dialogue on hand holding the industry as well as on long term engagement between IDMA & Kenya.

DGFT Public Notice on amending the Handbook of Procedures 2015-2020 till 30.9.2022

Public Notice No. 53/2015-2020, dated 31st March, 2022

In exercise of powers conferred under paragraph 2.04 of the Foreign Trade Policy (FTP) 2015 2020, the Director General of Foreign Trade hereby makes, with immediate effect, the following amendments:

In the Handbook of Procedures (HBP), 2015-20:

1. In para 1.01, the phrase “shall remain in force until 31st March, 2022' is substituted by the phrase "shall remain in force until 30.09.2022'.

2. In para 3.20 (a), the phrase 'or 31.03.2022, whichever is later' is substituted by the phrase for 30.06.2022, whichever is later'.

3. In para 4.12(vi), the date ‘31.03.2022', as appearing in the first sentence is substituted by “30.09.2022.

Effect of this Public Notice: Validity of the existing Hand Book of Procedures, 2015-20 is extended upto 30th September, 2022.

File no. 01/75/171/00020/AM22/FTP Cell

Santosh Kumar Sarangi,
Director General of Foreign Trade
Ex-officio Addl. Secretary,
Commerce and Industry, Department of Commerce
Directorate General of Foreign Trade,
New Delhi.

● ● ●

DGFT Notification on extending the validity of Foreign Trade Policy 2015-2020 up to 30.9.2022

Notification No. S.O.64/2015-2020, dated 31st March, 2022

In exercise of powers conferred by Section 5 of the Foreign Trade (Development & Regulation) Act, 1992 read with paragraph 1.02 of the Foreign Trade Policy (FTP) 2015-2020, as amended, the Central Government hereby makes, with immediate effect, the following amendments in the FTP 2015-2020:

In para 1.01, the phrase "shall remain in force upto 31st March, 2022 unless otherwise specified' is substituted by the phrase "shall remain in force upto 30.09.2022 unless otherwise specified.

Effect of this Notification: The existing Foreign Trade Policy 2015-2020 which is valid upto 31.03.2022 is extended upto 30th September, 2022.

Santosh Kumar Sarangi,
Director General of Foreign Trade
Ex-officio Addl. Secretary,
Commerce and Industry,
Department of Commerce,
Directorate General of Foreign Trade,
New Delhi.

● ● ●

Amendment in import policy condition of Urea [Exim Code 31021000] in the ITC (HS) 2022, Schedule - I (Import Policy)

DGFT Notification No.65/2015-2020, dated 01st April 2022

In exercise of powers conferred by Section 3 and Section 5 of FT (D&R) Act, 1992, read with paragraph 1.02 and 2.01 of the Foreign Trade Policy, 2015-2020, as amended from time to time, the Central Government hereby amends the policy condition of Urea [EXIM code 31021000] of Chapter 31 of ITC (HS), 2022,Schedule — I (Import Policy), with immediate effect, as under :

Exim Code	Item Description	Policy	Existing Policy Condition	Revised Policy Condition
31021000	Urea, whether or not in aqueous solution	State Trading Enterprise	Import allowed through RCF and **NFL** subject to Para 2.20 and of Foreign Trade Policy, 2015-of **2020. In addition import of 2015-2020. Urea is also allowed through** IPL for a period up to allowed 31.3.2022. However, import of Technical Grade Urea (TGU) meant for non-agricultural purpose/industrial use/NPK Manufacturing shall be "Free".	Import allowed through RCF and NFL subject to Para 2.20 Foreign Trade Policy, **In addition import of Urea is also through IPL for a period up to 31.3.2023.** However, import of Technical Grade Urea (TGU) meant for non-agricultural purpose/ industrial use/ NPK Manufacturing shall be "Free".

2. <u>Effect of this Notification:</u>

Import of Urea on Government account is allowed through Indian Potash Limited (IPL) subject to Para 2.20 of Foreign Trade Policy, 2015-2020, **till 31.03.2023.**

This issues with the approval of Minister of Commerce & Industry.

F. No. 01/89/180/102/AM-02/PC-2(A)Part-II/E-1715

Santosh Kumar Sarangi, Director General of Foreign Trade & Ex-officio Addl. Secretary, Ministry of Commerce & Industry, Department of Commerce, Directorate General of Foreign Trade, New Delhi.

● ● ●

Amendments to Foreign Trade Policy 2015-2020 - Extension of Integrated Good and Service Tax (IGST) and Compensation cess exemption under Advance Authorisation, EPCG and EOU scheme up to 30.06.2022

DGFT Notification No.66/2015-2020 dated 01st April 2022

In exercise of powers conferred by Section 5 of FT(D&R) act 1992, read with Paragraph 1.02 of the Foreign Trade Policy, 2015-20, as amended from time to time the Central Goverment hereby makes following amendments in Foreign Trade Policy 2015-20.

1. Exemption from Integrated Tax and compensation Cess under Advance Authorization under Para 4.14 of FTP 2015 -20 is extended upto 30.06.2022.
2. Exemption from Integrated Tax and Compensation Cess under EPCG scheme under Para 5.01 (a) of FTP 2015-20 is extended upto 30.06.2022.
3. Exemption from Integrated Tax and Compensation Cess under EOU scheme under Para 6.01(d)(ii) ofFTP 2015-20 is extended upto 30.06.2022.

Effect of this Notification: Para 4.14, Para 5.01(a) and Para 6.01(d)(ii) of FTP 2015-20 are amended as above.

File No. 01/94/ 180/029/AM22/PC-4)

Santosh Kumar Sarangi, Director General of Foreign Trade & Ex-officio Addl. Secretary, Ministry of Commerce & Industry, Department of Commerce, Directorate General of Foreign Trade, New Delhi.

● ● ●

Implementation of the Track and Trace system for export of Pharmaceuticals and drug consignments along with maintaining the Parent-Child relationship in the levels of packaging and their movement in supply chain - Extension of date of implementation - reg.

DGFT Public Notice No.01/2015-20, dated 04th April 2022

1. In exercise of the powers conferred under Paragraph 2.04 of the Foreign Trade Policy, 2015-20, as amended from time to time, the Director General of Foreign Trade hereby amends Para 2.90 A of Handbook of Procedure- 2015-20, as notified vide Public Notice No.43/2015-20 dated 05.12.2017 read with Public Notice No.52/2015-20 dated 05.01.2016, Public Notice No.05/2015-20 dated 09.05.2018, Public Notice No.43/2015-2020 dated 01.11.2018, Public Notice No.16/2015-2020 dated 04.07.2019, Public Notice No. 66/2015-2020 dated 30.03.2020, Public Notice No.16/2015-2020 dated 22.9.2020 and Public Notice No.46/2015-20 dated 30.03.2021 on laying down the procedure for implementation of the Track and Trace system for export consignments of drug formulations.

2. In Para 2.90 A (vi) and (vii) of Handbook of Procedure - 2015-20 (as amended vide Public Notice No.46/2015-20 dated 30.03.2021), "01.04.2022" may be substituted by "31.3.2023".

3. Effect of this Public Notice:

The date for implementation of Track and Trace system for export of drug formulations with respect to maintaining the Parent-Child relationship in packaging levels and its uploading on Central Portal has been extended upto 31.3.2023 for both SSI and non SSI manufactured drugs.

F.No.01/91/180/648/AM-09/EC/E-21052

Santosh Kumar Sarangi, Director General of Foreign Trade, Directorate General of Foreign Trade, Ex-Officio Additional Secretary, Government of India, Ministry of Commerce and Industry, Department of Commerce, New Delhi.

● ● ●

NPPA revises ceiling prices (Wholesale Price Index) of 8 Scheduled formulations of Schedule-I under Drugs (Prices Control) order, 2013

NPPA Order S.O.1500(E), dated 30th March 2022

In exercise of powers, conferred by sub paragraph (3) and (4) of paragraph 11 and paragraph 14 of the Drugs (Prices Control) Order, 2013, read with S.O. 1394(E) dated the 30th May, 2013, S.O. 1192(E) dated 22nd March, 2016 issued by the Government of India in the Ministry of Chemicals and Fertilizers and in supersession of the order of the Government of India in the Ministry of Chemicals and Fertilizers (National Pharmaceutical Pricing Authority) No. S.O. 1332(E) dated 25.03.2021, S.O. 1726(E) dated 30.04.2021 and S.O. 3163(E) dated 06.08.2021, in so far as they relate to formulation packs of Non-Glass with special features (mentioned as Non-PVC in S.O. 1993(E) dated 3rd June 2016) mentioned in the Table A herein below, manufactured by the manufacturers specified in Table B for specified products and pack-sizes, except in respect of things done or omitted to be done before such supersession, the National Pharmaceutical Pricing Authority, hereby revises the price based on Wholesale price index(WPI) of 2021 as specified in column (5) of the Table A herein below as separate ceiling price exclusive of Goods and Services Tax applicable, if any, in respect of the scheduled formulations specified in the corresponding entry in column (2) of the said Table with the dosage form and strength and unit/packaging specified respectively in the corresponding entries in columns (3) and (4) thereof:

Table A: Price Revision as per Annual Wholesale Price Index (WPI) @ 10.76607% increase

Sl. No.	Medicines	Dosage form and Strength	Unit	Ceiling price (w.e.f. 01.04.2022 with WPI @ 10.76607%)
(1)	(2)	(3)	(4)	(5)
1	Glucose	Injection 5%	1000ml Non Glass with special features	84.82
2	Glucose	Injection 5%	500ml Non Glass with special features	73.38
3	Glucose(A) +Chloride (B) Sodium	Injection 5% 0.9% (B) (A) +	1000ml Non Glass with special features	89.13
4	Glucose(A) +Chloride (B) Sodium	Injection 5% 0.9% (B) (A) +	500ml Non Glass with special features	76.27
5	Sodium Chloride	Injection 0.9%	100ml Non Glass with special features	37.51
6	Sodium Chloride	Injection 0.9%	250ml Non Glass with special features	55.39
7	Sodium Chloride	Injection 0.9%	500ml Non Glass with special features	78.43
8	Sodium Chloride	Injection 0.9%	1000ml Non Glass with special features	87.85

TABLE 'B'

Sl. No.	Name of Manufacturer	Product /Brand Name
(1)	(2)	(3)
1	M/s B.Braun Medical (I) Pvt Ltd.	Ecoflac Plus bottle with Eurohead
2	M/s Amanta Healthcare Ltd.	Steriport bottle
3	M/s Aculife Healthcare Pvt Ltd.	Aculife bottle with Eurohead
4	M/s Albert David Limited	Albert David bottle with Eurohead
5	M/s Denis Chem Limited	Aquapulse with Eurohead
6	M/s Claris Life Sciences Limited	Claris bottle with Eurohead
7	M/s Fresenius Kabi India Pvt Limited	Freeflex bags
8	M/s Otsuka Pharmaceutical India Private Ltd. (previously known as Claris Otsuka Private Limited)	Unibag
9	M/s Aishwarya Lifesciences	Lifusion Eurohead bottle
10	M/s Baxter (India) Pvt. Ltd.	Viaflex bags
11	M/s Otsuka Pharmaceutical India Private Ltd. (previously known as Claris Otsuka Private Limited)	Eurohead bottle
12	M/s Fresenius Kabi India Pvt Limited	Eurohead bottle
13	M/s Axa Parenterals Ltd	Steri Drip bottle with Eurohead
14	M/s Shree Krishna Keshav Laboratories Ltd	Easyport bottle with Eurohead
15	M/s Rusoma Laboratories Pvt. Ltd.	Puradrip
16	M/s R.K. Laboratories Pvt. Ltd.	Eurohead bottle
17	M/s Eurolife Healthcare Pvt. Ltd.	Life port
18	M/s Realcade Lifescience Pvt. Ltd.	Euro head bottle
19	M/s Puniska Healthcare Pvt. Ltd [Note (b) below]	Non –PVC bag
20	M/s Abaris Healthcare Pvt. Ltd	Duo Port
21	M/s Higgs Healthcare [Note (c) below]	Aqua Drip
22	M/s Rusoma Laboratories Pvt. Ltd.	Eurohead Bottles with Brand name "Dewdrip"

Note :

(a) The ceiling prices are applicable with effect from 01.04.2022 (ceiling prices are inclusive of Wholesale Price Index (WPI) @10.76607 % for the year 2021 over 2020).

(b) In case of M/s Puniska Healthcare Pvt. Ltd. mentioned in Sl. No. 19 of Table B, only the prices of the formulations specified in Sr. No. 5, 6, 7 & 8 of Table A are applicable.

(c) In case of M/s Higgs Healthcare mentioned in Sl. No. 21 of Table B, only the prices of the formulations specified in Sl. No. 1, 2, 3, 4, 5, 7 & 8 of Table A are applicable.

(d) The manufacturers of scheduled formulations, selling abovesaid products/brandname of scheduled formulations at price higher than the ceiling price (plus goods and services tax as applicable) so fixed and notified by the Government, shall revise the prices of all such formulations downward not exceeding the ceiling price specified in column (5) in the above table plus goods and services tax as applicable, if any.

(e) The manufacturers of above mentioned scheduled formulations having MRP lower than the ceiling price specified in column (5) in the above table (plus goods and services tax as applicable, if any), may revise the existing M.R.P. of their formulations, on the basis of WPI @ 10.76607% for year 2021 over 2020 in accordance with paragraph 16(2) of DPCO, 2013, read with para 13(2) of DPCO, 2013.

(f) The manufacturers may add goods and services tax only if they have paid actually or if it is payable to the Government on the ceiling price mentioned in column (5) of the above said table.

(g) *Any other manufacturer claiming separate ceiling price for Non-Glass with special feature shall apply to NPPA for separate ceiling price approval with details and demonstrate, that such pack has all of the features as (i) self collapsibility and self-sealability (ii) not having air-vent and (iii) there is no chance of contamination during manufacture/ infusion/ admixing levels alongwith documentation and demonstration.*

(h) *For other special features claimed or any other pack size manufactured, the manufacturer shall approach the NPPA for specific price approval for its formulation.*

(i) *The ceiling price for a pack of the scheduled formulation shall be arrived at by the concerned manufacturer in accordance with the ceiling price specified in column (5) of the above table as per provisions contained in paragraph 11 of the Drugs (Prices Control) Order, 2013. The manufacturer shall issue a price list in Form–V from date of Notification as per paragraph 24 of the DPCO, 2013 to NPPA through IPDMS and submit a copy to State Drug Controller and dealers.*

(j) *As per para 24(4) of DPCO 2013, every retailer and dealer shall display price list and the supplementary price list, if any, as furnished by the manufacturer, on a conspicuous part of the premises where he carries on business in a manner so as to be easily accessible to any person wishing to consult the same.*

(k) *Where an existing manufacturer of scheduled formulation with dosage or strength or both as specified in the above table launches a new drug as per paragraph 2 (u) of the DPCO, 2013 such existing manufacturer shall apply for prior price approval of such new drug to the NPPA in Form I as specified under Schedule-II of the DPCO, 2013.*

(l) *The manufacturers of above said scheduled formulations shall furnish quarterly return to the NPPA, in respect of production / import and sale of scheduled formulations in Form-III of Schedule-II of the DPCO, 2013 through IPDMS. Any manufacturer intending to discontinue production of above said scheduled formulation shall furnish information to the NPPA, in respect of discontinuation of production and / or import of scheduled formulation in Form-IV of Schedule-II of the DPCO, 2013 at least six months prior to the intended date of discontinuation.*

(m) *The manufacturers not complying with the ceiling price and notes specified hereinabove shall be liable to deposit the overcharged amount along with interest thereon under the provisions of the Drugs (Prices Control) Order, 2013 read with Essential Commodities Act, 1955.*

(n) *Consequent to the issue of ceiling prices of such formulations as specified in column (2) of the above table in this notification, the price order(s) fixing ceiling or retail price, if any, issued prior to the above said date of notification, stand(s) superseded.*

P.N./228/96/2022/F/F. No. 8(96)/2022/D.P./NPPA-Div.-II

Prasenjit Das, Deputy Director, Ministry of Chemicals and Fertilizers, Department of Pharmaceuticals, National Pharmaceutical Pricing Authority, New Delhi.

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NPPA revises ceiling prices (Wholesale Price Index) of 4 Scheduled formulations of Schedule-I under Drugs (Prices Control) order, 2013

NPPA Order S.O.1501, dated 30th March, 2022

In exercise of powers, conferred by sub paragraph (3) and (4) of paragraph 11 of the Drugs (Prices Control) Order, 2013, read with S.O. 1394(E) dated the 30th May, 2013, S.O. 1192(E) dated 22nd March, 2016 issued by the Government of India in the Ministry of Chemicals and Fertilizers and in supersession of the order of the Government of India in the Ministry of Chemicals and Fertilizers (National Pharmaceutical Pricing Authority) No.S.O.1333(E) dated 25.03.2021, S.O. 1727(E) dated 30.04.2021, and S.O. 3164(E) dated 06.08.2021, in so far as it relates to ringer lactate injection in pack having special features like (i) self collapsibility and self-sealability (ii) not having air-vent and (iii) there is no chance of contamination during manufacture/ infusion/ admixing levels, manufactured by the manufacturers specified in **Table B** for specified products and pack-sizes, except in respect of things done or omitted to be done before such supersession, the National Pharmaceutical Pricing Authority, hereby revises the price based on Wholesale price index (WPI) of 2021 as specified in column (5) of the **Table A** herein below as separate ceiling price exclusive of Goods and Services Tax applicable, if any, in respect of the scheduled formulations specified in the corresponding entry in column (2) of the said Table with the dosage form and strength and unit/packaging specified respectively in the corresponding entries in columns (3) and (4) thereof:

Table A : Price Revision as per Annual Wholesale Price Index (WPI) @ 10.76607% increase

Sl. No.	Medicines	Dosage form and Strength	Unit	Ceiling price (w.e.f. 01.04.2022 with WPI @ 10.76607%)
(1)	(2)	(3)	(4)	(5)
1	Ringer lactate	Injection 100 ml	Each 100100 ml pack having special features	26.67
2	Ringer lactate	Injection 250 ml	Each 250 ml pack having special features	45.48
3	Ringer lactate	Injection 500 ml	Each 500 ml pack having special features	57.94
4	Ringer lactate	Injection 1000 ml	Each 1000 ml pack having special features	101.85

TABLE B

Sl. No.	Name of Manufacturer
(1)	(2)
1	M/s Albert David Ltd.
2	M/s Aculife Healthcare Pvt Ltd.
(1)	(2)
3	M/s B. Braun Medical (India) Pvt. Ltd.
4	M/s Fresenius Kabi India Pvt Ltd.
5	M/s Ostuka Pharmaceuticals India Pvt. Ltd.
6	M/s Denis Chem lab Ltd.
7	M/s Amanta Healthcare Ltd.
8	M/s Shree Krishna Keshav Laboratories Ltd.
9	M/s Axa Parenterals Ltd.
10	M/s Rusoma Laboratories Pvt. Ltd.
11	M/s R. K Laboratories Pvt. Ltd.
12	M/s Realcade Lifescience Pvt. Ltd.
13	M/s Abaris Healthcare Pvt. Ltd. (Note (b) below)
14	M/s Higgs Healthcare (Note (c) below)
15	M/s Rusoma Laboratories Pvt. Ltd (Eurohead Bottles with Brand name “Dewdrip”) [Note (b)]below]

Note:

(a) The ceiling prices are applicable with effect from 01.04.2021 (ceiling prices are inclusive of Wholesale Price Index (WPI) @10.76607% for the year 2021 over 2020).

(b) In case of M/s Abaris Healthcare Pvt. Ltd (Sl. No. 13 of Table B) & M/s Rusoma Laboratories Pvt. Ltd. (Sl. No. 15 of Table B), only the prices of the formulations specified in Sl. No. 2, 3 & 4 of Table A are applicable.

(c) In case of M/s Higgs Healthcare mentioned in Sl. No. 14 of Table B, only the prices of the formulations specified in Sl. No. 3 & 4 of Table A are applicable.

(d) The manufacturers of scheduled formulations, selling abovesaid products/brandname of scheduled formulations at price higher than the ceiling price (plus goods and services tax as applicable) so fixed and notified by the Government, shall revise the prices of all such formulations downward not exceeding the ceiling price specified in column (5) in the above table plus goods and services tax as applicable, if any.

(e) The manufacturers of above mentioned scheduled formulations having MRP lower than the ceiling price specified in column (5) in the above table (plus goods and services tax as applicable, if any), may revise the existing M.R.P. of their formulations,

on the basis of WPI @ 10.76607% for year 2021 over the year 2020 in accordance with paragraph 16(2) of DPCO, 2013, read with para 13(2) of DPCO, 2013.

(f) The manufacturers may add goods and services tax only if they have paid actually or if it is payable to the Government on the ceiling price mentioned in column (5) of the above said table.

(g) Any other manufacturer claiming separate ceiling price for ringer lactate injection in pack having special features like (i) self collapsibility and self-sealability (ii) not having air-vent and (iii) there is no chance of contamination during manufacture/ infusion/ admixing levels shall apply to NPPA for separate ceiling price approval.

(h) For other special features claimed or any other pack size manufactured, the manufacturer shall approach the NPPA for specific price approval for its formulation.

(i) The ceiling price for a pack of the scheduled formulation shall be arrived at by the concerned manufacturer in accordance with the ceiling price specified in column (5) of the above table as per provisions contained in paragraph 11 of the Drugs (Prices Control) Order, 2013. The manufacturer shall issue a price list in Form–V from date of Notification as per paragraph 24 of the DPCO, 2013 to NPPA through IPDMS and submit a copy to State Drug Controller and dealers.

(j) As per para 24(4) of DPCO 2013, every retailer and dealer shall display price list and the supplementary price list, if any, as furnished by the manufacturer, on a conspicuous part of the premises where he carries on business in a manner so as to be easily accessible to any person wishing to consult the same.

(k) Where an existing manufacturer of scheduled formulation with dosage or strength or both as specified in the above table launches a new drug as per paragraph 2 (u) of the DPCO, 2013 such existing manufacturer shall apply for prior price approval of such new drug to the NPPA in Form I as specified under Schedule-II of the DPCO, 2013.

(l) The manufacturers of above said scheduled formulations shall furnish quarterly return to the NPPA, in respect of production / import and sale of scheduled formulations in Form-III of Schedule-II of the DPCO, 2013 through IPDMS. Any manufacturer intending to discontinue production of above said scheduled formulation shall furnish information to the NPPA, in respect of discontinuation of production and / or import of scheduled formulation in Form-IV of Schedule-II of the DPCO, 2013 at least six months prior to the intended date of discontinuation.

(m) The manufacturers not complying with the ceiling price and notes specified hereinabove shall be liable to deposit the overcharged amount along with interest thereon under the provisions of the Drugs (Prices Control) Order, 2013 read with Essential Commodities Act, 1955.

(n) Consequent to the issue of ceiling prices of such formulations as specified in column (2) of the above table in this notification, the price order(s) fixing ceiling or retail price, if any, issued prior to the above said date of notification, stand(s) superseded.

P.N./228/96/2022/F /F.No.8(96)/2022/D.P./NPPA-Div.-II

Prasenjit Das, Deputy Director, Ministry of Chemicals and Fertilizers, Department of Pharmaceuticals, National Pharmaceutical Pricing Authority, New Delhi.

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NPPA revises ceiling prices (Wholesale Price Index) of 2 Scheduled formulations of Schedule-I under Drugs (Prices Control) order, 2013

NPPA Order S.O.1502, dated 30th March, 2022

In continuation of the notifications issued by National Pharmaceutical Pricing Authority, Department of Pharmaceuticals, Ministry of Chemical and Fertilizers vide S.O. 639(E) dated 12.02.2018, S.O. 1464(E) dated 02.04.2018, S.O. 1488(E) dated 29.03.2019, S.O. 1217(E) dated 25.03.2020 and S.O. 1334(E) dated 25.03.2021 regarding the fixation of ceiling price of the Coronary Stents as specified in column no. (2) mentioned in the table below; after considering the Wholesale Price Index (WPI) @10.76607% for the year 2021 over 2020, it has been decided to revise the ceiling prices of Coronary Stents as mentioned in column no. (4) in the table below, exclusive of Goods and Services Tax as applicable, and unit specified in column (3) with effect from 01.04.2022, as under:

TABLE

Sl. No.	Coronary Stents (Sl. No. 31 in Schedule-I of the DPCO, 2013)	Unit (in Number)	Ceiling Price (in Rs.)
(1)	(2)	(3)	(4)
1	Bare Metal Stents	1	9373.03
2	Drug Eluting Stents (DES) including metallic DES and Bioresorbable Vascular Scaffold (BVS)/ Biodegradable Stents	1	34128.13

Notes:

(a) All the existing manufacturers/importers of Coronary Stents having MRP lower than the ceiling price specified in column (4) in the above table (plus Goods and Services Taxes as applicable, if any), may revise the existing MRP of Coronary Stent, on the basis of WPI @ 10.76607% for the year 2021 over 2020 in accordance with Paragraph 16(2) of DPCO, 2013, read with Para 13(2) of DPCO, 2013.

(b) The manufacturers/importers of Coronary Stents may add Goods and Services Taxes only if they have paid actually or if it is payable to the Government on the ceiling price mentioned in column of the aforesaid table.

(c) As per Para 24(4) of DPCO 2013, every retailer and dealer shall display price list and the supplementary price list, if any, as furnished by the manufacturer/importers, on a conspicuous part of the premises where he carries on business in a manner so as to be easily accessible to any person wishing to consult the same.

(d) The manufacturers not complying with the ceiling price and notes specified hereinabove shall be liable to deposit the overcharged amount along with interest thereon under the provisions of the Drugs (Prices Control) Order, 2013 read with Essential Commodities Act, 1955.

P.N./228/96/2022/F/F.No.8(96)/2022/D.P./NPPA-Div.-II

Prasenjit Das, Deputy Director, Ministry of Chemicals and Fertilizers, Department of Pharmaceuticals, National Pharmaceutical Pricing Authority, New Delhi.

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NPPA revises ceiling prices (Wholesale Price Index) of 9 Scheduled formulations of Schedule-I under Drugs (Prices Control) order, 2013

NPPA Order S.O.1503, dated 30th March, 2022

In exercise of the powers, conferred by paragraph 4, 6, 10, 11, 14, 16, 17 and 18 of the Drugs (Prices Control) Order, 2013, read with S.O. No.1394(E) dated the 30th May, 2013 issued by the Government of India in the Ministry of Chemicals and Fertilizers, and in supersession of the Order(s) of the Government of India in the Ministry of Chemicals and Fertilizers (National Pharmaceutical Pricing Authority) S.O. Number and date specified in column No. 6(a) & 6(b) mentioned in the table below, the National Pharmaceutical Pricing Authority, hereby fixes the prices as specified in column (5) of the table herein below as ceiling prices exclusive of Goods and Services Tax applicable, if any, in respect of the Scheduled formulations specified in the corresponding entry in column (2) of the said Table with the dosage form & strength and unit specified respectively in the corresponding entries in columns (3) and (4) thereof:

TABLE: Price Revision as per Annual Wholesale Price Index (WPI) @ 10.76607% increase

Sl. No.	Medicines	Dosage form and Strength	Unit	Ceiling price (wef 01.04.2022 with WPI @ 10.76607%)	Existing S.O. No. & Date	
(1)	(2)	(3)	(4)	(5)	6(a)	6(b)
1	Acetyl Salicylic Acid	Tablet 300mg	1 Tablet	0.25	1331 (E)	25.03.2021
2	Calcium carbonate	Tablet 250 mg	1 Tablet	2.17	1331 (E)	25.03.2021

3	Condoms		1 Condom	10.14	1331 (E)	25.03.2021
4	Dapsone	Tablet 50 mg	1 Tablet	0.26	1331 (E)	25.03.2021
5	Etoposide	Capsules 100 mg	1 Capsule	67.22	1331 (E)	25.03.2021
6	Framycetin Sulphate	Cream 0.50%	1 GM	0.97	1331 (E)	25.03.2021
7	Isoniazid	Syrup 100 mg/5ml	1 ML	0.29	1331 (E)	25.03.2021
8	Medroxy Progesterone Acetate	Tablet 5mg	1 Tablet	3.32	1331 (E)	25.03.2021
9	Rifampicin	Tablet 450mg	1 Tablet	4.92	1331 (E)	25.03.2021

Notes:

(a) The ceiling prices are applicable with effect from 01.04.2022 (ceiling prices are inclusive of Wholesale Price Index (WPI) @10.76607% for the year 2021 over 2020).

(b) All manufacturers of scheduled formulations, selling the branded or generic or both the versions of scheduled formulations at a price higher than the ceiling price (plus goods and services taxes as applicable) so fixed and notified by the Government, shall revise the prices of all such formulations downward not exceeding the ceiling price specified in column (5) in the above table plus goods and services taxes as applicable, if any.

(c) All the existing manufacturers of above mentioned scheduled formulations having MRP lower than the ceiling price specified in column (5) in the above table (plus goods and services taxes as applicable, if any), may revise the existing M.R.P. of their formulations, on the basis of WPI @ 10.76607% for year 2021 over 2020 in accordance with paragraph 16(2) of DPCO, 2013, read with para 13(2) of DPCO, 2013.

(d) The manufacturers may add goods and services taxes only if they have paid actually or if it is payable to the Government on the ceiling price mentioned in column (5) of the above said table.

(e) The ceiling price for a pack of the scheduled formulation shall be arrived at by the concerned manufacturer in accordance with the ceiling price specified in column (5) of the above table as per provisions contained in paragraph 11 of the Drugs (Prices Control) Order, 2013. The manufacturer shall issue a price list in Form–V from date of Notification as per paragraph 24 of the DPCO, 2013 to NPPA through IPDMS and submit a copy to State Drug Controller and dealers.

(f) As per para 24(4) of DPCO 2013, every retailer and dealer shall display price list and the supplementary price list, if any, as furnished by the manufacturer, on a conspicuous part of the premises where he carries on business in a manner so as to be easily accessible to any person wishing to consult the same.

(g) Where an existing manufacturer of scheduled formulation with dosage or strength or both as specified in the above table launches a new drug as per paragraph 2 (u) of the DPCO, 2013 such existing manufacturer shall apply for prior price approval of such new drug to the NPPA in Form I as specified under Schedule-II of the DPCO, 2013.

(h) The manufacturers of above said scheduled formulations shall furnish quarterly return to the NPPA, in respect of production / import and sale of scheduled formulations in Form-III of Schedule-II of the DPCO, 2013 through IPDMS. Any manufacturer intending to discontinue production of above said scheduled formulation shall furnish information to the NPPA, in respect of discontinuation of production and / or import of scheduled formulation in Form-IV of Schedule-II of the DPCO, 2013 at least six months prior to the intended date of discontinuation.

(i) The manufacturers not complying with the ceiling price and notes specified hereinabove shall be liable to deposit the overcharged amount along with interest thereon under the provisions of the Drugs (Prices Control) Order, 2013 read with Essential Commodities Act, 1955.

(j) Consequent to the issue of ceiling prices of such formulations as specified in column (2) of the above table in this notification, the price order(s) fixing ceiling or retail price, if any, issued prior to the above said date of notification, stand(s) superseded.

P.N./228/96/2022/F/F. No. 8(96)/2022/D.P./NPPA-Div.-II

Prasenjit Das, Deputy Director, Ministry of Chemicals and Fertilizers, Department of Pharmaceuticals, National Pharmaceutical Pricing Authority, New Delhi.

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NPPA revises ceiling prices (Wholesale Price Index) of 1 Scheduled formulations of Schedule-I under Drugs (Prices Control) order, 2013

NPPA Order S.O.1504, dated 30th March, 2022

In exercise of powers, conferred by sub paragraph (3) and (4) of paragraph 11 and paragraph 14 of the Drugs (Prices Control) Order, 2013, read with S.O. 1394(E) dated the 30th May, 2013, S.O. 1192(E) dated 22nd March, 2016 issued by the Government of India in the Ministry of Chemicals and Fertilizers and in supersession of the order of the Government of India in the Ministry of Chemicals and Fertilizers (National Pharmaceutical Pricing Authority) No. S.O. 3937(E) dated 23.09.2021 and S.O. 5426(E) dated 28.12.2021, in so far as they relate to Metronidazole Injection IP (0.5% w/v)/ 500mg/100ml in 100ml pack for packages in non-glass container in plastic bottle with euro head having special features like (i) self-collapsibility and self-sealeability (ii) not having air-vent and (iii) there is no chance of contamination during manufacture/ infusion/ admixing levels mentioned in the Table A herein below, manufactured by the manufacturers specified in Table B for specified products and pack-sizes, except in respect of things done or omitted to be done before such supersession, the National Pharmaceutical Pricing Authority, hereby revises the price based on Wholesale price index(WPI) of 2021 as specified in column (5) of the Table A herein below as separate ceiling price exclusive of goods and services tax applicable, if any, in respect of the scheduled formulations specified in the corresponding entry in column (2) of the said Table with the dosage form and strength and unit/packaging specified respectively in the corresponding entries in columns (3) and (4) thereof:

Table A: Price Revision as per Annual Wholesale Price Index (WPI) @ 10.76607% increase.

Sl. No.	Medicines	Dosage form and Strength	Unit	Ceiling price (wef 01.04.2022 with WPI @ 10.76607%)
(1)	(2)	(3)	(4)	(5)
1	Metronidazole	Injection (0.5%w/v)/500mg/100ml in 100ml pack for packages in nonglass container in plastic bottle with euro head having special features	Per ml	0.25

TABLE 'B'

Sl. No.	Name of Manufacturer
(1)	(2)
1	M/s Otsuka Pharmaceutical India Private Ltd.
2	M/s Denis Chem Lab Ltd.
3	M/s Rusoma Laboratories Pvt. Ltd.

Note :

(a) The ceiling prices are applicable with effect from 01.04.2022 (ceiling prices are inclusive of Wholesale Price Index (WPI) @10.76607% for the year 2021 over 2020).

(b) The manufacturers of scheduled formulations, selling abovesaid products/brandname of scheduled formulations at price higher than the ceiling price (plus goods and services tax as applicable) so fixed and notified by the Government, shall revise the prices of all such formulations downward not exceeding the ceiling price specified in column (5) in the above table plus goods and services tax as applicable, if any.

(c) The manufacturers of above mentioned scheduled formulations having MRP lower than the ceiling price specified in column (5) in the above table (plus goods and services tax as applicable, if any), may revise the existing M.R.P. of their formulations, on the basis of WPI @ 10.76607% for year 2021 over 2020 in accordance with paragraph 16(2) of DPCO, 2013, read with para 13(2) of DPCO, 2013.

(d) The manufacturers may add Goods and Services Tax only if they have paid actually or if it is payable to the Government on the ceiling price mentioned in column (5) of the above said table.

(e) Any other manufacturer claiming separate ceiling price for Metronidazole Injection (0.5%w/v) / 500mg/100ml in 100ml pack for packages in non-glass container in plastic bottle with euro head having special features like (i) self collapsibility and self-sealability (ii) not having air-vent and (iii) there is no chance of contamination during manufacture/ infusion/ admixing levels shall apply to NPPA for separate ceiling price approval.

(f) For other special features claimed or any other pack size manufactured, the manufacturer shall approach the NPPA for specific price approval for its formulation

(g) The ceiling price for a pack of the scheduled formulation shall be arrived at by the concerned manufacturer in accordance with the ceiling price specified in column (5) of the above table as per provisions contained in paragraph 11 of the Drugs (Prices Control) Order, 2013. The manufacturer shall issue a price list in Form–V from date of Notification as per paragraph 24 of the DPCO, 2013 to NPPA through IPDMS and submit a copy to State Drug Controller and dealers.

(h) As per para 24(4) of DPCO 2013, every retailer and dealer shall display price list and the supplementary price list, if any, as furnished by the manufacturer, on a conspicuous part of the premises where he carries on business in a manner so as to be easily accessible to any person wishing to consult the same.

(i) Where an existing manufacturer of scheduled formulation with dosage or strength or both as specified in the above table launches a new drug as per paragraph 2 (u) of the DPCO, 2013 such existing manufacturer shall apply for prior price approval of such new drug to the NPPA in Form I as specified under Schedule-II of the DPCO, 2013.

(j) The manufacturers of above said scheduled formulations shall furnish quarterly return to the NPPA, in respect of production / import and sale of scheduled formulations in Form-III of Schedule-II of the DPCO, 2013 through IPDMS. Any manufacturer intending to discontinue production of above said scheduled formulation shall furnish information to the NPPA, in respect of discontinuation of production and / or import of scheduled formulation in Form-IV of Schedule-II of the DPCO, 2013 at least six months prior to the intended date of discontinuation.

(k) The manufacturers not complying with the ceiling price and notes specified hereinabove shall be liable to deposit the overcharged amount along with interest thereon under the provisions of the Drugs (Prices Control) Order, 2013 read with Essential Commodities Act, 1955.

(l) Consequent to the issue of ceiling prices of such formulations as specified in column (2) of the above table in this notification, the price order(s) fixing ceiling or retail price, if any, issued prior to the above said date of notification, stand(s) superseded.

P.N./228/96/2022/F/F. No. 8(96)/2022/D.P./NPPA-Div.-II

Prasenjit Das, Deputy Director, Ministry of Chemicals and Fertilizers, Department of Pharmaceuticals, National Pharmaceutical Pricing Authority, New Delhi.

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NPPA revises ceiling prices (Wholesale Price Index) of 1 Scheduled formulations of Schedule-I under Drugs (Prices Control) order, 2013

NPPA Order S.O.1505, dated 30th March, 2022

In exercise of powers, conferred by sub paragraph (3) and (4) of paragraph 11 and paragraph 14 of the Drugs (Prices Control) Order, 2013, read with S.O. 1394(E) dated the 30th May, 2013, S.O. 1192(E) dated 22nd March, 2016 issued by the Government of India in the Ministry of Chemicals and Fertilizers and in supersession of the order of the Government of India in the Ministry of Chemicals and Fertilizers (National Pharmaceutical Pricing Authority) No. S.O. 3938(E) dated 23.09.2021 and S.O.5427(E) dated 28.12.2021, in so far as they relate to Mannitol Injection 20% in 100 ml pack for packages in non-glass container in plastic bottle with euro head having special features like (i) self-collapsibility and selfsealeability (ii) not having air- vent and (iii) there is no chance of contamination during manufacture/infusion/ admixing levels mentioned in the Table A herein below, manufactured by the manufacturers specified in Table B for specified products and pack-sizes, except in respect of things done or omitted to be done before such supersession, the National Pharmaceutical Pricing Authority, hereby revises the price based on Wholesale price index(WPI) of 2021

as specified in column (5) of the Table A herein below as separate ceiling price exclusive of goods and services tax applicable, if any, in respect of the scheduled formulations specified in the corresponding entry in column (2) of the said Table with the dosage form and strength and unit/packaging specified respectively in the corresponding entries in columns (3) and (4) thereof:

TABLE A: Price Revision as per Annual Wholesale Price Index (WPI) @ 10.76607% increase.

Sl. No.	Medicines	Dosage form and Strength	Unit	Ceiling price (wef 01.04.2022 with WPI @ 10.76607%)
(1)	(2)	(3)	(4)	(5)
1	Mannitol	Injection 20% in 100 ml pack for packages in non-glass container in plastic bottle with euro head having special features	Per ml	0.382

TABLE 'B'

Sl. No.	Name of Manufacture
(1)	(2)
1	M/s Otsuka Pharmaceutical India Private Ltd.
2	M/s Denis Chem Lab Ltd.
3	M/s Rusoma Laboratories Pvt. Ltd.

Note :

(a) The ceiling prices are applicable with effect from 01.04.2022 (ceiling prices are inclusive of Wholesale Price Index (WPI) @10.76607% for the year 2021 over 2020).

(b) The manufacturers of scheduled formulations, selling abovesaid products/brandname of scheduled formulations at price higher than the ceiling price (plus goods and services tax as applicable) so fixed and notified by the Government, shall revise the prices of all such formulations downward not exceeding the ceiling price specified in column (5) in the above table plus goods and services tax as applicable, if any.

(c) The manufacturers of above mentioned scheduled formulations having MRP lower than the ceiling price specified in column (5) in the above table (plus goods and services tax as applicable, if any), may revise the existing M.R.P. of their formulations, on the basis of WPI @ 10.76607% for year 2021 over 2020 in accordance with paragraph 16(2) of DPCO, 2013, read with para 13(2) of DPCO, 2013.

(d) The manufacturers may add goods and services tax only if they have paid actually or if it is payable to the Government on the ceiling price mentioned in column (5) of the above said table.

(e) Any other manufacturer claiming separate ceiling price for Mannitol Injection 20% in 100 ml pack for packages in non-glass container in plastic bottle with euro head having special features like (i) self collapsibility and self-sealability (ii) not having air-vent and (iii) there is no chance of contamination during manufacture/ infusion/ admixing levels shall apply to NPPA for separate ceiling price approval.

(f) For other special features claimed or any other pack size manufactured, the manufacturer shall approach the NPPA for specific price approval for its formulation.

(g) The ceiling price for a pack of the scheduled formulation shall be arrived at by the concerned manufacturer in accordance with the ceiling price specified in column (5) of the above table as per provisions contained in paragraph 11 of the Drugs (Prices Control) Order, 2013. The manufacturer shall issue a price list in Form–V from date of Notification as per paragraph 24 of the DPCO, 2013 to NPPA through IPDMS and submit a copy to State Drug Controller and dealers.

(h) As per para 24(4) of DPCO 2013, every retailer and dealer shall display price list and the supplementary price list, if any, as furnished by the manufacturer, on a conspicuous part of the premises where he carries on business in a manner so as to be easily accessible to any person wishing to consult the same.

(i) Where an existing manufacturer of scheduled formulation with dosage or strength or both as specified in the above table launches a new drug as per paragraph 2 (u) of the DPCO, 2013 such existing manufacturer shall apply for prior price approval of such new drug to the NPPA in Form I as specified under Schedule-II of the DPCO, 2013.

(j) The manufacturers of above said scheduled formulations shall furnish quarterly return to the NPPA, in respect of production / import and sale of scheduled formulations in Form-III of Schedule-II of the DPCO, 2013 through IPDMS. Any manufacturer intending to discontinue production of above said scheduled formulation shall furnish information to the NPPA, in respect of discontinuation of production and / or import of scheduled formulation in Form-IV of Schedule-II of the DPCO, 2013 at least six months prior to the intended date of discontinuation.

(k) The manufacturers not complying with the ceiling price and notes specified hereinabove shall be liable to deposit the overcharged amount along with interest thereon under the provisions of the Drugs (Prices Control) Order, 2013 read with Essential Commodities Act, 1955.

(l) Consequent to the issue of ceiling prices of such formulations as specified in column (2) of the above table in this notification, the price order(s) fixing ceiling or retail price, if any, issued prior to the above said date of notification, stand(s) superseded.

P.N./228/96/2022/F/F. No. 8(96)/2022/D.P./NPPA-Div.-II

Prasenjit Das, Deputy Director, Ministry of Chemicals and Fertilizers, Department of Pharmaceuticals, National Pharmaceutical Pricing Authority, New Delhi.

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NPPA revises ceiling prices (Wholesale Price Index) of 1 Scheduled formulations of Schedule-I under Drugs (Prices Control) order, 2013

NPPA Order S.O.1506, dated 30th March, 2022

In exercise of powers, conferred by sub paragraph (3) and (4) of paragraph 11 and paragraph 14 of the Drugs (Prices Control) Order, 2013, read with S.O. 1394(E) dated the 30th May, 2013, S.O. 1192(E) dated 22nd March, 2016 issued by the Government of India in the Ministry of Chemicals and Fertilizers and in supersession of the order of the Government of India in the Ministry of Chemicals and Fertilizers (National Pharmaceutical Pricing Authority) No. S.O. 3939(E) dated 23.09.2021 and S.O.5428(E) dated 28.12.2021, in so far as they relate to Dextrose (Glucose) Injection (25% w/v) in 100 ml pack for packages in non-glass container in plastic bottle with euro head having special features like (i) selfcollapsibility and self-sealeability (ii) not having air-vent and (iii) there is no chance of contamination during manufacture/ infusion/ admixing levels mentioned in the Table A herein below, manufactured by the manufacturers specified in Table B for specified products and pack-sizes, except in respect of things done or omitted to be done before such supersession, the National Pharmaceutical Pricing Authority, hereby revises the price based on Wholesale price index(WPI) of 2021 as specified in column (5) of the Table A herein below as separate ceiling price exclusive of goods and services tax applicable, if any, in respect of the scheduled formulations specified in the corresponding entry in column (2) of the said Table with the dosage form and strength and unit/packaging specified respectively in the corresponding entries in columns (3) and (4) thereof:

Table A: Price Revision As Per Annual Wholesale Price Index (Wpi) @ 10.76607% Increase.

Sl. No.	Medicines	Dosage form and Strength	Unit	Ceiling price (wef 01.04.2022 with WPI @ 10.76607%)
(1)	(2)	(3)	(4)	(5)
1	Dextrose (Glucose)	Injection (25% w/v) in 100 ml pack for packages in non-glass container in plastic bottle with euro head having special features	Per ml	0.2165

Table 'B'

Sl. No.	Name of Manufacture
(1)	(2)
1	M/s. Otsuka Pharmaceutical India Private Ltd.
2	M/s. Denis Chem Lab Ltd.
3	M/s. Rusoma Laboratories Pvt. Ltd.

Note :

(*a*) *The ceiling prices are applicable with effect from 01.04.2022 (ceiling prices are inclusive of Wholesale Price Index (WPI) @10.76607% for the year 2021 over 2020).*

(b) The manufacturers of scheduled formulations, selling abovesaid products/brand name of scheduled formulations at price higher than the ceiling price (plus goods and services tax as applicable) so fixed and notified by the Government, shall revise the prices of all such formulations downward not exceeding the ceiling price specified in column (5) in the above table plus goods and services tax as applicable, if any.

(c) The manufacturers of above mentioned scheduled formulations having MRP lower than the ceiling price specified in column (5) in the above table (plus goods and services tax as applicable, if any), may revise the existing M.R.P. of their formulations, on the basis of WPI @ 10.76607% for year 2021 over 2020 in accordance with paragraph 16(2) of DPCO, 2013, read with para 13(2) of DPCO, 2013.

(d) The manufacturers may add goods and services tax only if they have paid actually or if it is payable to the Government on the ceiling price mentioned in column (5) of the above said table.

(e) Any other manufacturer claiming separate ceiling price for Dextrose (Glucose) Injection (25% w/v) in 100 ml pack for packages in non-glass container in plastic bottle with euro head having special features like (i) self collapsibility and self-sealability (ii) not having air-vent and (iii) there is no chance of contamination during manufacture/ infusion/ admixing levels shall apply to NPPA for separate ceiling price approval.

(f) For other special features claimed or any other pack size manufactured, the manufacturer shall approach the NPPA for specific price approval for its formulation

(g) The ceiling price for a pack of the scheduled formulation shall be arrived at by the concerned manufacturer in accordance with the ceiling price specified in column (5) of the above table as per provisions contained in paragraph 11 of the Drugs (Prices Control) Order, 2013. The manufacturer shall issue a price list in Form–V from date of Notification as per paragraph 24 of the DPCO, 2013 to NPPA through IPDMS and submit a copy to State Drug Controller and dealers.

(h) As per para 24(4) of DPCO 2013, every retailer and dealer shall display price list and the supplementary price list, if any, as furnished by the manufacturer, on a conspicuous part of the premises where he carries on business in a manner so as to be easily accessible to any person wishing to consult the same.

(i) Where an existing manufacturer of scheduled formulation with dosage or strength or both as specified in the above table launches a new drug as per paragraph 2 (u) of the DPCO, 2013 such existing manufacturer shall apply for prior price approval of such new drug to the NPPA in Form I as specified under Schedule-II of the DPCO, 2013.

(j) The manufacturers of above said scheduled formulations shall furnish quarterly return to the NPPA, in respect of production / import and sale of scheduled formulations in Form-III of Schedule-II of the DPCO, 2013 through IPDMS. Any manufacturer intending to discontinue production of above said scheduled formulation shall furnish information to the NPPA, in respect of discontinuation of production and / or import of scheduled formulation in Form-IV of Schedule-II of the DPCO, 2013 at least six months prior to the intended date of discontinuation.

(k) The manufacturers not complying with the ceiling price and notes specified hereinabove shall be liable to deposit the overcharged amount along with interest thereon under the provisions of the Drugs (Prices Control) Order, 2013 read with Essential Commodities Act, 1955.

(l) Consequent to the issue of ceiling prices of such formulations as specified in column (2) of the above table in this notification, the price order(s) fixing ceiling or retail price, if any, issued prior to the above said date of notification, stand(s) superseded.

P.N./228/96/2022/F/F. No. 8(96)/2022/D.P./NPPA-Div.-II

Prasenjit Das, Deputy Director, Ministry of Chemicals and Fertilizers, Department of Pharmaceuticals, National Pharmaceutical Pricing Authority, New Delhi.

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The ceiling prices of Heparin Injection 1000IU/ml and Heparin Injection 5000IU/ml fixed vide notification S.O.2151(E) dated 30.06.2020 are extended - reg.

Order S.O.1507(E) dated 30th March, 2022

1. The ceiling prices of Heparin Injection 1000IU/ ml and Heparin Injection 5000IU/ ml fixed under Para 19 of the DPCO, 2013 vide notification S.O.2151(E) dated 30.06.2020 valid up to 31.12.2020 which was extended up to 31.03.2021 vide S.O. 4333(E) dated 03.12.2020, then up to 30.09.2021 vide S.O. 1236(E) dated 17.03.2021 and again extended 'up to 31.03.2022 or until further order, whichever is earlier' vide S.O.3935(E) dated 23.09.2021, issued by National Pharmaceutical Pricing Authority, Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Government of India are further extended up to 30.09.2022 or until further order, whichever is earlier.

2. All the notes and other contents mentioned in the original order S.O. 2151(E) dated 30.06.2020 read with extension orders S.O. 4333(E) dated 03.12.2020, S.O. 1236(E) dated 17.03.2021 and S.O. 3935(E) dated 23.09.2021 shall remain the same and are applicable except that in Para 6, Notes (a) and Note (k) for the phrase "31st March 2022 or until further order, whichever is earlier", it is to be read as "30th September 2022 or until further order, whichever is earlier".

P.N./228/96/2022/F/F. No. 8(96)/2022/DP/NPPA-Div.-II

Prasenjit Das, Deputy Director, National Pharmaceutical Pricing Authority, Ministry of Chemicals and Fertilizers, Department of Pharmaceuticals, New Delhi.

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The prices of "Liquid Medical Oxygen (LMO)" and "Oxygen Inhalation (Medicinal gas) in cylinder" fixed under para 19 of the DPCO, 2013 vide Order No.Z-33014/45/2020-RCH/ Pt.File-3 dated 23.09.2020 & vide notification S.O.3322(E) dated 25.09.2020, are extended - reg.

Order S.O.1508(E) dated 30th March, 2022

1. The prices of 'Liquid Medical Oxygen (LMO)' and 'Oxygen Inhalation (Medicinal gas) in cylinder' fixed under Para 19 of the DPCO, 2013 and powers conferred under section 10(2)(l) of Disaster Management Act, 2005 delegated by Ministry of Health and Family Welfare vide Order No.Z-33014/45/2020-RCH/Pt.File-3 dated 23.09.2020, vide notification S.O.3322(E) dated 25.09.2020, issued by National Pharmaceutical Pricing Authority, Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Government of India, applicable up to '31.03.2021 and 'extended up to 30.09.2021 vide S.O. 1335(E) dated 25.03.2021, then extended up to 31.12.2021 vide S.O.3936(E) dated 23.09.2021 and again extended upto 31.03.2022 or until further order whichever is earlier vide S.O. 5424(E) dated 28.12.2021 are further extended upto 30.06.2022 or until further order, whichever is earlier.

2. All the notes and other contents mentioned in the original order S.O.3322(E) dated 25.09.2020 read with S.O.1335(E) dated 25.03.2021, S.O.3936(E) dated 23.09.2021 and S.O. 5424(E) dated 28.12.2021 shall remain the same and are applicable except that

in Note (a) for the phrase "31st March 2022 or until further orders, whichever is earlier" it is to be read as "30th June 2022 or until further orders, whichever is earlier."

P.N./228/96/2022/F/F. No. 8(96)/2022/DP/NPPA-Div.-II

Prasenjit Das, Deputy Director, National Pharmaceutical Pricing Authority, Ministry of Chemicals and Fertilizers, Department of Pharmaceuticals, New Delhi.

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Ethylene Vinyl Acetate Copolymers (Quality Control) Order, 2022 published

Chemicals & Fertilizers Order S.O.1643(E) dated 05/04/2022

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), and in supersession of the Ethylene Vinyl Acetate Copolymers (Quality Control) Order, 2021, the Central Government, after consulting the Bureau of Indian Standards, is of the opinion that it is necessary or expedient so to do in the public interest, hereby makes the following Order, namely:-

1. Short title, commencement and application:

(1) This order may be called the **Ethylene Vinyl Acetate Copolymers (Quality Control) Order, 2022.**

(2) It shall come into force on the **3rd October, 2022.**

(3) It shall apply to goods or article specified in column (1) of the Table below and shall not apply to such goods or article meant for export.

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

3. Certification and enforcement authority: In respect of the goods or article specified in column (1) of the said Table, the Bureau of Indian Standards shall be the certifying and enforcing authority.

4. Penalty for contravention. - Any person

Goods or articles	Indian Standard	Title of Indian Standard
(1)	(2)	(3)
Ethylene Vinyl Acetate (EVA) Copolymers	IS 13601 : 1993	Ethylene Vinyl Acetate (EVA) copolymers for its safe use in contact with foodstuffs, pharmaceuticals and drinking water - Specification

F.No.PC-II 46016/ 6/2020-Tech.CPC Pt-1

Kashi Nath Jha, Joint Secretary, Department of Chemicals and Petrochemicals, Ministry of Chemicals and Fertilizers, New Delhi.

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Maleic Anhydride (Quality Control) Order, 2022 published

Chemicals & Fertilizers Order S.O.1644(E), dated 05th 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), and in supersession of the Maleic Anhydride (Quality Control)

Order, 2020, the Central Government, after consulting the Bureau of Indian Standards, is of the opinion that it is necessary or expedient so to do in the public interest, hereby makes the following Order, namely:-

1. Short title, commencement and application:

(1) This order may be called the Maleic **Anhydride (Quality Control) Order, 2022.**

(2) It shall come into force on the **24th October, 2022.**

(3) It shall apply to goods or article specified in column (1) of the Table below and shall not apply to such goods or article meant for export.

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

3. Certification and enforcement authority – In respect of the goods or article specified in column (1) of the said Table, the Bureau of Indian Standards shall be the certifying and enforcing authority.

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)
Maleic Anhydride, Technical	IS 5149:2020	Specification for Maleic Anhydride, Technical

F.No.PC-II 46016/ 6/2020-Tech.CPC Pt-1

Kashi Nath Jha, Joint Secretary, Ministry of Chemicals and Fertilizers, Department of Chemicals and Petrochemicals, New Delhi

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Draft rules to further amend Medical Device Rules, 2017 published

Drugs & Cosmetics Notification G.S.R.228(E) dated 29th March 2022

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

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

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

DRAFT RULES

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

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

2. In the Medical Devices Rules, 2017, in Fourth Schedule, in Part III, in Appendix II, in item no. 7.4, in sub item no. (i), the following Proviso shall be inserted, namely:-

"Provided that the requirement of Transmissible Spongiform Encephalopathies (TSEs) or Bovine Spongiform Encephalopathy (BSE) Certificates shall not be necessary if the source is from

animal species from a country of origin recognized as having negligible Bovine Spongiform Encephalopathy risk in accordance with the recommendations of the World Organisation for Animal Health.".

F.No. X.11014/25/2021-DR

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

Note: *The Medical Devices Rules, 2017 was published in the Official Gazette vide notification number G.S.R. 78 (E), dated the 31st January, 2017 and last amended vide notification number G.S.R. … (E), dated the ……*

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GOVERNMENT COMMUNICATIONS

Round-III - Invitation of Applications under the Production Linked Incentive (PLI) Scheme for Promotion of Domestic Manufacturing of critical Key Starting Materials(KSMs)/ Drug Intermediates and Active Pharmaceuticals Ingredients (APIs) – extension till 30.4.2022 - reg

No. 31026/16/2020-Policy/Scheme, dated 31st March, 2022

1. Reference is invited to this Department's Notice of even number dated 27.01.2022 and 13.03.2022 on the above-mentioned subject. It has been decided to extend the timeline for submission of applications under the "Production Linked Incentive Scheme for Promotion of Domestic Manufacturing of Critical Key Starting Materials (KSMs)/ Drug Intermediates and Active Pharmaceutical Ingredients(APIs) in India" till 30.04.2022.

2. The eligible applicants may apply through online only. The link is https://plibulkdrugs.ifciltd.com. Detailed guidelines of the Scheme are available at https://pharmaceuticals.gov.in/schemes.

3. The other credentials will remain same.

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

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In Lok Sabha & In Rajya Sabha

In Lok Sabha

Foreign Trade Policy

Lok Sabha Starred Question No. 218 (H)

Shri Kunwar Pushpendra Singh Chandel:

Shrimati Mala Rajya Laxmi Shah:

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

(a) whether the Government has taken any initiative for formulation of foreign trade policy;

(b) if so, the details thereof;

(c) whether the Government has also taken any initiative for free trade agreement with various countries;

(d) if so, the details thereof including the likely benefit for India therefrom;

(e) whether the Government has also made any assessment of impact of these trade agreements on the trade of agricultural products, especially on dairy and dairy products of the country; and

(f) if so, the details thereof?

Answered on 16th March 2022

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

The Minister of Commerce and Industry
(Shri Piyush Goyal)

STATEMENT REFERRED TO IN REPLY TO PARTS (a) to (f) OF LOK SABHA STARRED QUESTION NO. 218(H) FOR ANSWER ON 16th MARCH, 2022 REGARDING "FOREIGN TRADE POLICY".

(a) : Yes, Sir.

(b) : The current Foreign Trade Policy 2015-2020 which was announced for a period for five years, was extended by a year till 31st March, 2021 due to COVID-19. Due to continuing impact of COVID- 19 and to revisit and review FTDR Act further, the Foreign Trade Policy, 2015-2020 was extended up to 31st March, 2022. As part of the consultative process to formulate a new Foreign Trade Policy, various meetings with stakeholders were held. All the suggestions have been taken on record for further examination. A separate Foreign Trade Policy cell was created to coordinate with various officials in formulation of the Foreign Trade Policy under the supervision of an officer of the level of Joint Secretary to the Government of India.

(c) & (d): India had signed 10 RTAs/FTAs with various countries/regions before 2015 and two since then. These FTAs are with ASEAN (The Association of Southeast Asian Nations), Japan, South Korea, SAARC (South Asian Association for Regional Cooperation), Mauritius and United Arab Emirates (UAE). India's merchandise exports to these countries/regions have registered a growth of 20.75% in the last five years. As regards India-Mauritius Comprehensive Economic Cooperation and Partnership Agreement (CECPA), as this has been implemented w.e.f. 01-04-2021, it is too early to calculate quantifiable benefits. Agreement with UAE was signed on 18 February 2022 and not yet implemented.

In addition to this, India has signed 6 Preferential Trade Agreements (PTAs) with various countries/regions. **A list of FTAs/PTAs signed by India is attached at Annexure-A & B.**

India is currently negotiating FTAs and PTAs with some other various countries/regions, including Australia, UK, Canada, Israel and the EU being some of the important ones.

The likely benefits of FTA include increased market access, level playing field vis-à-vis competitors, increased bilateral trade, greater employment opportunities, etc.

(e) & (f): Export of Agri products (including dairy and dairy products) has increased from USD 32.662 billion in April-Jan 2021 to USD 40.873 billion in April-Jan 2022 i.e. an increase of 25.14%. Some of the increase in exports of Agri Products is as a result of the trade agreements.

ANNEXURE - A

FTA's already in force

Sr. No.	Name of the Agreement	Date of Signing of the Agreement	Date of Implementation of the Agreement
1	India – Sri Lanka FTA	28th December, 1998	1st March, 2000
2	Agreement on SAFTA (India, Pakistan, Nepal, Sri Lanka, Bangladesh, Bhutan, the Maldives and Afghanistan)	4th January, 2004	1st January, 2006 (Tariff concessions implemented from 1st July, 2006)
3	India Nepal Treaty of Trade	27th October, 2009	The Treaty has been extended for a further period of 7 years and is currently in force till 26th October 2023.
4	India – Bhutan Agreement on trade Commerce and Transit	17th January, 1972	Renewed periodically, with mutually agreed modifications. Agreement dated 29th July 2006 was valid for 10 years. With mutual consent, the validity was extended for a period of one year or the period till the proposed new Agreement comes into force. The renewed Agreement has been signed on 12.11.2016 and came into force with effect from 29 July 2017, for a period of 10 years.
5	India – Thailand FTA – Early Harvest Scheme (EHS)	9th October, 2003	1st September, 2004
6	India – Singapore CECA	29th June, 2005	1st August, 2005
7	India – ASEAN-CECA-Trade in Goods, Services and Investment Agreement (Brunei, Cambodia, Indonesia, Laos, Malaysia, Myanmar, Philippines, Singapore, Thailand and Vietnam)	13th August, 2009 for goods and November 2014 for Services and Investment	Goods • 1st January 2010 in respect of India and Malaysia, Singapore, Thailand. • 1st June 2010 in respect of India and Vietnam. • 1st September 2010 in respect of India and Myanmar. • 1st October 2010 in respect of India and Indonesia. • 1st November 2010 in respect of India and Brunei. • 24 January 2011 in respect of India and Laos. • 1st June 2011 in respect of India and the Philippines. • 1st August, 2011 in respect of India and Cambodia. Services and Investment 1 July, 2015
8	India – South Korea CEPA	7th August, 2009	1st January, 2010
9	India – Japan CEPA	16th February, 2011	1st August, 2011

10	India – Malaysia CECA	18th February, 2011	1st July, 2011
11	India – Mauritius Comprehensive Economic Cooperation and Partnership Agreement (CECPA)	22nd February, 2021	1st April, 2021
12	India-UAE FTA	18th February, 2022	Not yet implemented.

ANNEXURE - B

PTAs already in force:

Sr. No.	Name of the Agreement	Date of Signing of the Agreement	Date of Implementation of the Agreement
1	Asia Pacific Trade Agreement (APTA) (Bangladesh China, India, Republic of Korea, Lao People's Democratic Republic and Sri Lanka)	July, 1975 (revised on 2nd November, 2005)	1st Nov, 1976
2	Global System of Trade Preferences (GSTP) (Algeria, Argentina, Bangladesh, Benin, Bolivia, Brazil, Cameroon, Chile, Colombia, Cuba, Democratic People's Republic of Korea, Ecuador, Egypt, Ghana, Guinea, Guyana, India, Indonesia, Iran, Iraq, Libya, Malaysia, Mexico, Morocco, Mozambique, Myanmar, Nicaragua, Nigeria, Pakistan, Peru, Philippines, Republic of Korea, Romania, Singapore, Sri Lanka, Sudan, Thailand, Trinidad and Tobago, Tunisia, Tanzania, Venezuela, Viet Nam, Yugoslavia, Zimbabwe)	13th April, 1988	19th April, 1989
3	SAARC Preferential Trading Agreement (SAPTA) (Bangladesh, Bhutan, India, Maldives, Nepal, Pakistan and Sri Lanka)	11 April, 1993	7 December,1995
4	India - Afghanistan	6th March, 2003	13th May, 2003
5	India – MERCOSUR (Argentina, Brazil, Paraguay and Uruguay)	25th January, 2004	1st June, 2009
6	India - Chile	8th March, 2006	11th September, 2007. The agreement has been expanded on 6th September, 2016 and came into force w.e.f 16th May, 2017.

INDO-UKRAINE Trade

Lok Sabha Starred Question No. 220

*220. Shri Sanjay Sadashivrao Mandlik: Shri Shrirang Appa Barne:

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

(a) the details of Indo-Ukraine trade during the last three years and the current year;

(b) whether the Government has made any assessment of the trade between India-Russia and India-Ukraine due to the present crisis and if so, the details thereof;

(c) the likely impact of present Russia-Ukraine war on India's trade with Ukraine and Russia in terms of India's exports to these countries;

(d) whether the Union Government is apprised of present business scenario in the light of Russia- Ukraine war and if so, the details thereof;

(e) whether the Government has assessed the post war scenario in Ukraine and if so, the details thereof and the likely future of Indian companies post war; and

(f) whether the present Ukraine-Russia crisis could provide an opportunity to India to export its bumper wheat stock to the countries in need and if so, the details thereof?

Answered on 16th March 2022

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

STATEMENT REFERRED TO IN REPLY TO PARTS (A) TO (F) OF LOK SABHA STARRED QUESTION NO. 220 FOR ANSWER ON 16TH MARCH, 2022 REGARDING " INDO-UKRAINE TRADE".

(a) : Details of Indo-Ukraine Trade during the last three years and the current year are as follows:

Value in USD Million

Years	Ukraine		
	Exports	Imports	Total Trade
2018-2019	390.8	2,341.03	2,731.82
2019-2020	463.81	2,060.79	2,524.60
2020-2021	450.97	2,139.86	2,590.83
April-January 2022 (P)	426.43	2,444.91	2,871.34

Source: DGC I &S

(b) : Yes Sir, major items of export from India to Russia is Pharmaceuticals, Telecom Instruments, Iron and Steel, Tea, Chemical Products and import is Petroleum, Pearl and Semi-precious stones, Coal, Fertilizers, Vegetable oils.

Major items of export from India to Ukraine is Pharmaceuticals, Telecom Instruments, Ground Nut, Ceramic, Iron & Steel and import is Vegetable oils, Fertilizers, Inorganic Chemicals, Plastic and Plywood and allied products.

(c) & (d) : Department of Commerce is apprised of the present situation and holding regular consultation with all stakeholders to ensure availability of essential imports. As per the feedback received from the Industry, exports of some products from India are likely to be affected including Pharmaceuticals, Telecom Instruments, Tea, Coffee, Marine Products, etc.

(e) : The more precise implication of the post war scenario can be assessed only after the situation stabilizes.

(f): As both Ukraine and Russia are major exporters of wheat with more than 25% share in global wheat trade, disruption of exports from these countries does provide India an opportunity to increase our export of wheat.

The Minister of Commerce and Industry
(Shri Piyush Goyal)

Data of Imports and Exports

Lok Sabha Unstarred Question No. 2360

Shri Sisir Kumar Adhikari:

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

(a) the details of year-wise data of imports and exports from FY 2009-10 to FY 2021-22;

(b) the country-wise details of the import and export growth between 2008-2014, 2014- 2019 and 2019-2022 (till January 2022) therein; and

(c) the steps being taken by the Government to increase exports?

Answered on 16th March 2022

A. (a): The details of overall export and import (merchandise plus services) from financial year 2009-10 to 2021-22 are as follows:

Year	Export (Value in US$ Billion)	Import (Value in US$ Billion)
2009-10	274.80	348.40
2010-11	374.45	450.32
2011-12	448.29	567.55
2012-13	446.08	571.50
2013-14	466.22	528.95
2014-15	468.45	529.61
2015-16	416.60	465.64
2016-17	440.05	480.21
2017-18	498.61	583.11
2018-19	538.08	640.14
2019-20	526.55	602.98
2020-21	497.90	511.96
2020-21 (Apr-Jan)	396.37	399.67
2021-22 (Apr-Jan)	544.73	613.65

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

(b) The values of export of India to top 25 countries between 2007-08 to 2013-14, 2013-14 to 2018-2019 and 2018-19 (April-January) to 2021-22 (April-January) are given at **Annexure – I, II and III** respectively. The values of import of India from top 25 countries between 2007-08 to 2013- 14, 2013-14 to 2018-2019 and 2018-19 (April-January) to 2021-22 (April-January 2022) are given at **Annexure –** IV, V and VI respectively.

(c) The Government has taken the following steps to increase India's exports:

(i) The mid-term review (2017) of the Foreign Trade Policy (2015-20) was carried out and corrective measures were undertaken.

(ii) Foreign Trade Policy (2015-20) extended by one year i.e. upto 31-3-2022 due to the COVID-19 pandemic situation.

(iii) Assistance provided through several schemes to promote exports, namely, Trade Infrastructure for Export Scheme (TIES) and Market Access Initiatives (MAI) Scheme.

(iv) A Central Sector Scheme, 'Transport and Marketing Assistance for Specified Agriculture Products' was launched for providing assistance for the international component of freight to mitigate the freight disadvantage for the export of agriculture products.

(v) Remission of Duties and Taxes on Exported Products (RoDTEP) scheme and Rebate of State and Central Levies and Taxes (RoSCTL) Scheme have been implemented with effect from 01.01.2021.

(vi) Common Digital Platform for Certificate of Origin has been launched to facilitate trade and increase Free Trade Agreement (FTA) utilization by exporters.

(vii) 12 Champion Services Sectors have been identified for promoting and diversifying services exports by pursuing specific action plans.

(viii) Districts as Export Hubs has been launched by identifying products with export potential in each district, addressing bottlenecks for exporting these products and supporting local exporters/ manufacturers to generate employment in the district.

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

(x) Package announced in light of the COVID pandemic to support domestic industry through various banking and financial sector relief measures, especially for MSMEs, which constitute a major share in exports.

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

Annexure-I

STATEMENT REFERRED TO IN REPLY OF PART (B) OF LOK SABHA UNSTARRED QUESTION NO. 2360 FOR ANSWER ON 16TH MARCH 2022.

The value of merchandise export of India in terms of value to top 25 countries between 2007-08 to 2013-14

(Value in US$ Million)

Sr. No	Country	2007-08	2008-09	2009-10	2010-11	2011-12	2012-13	2013-14
1	U S A	20731	21150	19535	25296	34746	36161	39159
2	U ARAB EMTS	15637	24477	23970	33822	35926	36317	30522
3	CHINA P RP	10871	9354	11618	14207	18118	13580	14868
4	BANGLADESH PR	2924	2498	2434	3243	3789	5145	6167
5	NETHERLAND	5249	6349	6398	7681	9153	10566	7998
6	HONG KONG	6313	6655	7888	10320	12932	12279	12732
7	SINGAPORE	7379	8445	7592	9825	16858	13619	12511
8	U K	6705	6650	6221	7312	8628	8649	9822

9	GERMANY	5122	6389	5413	6754	7946	7253	7523
10	NEPAL	1507	1570	1533	2168	2722	3089	3592
11	BELGIUM	4207	4480	3759	5784	7161	5507	6378
12	SAUDI ARAB	3711	5110	3907	4684	5683	9786	12219
13	TURKEY	1753	1417	1539	2749	3547	3964	4434
14	INDONESIA	2164	2560	3063	5701	6678	5331	4850
15	ITALY	3914	3825	3400	4554	4885	4373	5274
16	AUSTRALIA	1152	1439	1385	1713	2477	2349	2300
17	KOREA RP	2861	3952	3421	3730	4355	4206	4210
18	MALAYSIA	2575	3420	2835	3871	3980	4444	4198
19	VIETNAM SOC REP	1610	1739	1839	2651	3719	3967	5442
20	BRAZIL	2526	2651	2414	4024	5770	6049	5553
21	JAPAN	3858	3026	3630	5092	6330	6101	6815
22	SOUTH AFRICA	2661	1980	2058	3912	4731	5107	5074
23	FRANCE	2600	3021	3820	5210	4558	4987	5109
24	THAILAND	1811	1938	1740	2274	2961	3733	3703
25	SRI LANKA DSR	2830	2426	2188	3508	4379	3984	4535

Source: DGCI&S

Annexure-II

STATEMENT REFERRED TO IN REPLY OF PART (B) OF LOK SABHA UNSTARRED QUESTION NO. 2360 FOR ANSWER ON 16TH MARCH 2022.

The value of merchandise export of India in terms of value to top 25 countries between 2013-14 to 2018-19

(Value in US$ Million)

Sr. No	Country	2013-14	2014-15	2015-16	2016-17	2017-18	2018-19
1	U S A	39159	42464	40340	42216	47882	52428
2	U ARAB EMTS	30522	33028	30316	31175	28146	30127
3	CHINA P RP	14868	11959	9015	10172	13334	16753
4	BANGLADESH PR	6167	6450	6035	6820	8615	9210
5	NETHERLAND	7998	6327	4727	5071	6263	8814
6	HONG KONG	12732	13600	12092	14047	14690	13002
7	SINGAPORE	12511	9810	7720	9565	10203	11572
8	U K	9822	9354	8858	8551	9713	9330
9	GERMANY	7523	7540	7095	7184	8689	8904
10	NEPAL	3592	4574	3903	5454	6613	7766
11	BELGIUM	6378	5520	5028	5657	6207	6730
12	SAUDI ARAB	12219	11163	6382	5110	5411	5562
13	TURKEY	4434	5359	4140	4627	5091	5452
14	INDONESIA	4850	4043	2819	3488	3966	5278
15	ITALY	5274	5093	4218	4903	5710	5594

16	AUSTRALIA	2300	2782	3263	2958	4012	3522
17	KOREA RP	4210	4604	3525	4243	4462	4705
18	MALAYSIA	4198	5817	3707	5225	5702	6436
19	VIETNAM SOC REP	5442	6258	5266	6787	7813	6507
20	BRAZIL	5553	5964	2650	2400	3063	3800
21	JAPAN	6815	5386	4663	3846	4735	4862
22	SOUTH AFRICA	5074	5302	3588	3546	3825	4067
23	FRANCE	5109	4957	4634	5250	4902	5235
24	THAILAND	3703	3465	2988	3133	3654	4441
25	SRI LANKA DSR	4535	6704	5311	3913	4476	4710

Source: DGCI&S

Annexure-III

STATEMENT REFERRED TO IN REPLY OF PART (B) OF LOK SABHA UNSTARRED QUESTION NO. 2360 FOR ANSWER ON 16TH MARCH 2022.

The value of merchandise export of India in terms of value to top 25 countries between 2018-19 (Till Jan,20) to 2021-22 (Till Jan,22)

(Value in US$ Million)

Sr.No	Country	2018- 19 (TillJan, 20)	2019-20 (TillJan,20)	2020-21 (TillJan,21)	2021-22 (Till Jan,22)*
1	U S A	43310	44701	41182	62284
2	U ARAB EMTS	24884	24256	12902	22360
3	CHINA P RP	13774	14428	16823	18405
4	BANGLADESH PR	7576	6742	6929	12923
5	NETHERLAND	7105	7082	4928	9276
6	HONG KONG	10391	9314	8160	9210
7	SINGAPORE	8674	7633	6941	9061
8	U K	7685	7417	6255	8562
9	GERMANY	7313	7007	6473	7918
10	NEPAL	6551	6069	5196	7886
11	BELGIUM	5658	5026	3820	7853
12	SAUDI ARAB	4465	5010	4797	7158
13	TURKEY	4467	4267	3068	6913
14	INDONESIA	3945	3070	3356	6674
15	ITALY	4532	4071	3534	6647
16	AUSTRALIA	3009	2410	3287	6334
17	KOREA RP	4016	4022	3734	6276
18	MALAYSIA	5598	5333	5067	5837
19	VIETNAM SOC REP	5482	4412	3903	5570
20	BRAZIL	3088	3430	3181	5415

21	JAPAN	4032	3820	3495	5163
22	SOUTH AFRICA	3474	3421	3303	4919
23	FRANCE	4289	4334	3700	4912
24	THAILAND	3706	3641	3205	4608
25	SRI LANKA DSR	3888	3244	2660	4487

Source: DGCI&S. Provisional*

Annexure-IV

STATEMENT REFERRED TO IN REPLY OF PART (B) OF LOK SABHA UNSTARRED QUESTION NO. 2360 FOR ANSWER ON 16TH MARCH 2022.

The value of merchandise import of India in terms of value from top 25 countries between 2007- 08 to 2013-14

(Value in US$ Million)

Sr. No	Country	2007-08	2008-09	2009-10	2010-11	2011-12	2012-13	2013-14
1	CHINA P RP	27146	32497	30824	43480	54691	52248	51036
2	U ARAB EMTS	13483	23791	19499	32753	36768	39139	29021
3	U S A	21067	18561	16974	20051	23381	25205	22506
4	SAUDI ARAB	19470	19973	17098	20385	31750	33631	36405
5	IRAQ	6838	7710	7027	9008	18919	19247	18521
6	SWITZERLAND	9758	11870	14698	24802	35242	32166	19311
7	HONG KONG	2698	6452	4734	9415	10417	7907	7322
8	SINGAPORE	8123	7655	6455	7139	8339	7486	6763
9	KOREA RP	6045	8677	8576	10475	12794	13105	12471
10	INDONESIA	4821	6666	8657	9919	14839	14879	14749
11	AUSTRALIA	7815	11098	12407	10789	15784	13086	9823
12	GERMANY	9885	12006	10318	11891	15498	14326	12933
13	JAPAN	6326	7886	6734	8632	11966	12412	9481
14	QATAR	2456	3499	4649	6820	12927	15693	15709
15	MALAYSIA	6013	7185	5177	6524	9474	9950	9230
16	SOUTH AFRICA	3605	5514	5674	7141	11237	8886	6075
17	KUWAIT	7704	9594	8249	10314	16334	16588	17154
18	NIGERIA	7612	8900	7288	10788	14755	12086	14098
19	BELGIUM	4350	5777	6019	8610	10374	10047	10752
20	RUSSIA	2478	4328	3567	3600	4787	4232	3895
21	THAILAND	2301	2704	2932	4272	5278	5353	5340
22	U K	4954	5872	4462	5397	7130	6294	6045
23	VIETNAM SOC REP	174	409	522	1065	1717	2315	2594
24	OMAN	1141	1205	3500	4002	3347	2010	2951
25	TAIWAN	2400	2869	2613	3961	4805	3963	4041

Source: DGCI&S

Annexure-V

STATEMENT REFERRED TO IN REPLY OF PART (B) OF LOK SABHA UNSTARRED QUESTION NO. 2360 FOR ANSWER ON 16TH MARCH 2022.

The value of merchandise import of India in terms of value from top 25 countries between 2013- 14 to 2018-19

(Value in US$ Million)

Sr. No	Country	2013-14	2014-15	2015-16	2016-17	2017-18	2018-19
1	CHINA P RP	51036	60413	61708	61283	76381	70320
2	U ARAB EMTS	29021	26140	19446	21510	21739	29787
3	U S A	22506	21815	21781	22307	26611	35550
4	SAUDI ARAB	36405	28108	20321	19972	22070	28479
5	IRAQ	18521	14248	10838	11708	17616	22372
6	SWITZERLAND	19311	22133	19299	17249	18923	18088
7	HONG KONG	7322	5572	6052	8204	10676	17987
8	SINGAPORE	6763	7124	7308	7087	7467	16282
9	KOREA RP	12471	13529	13047	12585	16362	16759
10	INDONESIA	14749	15005	13132	13428	16439	15854
11	AUSTRALIA	9823	10247	8899	11154	13994	13131
12	GERMANY	12933	12788	12088	11584	13296	15167
13	JAPAN	9481	10131	9850	9755	10973	12773
14	QATAR	15709	14605	9022	7646	8409	10722
15	MALAYSIA	9230	11118	9084	8934	9012	10819
16	SOUTH AFRICA	6075	6497	5948	5834	6835	6517
17	KUWAIT	17154	13382	4970	4462	7166	7431
18	NIGERIA	14098	13683	9949	7659	9501	10885
19	BELGIUM	10752	10806	8256	6625	5993	10469
20	RUSSIA	3895	4249	4585	5552	8573	5840
21	THAILAND	5340	5866	5510	5415	7134	7442
22	U K	6045	5018	5193	3665	4807	7562
23	VIETNAM SOC REP	2594	3003	2560	3321	5019	7192
24	OMAN	2951	1752	1675	1290	4264	2759
25	TAIWAN	4041	4029	3354	3143	3926	4577

Source: DGCI&S

Annexure-VI

STATEMENT REFERRED TO IN REPLY OF PART (B) OF LOK SABHA UNSTARRED QUESTION NO. 2360 FOR ANSWER ON 16TH MARCH 2022.

The value of merchandise import of India in terms of value from top 25 countries between 2018- 19 (Apr-Jan) to 2021-22 (Apr-Jan)

(Value in US$ Million)

Sr. No	Country	2018-19 (Apr-Jan)	2019-20 (Apr- Jan)	2020-21 (Apr-Jan)	2021-22 (Apr-Jan)*
1	CHINA P RP	60109	57936	52045	76622
2	U ARAB EMTS	24743	25767	19660	35919

3	U S A	29713	30566	21762	34444
4	SAUDI ARAB	24241	22978	13030	26175
5	IRAQ	18812	19839	10991	24316
6	SWITZERLAND	15152	14798	10672	20320
7	HONG KONG	15050	14617	12349	15702
8	SINGAPORE	13453	12194	9919	14927
9	KOREA RP	14046	13227	9885	14395
10	INDONESIA	13417	12772	10041	14149
11	AUSTRALIA	11370	8537	6146	13501
12	GERMANY	13006	11662	11038	12446
13	JAPAN	10645	10598	8396	12045
14	QATAR	9118	7857	6184	10486
15	MALAYSIA	9057	8488	6423	10201
16	SOUTH AFRICA	5574	5447	5533	9155
17	KUWAIT	6032	7978	4103	8633
18	NIGERIA	8941	8623	4406	8124
19	BELGIUM	8737	7556	5421	7995
20	RUSSIA	4948	5976	4369	7972
21	THAILAND	6232	5722	4223	7514
22	U K	6393	5858	3827	5915
23	VIETNAM SOC REP	6155	6313	4808	5761
24	OMAN	2301	2961	2232	5335
25	TAIWAN	3846	3430	3155	5015

Source: DGCI&S. Provisional*

FDI From Neighbouring Countries

Lok Sabha Unstarred Question No. 2421.

Shri Ram Mohan Naidu Kinjarapu:

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

(a) the total number of FDI proposals received by the Government from nations sharing land border with India or where the beneficial owner of an investment into India is situated in or is a citizen of any such country since 18th April 2020;

(b) the value of investments proposed in the afore mentioned proposals received by the Government; and

(c) the details and the number of proposals that were granted permission to invest including the sector-wise breakup of the accepted proposals along with the total value of investments in the sector by the aforementioned FDI proposals?

Answered on 16th March 2022

A. (a): Since 18th April, 2020, 347 FDI Proposals have been received by the Government from countries sharing land border with India or where the beneficial owner of an investment into India is situated in or is a citizen of any such country.

(b):The value of investments proposed in the afore mentioned proposals received by the Government is approximately INR 75,951 Crore.

(c): Of the aforementioned proposals, 66 proposals have so far been granted approval by the Government. 193 cases have been rejected or closed or withdrawn. The sector-wise breakup of approved proposals along with total value of investments in the sector is placed at **Annexure.**

ANNEXURE

ANNEXURE REFERRED TO IN REPLY TO PART (c) OF THE LOK SABHA UNSTARRED QUESTION NO. 2421 FOR ANSWER ON 16.03.2022.

Sector-wise breakup of approved proposals along with total value of investments in the sector:

S. No	Sector	Number of Pro-posals	Total value of investments in the sector (approximately) in INR Crore
1	Automobile Industry	7	79.61
2	Chemicals (Other Than Fertilizers)	5	82.25
3	Computer Software & Hardware	3	10.68
4	Drugs & Pharmaceuticals	4	5037.00
5	Dye-Stuffs	1	5.44
6	Education	1	0.10
7	Electrical Equipments	1	20.00
8	Electronics	8	1575.79
9	Food Processing Industries	2	5.93
10	Information & Broadcasting (Including Print Media)	1	3.00
11	Machine Tools	1	37.80
12	Miscellaneous Industries	8	241.92
13	Non- Conventional Energy	6	2810.00
14	Petroleum And Natural Gas	1	20.00
15	Power	1	755.00
16	Services Sector (Fin., Banking, Insurance, Non Fin/Business, Outsourcing, R&D, Courier, Tech. Testing And Analysis, Other)	11	2907.81
17	Telecommunications	1	0.00
18	Textiles (Including Dyed, Printed)	1	1.90
19	Trading	3	30.65
Total		**66**	**13,624.88**

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

In Rajya Sabha

Price Control Mechanism for Life-Saving Drugs

Rajya Sabha Unstarred Question No.2171

Shri Md. Nadimul Haque:

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

a) whether it is a fact that Government is currently levying 12 per cent GST on life-saving drugs;

b) whether Government has conducted any studies to understand the financial hardships that have resulted from it;

c) if so, the details thereof;

d) whether Government is planning to institute a price control mechanism to make these drugs more affordable to the people; and

e) if so, the details thereof, if not, the reasons therefor?

Answered on 22nd March 2022

A. (a to e): As informed by Department of Revenue, Specified Drugs, Medicines and vaccines attract 5% GST and Other medicines, in general attract 12% GST. Serial No.173 to 181 of notification No. 1/2017-Central Tax (Rate) provides 5% GST on specified drugs and medicines. The associated list of drugs and medicines is available at (https://egazette.nic.in/WriteReadData/2017/176965.pdf Page No.239-306).

As informed by Department of Pharmaceuticals, pursuant to notification of the National Pharmaceutical Pricing Policy (NPPP) on 7th December, 2012, the Government has notified the Drugs (Prices Control) Order, 2013 (DPCO-2013) with an objective to put in place a regulatory framework for pricing of drugs so

as to ensure the availability of essential medicines at reasonable prices.

As per provisions of DPCO, 2013, the ceiling price of all scheduled formulations figuring in the National List of Essential Medicines (NLEM) issued by the Ministry of Health & Family Welfare are fixed by the National Pharmaceutical Pricing Authority (NPPA) under the Department of Pharmaceuticals. All manufacturers of these scheduled drugs are required to sell their products at a price equal to or lower than the ceiling price. Further, NPPA monitors the prices of non-scheduled drugs so as to ensure that increase in their Maximum Retail Price (MRP) is not more than 10% of what was prevalent during the preceding twelve months. The details of various medicines and medical devices under price control is available at the website of NPPA, i.e., www.nppaindia.nic.in.

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

Janaushadhi Kendras

Rajya Sabha Unstarred Question No. 2098

Shri Prasanna Acharya:

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

(a) the number of Janaushadhi Kendras that have been set up so far and how many of them are functional including that in Odisha;

(b) the number of varieties of drugs being supplied to Janaushadhi Kendras and whether it is as per the requirements of patients;

(c) the average price and quality difference between Janaushadhi and other drugs; and

(d) the percentage of people benefitted by Janaushadhi and what more steps are required to be taken to cover more people under this scheme and steps taken by Government to remove the deficiencies?

Answered on 22nd March 2022

A. (a): As on 28.02.2022, about 8,689 Pradhan Mantri Bhartiya Janaushadhi Kendras (PMBJKs) have been opened under the scheme of Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) covering all districts of the country. Out of which, 354 PMBJKs are functional in the State of Odisha.

(b): The product basket under the scheme comprises of 1,616 medicines and 250 surgical items covering all major therapeutic groups such as Cardiovascular, Anti-cancers, Anti-diabetics, Anti-infectives, Anti-allergic, Gastro-intestinal medicines, Nutraceuticals, etc. All generic medicines included in National List of Essential Medicines (NLEM) are included in the product basket except the lab reagents. Further, few AYUSH products have also been included in the product basket.

(c): A medicine under PMBJP is priced on the principle of a maximum of 50% of average price of the top three branded medicines. Therefore, the cost of the Jan Aushadhi Medicines is cheaper at least by 50% and in some cases, by 80% to 90% of the market price of branded medicines. The medicines are procured only from World Health Organization – Good Manufacturing Practices (WHO-GMP) certified private manufacturers / CPSUs for ensuring the quality of the products. Apart from this, each batch of drug is tested at laboratories accredited by the National Accreditation Board for Testing and Calibration Laboratories (NABL) for quality assurance. Only after passing the quality tests, the medicines are dispatched to PMBJKs for sale. Further, Quality Standard Operating Procedures have been developed to ensure better quality of products. Moreover, the warehouses, as per WHO-GDP guidelines, ensure quality in logistics and distribution. Hence, there is no difference in quality between Jan Aushadhi generic drugs and branded medicines available in the market.

(d): In a month, around 1.25 to 1.50 Crore people on an average are purchasing medicines from more than 8,600 PMBJKs across the country. The Government has set a target to have 10,500 Kendras by March 2025 across the country. Further, the Department has enhanced the incentive available to Kendra owner from Rs. 2.50 lakh to Rs. 5.00 Lakh. In addition, one-time incentive of Rs. 2.00 lakh has been also introduced for opening of PMBJKs by women, Divyang, SC & ST entrepreneurs and for the Kendras opened in aspirational districts, Himalayan, Island territories and North-Eastern States.

Minister of State in the Ministry of Chemicals & Fertilizers (Shri Bhagwant Khuba)

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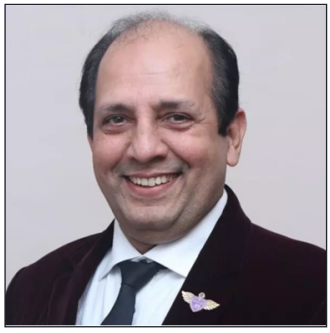
India set to emerge as pharmacy of the world: IDMA



The world is buying medicines from India and it will only increase, going forward, says IDMA's Daara B Patel

Indian Drug Manufacturers' Association (IDMA) has traversed a long way over the last 60 years to become what it is today and at the same time to take the Indian pharma industry where it is today. IDMA seems to well set to emerge as the 'global pharmacy', rising to the occasion and supplying quality drugs at competitive prices to the world. Speaking to Bizz Buzz exclusively, Daara B Patel, Secretary General, Indian Drug Manufacturers' Association (IDMA), who is spearheading the organisation's journey and activities through the challenging times, outlines organisation's plans in its diamond jubilee year and beyond and the way forward for the Indian pharma industry.

In the Budget 2021-22, the Finance Minister announced an outlay of Rs 1.97 lakh crore to be utilised over 5 years for the PLI schemes in 13 key sectors. The thrust to reinforce India as the "pharmacy of the world" is evident from the PLI schemes for this sector. (PLI) schemes are a cornerstone of the government's push for achieving an Atmanirbhar Bharat. The objective is to make India's domestic manufacturing globally competitive and to create global champions in manufacturing. Exports from Ukraine aren't an important issue for the small people in medicine, not an alarming situation for India. When it comes to Russia, India's export volume is big, nearly $600 million. There is a stoppage in transport, no container available, people have reasons to be worried about. We don't know when all will be normal but the demand for medicine won't go down, for sure.

How are you planning to celebrate this diamond jubilee celebration for your organisation including that of the global conclave, which you have planned?

See, the theme for the diamond jubilee year of IDMA is "Indian pharma – global healthcare". Unfortunately, we had to postpone our celebration and the global conclave, thanks to the possibility of the third wave of the Covid-19 pandemic. It is now happening on April 14 and 15 in Mumbai. Dr Mansukh Mandaviya, Union Minister of Health & Family Welfare and Chemicals & Fertilizers has confirmed to be the chief guest at the inaugural ceremony on April 14 and Piyush Goyal, Union Minister for Commerce & Industry, Consumer Affairs, Food & Public Distribution and Textiles has confirmed to be the chief guest at the valedictory ceremony on April 15. Dr Gnanvatsal Swami Ji will deliver a spiritual address on April 15. We have industry stalwarts who have confirmed their presence for various panel discussion scheduled over the two days, such as Dilip Shanghvi (Sun Pharmaceutical Industries), Satish Reddy (Dr Reddy's Laboratories), Amit Varma (Quadria Capital), Rakesh Jhunjhunwala, Dhaval Shah (PharmEasy), KV Subramaniam (Reliance Life Sciences), Dr Satyanarayana Chava (Laurus Labs Ltd), Premchand Godha (IPCA Laboratories) and Rajeev Nanapanenni (Natco Pharma), among others. Bain & Co is our 'knowledge partner' for this event.

The Association has come a long way and many milestones have been achieved in the last 60 Years and specially the last two years which have been different, difficult and trying times. The active participation & interaction with the virtual who's who of the Pharmaceutical Industry as well as Ministry Officials and Bureaucrats, from the Centre as well as States, will not only add value to the pharma business but also ensure that the flag of our association continues to fly higher in the Global Pharmaceutical Industry.

The pandemic has changed the way industry across verticals had been operating. It's more true with Pharma industry. So what are most perceptible changes that pharmaceutical industry had to bring in?

During Covid-19 pandemic, IDMA Secretariat has played an important role in facilitating uninterrupted

supply of quality medicines with excellent coordination between the industry, government, regulators and other associations. In March 2020, the production utilisation was hardly about 18-20 per cent and because of all these initiatives undertaken by us and working closely with the government, All Indian Origin Chemists & Distributors Ltd (AIOCD), with the transporters and regulators, we were able to scale up to 80 per cent in two months. Eventually it went up to 100 per cent and there was no looking back since then. During the pandemic or in the current scenario when the intensity and severity of situation are much lesser, the momentum is the same, the regulators have been burning the midnight oil and approving medicines and vaccines on a war footing. The stakeholders, regulators, government, pharmaceutical manufacturers, packaging material manufacturers, the API suppliers - all are together as a team now and the common goal is patient centricity. The AIOCD was used to keep the chemist's shop open so that the goods could be delivered and stored. We also told the suppliers not to panic buy.

I read somewhere and you just mentioned and described India as the global pharmacy. What did you actually mean by that?

The Indian government announced a production-linked incentive (PLI 1.0) scheme on 21 July, 2020, aimed at boosting India's bulk drug security. This covered identified active pharmaceutical ingredients (APIs)/key starting materials /drug intermediates. The financial outlay for the said PLI scheme was Rs 6,940 crore. In the Budget 2021-22, the Finance Minister announced an outlay of Rs 1.97 lakh crore to be utilised over 5 years for the PLI schemes in 13 key sectors. The thrust to reinforce India as the "pharmacy of the world" is evident from the PLI schemes for this sector. (PLI) schemes are a cornerstone of the government's push for achieving an Atmanirbhar Bharat. The objective is to make India's domestic manufacturing globally competitive and to create global champions in manufacturing.

At this outset, Indian pharma industry navigated the challenges of the pandemic so well. The country's pharma industry got together to showcase instances of preparedness, rapid response and took proactive measures to prove that India is the pharmacy of the world. I say this emphatically because the whole world has started buying medicines from India and it will only increase, going forward.

How has the ongoing Russia-Ukraine armed conflict impacted Indian pharma industry?

One has to keep in mind that we do not export much to Ukraine. Ukraine exports are around $180 million. Even that amount is not coming now, as at present everything is at a standstill, no transport, no ships sailing, with the war going on. Exports from Ukraine aren't an important issue for the small people in medicine, not an alarming situation for India. When it comes to Russia, India's export volume is big, nearly $600 million. There is a stoppage in transport, no container available, people have reasons to be worried about. We don't know when all will be normal but the demand for medicine won't go down, for sure.

But I think it's a temporary disruption. Interestingly, we are not a competitive country and are not joining hands with other countries which are supporting Ukraine. So sanctions are already there for Russia from various countries. Talking about the overall economy, buying power all will be affected, payments will also be delayed. But we have to face it, after all, it's a business risk, everyone has to take. It should be reconfirmed at the earliest because we need to supply medicines for export purposes and at the same time medicines are required by people to take care of their health. We all hope that India and Russia will work out some solution at the earliest.

Safe disposal of unused and post expiry drugs have been an issue for years. What are your thoughts on that?

Mind you that IDMA has already issued a guideline to all the members on the safe disposal of unused, expired or rejected drugs. All the members have been informed to keep the products separate once they expire and also to call back the stockists who will withdraw the expired, rejected drugs from the retailers, these drugs should not be sold in the market, by any means. They should be destroyed through a proper procedure like in the presence of the FDA, inspector or someone from the drug circle or CDSCO.

Source: Hans India Bizz Buzz, 05.04.2022

Costlier APIs hurting pharma manufacturers: IDMA

Ahmedabad: Like most other sectors, even the pharmaceutical industry is reeling under steep rise in prices of raw materials, affecting profitability. Despite the 10.7% increase in prices of some 800 medicines permitted by the National Pharmaceutical Pricing Authority (NPPA), pharma makers are unable to meet input costs as the prices of active pharma ingredients have gone up.

Prices of basic APIs such as paracetamol, azithromycin, doxycycline, metformin, among others have gone up by at least 30% since April 2020 as a result of which profitability of pharma companies is getting affected , said the Indian Drug Manufacturers' Association (IDMA).

Atul Shah, treasurer, IDMA-Gujarat, said, "We are heavily dependent on China for procuring APIs. This hurt the industry during the pandemic as the imports got costlier. The increase in input costs have not only affected production across the pharmaceutical value chain, but also put pressure on companies to maintain operating margins. In such a situation, growth of the industry will be adversely affected."

Medicines have become costlier by 10.7% for people but it is insufficient to ensure smooth development of the industry, according to IDMA.

"Since April 2020, prices of several APIs have increased by average 30-40% and some have increased by as much as 100%. Moreover, packaging materials have also become costlier during the past two years. However, as per rules, prices of medicines cannot be increased in tandem with the increase in raw material prices. Due to this, profit margins of pharma manufacturers are shrinking," said Dr Shrenik Shah, Chairman, IDMA-Gujarat.

According to IDMA, the maximum retail price of lifesaving medicines can only be increased in accordance with the wholesale price index. "Therefore, we can only increase MRP by a maximum of 10% for non-lifesaving drugs in a year. On the contrary, APIs and packaging materials have become much costlier," Shah added. The industry players have a long-pending demand to allow drug makers to increase MRP of all non-scheduled formulations by at least 20%. IDMA in its representation last year had sought to increase prices of certain scheduled formulations, whose retail prices are below the ceiling price, to be raised up to the ceiling price.

Drug makers also sought to change the method of revising ceiling prices in accordance with consumer price index instead of wholesale price index, as the former is a realistic indicator of inflation.

Source: Times of India, 07.04.2022

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Covid has been an inflection point for India to emerge as a global life sciences leader

Covid Made Our Pharma Firmer

Kiran Mazumdar Shaw is executive chairperson, Biocon & Biocon Biologics

The tectonic shifts that the Covid-19 pandemic brought with it has thrust the Indian biotechnology industry into the global limelight. The industry responded with grit, agility and creativity to address India's health care needs in the face of a rampaging viral outbreak. This global emergency galvanised India's life sciences ecosystem to indigenously develop a range of innovative biomedical solutions— RT-PCR (reverse transcription polymerase chain reaction) diagnostic kits, vaccines, therapies, mobile apps for contract tracing and vaccine registration, artificial intelligence (AI)-based medical imaging and telehealth tools.

Even as the government, industry and startups joined hands to respond to the need of the hour, the pandemic unleashed opportunities we never thought existed. Several cost effective vaccines were produced at scale to immunise a billion people. It spanned indigenously developed ones such as Bharat Biotech's Covaxin, Zydus Cadila's DNA shot ZyCoV-D and Biological E's Corbevax, as well as domestically produced jabs of Covishield (Oxford-AstraZeneca) and Covovax (Novavax), both manufactured by the Serum Institute of India (SII). This has led to nearly 2 billion vaccine doses being administered in the country till date, generating about $7 billion in domestic sales.

From just one test conducted in the lab at the National Institute of Virology (NIV), Pune, in January 2020 to nearly

0.8 billion Covid-19 tests conducted as of March 30,2022, according to Indian Council of Medical Research (ICMR) data, India has grown its testing capacity exponentially, resulting in a domestic market of about $10 billion. Several therapies, including antiviral remdesivir, CD6 (Cluster of differentiation 6, a cell surface glycoprotein involved in T cell activation)-targeting itolizumab and steroids, were mass produced and used to treat patients suffering from severe Covid related symptoms, generating an estimated $5 billion in sales in India.

The local clinical trials industry also got a booster shot from the pandemic. Over 100 trials were approved in the country in 2021— the largest in a decade— as vaccine and pharma companies rushed to test the safety and efficacy of their products. These generated business of about $1billion for clinical research organisations in India.

The health crisis also led to a huge demand for rapid and accurate diagnostic tests to identify and manage infected individuals, creating a domestic market of about $3 billion for such kits. Moreover, about $9 billion worth of personal protective equipment (PPE), masks, gloves and sanitizers were sold in India.

In these two years of the pandemic, $30 billion worth of domestic demand was created for various products and services to tackle the coronavirus, which was catered to by both Indian and international life sciences players. Thanks to the ministry of science and technology Department of Biotechnology, focused pursuit of Aatmanirbhar Bharat initiatives. India has taken a leading global role in the manufacture of diagnostics and vaccines. Last year. India became the second largest country in manufacturing PPE kits, producing more than 5 lakh PPEs and over 1 crore N-95masks per day.

At the same time, the country was able to build a robust information technology (IT) backbone to track and trace infections, create advanced databases and real-time dashboards to map the pandemic and deploy vaccines at scale through platforms like CoWin and AarogyaSetu. CoWin is undoubtedly the world's largest Covid-19 vaccination database and can be leveraged as a health data stack.

The coronavirus crisis provided India the opportunity to manifest it's robust capabilities in both high-end scientific research and global scale manufacturing, thanks to the deep reservoir of scientific and engineering competencies within the country. Several policy boosts by the government can potentially set the stage for exponential growth of India's life sciences industry.

The 2022 Union budget more than doubled the outlay for healthcare and well being, including allocations towards Covid-19 vaccination and initiatives to strengthen the country's primary, secondary and tertiary health infrastructure. As the pandemic wanes, the government should redeploy the funds to strengthen India's healthcare infrastructure. GoI's performance linked incentive (PLI) scheme is bolstering local manufacturing of biopharmaceuticals and complex generic drugs, which play to the Indian biopharmaceuticals industry, evolving strengths. Regulations supporting e-pharmacies and telehealth can prove to be gamechangers.

The recent thinking around research-linked incentives (RLI) to drive innovation and garner a greater thereof the value of the global pharma market, needs to translate urgently into policy implementation. To boost exports, GoI needs to include the pharmaceuticals sector under the Remission of Duties and Taxes on Exported Products (RoDTEP) export promotion scheme.

The Covid-19 pandemic is an inflection point for India to emerge as a global life sciences leader. We should capitalise on the momentum we have built over the last two years to establish 'Brand India' as one that stands for value, innovation and the highest impact in global healthcare.

Source: Economic Times, 05.04.2022

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Gearing up for an era of innovation

SM Mudda, MD, Misom Labs highlights that we have entered into an era of disruptive innovation and emphasises that those who keep pace with innovation will be the future leaders

Afew years ago, the hot topic that was discussed at most of the forums was how to deal with the challenges posed by the VUCA world, not knowing that we will face one such real global disruption in the form of COVID-19 pandemic soon.

"There are decades when nothing happens but there are weeks when decades happen." COVID pandemic was one such brutal disruption the world went through, and has come out much wiser with a lot of learnings that are known as 'New Normal.'

The world has learnt that with the help of innovative technology, it is possible to witness a never-seen-before feat of producing a potential vaccine candidate in mere months for a novel virus.

We realise like never before that we have entered into an era of disruptive innovation and recognise that those who keep pace with innovation will be the future leaders.

Challenges of the VUCA world

Talking about the challenges in the pre-COVID era, there are questions and realisations that:

- India is no longer the low-cost centre for the manufacturing of pharmaceuticals?
- The price of medicines (patented and generic) will fall in the next five years?
- Cost of manufacturing will increase?
- Our compliance with regulatory expectations, particularly the US FDA, continued to be a lingering issue and remain an ongoing concern.
- Amazon, Google and Apple will have a profound impact in healthcare in the next decade

Balancing three Cs - Customer, Cost and Compliance

The pharma industry is faced with the challenge of balancing overlapping three circles—Customer expectations; Profit and efficiency – Cost control; Legacy and reputation – License to operate; within the constraints of shrinking resources and time.

The pharma industry has been focussing, amongst others, at the latest technologies like complete digitisation of operations, automation at manufacturing units and Big Data and Machine Learning to enhance accuracy, reduce time and efforts, and remain in the state of compliance.

The focus has already shifted to smart innovation that will givea disproportionate return in terms of improved efficiency. We need to work on the principle of 'Less is More' which is the new mantra.

Industry 4.0

The tremendous ongoing digital transformation – better known as Industry 4.0 – is profoundly changing manufacturing, processing and production industries. The term Industry 4.0 encapsulates all the rapidly evolving technologies, processes and practices that are currently changing the world of manufacturing.

Advanced technology is undoubtedly becoming the backbone of futuristic quality assurance in the pharma and biotech industry.

Digitisation – A strategic priority in post-COVID era

Post-COVID-19, adoption of digitisation has become a strategic priority for business in the pharma industry. Such benefits will be highlighted in the areas of:

- R&D
- Manufacturing and Quality
- Role of regulators in supporting innovation

Pharma R&D

The advent of new emerging technologies like AI, IoT, digitisation and automation have the potential to revolutionise every element of the pharma industry from drug discovery to production to efficient and secure supply chain to monitoring of ADRs.

Some of the benefits in the area of drug discovery and R&D include use of digital tools in

- predicting the behaviour of new chemical compounds in potential drugs
- selection of target molecules using high-throughput screening
- predicting patient outcomes from Electronic Health Records (EHRs)
- Virtual and decentralised clinical trials, etc.

These tools will help in developing new innovative product for patient benefit that include the patient-related quality attributes in the design of the product and make the novel drugs available to the patients on fast track.

Pharma manufacturing

Some of the potential applications of Industry 4.0 are seen in the form of continuous manufacturing technology.

- Use of Internet of Things (IoT) for data collection in real time from the networked equipment can help in predictive maintenance of equipment, thus reducing the downtime.
- Use of track-and-trace technology for ensuring supply chain integrity, etc.
- Predictive quality analytics is a tool used by manufacturers to forecast the quality of the products, components and materials that are already in the production process. It can address the root causes of problems in advance—before any quality issues occur.

Pharma labs

Quality 4.0 is a less-hyped, but quickly emerging concept within Industry 4.0.

Creating a fully integrated lab of the future that adopts modern technologies andpractices, and is data-driven, enables manufacturers to develop, manage and maintain quality standards throughout their supply chains.

As a subset of Industry 4.0, the development of analytical methods alongside the product developments assumes a significant importance, and it is expected that the tools of digitisation are used in developing robust, simplified and validated test methods. These methods have to be transferrable and have to be integrated in the smart lab of the future.

The big pharma companies have adopted these technologies in building digitised and automated labs and have improved operational efficiency in terms of savings up to 40 per cent of the cost. The concept of distributed labs is being used in supporting the continuous manufacturing technologies for providing realtime on-line feedback on key quality parameters.

Role of regulators

The role of the regulators and the government is equally important in providing an ecosystem that encourages and facilitates innovation. During the development of COVID vaccine and related drugs, we have seen the regulators world over adopting flexibilities in the process of:

- approval of new products for emergency use,
- providing GMP flexibilities in terms of accepting remote /virtual inspections,
- extension of validity periods of GMP certificates, etc.

The learnings from this period can be leveraged to introduce simplified regulatory processes by adopting a risk based approach. The industry and the regulators have to work together to bring such approaches in practice for alleviating the concerns about compromise to patient safety.

Adaptive challenges

The adoption of new innovative technologies of this scale is a transformational change that requires a huge capital investment and a compelling business case. Besides, we need to have a qualified team with the required capabilities for such adoption.

This is an adaptive challengemore than a technical challenge since we have to break the barrier of inherent immunity to change that exists in us and in our systems.

Therefore, it is important that digitalisation initiatives are built within the company's quality system. This requires a leadership team with systems' thinking abilities to appreciate that a modern pharma quality system integrates all five manufacturing systems to operate within and interact with each other.

Improving a part taken separately will not improve the whole system, but, at times, can damage it. Any improvement implemented outside of a QMS willnot be scalable and sustainable. Therefore, we need to focus not only on a small q (QC) but a BIG Q (Quality System).

We cannot do today's work with yesterday's methods and still be hopeful to succeed tomorrow. What brought us here will not take us any further if we do not focus on innovation. Innovation is the key to success for the pharma industry.

Automation and digitalisation will not replace humans, but instead augment the human capability. It is this integration of human capabilities with technology that will lead to beneficial results that neither humans nor technology can alone deliver.

Source: Express Pharma, April 2022

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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
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