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IDMA BULLETIN

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Indian APIs & Formulations for Global Healthcare

INDIAN DRUG MANUFACTURERS' ASSOCIATION

HIGHLIGHTS

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IDMA BULLETIN

Vol. No. 53 **Issue No. 02** **08 to 14 January 2022**

Dr Viranchi Shah address as IDMA's National President, at Annual General Meeting held on 06th January, 2022

Respected Shri Mahesh Doshi, Past National Presidents, Shri Deepnath Roy Chowdhury, Shri S V Veeramani, Shri Yogin Majmudar, Dr. Gopakumar G Nair; also Shri Dinesh Dua Past Chairman Pharmexcil, Shri B R Sikri- Chairman FOPE, Shri Vinod Kalani- President FOPE, Shri Uday Bhaskar- DG Pharmexcil, Members of the National Executive Committee, Incoming Honorary Secretary Shri Mehul Shah, Outgoing Honorary Secretary Dr. George Patani, Incoming Senior Vice President Shri Bharat Shah, Shri Daara Patel Secretary General, Shri Ashok Madan Executive Director, State Board Chairmen, Members of Executive Committee of State boards, Members of IDMA and friends.

Good afternoon, it's a privilege and a great honor for me on being elected to this very prestigious position of the National President of IDMA for the years 2022 and 2023.

It has been a particular pleasure for me, in getting the opportunity to work as Senior Vice President under the leadership of Shri Maheshbhai Doshi. I congratulate him and the entire team of the Office Bearers and Executive Committee, who have work hard under his leadership during the last two years. His tenure was particularly very challenging, with disruptions that were never witnessed in the past. I applaud him for the work he did to ensure that the Pharma Industry's activities and its supply chain were maintained. In the deepest of health crises, the Indian industry could continue its supply of critical drugs, which helped Nations manage the health crises better. I have seen him ensuring that important issues were escalated to the right people in the power, so that our commitment towards the society as a responsible wing of healthcare sector could be upheld. Sometimes he has been trending multiple virtual meetings in a day, all to ensure that our views are heard. Thank you Maheshbhai, Dr. George and the entire team.

End of 2021, we all witnessed a big spike in global covid cases. Most remarkable are the US cases of over 1 Mn on two consecutive dates. The global covid dashboard suggests that almost 4.5Mn people have lost lives due to covid in last 2 years. Imagine if we had a similar dashboard for other diseases; it might show that we lose almost 10Mn people annually due to cancer and another 1.5Mn due to diabetes. This is despite the fact that the Pharma and Healthcare Industry, and the Governments & Regulators are working very hard and that the life expectancy has improved considerably. I take two indications from these numbers - one that mortalities could have been much more, had the pharma and healthcare industry not evolved over the years, and second that there is a lot more to be done.

We are happy that we contribute to years of better, longer and healthier life for millions of people worldwide. As IDMA- perhaps the world's largest Association of pharma manufacturers we are proud to be actively contributing. We build and run businesses that employ

hundreds of thousands of talented and skilled people. This industry drives billions of dollars of Indian economy every year and earns significant amounts of foreign exchange for India. Our Industry has sharpened India's competitive edge. And over and above all, we add smiles to millions of faces every day. My most important task for the next 2 years is to take this legacy forward.

We know that looking backwards is easy and there is no risk in it. It is difficult to look far forward, to come out of comfort zone and to do something that is entirely new. Experts believe that the events of recent years have accelerated many changes in this industry, and our future is far more interesting, but it surely will not come easy. The global pharmaceutical markets are likely to grow faster than in the past. With the focus shifting from illness to wellness, the market is likely to grow faster. Initiatives like Atmanirbhar Bharat, Pradhan Mantri Jan Aushadhi Pariyojna and Ayushman Bharat will further propel this growth in India. The Indian industry is poised to grow from USD 45Bn to USD 130Bn by 2030 at a CGR of over 12%.

However we also have other emerging manufacturing economics that can eat the global generic markets. Over dependence on generics itself is a big challenge for India, and we need to shift our efforts higher up the value chain in coming years in order to grab these growth opportunities. Focus on Innovation, NDDS, Complex Generics, bringing home APIs through PLIs, could be some important steps we must focus on. Accelerated use of digitalization, automation and AI across the value chain is likely to bring changes in the way we transact out business.

The Indian Pharmaceutical Industry has the potential to outperform the most optimistic observers forecast. Of course, that needs serious efforts from all of us.

I have designed my plan for the next 2 years in form of 4 main actionpoints that I have defined under acronym**"RITE"**. RITE= R stands for Regulatory Reforms, I stands for Innovation, T stands for Team Building and E stands for Entrepreneurship.

Regulatory Reforms

The policy choices that we make today shall have big ramifications on our success tomorrow. Under my leadership, IDMA shall continue to work closely with the government, with regulators and with other stakeholders. When given a chance by regulators and government to participate or review, we shall try to ensure that balanced and progressive policies that are derived keeping in mind the national interests,industry's views and interest of patients. We shall continue to drive our efforts in requesting reforms aimed at decriminalization of minor offenses under certain laws, reduction in compliance burden, revision of the Schedule M to make it more guideline driven, prospective implementation of price revisions, introduction of legit entities under the NDPS, etc. are highlighted for review. The Regulatory affairs committee, the Pricing /Consumer Affairs Committee, the NDPS Committee and the Nutraceuticals Committee headed by subject experts may please devise a plan. We will make our representations in such a way that the Nation's need for affordability and quality is kept in mind and that the policies promote ease of doing business.

Innovation

I believe that research and innovation capabilities shall play an important role in the growth of this industry in coming years. If we want to achieve the target of 130 Bnby 2030, we shall have to integrate innovation and R&D as part of our growth strategy. We shall have a new Committee to focus on Innovations and R&D initiatives at IDMA. This committee will help the industry towards innovation, and shall also participate with regulators on policy making.

Team building and networking.

In these very challenging yet interesting times, collaborative efforts shall be the key to how we progress. Under my leadership I will take definitive steps to forge collaboration within the Industry and beyond. I wish to set up a digital initiative task force, in order to create a digital interface exclusively for our members. If a particular member wishes to collaborate with another, wants to find an injection manufacturer with a particular approval or accreditation our database should help; if you need to find a specific API supplier our database should help, if you have a question or query IDMA's chatbot could help. This will help IDMA members in their businesses. I also wish to drive membership initiatives through our membership committee and hope that we can increase our membership by at least 20% for next 2 years. I will also request each State board chairmen to help in this initiative. Being the Pharmacy of the world, we have global interest. I propose to invite Pharma entrepreneurs of Indian origin settled in different countries, to become

our ambassadors, so that if any of our members need some information or help in a specific country or region, we could leverage on them.

Entrepreneurship

We wish to focus on supporting entrepreneurs. I understand many of our members are looking forward to unlock their brand or corporate values. Many entrepreneurs are in the process of making new investments in brown field or green field projects. Many SME members need help in finding vision beyond next 5-7 years and in helping them unlock their hidden value to fund the actions towards that vision. We propose to take help of consultants, global leaders and successful entrepreneurs in helping other members progress. We can use resources such as Shri Dushyantbhai, Shri Mehulbhai and Shri Niravbhai to help in value creation plan. I urge our member entrepreneurs who are successful in various verticals to come forward and help other entrepreneurs who are a part of IDMA.

As a short term measure, I am also setting up an Emergency Response Team that will address the IDMA's response on the crises posed by the pandemic.

As we enter deeper into the crises, the situation may become more volatile, we shall definitely keep adjusting our path and efforts so that we ultimately can push this industry forward.

Let's all be optimistic about India and IDMA in the years to come. We shall prevail and succeed.

Once again thank you for the honor that you have bestowed on me.

Jai Hind.

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IDMA HOLIDAYS FOR THE YEAR 2022

1.	**26th January**	Wednesday	Republic Day
2.	**1st March**	Tuesday	Mahashivaratri
3.	**18th March**	Friday	Holi (Second Day)
4.	**15th April**	Friday	Good Friday
5.	**16th May**	Monday	Buddha Purnima
6.	**15th August**	Monday	Independence Day
7.	**19th August**	Friday	Janmasthami (Dahi Handi)
8.	**31st August**	Wednesday	Ganesh Chaturthi
9.	**5th October**	Wednesday	Dassera
10.	**24th October**	Monday	Diwali (Laxmi Pujan)
11.	**25th October**	Tuesday	Diwali (Balipratida)
12.	**26th October**	Wednesday	Diwali (Bhau Beej)

January 13, 2022

Daara B Patel
Secretary - General

US FDA Registration Requirements - reg.

IDMA have received email communication dated 13th January 2022 from Mr Dhruv Shah, Medical Product Safety Coordinator, India Office, Office of Global Policy and Strategy, U.S. Embassy New Delhi, U.S. Food and Drug Administration on the above subject.

Greetings from US FDA India Office!

During our last meeting we discussed publishing the FDA registration requirements in IDMA bulletin for general awareness amongst the members. The following is the information we have compiled for publishing:

"United States law and regulation requires any establishment in any country which manufactures prepares, propagates, compounds, or processes a drug that is imported or offered for import into the US to register with the FDA, and to renew that registration annually during the period beginning on October 1 and ending on December 31 each year. Registration with the FDA includes the submission of a drug product listing, prior to importation, for each drug it ships to the US. This includes both finished and unfinished bulk drugs, including active pharmaceutical ingredients. Further, drug listing data should be reviewed and updated regularly. During the registration period of October 1 through December 31 each year, establishments must review their drug listing data on file with the FDA, and either submit updates for any changes to the data or certify that the data is up to date since the last review. For more information and assistance with drug registration and listing submissions, visit Electronic Drug Registration and Listing System (eDRLS) and Human Drug establishment registration and drug listing compliance course.

Kindly note that newly registered facilities in India may be contacted by a representative from the FDA India Office for vetting of the registration details"

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DoP MATTERS

Information about Exports to various countries - reg.

Dear Members,

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

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

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

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

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

Looking forward to your prompt positive response.

Thanks & regards,

Daara B Patel
Secretary – General

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Notification No.08/2017 - Integrated Tax (Rate), dated the 28th June 2017 amended - reg.

GST Integrated Tax (Rate) Notification No.22/2021, dated 31st December 2021 :

1. In exercise of the powers conferred by sub-sections (1), (3) and (4) of section 5, sub-section (1) of section 6 and clauses (iii), (iv) and (xxv) of section 20 of the Integrated Goods and Services Tax Act, 2017 (13 of 2017), read with sub-section (5) of section 15, sub-section (1) of section 16 and section 148 of the Central Goods and Services Tax Act, 2017 (12 of 2017), the Central Government, on being satisfied that it is necessary in the public interest so to do, on the recommendations of the Council, and in supersession of notification of the Government of India in the Ministry of Finance (Department of Revenue), No.15/2021–Integrated Tax (Rate), dated the 18th November, 2021, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), vide number G.S.R.808(E), dated the 18th November, 2021, hereby makes the following amendments in the notification of the Government of India, in the Ministry of Finance (Department of Revenue), No.8/2017-Integrated Tax (Rate), dated the 28th June, 2017, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), vide number G.S.R.683(E), dated the 28th June, 2017, namely:-

In the said notification, in the TABLE, against serial number 3,-

1) in column (3), in the heading "Description of Service", in items (iii), (vi), (ix) and (x), for the words and symbols "Union territory, a local authority, a Governmental Authority or a Government Entity" the words and symbols "Union territory or a local authority" shall be substituted;

2) in column (3), in the heading "Description of Service", in item (vii), for the words and symbols "Union territory, local authority, a Governmental Authority or a Government Entity" the words and symbols "Union territory or a local authority" shall be substituted;

3) in column (5), in the heading "Condition", the entries against items (iii), (vi), (vii), (ix) and (x), shall be omitted.

2. This notification shall come into force with effect from the **1st day of January, 2022.**

F.No.354/79/2021-TRU

Gaurav Singh, Deputy Secretary, Ministry of Finance, Department of Revenue, New Delhi.

Note: *The principal notification No.08/2017-Integrated Tax (Rate), dated the 28th June, 2017 was published in the Gazette of India, Extraordinary, vide number G.S.R.683(E), dated the 28th June, 2017 and last amended by notification No.06/2021-Integrated Tax (Rate), dated the 30th September, 2021 vide number G.S.R.689(E), dated the 30th September, 2021*

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Notification No.11/2017 - Central Tax (Rate), dated the 28th June 2017 amended - reg.

GST Central Tax (Rate) Notification No.22/2021, dated 31st December 2021

1. In exercise of the powers conferred by sub-section (1), sub-section (3) and sub-section (4) of section 9, sub-section (1) of section 11, sub-section (5) of section 15, sub-section (1) of section 16 and section 148 of the Central Goods and Services Tax Act, 2017 (12 of 2017), the Central Government, on being satisfied that it is necessary in the public interest so to do, on the recommendations of the Council, and in supersession of notification of the Government of India in the Ministry of Finance (Department of Revenue), No.15/2021–Central Tax (Rate), dated the 18th November, 2021, published in the Gazette

of India, Extraordinary, Part II, Section 3, Sub-section (i), vide number G.S.R.807(E), dated the 18th November, 2021, hereby makes the following amendments in the notification of the Government of India, in the Ministry of Finance (Department of Revenue) No.11/2017-Central Tax (Rate), dated the 28th June, 2017, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), vide number G.S.R.690(E), dated the 28th June, 2017, namely:-

In the said notification, in the TABLE, against serial number 3,-

1) in column (3), in the heading "Description of Service", in items (iii), (vi), (ix) and (x), for the words "Union territory, a local authority, a Governmental Authority or a Government Entity" the words "Union territory or a local authority" shall be substituted;

2) in column (3), in the heading "Description of Servicell, in item (vii), for the words "Union territory, local authority, a Governmental Authority or a Government Entity" the words "Union territory or a local authority" shall be substituted;

3) in column (5), in the heading "Conditionll, the entries against items (iii), (vi), (vii), (ix) and (x), shall be omitted.

2. This notification shall come into force with effect from the **1st day of January, 2022.**

F.No.354/79/2021-TRU

Gaurav Singh, Deputy Secretary, Ministry of Finance, Department of Revenue, New Delhi.

Note: *The principal notification No .11/2017-Central Tax (Rate), dated the 28th June, 2017 was published in the Gazette of India, Extraordinary, vide number G.S.R.690(E), dated the 28th June, 2017 and last amended by notification No.06/2021-Central Tax (Rate), dated the 30th September, 2021 vide number G.S.R.687(E), dated the 30th September, 2021*

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Guidelines for recovery proceedings under the provisions of section 79 of the CGST Act, 2017 in cases covered under explanation to sub-section (12) of section 75 of the CGST Act, 2017 - reg.

GST Instruction No.01/2022-GST, dated 07th January 2022

To,
The Principal Chief Commissioners/Chief Commissioners/ Principal Commissioners/
Commissioners of Central Tax (All)
The Principal Directors General/Directors General (All).

1. Sub-section (12) of section 75 of the CGST Act, 2017 (hereinafter referred to as "the Act") provides that notwithstanding anything contained in section 73 or section 74 of the Act, where any amount of self-assessed tax in accordance with the return furnished under section 39 remains unpaid, either wholly or partly, or any amount of interest payable on such tax remains unpaid, the same shall be recovered under the provisions of section 79. An explanation has been added to sub-section (12) of section 75 vide section 114 of the Finance Act, 2021 with effect from 01.01.2022 to clarify that "self-assessed tax" shall include the tax payable in respect of outward supplies, the details of which have been furnished under section 37, but not included in the return furnished under section 39.

2. Doubts are being raised by the trade and the field formations regarding modalities for initiation of the recovery proceedings under section 79 of the Act in the cases covered under the explanation to sub-section (12) of section 75 of the Act. In view of the above, the following guidelines are hereby issued with respect to the recovery proceedings under section 79 of the Act in such cases.

3.1 Sub-section (12) of section 75 of the Act is reproduced hereunder for reference:

"(12) Notwithstanding anything contained in section 73 or section 74, where any amount of

self-assessed tax in accordance with a return furnished under section 39 remains unpaid, either wholly or partly, or any amount of interest payable on such tax remains unpaid, the same shall be recovered under the provisions of section 79.

Explanation *- For the purposes of this sub-section, the expression "self-assessed tax" shall include the tax payable in respect of details of outward supplies furnished under section 37, but not included in the return furnished under section 39."*

*From the perusal of th*e above provision, it is clear that where the tax payable in respect of details of outward supplies furnished by the registered person in GSTR-1, has not been paid through GSTR-3B return, either wholly or partly, or any amount of interest payable on such tax remains unpaid, then in such cases, the tax short paid on such self-assessed and thus self-admitted liability, and the interest thereon, are liable to be recovered under the provisions of section 79.

3.2 There may, however, be some cases where there may be a genuine reason for difference between the details of outward supplies declared in GSTR-1 and those declared in GSTR-3B. For example, the person may have made a typographical error or may have wrongly reported any detail in GSTR-1 or GSTR-3B. Such errors or omissions can be rectified by the said person in a subsequent GSTR-1/ GSTR-3B as per the provisions of sub-section (3) of section 37 or the provisions of sub-section (9) of section 39, as the case may be. There may also be cases, where a supply could not be declared by the registered person in GSTR-1 of an earlier tax period, though the tax on the same was paid by correctly reporting the said supply in GSTR-3B. The details of such supply may now be reported by the registered person in the GSTR-1 of the current tax period. In such cases, there could be a mis-match between GSTR-1 and GSTR-3B (liability reported in GSTR-1> tax paid in GSTR-3B) in the current tax period. Therefore, in all such cases, an opportunity needs to be provided to the concerned registered person to explain the differences between GSTR-1 and GSTR-3B, if any, and for short payment or non-payment of the amount of self-assessed tax liability, and interest thereon, before any action under section 79 of the Act is taken for recovery of the said amount.

3.3 Accordingly, where ever any such amount of tax, self-assessed by the registered person in his outward supply statement GSTR-1 is found to be short paid or not paid by the said person through his GSTR-3B return in terms of the provisions of sub-section (12) of section 75 of the Act, the proper officer may send a communication (with DIN, in terms of guidelines issued vide Circular No.122/4112019-GST dated 5th November 2019) to the registered person to pay the amount short paid or not paid, or to explain the reasons for such short payment or non-payment of self-assessed tax, within a reasonable time, as prescribed in the communication. If, the concerned person is able to justify the differences between GSTR-1 and GSTR-3B, or is able to explain the reasons of such short-payment or non-payment of tax, to the satisfaction of the proper officer, or pays the amount such short paid or not paid, then there may not be any requirement to initiate proceedings for recovery under section 79.

3.4 However, if the said registered person either fails to reply to the proper officer, or fails to make the payment of such amount short paid or not paid, within the time prescribed in the communication or such further period as may be permitted by the proper officer, then the proceedings for recovery of the said amount as per provisions of section 79 may be initiated by the proper officer. Further, where the said registered person fails to explain the reasons for such difference/ short payment of tax to the satisfaction of the proper officer, then the proper officer may proceed for recovery of the said amount as per provisions of section 79.

4. Difficulty, if any, in implementation of the above guidelines may please be brought to the notice of the Board.

CBEC-20/16/05/2021-GST/23

Sanjay Mangal, Principal Commissioner (GST), Central Board of Indirect Taxes and Customs, GST Policy Wing, Ministry of Finance, Department of Revenue, New Delhi

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Sea Cargo Manifest and Transhipment Regulations, 2018 amended (Ninth Amendment of 2021)

Notification No.109/2021-Customs (N.T.) dated 31st December 2021

In exercise of the powers conferred by section 157, read with sections 30, 30A, 41, 41A, 53, 54, 56, sub-section (3) of section 98 and sub-section (2) of section 158 of the Customs Act, 1962 (52 of 1962), the Central Board of Indirect Taxes and Customs hereby makes the following regulations further to amend the Sea Cargo Manifest and Transhipment Regulations, 2018, namely:-

1. Short title and commencement:

(1) These regulations may be called the Sea Cargo Manifest and Transhipment (Ninth Amendment) Regulations, 2021.

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

2. In the said regulations, in regulation 15,-

a. in sub-regulation (2), for the words, figures and letters, "till 31st December 2021, 2021", the words, figures and letters, "till 30th June 2022" shall be substituted.

F.No.450/58/2015- Cus IV(Pt)

Manish Kumar Choudhary, Under Secretary, Central Board of Indirect Taxes and Customs, Ministry of Finance, Department of Revenue, New Delhi

Note : *The principal regulations were published in the Gazette of India, Extraordinary, Part II, Section 3 Sub-section (i) vide number G.S.R.448(E), dated the 11th May, 2018 and were last amended vide notification No. 78/2021-Customs (N.T), dated the 30th September, 2021 vide number G.S.R. 677(E), dated the 30th September, 2021.*

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Notification No.45/2021-Customs, dated 29th September 2021 amended - reg.

Notification No.61/2021-Customs dated 31st December 2021

In exercise of the powers conferred by sub-section (1) of section 25 of the Customs Act, 1962 (52 of 1962), the Central Government, on being satisfied that it is necessary in the public interest so to do, hereby makes the following amendment in the notification of the Government of India, in the Ministry of Finance (Department of Revenue), No. 45/2021-Customs, dated the 29th September, 2021, published in the Gazette of India, Extraordinary, Part II, Section 3, Subsection (i), vide number G.S.R.672(E), dated the 29th September, 2021, namely:-

In the said notification, in paragraph 2, for the figures, letters and word "31st December, 2021", the figures, letters and word "30th June, 2022" shall be substituted.

F.No.CBIC-190354/66/2021-TO(TRU-I)-CBEC

Gaurav Singh, Deputy Secretary, Department of Revenue, Ministry of Finance, New Delhi

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Companies (Registration Offices and Fees) Rules, 2014 amended (1st Amendment of 2022) - reg.

Corporate Affairs Notification G.S.R.12(E) dated 11th January 2022

(Published in the Gazette of India on 12th January, 2022)

In exercise of the powers conferred by sections 396, 398, 399, 403 and 404 read with sub sections (1) and (2) of section 469 of the Companies Act, 2013 (18 of 2013), the Central Government hereby makes the following rules further to amend the Companies (Registration Offices and Fees) Rules, 2014, namely:-

1. Short title and commencement.

(1) These rules may be called the **Companies (Registration Offices and Fees) Amendment Rules, 2022.**

(2) They shall come into force **with effect from 1st July, 2022.**

2. In the Companies (Registration Offices and Fees) Rules, 2014, in the Annexure, in item I (Fee for filing under section 403 of the Companies Act, 2013), for sub-item B, the following sub-item shall be substituted, namely:-

"B. Following Table of additional fee and higher additional fee (in certain cases) shall be applicable for delay in filing of forms other than for increase in Nominal share capital or forms under section 92/137 of the Act or forms for filing charges.

TABLE

Sr. No.	Period of delays	Additional fee as a multiple of normal fees	Higher additional fee as a multiple of normal fees (for certain cases)
(1)	(2)	(3)	(4)
1	Upto 15 days (sections 139 and 157)	One time of normal fees	-
2	More than 15 days and upto 30 days (Section 139 and 157) and upto 30 days in remaining forms.	2 times of normal filing fees	3 times of normal filing fees
3	More than 30 days and upto 60 days	4 times of normal filing fees	6 times of normal filing fees
4	More than 60 days and upto 90 days	6 times of normal filing fees	9 times of normal filing fees
5	More than 90 days and upto 180 days	10 times of normal filing fees	15 times of normal filing fees
6	Beyond 180 days	12 times of normal filing fees	18 times of normal filing fees

Note 1: *Higher additional fees shall be payable, if there is a delay in filing e-form INC-22, or e-form PAS-3, as the case may be, on two or more occasions, within a period of three hundred and sixty five days from the date of filing of the last such belated e-form for which additional fee or higher additional fee, as the case may be, was payable.*

Note 2: *Wherever higher additional fee is payable, additional fee shall not be charged.*

Note 3: *E-form INC-22, or e-form PAS-3, as the case may be, filed prior to the commencement of the Companies (Registration Offices and Fees) Amendment Rules, 2022 shall not be reckoned for the purposes of determining higher additional fee.*

F. No. 01/16/2013 CL-V (Pt-I)

K V R Murty, Joint Secretary, Ministry of Corporate Affairs, New Delhi.

Note: *The principal rules were published in the Gazette of India, Part II, Extra ordinary, Section 3, Sub-section (i) vide number G.S.R.268(E), dated the 31st March, 2014 and subsequently amended by:-*

Serial Number	Notification Number	Notification Date
1.	G.S.R. 297(E)	28-04-2014
2.	G.S.R. 122(E)	24-02-2015
3.	G.S.R. 438 (E)	29-05-2015
4.	G.S.R. 493(E)	06-05-2016
5.	G.S.R. 48(E)	20-01-2018
6.	G.S.R. 435(E)	07-05-2018
7.	G.S.R.616 (E)	05-07-2018
8.	G.S.R.797 (E)	21-08-2018
9.	G.S.R.905(E)	20-09-2018
10.	G.S.R.143 (E)	21-02-2019
11.	G.S.R.329 (E)	25-04-2019
12.	G.S.R.340 (E)	30-04-2019
13.	G.S.R. 527(E)	25-07-2019
14.	G.S.R. 749(E)	30-09-2019
15.	G.S.R. 127(E)	18-02-2020
16.	G.S.R. 170(E)	12-03-2020

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Provisions of second and third proviso of section 80(i) of the Companies (Amendment) Act, 2017 enforced w.e.f. 01st July, 2022 - reg.

Corporate Affairs Notification S.O.147(E), dated 11th January 2022

(Published in the Gazette of India on 12th January, 2022)

In exercise of the powers conferred by sub-section (2) of section 1 of the Companies (Amendment) Act, 2017 (1 of 2018), the Central Government hereby appoints the 1st July, 2022, as the date on which the provisions of second and third proviso to clause (i) of section 80 of the said Act shall come into force.

F.No.1/1/2018-CL.I

K V R Murty, Joint Secretary, Ministry of Corporate Affairs, New Delhi.

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Provisions of section 56 of the Companies (Amendment) Act, 2020 enforced w.e.f. 01st July, 2022 - reg.

Corporate Affairs Notification S.O.148(E), dated 11th January 2022

(Published in the Gazette of India on 12th January, 2022)

In exercise of the powers conferred by sub-section (2) of section 1 of the Companies (Amendment) Act, 2020 (29 of 2020), the Central Government hereby appoints the 1st July, 2022, as the date on which the provisions of section 56 of the said Act shall come into force.

F.No.1/3/2020-CL.I.

K V R Murty, Joint Secretary, Ministry of Corporate Affairs, New Delhi.

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Central Government delegates its powers to the National Financial Reporting Authority - reg.

Corporate Affairs Notification S.O.35(E), dated 04th January 2022

In exercise of the powers conferred by sub-section (1) of section 458 of the Companies Act, 2013 (18 of 2013), the Central Government hereby delegates its powers under sub-section (11) of section 132 of the said Act to the National Financial Reporting Authority for the purpose of the appointment to the posts of Chief General Manager (CGM), General Manager (GM), Deputy General Manager (DGM), Assistant General Manager (AGM), Manager, Assistant Manager, Personal or General Assistant, Sr. PS., Private Secretary and Driver in the said Authority.

F.No.NFRA-05/9/2021-Comp-MCA

K.V.R. Murty, Joint Secretary, Ministry of Corporate Affairs, New Delhi

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GOVERNMENT NOTIFICATIONS

Acrylonitrile Butadiene Styrene (ABS) (Quality Control) Order, 2021 amended (First Amendment of 2022) - reg.

Chemicals & Fertilizers Notification S.O.88(E), dated 07th January 2022

In exercise of the powers conferred by section 16 read with Sub-section (3) of section 25 of the Bureau of Indian Standards Act, 2016 (11 of 2016), (hereinafter referred to as the said Act), 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 to amend the Acrylonitrile Butadiene Styrene (ABS) (Quality Control) Order, 2021, namely:-

1. Short title, commencement and application

(1) This order may be called the **Acrylonitrile- Butadiene Styrene (ABS) (Quality Control) Amendment Order, 2022.**

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

2. In the Acrylonitrile- Butadiene Styrene (ABS) (Quality Control) Order, 2021, the Table in para 4, shall be substituted as under:

Goods or articles	Indian Standard	Title of Indian Standard
(1)	(2)	(3)
Acrylonitrile Butadiene Styrene (ABS)	IS 17077 : 2019/ ISO 19062-1 : 2015	Plastic - Acrylonitrile - Butadiene styrene (ABS) Moulding and Extrusion Materials Part 1 Designation System and Basis for Specification

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

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

Note: *The principle order was published in the Gazette of India, Extraordinary, Part II, Section 3, Sub section (ii) vide notification number S.O.3927 Dated 13th September, 2021.*

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Polyurethanes (Quality Control) Order, 2021 amended (First Amendment of 2022)

Chemicals & Fertilizers Notification S.O.89(E), dated 07th January 2022

In exercise of the powers conferred by section 16 read with Sub-section (3) of section 25 of the Bureau of Indian Standards Act, 2016 (11 of 2016), (hereinafter referred to as the said Act), 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 to amend the Polyurethanes (Quality Control) Order, 2021, namely:-

1. Short title, commencement and application:

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

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

2. In the Polyurethanes (Quality Control) Order, 2021, the Table in para 4, shall be substituted as under:

Goods or articles	Indian Standard	Title of Indian Standard
(1)	(2)	(3)
Polyurethanes	IS 17397 (Part 1) : 2020/ ISO 16365-1 : 2014	Plastic – Thermoplastic Polyurethanes for Moulding and Extrusion Materials Part 1 Designation System and Basis for Specification

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

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

Note: *The principle order was published in the Gazette of India, Extraordinary, Part II, Section 3, Sub section (ii) vide notification number S.O.3931 Dated 13th September, 2021.*

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The State Level Environment Impact Assessment Authority, Tamil Nadu constituted - reg.

Environment Notification S.O.146(E), dated 11th January 2022

1. In exercise of the powers conferred by sub-section (3) of section 3 of the Environment (Protection) Act, 1986 (29 of 1986) and in pursuance of the notification of the Government of India, in the erstwhile Ministry of Environment and Forests, number S.O.1533(E), dated the 14th September, 2006 (hereinafter referred to as the said notification), and in supersession of the notification of the Government of India, in the Ministry of Environment, Forest and Climate Change, number S.O.5651, dated the 5th November, 2018, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (ii), except as respects things done or omitted to be done before such supersession, the Central Government hereby constitutes the State Level Environment Impact Assessment Authority, Tamil Nadu (hereinafter referred to as the Authority, Tamil Nadu) comprising of the following Members, namely:-

1	Dr. N. Krishnakumar, IFS (Retired), G/3/1, TAISHA AIS Housing Complex, Natesan Nagar West 3rd Street, Virugambakkam, Chennai-600092	Chairman;
2	Dr. S. Ganapathy Venkatasubramanian, B-189, 5th Link Road, Ammaa Ashram, Madras University Staff Colony, Palkalai Nagar, Palavakkam, Chennai-600041	Member;
3	Director of Environment, Chennai f 600 015	Member Secretary.

2. The Chairman and Members of the Authority, Tamil Nadu shall hold office for a term of three years from the date of publication of this notification in the Official Gazette.

3. The Authority, Tamil Nadu shall exercise such powers and follow such procedures as specified in the said notification.

4. The Authority, Tamil Nadu shall take its decision on the recommendations of the State Level Expert Appraisal Committee constituted under paragraph 5 for the State of Tamil Nadu.

5. For the purpose of assisting the Authority, Tamil Nadu, the Central Government, in consultation with the State Government of Tamil Nadu, hereby constitutes the State Level Expert Appraisal Committee (hereinafter referred to as SEAC), Tamil Nadu comprising of the following Members, namely:-

1	Shri K. Deenabandu, IAS (Retired) 5, Rajarajan Street, Kalakshetra Colony, Besant Nagar, Chennai-600090	Chairman;
2	Shri. K. Kumar, Former JCEE, TNPCB BBCL Vajra, Flat No:12C, Tower No:3, Service Road, Nolambur, Chennai-600037	Member;
3	Dr. B. Gowtham, Assistant Professor & Head, Presidency College, Department of Geology, Presidency College (Autonomous), Chennai-600005	Member;
4	Dr. P. Balamadeswaran, Assistant Professor, Department of Mining Engineering College of Engineering Guindy, Anna University, Chennai-600025	Member;
5	Shri. Velazhagan D, Assistant Environmental Engineer (Retired), TNPCB F1B- Block, New castle apartment, 17/3, Thiruvalluvar Nagar Main Road, Keelkattalai, Chennai-600117	Member;
6	Dr. V. Selvam Former Director, MSSRF 23, Thillai Natarajar Road, Kanagasabai Nagar, Chidambaram -608001	Member;

7	Dr. G. Anne Josephine Selvam, Manager (Retired), TNPCB Plot No.59, West Main Road, Balaji Nagar, Madambakkam, Chennai 600126	Member;
8	Shri. K.S.S.V.P. Reddy, IFS (Retired), C/902, TAISHA Housing Complex, Near Natesan Nagar, Virugambakkam, Chennai-600092	Member;
9	Shri R. Thangaprakasam, Former CE, Public Works Department, HIG 26/TNHB Apartments, 4th Avenue, Indra Nagar, Adyar 600020	Member;
10	Dr. Kurian Joseph, Professor of Environmental Engineering Centre of Environmental Studies, Anna University, Chennai-600025	Member;
11	Dr. D. Narasimhan, Associate Professor (Rtd), Madras Christian college (Autonomous), Tambaram 5, Santhana Lakshmi Street, Rajeswari Nagar, Selaiyur, Chennai - 600 059.	Member;
12	Dr. Ramasubramaniyan, Executive Director, National Aqua Foundation. Flat B-4, Sri Jal Ganapathy Flats, 9/4, School Street, Radhanagar, Chromepet, Chennai-600044	Member;
13	Dr. Kavi Kumar, Professor, Madras School of Economics Chennai-600025	Member;
14	Member Secretary, Tamil Nadu Pollution Control Board, Guindy, Chennai- 600 032	Member Secretary.

6. The Chairman and Members of SEAC, Tamil Nadu shall hold office for a term of three years from the date of publication of this notification in the Official Gazette.

7. The SEAC, Tamil Nadu shall exercise such powers and follow such procedures as specified in the said notification.

8. The SEAC, Tamil Nadu shall function on the principle of collective responsibility and the Chairman shall endeavour to reach a consensus in each case, and if consensus cannot be reached, the view of the majority shall prevail.

9. In order to avoid any conflict of interest –

   a. the Chairman and Members of the Authority, Tamil Nadu and SEAC, Tamil Nadu shall declare as to which consulting organisation they have been associated with and also the project proponents;

   b. the Chairman and Members of the Authority, Tamil Nadu and SEAC, Tamil Nadu shall not undertake any consultation or associate with preparation of Environmental Impact Assessment (EIA) Environment Management Plan for a project, which is to be appraised by the Authority, Tamil Nadu and SEAC, Tamil Nadu during their tenure; and

   c. if in the past five years, the Chairman or any of the Members of the Authority, Tamil Nadu and SEAC, Tamil Nadu have provided consultancy services or conducted EIA studies for any project proponent, in that event they shall recuse themselves from the meeting of the Authority, Tamil Nadu and SEAC, Tamil Nadu in the process of appraisal of any project being proposed by such proponents.

10. The Government of Tamil Nadu shall notify an agency to act as Secretariat for the Authority, Tamil Nadu and SEAC, Tamil Nadu and the Secretariat shall provide all financial and logistic support including accommodation, transportation and such other facilities in respect of all their statutory functions.

11. The sitting fee, travelling allowances and dearness allowances to the Chairman and Members of the Authority, Tamil Nadu and SEAC, Tamil Nadu shall be paid as per the rules of the State Government of Tamil Nadu.

F.No.IA3-1/4/2021-IA.III

Dr. Sujit Kumar Bajpayee, Joint Secretary, Ministry of Environment, Forest and Climate Change, New Delhi

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Notification Number G.S.R.45(E), dated 19th January 2018 amended - reg.

Environment Notification G.S.R.3(E), dated 04 January 2022

Whereas, sale and use of pet coke in lime kilns in the National Capital Region (NCR) States was notified vide notification of the Government of India in the Ministry of Environment, Forest and Climate Change, number G.S.R.45(E), dated the 19th January, 2018, wherein sale of pet coke are made only to the industrial units mentioned in the list annexed to the said notification as Annexure and any change in the said list shall be made on the recommendation of the concerned State Government and with the approval of the Central Pollution Control Board;

And whereas, on the recommendation of the State Government of Rajasthan, the Central Pollution Control Board has approved further addition of two units of seven lime kilns in the Annexure of the said notification.

Now, therefore, in exercise of the powers conferred by sub-sections (1) and (2) of section 3 of the Environment (Protection) Act, 1986 (29 of 1986), the Central Government hereby makes the following amendments further to amend the said notification, namely:-

In the said notification, in the Annexure, after serial number 446 and the entries relating thereto, the following serial numbers and entries shall be inserted, namely:-

447	M/s. Maa Parwati Lime Works,	K. No. 165, Village- Basni Hari Singh, Tehsil-Bhopalgarh, Distt- Jodhpur, Rajasthan	5	3000	6300	600
448	M/s. Skylar Minerals,	K. No. 1581/529, Prem Nagar, Tehsil-Khinvsar, Distt- Nagaur, Rajasthan	2	1250	2500	250

F.No.Q-16017/04/2018-CPA(pt)

Naresh Pal Gangwar, Joint Secretary, Ministry of Environment, Forest and Climate Change, New Delhi

Note: *The Principle notification was published vide number G.S.R.45(E), dated the 19th January, 2018 and subsequently amended vide notification number G.S.R.495(E), dated the 25th May, 2018, G.S.R.397(E), dated the 31st May, 2019, G.S.R.906(E), dated the 12th December, 2019, G.S.R.113(E), dated the 14th February, 2020, G.S.R.714(E), dated the 13th November, 2020, G.S.R.46(E), dated the 22nd January, 2021 and G.S.R 350(E), dated the 28th May, 2021.*

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Guidelines for submission of online application for One time registration for SCOMET license and Post-reporting requirements for Export of chemicals under General authorization for export of Chemicals and related equipments (GAEC) w.e.f 19.01.2022 – reg.

DGFT Trade Notice No.30/2021-22, dated 13th January 2022

To
1. All IEC Holders,
2. All RAs of DGFT,
3. All Members of Trade & Industry.

1. Reference is invited to DGFT's Notification No. 47 dated 20.12.2021 regarding SCOMET updates 2021 and policy of General authorization for export of Chemicals and related equipments (GAEC) and Public Notice No. 45 dated 13.01.2022 regarding procedure for obtaining authorization under GAEC. Further, attention is also invited to Trade Notice No. 11 dated 26th July 2021.

2. The one time registration for obtaining General SCOMET license is required to be obtained from DGFT for export under General authorization for export of Chemicals and related equipments (GAEC) separately for each Category/Sub-Category (i.e. one general license for each 1C, 1D, 1E, 3D001 and 3D004) falling under this policy. This would provide the Exporters a Unique Authorization/License number for export of Chemicals (Under 1C, 1D, 3D001 and 3D004) to any end user in 42 specified countries and 1E chemicals to Chemical Weapon Convention (CWC) signatory parties with a validity of 5 years. All such applications for one time Registration for obtaining GAEC SCOMET license are required to be filed and submitted through DGFT's online portal w.e.f 19.01.2022.

3. Post Reporting of export of chemicals under General authorization for export of Chemicals and related equipments (GAEC) permitted to specified countries as per DGFT's Notification No.47 dated 20.12.2021 is also required to be filled through DGFT online post-reporting module for exports w.e.f. 19.01.2022

4. All applicant exporters seeking GAEC authorization for SCOMET items are advised to apply online for by navigating to the DGFT website (https://www.dgft.gov.in) -> Services -> Export Management Systems -> License for SCOMET exports -> Apply for New Authorization -> Fresh export under GAEC.

5. Apply online for post-reporting for export under GAEC by navigating to the DGFT website (https://www.dgft.gov.in) -> Services -> Export Management System -> License for SCOMET exports -> Post- reporting of issued SCOMET Export Authorization

6. For any technical support and guidance on this new process, the Help manual & FAQs may be accessed on DGFT Website -> Learn -> Application Help & FAQs.

For any further assistance any of the following channels may be accessed:

I. To raise a service request ticket through the DGFT Helpdesk service under Services -> 'Trade Helpdesk Service'

II. Call the DGFT Toll-free-Helpline number 1800-111-550

III. Send an email to the Helpdesk on dgftedi@gov.in.

7. This issues with the approval of the Competent Authority.

F.No.01/91/180/01/AM22

Nitish Suri, Deputy Director General of Foreign Trade, Directorate General of Foreign Trade, Ministry of Commerce & Industry, Department of Commerce, New Delhi.

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Inclusion of Paragraph 2.79G in the Handbook of Procedures of the Foreign Trade Policy (FTP) 2015-20 to notify the procedure for General Authorisation for Export of Chemicals and related equipment (GAEC)

Public Notice No.45/2015-20, dated 13th January, 2022

1. In exercise of the powers conferred under Paragraph 1.03 of the Foreign Trade Policy (FTP) 2015-20, the Director General of Foreign Trade (DGFT) hereby makes amendment to Handbook of Procedures (HBP) of FTP 2015-20 for inclusion of new entry at Paragraph 2.79G with immediate effect.

2. **After Sub Para** 2.79F of the HBP of FTP 2015-2020, a new entry shall be inserted as under:

"2.79G - General Authorisation for Export of Chemicals and related equipment (GAEC) under SCOMET List

A. **Procedure for grant of General Authorization for Export of Chemicals and related equipment (GAEC)**

I. In respect of export/re-export of SCOMET items under the Categories / Sub Categories of 1C, 1D, 1E, 3D001 and 3D004 (excluding software and technology), the applicant exporter shall submit an application for GAEC through online SCOMET portal and attach information in proforma -ANF 20;

II. The application would be reviewed/examined for the issuance of GAEC bi Inter-Ministerial Working Group (IMWG) based on the submitted application and other supporting documents submitted by the applicant exporter in the prescribed proforma including;

a. Detailed description of the items that are intended to be exported under this authorization with relevant technical details / specifications, such as model, part number, etc. to be provided (as applicable); In case of first intended export of items under the above Categories / Sub Categories, details of the entire supply chain (buyer, consignee, end user, etc.) of an intended export is to be provided. In case of previous exports of items under the above Categories / Sub Categories having been carried out, details of past exports including the EUC is to be provided.

b. Undertaking on the letterhead of the firm duly signed and stamped by the authorized signatory stating the following:

i. Any on-site inspection will be allowed by the applicant exporter, if required by the DGFT or authorized representatives of Government of India;

ii. The applicant exporter declares that the items that are intended to be exported shall not be used for any purpose other than the purpose(s) stated in the EUC and that such use shall not be changed nor the items modified or replicated without the prior consent of the Government of India.;

iii. The applicant exporter declares that subsequent to issue of export authorisation, if the licensee has been notified in writing by DGFT or if they know or has reason to believe that an item may be intended for military end use or has a potential risk of use in or diversion to weapons of mass destruction (WMD) or in their missile system, the exporter would not be eligible for GAEC for export of that/those item(s) and would apply separately to DGFT for a fresh authorization in terms of regular policy.

iv. Action will be taken against the exporter under FT (D & R) Act, 1992 for any mis-declaration.

c. After issuance of GAEC authorization and before actual export, the applicant exporter must ensure the following:

i. They shall notify the relevant

government authorities in the online portal of DGFT, within 30 days of such export in the prescribed format [Aayat Niryat Form (ANF) - 20], along with the End-Use Certificate (EUC) in the pr-scribed proforma [Appendix 2S(ii)] and a copy of the bill of entry into the destination country within 30 days of delivery at destination point.

ii. They have an agreement or a purchase order, excerpt of contract from entity (consignee / end user) receiving the items which states that the export is for a permitted use / an end use as declared in the EUC before actual export;

iii. They possess documents include the name, contact number and email id of the authority signing the EUC before actual export.

iv. Additional details, if any sought by DGFT

B. Post reporting for export / re-export of items under GAEC

a. The Indian exporter shall submit post-shipment details of each export/ re-export of SCOMET items under the above Categories/ sub-categories under GAEC, as mentioned above at II.c. (i) and within the timelines specified therein;

b. Gailure to do so may entail imposition of penalty and / or suspension/revocation of GAEC.

C. Record Keeping

The exporter will be required to keep records of all the export documents, in manual or electronic form, in terms of Para 2.73 (c) of HBP, for a period of 5 years from the date of GAEC issued by DGFT.

D. General Conditions & Exclusions

a. GAEC would riot be issued in case of items to be used to design, develop, acquire, manufacture, possess, transport, transfer and / or used for chemical, biological, nuclear weapons or for missiles capable of delivering weapons of mass destruction and their delivery system;

b. GAEC would not be issued for countries or entities covered under UNSC embargo or sanctions list or on assessment of proliferation concerns, or national security and foreign policy considerations, etc.;

c. IMWG shall reserve the right to deny issue of GAEC without assigning any reason(s).

E. Validity

a. GAEC issued for export / re-export of SCOMET items under the above Categories / Sub Categories (excluding software and technology) shall be valid for a period of **five years** from the date of issue of GAEC subject to subsequent post reporting(s) on quarterly basis to be reported within 30 days from the last quarter;

b. GAEC cannot be revalidated in terms of Paragraph 2.80 of HBP of FTP 2015-20.

F. Suspension / Revocation

GAEC issued shall be liable to be suspended/ revoked by the DGFT on receipt of an adverse report on proliferation concern or for non-submission of mandatory post-shipment details / reports / documents within the prescribed timelines or for non-compliance with the conditions of the proposed policy.

Eftect of this Public Notice:

Paragraph 2.79G has been added in the Handbook of Procedures (HBP) of FTP Foreign Trade Policy (FTP) 2015-20 to lay down the procedure for General Authorisation for Export of Chemicals and related equipments.

F. No. 01/91/180/01/AM22

Amit Yadav, Director General of Foreign Trade, Ex-officio Additional Secretary, Ministry of Commerce & Industry, Department of Commerce, Directorate General of Foreign Trade, New Delhi

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Amendment in Export Policy of Enoxaparin (formulation and API) and Intra-Venous Immunoglobulin (IVIG) (formulation and API) - reg.

Notification No.50/2015-2020, dated 10th January, 2022

1. In exercise of powers conferred by Section 3 read with Section 5 of the Foreign Trade (Development & Regulation) Act, 1992 (No. 22 of 1992), as amended, read with Para 1.02 and 2.01 of the Foreign Trade Policy. 2015-20, the Central Government hereby makes the following amendment in Chapter 29 and 30 of Schedule 2 of the ITCHS Export policy 2018 related to export of Enoxaparin and Intra-Venous Immunoglobulin (IVIG):

S.No	ITC HS Codes	Description	Present Policy	Revised Policy
207AE	Ex2942 Ex3001 Ex3002	Enoxaparin (Formulation and API)	Free	Restricted
207 AF	Ex3002	Intra-Venous Immunoglobulin (IVIG) (Formulation and API)	Free	Restricted

2. Effect of this Notification:

The export of Enoxaparin (Formulation and API) and Intra-Venous Immunoglobulin (IVIG) (Formulation and API) falling under the ITC (HS) Codes specified above or falling under any other HS Code has been put under restricted category, with immediate effect.

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

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Promoting Use of Authentic Copies of the Indian Pharmacopoeia 2018 and its Addenda 2019 & 2021-reg.

No. T.11013/02/2018-AR&D, dated 10th January, 2022

1. In order to fulfill the requirements of the Drugs and Cosmetics (D&C) Act, 1940 and Rules 1945 there under, Indian Pharmacopoeia Commission (IPC) has published the Indian Pharmacopoeia (IP) 2018 and its Addenda 2019 & 2021 on behalf of the Ministry of Health & Family Welfare, Government of India.
2. IPC has been making efforts to promote the use of authorized copies of the IP by its stakeholders and steps are being taken to stop the use of unauthorized copies of the IP. In this regard, the Drugs Controller General (India) vide letter No.12.01/18-DC (Pt-241) dated 24-09-2018 instructed CDSCO Zonal/ Sub-zonal Offices as well as all State/UT Drugs Controllers to ensure the availability of authenticated copies of IP 2018 during inspection of manufacturing premises/laboratories.
3. Moreover, as per Schedule M of the D&C Act, Part I, Quality Control System (16.14) -"Pharmacopoeia reference standards, working standards, references, spectra, other reference materials and technical books, as required, shall be available in the Quality Control Laboratory of the licensee".
4. However, despite all these efforts, the current trends of the sale of IP 2018 and its Addenda do not match with the number of pharmaceutical manufacturers, testing laboratories, and other stakeholders of the IP in the country. Rather, it has been observed that there is tendency among some of the stakeholders to procure counterfeit copies of the IP from dubious sources.
5. Using counterfeit copies of the IP is an illegal act as IP is being published by the IPC on behalf of the Govt. of India and making its copy is an offence under the Copyright Act. Also, such malpractices could be the cause of manufacture and marketing of counterfeit/ spurious drugs in India which may have serious consequences on the health of its citizens.
6. In order to further promote the use of authentic copies of IPC publications, IPC has taken an initiative to trace the details of sold IP sets and letters have been issued to various stakeholders to share with IPC necessary information w.r.t. purchase of IP 2018 or its Addenda. In addition, necessary actions are being taken to stop use of couterfeit copies of the IP.
7. Stakeholders are encouraged to purchase their authentic copies of IP 2018 or its Addenda 2019 & 2021 by visiting IPC website (www.ipc.qov.in) for further details in this regard.

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

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In Lok Sabha & In Rajya Sabha

In Lok Sabha

National Digital Drugs Databank

Lok Sabha Unstarred Question No: 3226

Shri D K Suresh:

Shrimati Sumalatha Ambareesh:

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

(a) whether the Competition Commission of India in a recent report has recommended for the creation of a National Digital Drugs Databank to ensure strict enforcement of drug quality standards and boost price competition among generic drugs in India;

(b) if so, the details thereof, whether the Government has taken any steps/proposes to take steps to create the said databank; and

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

Answered on 17th December 2021

A. (a) to (c): Competition Commission of India has released a report titled "Market Study on the Pharmaceutical Sector in India: Key Findings and Observations", wherein it has been recommended to create a National Digital Drugs Data bank consolidating real-time data on active pharmaceutical manufacturing companies in the country, therapeutic class wise/ formulation-wise approved branded/ unbranded products etc.

Drug and Cosmetics Rules, 1945, implemented by the Ministry of Health & Family Welfare, have already been amended in the year 2019 making it mandatory for manufacturing licensees to register with portal SUGAM operated by the Central Drugs Standard Control Organisation (CDSCO) and upload information pertaining to the licences granted for manufacture for sale or distribution of drugs.

National Pharmaceutical Pricing Authority (NPPA) under the Department of Pharmaceutics, in collaboration with the National Informatics Centre (NIC), has set up a Pharma Data Bank (PDB) through an Integrated Pharmaceutical Database Management System (IPDMS). This comprehensive online system provides a platform to the pharmaceutical manufacturer/marketing importer/ distributor companies to file mandatory returns prescribed under the Drugs (Prices Control) Order, 2013 (DPCO, 2013). The application for price approval of 'new drug' in Form–I of DPCO, 2013 can also be filed through this portal. The portal provides industry with a user-friendly mechanism to comply with the mandatory requirement of filing returns and also help NPPA to monitor price compliance. As on 30th November, 2021, about 975 pharma companies have registered themselves under IPDMS and have registered 86,822 products.

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

Promotion and Expansion of Pharma and Medical Devices Industry

Lok Sabha Unstarred Question No. 3236

Shri Naranbhai Kachhadiya:

Shri Parbatbhai Savabhai Patel:

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

(a) whether there are enormous opportunities for participation in the field of manufacturing of medicine and medical equipments and if so, the details thereof;

(b) the details of expansion of existing pharmaceutical industry undertaken in the country; and

(c) the efforts made/being made by the Government to establish new pharmaceutical industry in the country including Gujarat?

Answered on 17th December 2021

A. (a) to (C): Yes, Sir.

India is the third largest player globally in Pharmaceuticals in terms of volume and is the largest supplier of low cost generics and vaccines to the world. The sector has immense growth potential in the sphere of generics, bulk drugs, vaccines and

biosimilars. The potential for the Medical Device industry growth is the highest among all the sectors in the healthcare market. Various categories of devices starting from consumables to implantable medical devices are being manufactured in India. The Medical Device industry is highly capital intensive with a long gestation period and requires development/induction of new technologies.

The FDI Policy of India is very liberal for the pharmaceutical and medical device sector. For Pharmaceuticals investment in greenfield sector upto 100% is permitted under automatic route while Investment in brownfield sector upto 74% is permitted under automatic route. For medical device sector, investment is permitted upto 100% under automatic route.

The government is also taking steps in the form of various schemes to attract investments in both the sectors. The following are the details of the schemes:

(I) Production Linked Incentive (PLI) Scheme for promotion of domestic manufacturing of critical Key Starting Materials (KSMs)/ Drug Intermediates (DIs) and Active Pharmaceutical Ingredients (APIs) In India: The objective of the Scheme is to attain self-reliance and reduce import dependence in critical Starting Materials (KSMs)/ Drug Intermediates (DIs) and Active Pharmaceutical Ingredients (APIs). The tenure of the sub-scheme is from financial year 2020-21 to 2029-30, with the total financial outlay of Rs.6,940 crore. The Financial incentive under the sub-scheme is provided on sales of 41 identified products categorized into four Target Segments. Under the Scheme, 50 applicants have been approved with committed investment of Rs 4,498.38 crore and employment generation of about 10,743.

(II) Production Linked Incentive Scheme for Pharmaceuticals: The scheme provides for financial incentives to manufacturers for drug formulations, bulk drugs and IVDs in three categories. The incentives are to be given on incremental sales to selected participants for a period of 6 years. The total financial outlay of the scheme is Rs. 15,000 crore and the tenure of the schemes from FY 2020-2021 to 2028-29. Fifty-five (55) applicants have been selected under the scheme.

(III) PLI Scheme for promoting Domestic Manufacturing of Medical Devices: The Scheme intends to boost domestic manufacturing and attract large investments in the Medical Devices Sector. The financial incentive is to be given to selected companies on incremental sales of medical devices manufactured in India and covered under the Target segments of the scheme, for a period of five (5) years. The tenure of the scheme is from FY 2020-21 to FY 2027-28 with total financial outlay of Rs.3,420 crore. Under the Scheme, 42 applicants have been approved with a total Committed Investment of Rs. 1059.33 Crore and employment generation of about 6,411.

(IV) Scheme for Promotion of Bulk Drug Parks: The scheme provides for grant-in-aid to three (03) Bulk Drug Parks for creation of Common Infrastructure Facilities (CIF) with a maximum limit of Rs.1000 crore per park or 70% of the project cost of CIF, whichever is less. In case of North Eastern states and Hilly States (Himachanl Pradesh, Uttarakhand, Union Territory of Jammu & Kashrnir and Union Territory of Ladakh), the maximum limit of financial assistance would be Rs 1000 crore or 90% of the project cost whichever is less than total financial outlay of the Scheme is Rs. 3000 crore and the tenure of the Scheme is from FY 2020-21 to 2024. Proposals from 13 States have been received under the scheme which are under evaluation.

(V) "Promotion of Medical Devices Parks": Under this Scheme a onetime grant-in-aid will be provided for creation of common infrastructure facilities in selected Medical Device Park proposed by a State Government. The total financial outlay of the scheme is Rs. 400 crore (Rs. 100 crore for each MD Park). The tenure of the scheme is from FY 2020-2021 to FY 2024- 2025. Under the scheme, proposals seeking financial assistance from 16 States/ Union Territories have been received. After evaluation of the proposals, the Government vide letter dated 24.09.2021 has in-principally approved financial assistance for common infrastructure facilities for 4 medical device parks i.e. Himachal Pradesh, Tamil Nadu, Madhya Pradesh and Uttar Pradesh.

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

Thalassaemia Patients

Lok Sabha Unstarred Question No. 3237

Shri V.K. Sreekandan:

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

a) whether the Government is aware that Thalassaemia patients across the country are facing difficulties to get life saving iron chelation injection due to its shortage;

b) if so, the steps taken by the Government to improve the supply of such injection and address the shortage;

c) whether the Government has taken note that there are no medicines for sickle cell anaemia due to which many infant children lost their lives at Attappadi in Palakkad district in Kerala; and

d) if so, the steps taken by the Government in this regard?

Answered on 17th December 2021

A. (a) & (b): No such information regarding the Thalassaemia patients across the country facing difficulties to get life-saving iron chelation injection due to its shortage have been reported to this Ministry. Also, National Pharmaceutical Pricing Authority (NPPA) has not received any complaints regarding shortage of the iron chelation injection used for treating thalassaemia from State Drug Controller/Non-Government Organization (NGO)/ Individuals.

Further, various drugs containing iron chelating agents are approved for thalassaemia under Drugs & Cosmetic Act 1940 & Rules there under.

(c) & (d): Public Health and Hospitals being a state Subject, the primary responsibility of management of sickle cell anaemia lies with the respective State Governments.

The blood transfusion services comprise of 3500 licensed blood centers across all States and sectors, of which Govt. of India supports 1131 blood centers, by way of equipment (one time), manpower and consumables, including blood bags and testing kits. As per the Guidelines for recovery of processing charge for Blood & Blood Components issued by Department of AIDS Control, Ministry of Health and Family Welfare, Government of India, in February 2014, it is mandatory for all blood banks to provide blood/blood component free of cost to the patients of Thalassaemia, Haemophilia, sickle cell anaemia and any other blood dyscrasia requiring repeated blood transfusions as a life saving measure. There are two blood centers in the Palakkad district in Kerala, supported by Government of India namely District Hospital, Palakkad and Taluk Head Quarters Hospital, Mannarkkad, Palakkad.

Under National Health Mission (NHM), support is provided to States/Union Territories (UTs) to strengthen their healthcare system including support for management of Thalassaemia and sickle cell anaemia patients at public healthcare facilities, for low income patients, based on the proposals submitted by the States/UTs in their respective Programme Implementation Plan. The details of the Interventions under NHM is annexed.

Annexure

Details of the Interventions under NHM are as given under:

- Comprehensive Guidelines on Prevention and Control of Hemoglobinopathies in India – Thalassemias, Sickle cell Disease and other variant Haemoglobins (2016) have been developed and shared with the States/UTs. These guidelines provide for screening of every pregnant woman during Ante natal checks, pre-marital counselling at the college level and one time screening for variant anaemia for children in Class VIII, new-born screening as well as prenatal diagnosis. The guidelines emphasize on management of thalassaemia and sickle cell anemia and advise free blood transfusion and iron chelation drugs to patients.
- Iron-chelation therapy and Iron chelation drugs for patients.
- To prevent the risk of having an affected child, health education is directed towards school children, the public and health providers.
- Upgradation of Blood banks in district hospitals with facility for component separation, availability of leuko-reduced red blood cells (less than 7 days old).
- Special trainings of technicians of new blood banks for quality assurance.
- Facilitating linkages with Medical colleges for trouble shooting.

- Promotion of regular voluntary blood donation to augment the blood availability.
- Blood collection and transportation vans with dedicated Human resource.
- Day care centers in transfusion and Management Facilities for Thalassaemia Patients.
- Preparation of National registry of Patients taking blood transfusion and identification & development of rare group donor registry for the Thalassaemia Patients at the blood banks through e-raktkosh.
- The Ministry has in collaboration with Coal India Limited, Ministry of Coal is coordinating Bone Marrow Transplant (BMT) free of cost for poor Thalassaemic children as a Corporate Social Responsibility (CSR) Initiative.

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

Medicine for Cancer Patients

Lok Sabha Unstarred Question No. 3261

Shrimati Poonam Mahajan:

Shri A. Ganeshamurthi:

Shri G.M. Siddeshwar:

Dr. Jayanta Kumar Roy:

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

(a) whether the Government is aware that there is increasing number of cancer patients in the country year after year and especially amongst the lower and lower middle income sections of the society;

(b) if so, whether medicines for cancer are available at cheaper rates and if so, the details thereof and if not, the reasons therefor;

(c) whether the National Pharmaceutical Pricing Authority issued notification of certain medicines for cancer in the schedule, and put price capping, if so, the details thereof; and

(d) the details of action taken by the Government to ensure that medicines for cancer are manufactured in large scale by drug companies and made available/ distributed at affordable rates?

Answered on 17th December 2021

A. (a): As per the latest report of the National Cancer Registry Programme (NCRP) of Indian Council of Medical Research (ICMR) under the Ministry of Health & Family Welfare for the year 2020, the annual figures of estimated incidence and mortality of cancer cases are as under:

Year	2017	2018	2019
Estimated incidence of cancer cases	12,92,534	13,25,232	13,58,415
Estimated mortality of cancer cases	7,15,010	7,33,139	7,51,517

Further, the projected number of incidences of cancer cases in the country for the year 2025 is about 15.7 lakhs.

(b) and (c): National Pharmaceutical Pricing Authority (NPPA) under the Department of Pharmaceuticals has fixed the ceiling prices of 86 anti-cancer scheduled formulations under the National List of Essential Medicines, 2015 (NLEM, 2015). Further, the NPPA, vide order S.O. 1041(E) dated 27th February, 2019 has put a cap on Trade Margin of 42 select non-scheduled anti-cancer medicines under 'Trade Margin Rationalization' Approach. By this approach, the Maximum Retail Price (MRP) of 526 brands of these medicines have been reduced by up to 90%. This move has resulted in annual savings of around Rs. 984 crore to the patients. The details of revised prices are available on the website of the NPPA, i.e., nppaindia.nic.in.

(d): The government ensures that the scheduled drugs for cancer are not sold above their ceiling price fixed by NPPA and non-scheduled drugs do not avail increase in MRP beyond 10 percent in preceding 12 months. Drugs (Prices) Control Order, 2013 (DPCO, 2013) provide for deposition of overcharge amount by the manufacturers in case of default in implementing the provisions of the Order. Further, in order to ensure adequate availability and regulate the distribution of drugs, the extant provisions of the DPCO provides for issuance of directions to manufacturers of scheduled formulations and active pharmaceuticals ingredients (APIs) contained in the scheduled formulation to increase their production in case of emergency or in circumstances of urgency, in public interest.

Minister In The Ministry of Chemicals and Fertilizers (Dr. Mansukh Mandaviya)

Pharma Parks

Lok Sabha Unstarred Question No. 3291

Shri Pasunoori Dayakar:

Shrimati Kavitha Malothu:

Dr. G. Ranjith Reddy:

Shri Venkatesh Netha Borlakunta:

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

(a) the status of the proposed pharma parks in the country;

(b) the details of criteria prescribed for awarding pharma park;

(c) whether it is true that some States are opposing this move and, if so, details thereof and the reasons therefor;

(d) whether the Government has not taken into account planning, environmental clearances, availability of ecosystem conducive to API manufacturing, demand from industry, etc., while awarding pharma park to any State and if so, the details thereof; and

(e) the reason for emphasizing only on cost, incentives for awarding pharma park?

Answered on 17th December 2021

A. (a) to (e): The scheme "Promotion of Bulk Drug Parks" provides for grant-in-aid support for creation of Common Infrastructure Facilities to 3 bulk drug parks. Under the scheme "Promotion of Bulk Drug Parks", financial assistance would be provided for creation of Common Infrastructure Facilities (CIF) like (i) Central Effluent Treatment Plant(s) (CETP) (ii) Solid waste management (iii) Storm water drains network (iv) Common Solvent Storage System, Solvent recovery and distillation plant (v) Common Warehouse (vi) Dedicated power sub-station and distribution system with the necessary transformers at factory gate (vii) Raw, Potable and Demineralized Water (viii) Steam generation and distribution system (ix) Common cooling system and distribution network (x) Common logistics (xi) Advanced laboratory testing Centre, suitable for even complex testing/ research needs of APIs, including microbiology laboratory and stability chambers (xii) Emergency Response Centre (xiii) Safety/ Hazardous operations audits centre and (xiv) Centre of Excellence etc. The selection criteria is laid down in the detailed guidelines of the scheme, which are available on the website of the Department of Pharmaceuticals i.e. http://pharmaceuticals.gov.in.

Suggestions were received from the Government of Telangana, to consider the factors such as recognizing the readiness of the project including planning, environmental clearances, etc., availability of ecosystem conducive to API manufacturing, demand from industries to set up manufacturing units, setting up of management committee for the parks, consideration of the already available common scientific infrastructure like testing labs, incubation centres, etc., while forming the guidelines.

Under this scheme, Department of Pharmaceuticals has received proposals from 13 states, including Telangana and the proposals are under evaluation.

Under the scheme, no park is awarded to any state so far. All the 13 States were instructed to furnish additional information to further evaluate their proposals.

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

Cluster Development Programme in Pharma Sector

Lok Sabha Unstarred Question No. 3297

Shri Hemant Tukaram Godse:

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

(a) the broad objectives of the Cluster Development Programme for pharma sector;

(b) the funds allocated to various Clusters/Parks thereunder in the country;

(c) whether the Government has any proposal for further growth of the pharmaceutical industry; and

(d) if so, the details thereof?

Answered on 17th December 2021

A. (a): Department of Pharmaceuticals implements a scheme, viz., 'Assistance to Pharmaceutical Industry for Common Facilities (API-CF) with an objective to strengthen the existing infrastructure facilities in order to make India a global leader in Pharma Sector by providing financial assistance to pharma clusters for creation of Common Facilities.

(b): The year-wise expenditure under the scheme during last three years is as under:

2018-19: Rs. 2.30 cr

2019-20: Rs. 2.23 cr.

2020-21: Rs. 7.22 cr.

Expenditure Finance Committee (EFC) has approved an outlay of Rs. 500 cr. for a period of five years, viz. 2021-22 to 2025-26 for the scheme for 'Assistance to Pharmaceutical Industry for Common Facilities (API-CF)' along with two other schemes namely, 'Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS)' and 'Pharmaceutical Promotion and Development Scheme (PPDS)'.

Another scheme namely 'Promotion of Bulk Drug Parks' intends to promote setting up of Bulk Drug parks in the country for providing easy access to world-class common infrastructure facilities to bulk drug units located in the parks with an outlay of Rs. 3,000 cr.

(c) & (d): In order to attain self-reliance and reduce import dependence in critical Active Pharmaceutical Ingredients/ Key Starting Materials/ Drug Intermediaries, a Production Linked Incentive (PLI) Scheme for Bulk Drugs has been launched by the Department with an outlay of Rs. 6,940 crores. Under the Scheme, 50 applicants have been approved. Further, another PLI Scheme for Pharmaceuticals, to enhance India's manufacturing capabilities by increasing investment and production in the sector has been launched with an outlay of Rs 15,000 cr., under which 55 applicants have been approved.

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

Spurious Medicines During Second Wave of COVID-19

Lok Sabha Unstarred Question No. 3319

Shrimati Harsimrat Kaur Badal:

Dr. Alok Kumar Suman:

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

(a) whether the Government is aware of the widespread exchange of spurious medicines in the country, if so, the details thereof;

(b) whether the Government has noted that during the second wave of COVID-19, spurious medicines were sold to patients of COVID-19 consequently affecting their recovery;

(c) if so, whether the Government has prepared any report in this regard;

(d) whether the Government has initiated any action against all those persons pedaling fake and spurious medicines for putting patients' lives at risk; and

(e) if so, the details thereof and the outcome thereof along with other steps taken to stop the use of spurious drugs in the country?

Answered on 17th December 2021

A. (a) to (e): Enforcement of the provisions of the Drugs and Cosmetics Act and the Rules made thereunder primarily lies with the State Drug Controllers/State Licensing Authorities. The Central Drugs Standard Control Organisation (CDSCO) has requested all States/UTs Licensing Authorities through several advisories to instruct their enforcement staff to keep strict vigil and to take stringent action against the offenders in cases related to medicines of suspected quality.

As per information available from various State Licensing Authorities, in cases of fake & spurious Covid management drugs, various enforcement actions like Drug seizure, arrests of accused persons / registration of FIR etc. have been carried out by the State Licensing Authorities.

Amidst reports of black-marketing/hoarding/ overcharging of Covid-19 management drugs received, CDSCO has requested all States/UTs Licensing authorities through several advisories to instruct their enforcement staff to keep strict vigil especially at sensitive places and to take stringent action against the offenders by conducting special drive of monitoring and investigation.

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

Verification of Imported Raw Pharma Materials

Lok Sabha Unstarred Question No. 3342

Shri Gnanathiraviam S.:

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

(a) whether import of cheap pharmaceutical raw materials and vaccines from some countries is allowed without physically verifying the compliance of its regulatory requirements or the equivalent international standard;

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

(c) whether there is a need of regulatory norms to be complied for import of pharmaceutical raw materials and vaccines and if so, the details thereof and the steps taken by the Government to ensure transparency in the system?

Answered on 17th December 2021

A. (a), (b) & (c): Import of Drugs including vaccines is regulated under Chapter III of Drugs & Cosmetics Act 1940 & Rules thereunder. For import and marketing of any drug including vaccine the overseas manufacturing site and drug/ vaccine are required to be registered and import licence is required to be obtained from CDSCO under the rules.

In case of New Drugs including Vaccines, import permission is also required from CDSCO under the New Drugs and Clinical Trials Rules, 2019.

The imported consignments are cleared through notified port offices. There is a provision under Rule 40 of the Drug Rules 1945 that If the Customs Collector has reason to doubt whether any drugs comply with the provisions of Chapter III of the Act and Rules thereunder he may, and if requested by an officer appointed for this purpose by the Central Government shall, take samples of any drugs in the consignment and forward them to the Director of the laboratory appointed for this purpose by the Central Government and may detain the drugs in the consignment of which samples have been taken until the report of the Director of the said laboratory or any other officer empowered by him on this behalf, subject to the approval of the Central Government, on such samples is received.

All the imported drugs including vaccines are required to comply with standards mentioned under Second Schedule of the Drugs & Cosmetics Act 1940.

Further sampling for drugs is carried out based on defined risk based criteria whereas 100% sampling is carried out for vaccines for imported consignments, at Port offices.

Application related to import of Drugs including Vaccines are cleared by port officers as and when referred through Indian Customs and Central Excise Electronic Commerce/Electronic Data Interchange Gateway (ICEGATE) system maintained by Customs.

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

In Rajya Sabha

Production of generic medicines by pharma companies

Rajya Sabha Unstarred Question No. 184

Shri Syed Zafar Islam

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

(a) whether Government has given any instructions to large pharma companies regarding compulsory production of generic medicines on a large scale in the country, including Uttar Pradesh;

(b) if so, the details thereof;

(c) if not, the reasons therefor; and

(d) the details regarding the guidelines and its repercussions so far?

Answered on 30th November 2021

A. (a): No, Sir. Government has not issued any instructions to large pharma comnanies regarding compulsory production of generic medicines on a large scale in the country.

(b): In view of reply to (a) above, does not arise.

(c): A predominant share of Medicines sold in India are off-patent (patent expired) and therefore generic medicines only.

(d): There are no guidelines on this subject.

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

Price regulation of cancer medicines

Rajya Sabha Unstarred Question No.176

Shri Y. S. Chowdary:

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

a) whether Government is aware that there is increasing number of cancer patients in the country year after year and especially among the lower class and lower middle class people;

b) if so, the steps taken to ensure that medicines for cancer are made available at cheaper rates;

c) whether the National Pharmaceutical Pricing Authority has issued notification of certain medicines for cancer in the Schedule, and has put price cap on it, if so, the details thereof; and

d) whether Government would ensure that cancer medicines are manufactured at large scale by drug companies and distributed at cheaper rates?

Answered on 30th November 2021

A. (a): As per the latest report of the National Cancer Registry Programme (NCRP) of Indian Council of Medical Research (ICMR) under the Ministry of Health & Family Welfare for the year 2020, the annual figures of estimated incidence and mortality of cancer cases are as under:

Year	2017	2018	2019
Estimated cases incidence of cancer	12,92,534	13,25,232	13,58,415
Estimated cases mortality of cancer	7,15,010	7,33,139	7,51,517

Further, the projected number of incidences of cancer cases in the country for the year 2025 is 15.7 lakhs.

(b) and (c): National Pharmaceutical Pricing Authority (NPPA) under the Department of Pharmaceuticals has fixed the ceiling prices of 86 anti-cancer scheduled formulations under the National List of Essential Medicines, 2015 (NLEM, 2015). Further, the NPPA, vide order S.O. 1041(E) dated 27th February, 2019 has put a cap on Trade Margin of 42 select non-scheduled anti-cancer medicines under 'Trade Margin Rationalization' Approach. By this approach, the Maximum Retail Price (MRP) of 526 brands of these medicines have been reduced by up to 90%. This move has resulted in annual savings of around Rs. 984 crore to the patients. The details of revised prices are available on the website of the NPPA, i.e., nppaindia.nic. in.

(d): The government ensures that the scheduled drugs for cancer are not sold above their ceiling pace fixed by NPPA and non-scheduled drugs do not avail increase in MRP beyond 10 percent in preceding 12 Drugs (Prices) Control Order, 2013 (DPCO, 2013) provide for deposition of overcharge amount by the manufacturers in case of default in implementing the provisions of the Order. Further, in order to ensure adequate availability and regulate the distribution of drugs, the extant provisions of the DPCO provides for issuance of directions to manufacturers of scheduled formulations and active pharmaceuticals ingredients (APIs) contained in the scheduled formulation to increase their production in case of emergency or in circumstances of urgency, in public interest.

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

Import of medical devices, surgical supplies and equipments

Rajya Sabha Starred Question No.21

Shri Sanjay Seth:

Q. Will the Minister of **Health and Family Welfare** be pleased to state:

(a) whether it is a fact that 70 per cent of the demand of medical devices, surgical supplies and equipments are imported from abroad;

(b) if so, the details of items imported during the last two years;

(c) whether Government is planning to set up Medical Device Park in the States especially in Uttar Pradesh; and (d) if so, the details thereof?

Answered on 30th November 2021

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

STATEMENT REFERRED TO IN REPLY TO RAJYA SABHA STARRED QUESTION NO. 21* FOR 30th NOVEMBER, 2021

(a) & (b) Based on the information provided by Department of Pharmaceuticals, the status of medical devices forming the top 5 categories of the total imports is as below:

S. NO.	Segment	Imports F.Y. 2019-20	Imports F.Y. 2020-21	% share F.Y. 2019-20	% share F.Y. 2020-21
1	Electronics Equipment	3646.53	3568.64	62.38	57.18
2	Surgical Instruments	180.10	103.62	3.08	1.66
3	Consumables & Disposables	1076.23	1470.77	18.41	23.57
4	IVD Reagent	527.20	871.89	9.02	13.97
5	Implants	415.35	225.63	7.11	3.62
	TOTAL	5845.41	6240.55		

(c) & (d) Department of Pharmaceuticals in the Ministry of Chemicals & Fertilizers, vide letter dated 24.09.2021, has given in-principle approval for providing financial assistance for creation of common infrastructure facilities in the medical device park to be developed by State Government of Uttar Pradesh under the scheme "Promotion of Medical Devices Parks".

The Minister of Health and Family Welfare (Shri Mansukh Mandaviya)

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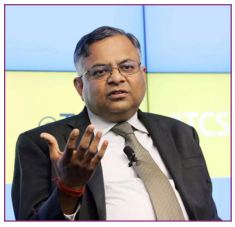
NATIONAL NEWS

Healthcare, education should be national priority: Tata Sons chairman



Tata Sons Chairman Natarajan Chandrasekaran

Mumbai: India should take up as national priority better access to healthcare and education for its people with the government creating a policy environment with participation from the corporate sector, **Tata Sons** Chairman Natarajan Chandrasekaran said on Tuesday.

In a conversation with **Microsoft India** President **Anant Maheshwari** at the Microsoft Future Ready event, Chandrasekaran highlighted the need for equitable digital access in areas such as education and health care across the country.

"We must realise that digital access has not been equitable (during the pandemic). If you take education, for example, all the urban kids who have access to your device and have access to the digital infrastructure could do online schooling. But, equally a large number of kids in the rural areas or poor people didn't have access to devices and didn't have access to the digital infrastructure, which is a big problem," said Chandrasekaran. "Years of schooling have been lost, or at least a couple of years have been lost for these people."

He expressed confidence that the huge infrastructure pipeline built in the country will contribute to help India lead the global growth rates significantly. But it requires helping more people become digitally native and access technology will also create a larger market bringing more people within the ambit of a formal economy. While the government is putting policy infrastructure in place, the corporate sector should also participate in this process to increase access, he said.

"I think it should be a national priority to enable national access to healthcare and education among other things. Government can put the policy infrastructure, but the corporate sector has to play its role," said Chandrasekaran.

He also added that this access to technology has to extend to sustainability goals as well. While commitments have been made towards COP26, he stated that the government and corporations alike will have to participate in providing access to renewable energy for the masses.

"I think what we need to do to make sustainability happen is- one, make a firm commitment which the government is leading and I'm sure all corporates will do. It's a good business. It's not only a low-carbon business but also a new economic model," he said.

Maheshwari added that India has a significant share of B2B players in the Indian startup ecosystem, indicating how India's SaaS ecosystem is maturing. With the power of India's large young population that is natively connected and mobile, India can scale the creation of digital assets without necessarily knowing how to code software," he said.

It is estimated that India's consumer digital economy, which was pegged at a sizable $85-90 billion in 2020 is now expected to become 10 times more i.e. $800 billion market by 2030.

"Fundamentally, we are moving from a mobile and cloud era to an era of ubiquitous computing and

ambient intelligence, an era which will experience more digitization over the next 10 years than the last 40 years. Every organisation will uniquely reimagine itself for the hybrid work era. And all of us are collectively learning and innovating on how we will shape the future of work in India," said SatyaNadella, chairman and CEO at Microsoft.

He added that while there is no standard yet, flexibility and productivity will be increasingly interconnected for organisations and employees such that they can enable collaboration in digital and physical workspaces with equal ease. Microsoft Work Trend index showed that 74% of employees in India, want more flexible remote work options, while at the same time 73% of them are also craving for more in person time with their teams and colleagues.

"As we continue the trend line of ubiquitous computing and ambient intelligence, we need to ensure that we drive tech intensity at scale for every individual and create a scalable talent engine for India's growth. Scaling is critical in bridging India's digital divide, placing India on the path to inclusive economic growth and preparing it for the future," said Nadella.

Source: Economic Times, 11.01.2022

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43% pharma marketers prefer programmatic messaging platforms in India for improved physician reach: Report

- As the latest report by Doceree, 43% of pharma marketers in India now prefer programmatic messaging platforms to reach out to physicians.
- It points that pharma's digital ad spending has risen considerably worldwide and the trend is expected to grow further on the back of programmatic fueling its growth.

Amid the chaos recurring waves of the pandemic have created, pharma marketers are shifting their focus to newer and innovative solutions to engage Physicians, apparent from the phenomenal rise in programmatic messaging technologies.

As the latest report by Doceree, the first global network of physician-only platforms for programmatic messaging, suggests around 43% of pharma marketers in India now prefer programmatic messaging platforms to reach out to physicians, utilizing its ability to segment healthcare experts and align their communication for optimization and better business outcomes.

To understand how programmatic is evolving, Doceree delved into inventory and campaign behavior trends of its multiple partners, studying over 1,100 campaigns. These were run on a mix of 165 physician-only publisher platforms via Doceree by 102 advertisers - consisting of consumer healthcare and medical devices companies, life sciences brands, hospitals, and diagnostics, covering 100+ specialties.

The report - 'Programmatic Trends in Pharma HCP Marketing 2022' – points that pharma's digital ad spending has risen considerably worldwide and the trend is expected to grow further on the back of programmatic fueling its growth.

"The trend looks promising as we see pharma brands earmarking a significant budget to programmatic marketing," said Harshit Jain MD, Founder & Global CEO, Doceree. "We are seeing 5 out of ten dollars spent on digital being set aside for programmatic messaging."

Besides, the report captures popular trends that are shaping the programmatic pharma physician marketing space:

1. **Programmatic gains prominence among endemic publishers**

   In 2021, there was a jump up to 53% in the exposed programmatic inventory of endemic publishers - HCP-only digital platforms such as medical education sites, HCP networking sites, medical associations, and medical journals that HCPs visit to advance their professional knowledge or to connect with their peer group - on the back of their partnership with specialized ad exchanges.

2. **First-party data makes contextual marketing valuable**

   Piqued interest of pharma brands in first party data and significant surge in performance campaigns on endemic walled-garden, and point of care platforms – e-prescribing (eRx), telehealth, and electronic health record (EHR) platforms - where data is collected directly from the physicians via log-ins. There has been a 39% year-on-year increase in the usage of such platforms.

3. **Big opportunity in physician's clinical workflow**

   Point-of-care networks are valuable assets for pharma marketers to enrich communications during

a physician's workflow - from lab test to the stage of diagnosis going to the point of writing a prescription - and deliver informative messages at decision-making moments while they are in a professional mindset.

Further, 29% of marketers globally are mulling boosting budgets for trigger-based campaigns on Point of Care channels as they are in dialogue with partners for planning and activation.

4. Account-based marketing creates a buzz

Brands are eager to keep up their spending across secondary-based institutions like hospitals, nursing homes and research institutes going into 2022 when targeting physicians of a particular specialty.

The data analysis of the report disclosed a 135% increase in spending on account-based campaigns by brand marketers handling medical devices in 2021 over the previous year.

"When executed properly, programmatic is a powerful tool to bring targeted scale for pharma marketers," adds Jain. "For publishers, it offers promise to align relevant messaging and platform experience for physicians visiting the respective sites."

Source: BI India Partner, 14.01.2022

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Top 5 trends for the pharma industry in 2022

The pharma industry has seen a rapid rise in the past three years with rapid digitization and the advanced research in the field has opened gates for newer avenues of treatment for mankind. The pharmaceutical industry is expected to grow to $ 1.5 trillion by 2023. Here are eight technology trends to watch for in 2022:

1. Rise in E-pharmacies: While the offline pharmacies may consider online pharmacies a threat to their business but an amalgamation of the two can lead to unimaginable growth prospects for both. An E-pharmacy is a boon as it is efficient and responsible in remote areas. It provides easy and affordable medicines to the people at their doorstep in just one click and additionally, gives information about the medicinal remedies' awareness to the purchaser. With the pandemic hitting the country, people avoid going to pharmacies and so the brick-and-mortar pharmacies are facing a setback. People have switched to buying medicines online for fear of getting infected by covid-19. There is a rift between the offline and online pharmacies but like other sectors there will be an ever-growing sync between the offline pharmacies opening an online market for themselves.
2. Rapid Digitization with AI/ML: One cannot disagree or neglect the fact that digitization and technological innovation is the backbone of a growing economy and the same is applicable to the pharmacy business. Hence, people have acknowledged this fact and aligned their offline business with the online opportunities to stay in line and pace with the ever-changing business environment in the technological world. Consumers no more want to step out to buy goods and it is a world where doorstep service is given preference. The use of AI/ML has also changed the entire consumer behavior and now the customers can experience real life shopping experiences/medical consultations sitting back at home, which will be the new era of online shopping in 2022, with an ongoing decline in offline pharmacy business.
3. Digital Records: The use of digital processes has been around for some time and will continue in 2022. Originally paper-based processes have been converted to digital to make operations more efficient. A unified Aadhaar synced medical history backup has been developed by different medical organizations. Digital processes are especially helpful in promoting regulatory compliance because they allow pharmaceutical companies to closely track data and how it is maintained. Pharmaceutical companies appreciate this switch to digitalization because of the transparency it provides across the organization and all departments and hence will continue to be the way ahead in 2022.
4. Cloud Computing: Cloud technology is used in every sector today. In the pharmaceutical industry, the cloud allows businesses to work with other stakeholders to become more effective. Cloud computing also provides an inexpensive way to use analytics. Pharmaceutical companies rely specifically on cloud security and central access to analyze complex data in clinical research. Cloud scalability keeps records of thousands of remotely monitored patients and the confidentiality records in maintained by the cloud environment.

5. Digital Trainings: Online training courses for new technologies in the pharmaceutical sector will be further expanded in 2022 to improve operations and compliance. Ensuring that teams have a solid understanding of the correct use of technologies such as digital signatures, patient planning portals, and electronic document software which will reduce the likelihood of errors, helping pharma organizations to meet the regulatory standards for using that information. Online training courses can be offered anytime, anywhere and can be personalized for each user, making them extremely cost-effective.

Blockchain technology and big data will further revolutionize the pharmaceutical industry in 2022, by helping them secure data and increase visibility, compliance, improved traceability of drugs, and simplified transactions. The upcoming pharmaceutical trends will add an ever evolving space for transformation in the pharmaceutical industry.

Source: Mithun Majumdar, TOI, 13.01.2022

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