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IDMA BULLETIN

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INDIAN PHARMA - GLOBAL HEALTH CARE

INDIAN DRUG MANUFACTURERS' ASSOCIATION

HIGHLIGHTS

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IDMA BULLETIN

Vol. No. 53 Issue No. 42 08 to 14 November 2022

IDMA ACTIVITIES:

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GOVERNMENT NOTIFICATION:

NATIONAL NEWS:

IDMA – GSB jointly with BCIL and SNL, USA Organizing Two day training programme on "Know-Your-Customer (KYC) best practices" for Indian Pharmaceutical industry at Hotel Courtyard by Marriott, Ahmedabad on November 14-15, 2022

Dear Member,

Greetings of the day!!!!!

We are pleased to inform you that Indian Drug Manufacturers' Association – Gujarat State Board (IDMA – GSB), jointly with Biotech Consortium India Limited (BCIL), New Delhi and Sandia National Laboratories (SNL), USA is organizing a 02 -day training programme on "**Know-Your-Customer (KYC) best practices**" for Indian Pharmaceutical industry at **Hotel Courtyard by Marriott, Ramdev Nagar Cross Road, Satellite Road, Ahmedabad on November 14-15, 2022.**

The objective of the training programme is to raise awareness of chemical weapons proliferation potential and to provide Know-your-customer best practices in the pharmaceutical industry. Details are in attached pamphlet. This training is appropriate for all pharmaceutical companies producing and using potentially lethal (e.g., fentanyl) and other incapacitating and/or dissociative agents (e.g., benzodiazepines). It is designed for **pharma industry managers, security officers, regulators, and transportation logistics company managers.** There are a total 20 slots and participants will be selected based on the activities undertaken by their organization in reference to the topic of the programme and the usefulness to the participant's organization thereby achieving the objective of the training.

Kindly note that expenses towards travel by Air (economy) / Train (2nd AC fare) / Taxi and boarding & lodging (accommodation at Hotel Courtyard by Marriott and meals) of participants will be borne by SNL/BCIL. More details and registration link are given in the attached pamphlet.

We request you to nominate concerned officials from your organization for the training programme.

There is No registration fee, however, the REGISTRATION IS MANDATORY for consideration in the training programme.

With kind regards,

Sumit J. Agrawal
Hon. Secretary
IDMA - GSB

Brief about organizing partners:

a) Biotech Consortium India Limited (BCIL), New Delhi

BCIL is a company set up in 1990 as an initiative of the Department of Biotechnology (DBT), Ministry of Science & Technology, Government of India and All India Financial Institutions. As part of our activities, we are engaged in capacity building related to biosafety and chemical security issues. Such activities are undertaken in collaboration with national and international agencies.

b) Sandia National Laboratories (SNL), USA

SNL undertakes capacity building programmes, with support from US Department of State's Chemical Security Program (CSP).

Know-Your-Customer (KYC) Workshop for Indian Pharmaceutical Industry

14-15 November 2022, 09:00-17:00 IST

Announcement: Biotech Consortium India Limited (BCIL), Indian Drug Manufacturers' Association (IDMA) and Sandia National Laboratories (SNL) on behalf of the United States Department of State's Chemical Security Program (CSP) are organizing an in-person workshop to raise awareness of the chemical weapons (CW) proliferation potential of key pharmaceuticals and to provide Know-Your-Customer (KYC) best practices for the Indian Pharmaceutical industry. During this workshop participants will learn how to recognize suspicious purchase requests, develop customer vetting strategies, and understand regulations regarding the sale of 'dual use' chemicals that may be misused as chemical weapons. Additional topics will also include chemical security threats and chemicals of concern. The overarching focus of this event is to develop strategies that deny access to weaponizable pharmaceuticals. This workshop is appropriate for all pharmaceutical companies producing and using potentially lethal (e.g., fentanyl) and other incapacitating and/or dissociative agents (e.g., benzodiazepines).

Audience:

- Up to 20 Indian Pharma industry managers, security officers, regulators, and transportation logistics company managers.

Goal:

- Provide participants with the awareness of the chemical weapons proliferation potential of key pharmaceuticals, an understanding of KYC, and the knowledge and resources to implement KYC best practices and policies at their institutions to ensure their products are not acquired for illicit purposes.

Agenda:

14 November 2022	15 November 2022
• Welcome, Introduction, Goals • Industry Case Study • Chemical Security Threats • Pharmaceuticals of Concern with exercise • Illicit Procurement Tactics with Case Studies	• Overview of KYC Principles and Practices • Interactive Scenario-Based Activities on KYC Indicators • KYC Implementation • Next Steps • Valedictory

Registration Site:
https://gcbs-events.sandia.gov/chemical-security-program/remote-know-your-customer-kyc-training-for-indian-pharmaceutical-industry

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IDMA facilitated the Roundtable Meeting on Investment Opportunities in Pharmaceutical and Medical Devices Sector in Madhya Pradesh

Roundtable Meeting on Investment Opportunities in Pharmaceutical and Medical Devices Sector in Madhya Pradesh was held on Thursday, November 10, 2022 at Presidential Ballroom, Taj President, Mumbai.

Meeting was Chaired by Shri Shivraj Singh Chouhan, Honourable Chief Minister of Madhya Pradesh in august presence of Shri Rajvardhan Singh Dattigaon, Honourable Cabinet Minister of Industry Policy and Investment Promotion, Government of Madhya Pradesh and Senior IAS Officers.

The Indian pharmaceutical industry was represented by IDMA leadership (Shri Mehul Shah, Hon. General Secretary, Shri Daara B. Patel, Secretary - General, Dr. George Patani, Vice President, Western Region), promoter leaders, and IPA leadership (Shri Sudarshan Jain, Secretary-General). The delegation had 10+ leaders including Ms. Neha Thakore, Shri Ajit Singh, Shri Yogin Majmudar, Shri Sundeep Bambolkar, Shri Jayesh Choksi, Shri B G Barve, Shri Vasudev Kataria, Shri Niraj Doshi, Ms. Anokhee Doshi, and Shri Rupesh Kamdar.

Shri Sanjay Shukla (Principal Secretary, Department of Industrial Policy and Investment Promotion) gave a walkthrough of the incentive policy of GoMP followed by remarks from the Honourable Chief Minister and Industries Minister.

Shri Daara B. Patel introduced IDMA at the roundtable and it's contribution to the nation and the world. Shri Sudarshan Jain introduced IPA and was generous to note that IPA members are/were IDMA members for IDMA being mother organization for all associations in the country.

Shri Mehul Shah conveyed expectations from the industry especially for specialized incentive package in the next 6-12m for greenfield, brownfield, and M&A of sick industrial units apart from significant support in electricity tariff rebate, electricity duty exemption, competitive land rates, environmental clearance, and CETP support.

Shri Yogin Majmudar elucidated concerns of bulk drug companies notably on facilitation of mandatory common ETP for secondary treatment and waste management and a competitive bidding process for a third-party to manage CETP operations with a view to rationalize cost of waste management which is today about 25% of the total cost of manufacturing.

Shri Shivraj Singh Chouhan reaffirmed GoMP's support to the Indian pharmaceutical industry and appointed Shri Manish Singh (MD, MPIDC) as the nodal officer to receive and respond to all queries from the industry on investments and ongoing support. He also conveyed that GoMP will

take suggestions from the industry with due regard and will soon announce a more encouraging investment policy that serves win-win value proposition for the government, industry, and the society at large.

Shri Mehul Shah and Shri Daara Patel accorded honor and gratitude on behalf of IDMA and the National President Dr.Viranchi Shah to Shri Shivraj Singh Chouhan and Shri Rajvardhan Singh Dattigaon with a plaque and bouquet.

● ● ●

PRESENTATION

Proposal for Development of Bulk Drug Park in Raigad District, Maharashtra

Dear Member,

IDMA have received a presentation on **Proposal for Development of Bulk Drug Park in Raigad District, Maharashtra** (In Marathi) from Shri. D. R. Gahane, Joint Commissioner FDA, Maharashtra. We have translated in English and reproduced below for members information.

Proposal for Development of Bulk Drug Park in Raigad District of Maharashtra State

Objectives of the Scheme

- ❖Facilitating the establishment of Pharmaceutical Industries (BDP) in the country, general infrastructure for global registration of pharmaceutical industries located in the country.
- ❖Making the facility easily available, thereby significantly reducing the manufacturing cost of pharmaceuticals and increasing the competitiveness of the pharmaceutical industry in the country.
- ❖To enable India to achieve self-reliance in pharmaceutical manufacturing.

Proposal for Development of Bulk Drug Park in Raigad District of Maharashtra State

Ministry of Implementation : Ministry of Chemical & Fertilizers, Department of Pharmaceuticals, Government of India

Financial Plan :

- ❖**Rs. 3000 Crore**
- ❖**Under this Scheme 3 (three) Bulk Drug Manufacturing Parks will be supported in the country.**
- ❖**Maximum limit of subsidy for one pharmaceutical park is Rs. 1000 crores.**
- ❖**Economic year 2020-21 to Economic year 2024-25**

Proposal for Development of Bulk Drug Park in Raigad District of Maharashtra State

Implementation of Plan :

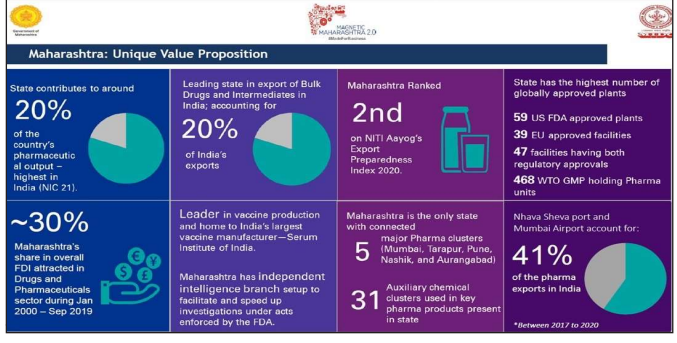
- ❖ **Grant Assistance available for general infrastructure development**
- ❖ **Implementation of the scheme will be done through the Special Implementation Agency (SIA) having legal status and formed by the concerned State Government.**
- ❖ **70% of the common infrastructure project value will be Subsidized.**

Proposal for Development of Bulk Drug Park in Raigad District of Maharashtra State

The Basic amenities provided to the park:

- ✓ Common Effluent Treatment Plant
- ✓ Solid waste management
- ✓ Storm water drains network
- ✓ Common Solvent Storage System
- ✓ Dedicated power sub-station and distribution system
- ✓ Raw, Potable and Demineralized Water
- ✓ Steam generation and distribution system
- ✓ Common cooling system and distribution network
- ✓ Internal road network, Compound Wall
- ✓ Common logistics
- ✓ Advanced laboratory testing centre
- ✓ Safety/Hazardous operations audits centre
- ✓ Centre of Excellence

Proposal for Development of Bulk Drug Park in Raigad District of Maharashtra State



Proposal for Development of Bulk Drug Park in Raigad District of Maharashtra State

Key Features of the Bulk Drug Development Park

Proposed Bulk Drug Park Location

Easy Access near the Park

Nearest National Highway
: 23.3 km towards Alibag NH-166 (Alibag to Wadkhal)
: 25.6 km Kolad – NH-66 (Mumbai to Goa)

Nearest Air Cargo/Airport
: 122 km from Mumbai Airport
: 90.1 km from proposed Navi Mumbai Airport

Nearest Seaport
: 34.2 km from Dighi Seaport towards south of the proposed area and 88.1 km Jawaharlal Nehru Port Trust, towards North of the proposed area.

Proposal for Development of Bulk Drug Park in Raigad District of Maharashtra State

Estimated cost of Park Construction and Estimated source of funds:

Cost of Park Construction : **Rs. 2442 Cr.**
(Excluding Land Acquisition cost) (Approx.)

Central Government Funds : **Rs. 1000 cr.**

State Government Funds & Grants : **Rs. 1442 cr. (from MIDC)**

Proposal for Development of Bulk Drug Park in Raigad District of Maharashtra State

Key Features for the Development of the Bulk Drug Park

Committed to provide 24x7 Electricity and Water Supply

ELECTRICITY SOURCES	WATER SOURCES
A. Roha Sub-station 21 km from proposed sight Capacity : 100 MVA Present Load : 50 MVA Balance Load : 50 MVA	Kundalika River, Dhatav, Taluka – Roha Availability of Water is 38 km from Jackwell at Dhatav, Roha
B. Kansai sub-station (near Nagothane) 25 km from proposed sight Capacity : 1315 MVA Present Load : 1118 MVA Balance Load : 197 MVA	Capacity : 130 MLD Capable of providing approx. demand of 128 MLD for the Proposed Bulk Drug Park
The above sub-stations are capable to provide the necessary Electricity demand of the Proposed Park	

Proposal for Development of Bulk Drug Park in Raigad District of Maharashtra State

Proposed Concession / Exemption provided by State Government to the Pharmaceutical Manufacturing Industries

Interest Subsidy Scheme	5% for Micro, Small and Medium Enterprises
GST reimbursement, subsidy etc. Subsidy on Investment	100% reimbursement of SGST for MSME, LSI, Special LSI & Mega/Ultra Mega Projects
Subsidy in Stamp Duty and Registration Fee for drug manufacturing unit.	100% subsidy for Land Acquisition proceeds & Term loan for MSME, LSI, Special LSI & Mega/Ultra Mega Projects.
Electricity at Concessional Rate	Rs. 5.77 KWH

Proposal for Development of Bulk Drug Park in Raigad District of Maharashtra State

Land Lease Rate

Proposed annual rent for setting up a manufacturing unit in the Park	There are 2 models of lease rent: a) Rs.110/- per Sq. m. per year (State Government will not increase rate more than 5% per year for next 10 years) b) Rs. 2200/- per Sq. m. (with long term lease of 95 years if paid in advance)

Proposal for Development of Bulk Drug Park in Raigad District of Maharashtra State

Proposed area for Bulk Drug Manufacturing Park

AREA STATEMENT			
Sr No	Taluka	Name of Village	Area in Hect.
1	Murud	Amali	85-54-40
2	Murud	Yesde	68-35-00
3	Murud	Shirgaon	79-62-20
4	Murud	Valke	176-68-60
5	Murud	Satirde	138-71-60
6	Murud	Tadgaon	200-51-50
7	Murud	Chorde	273-05-50
8	Murud	Savaroli	91-09-70
9	Murud	Tale	74-10-00
10	Murud	Talekhar	28-55-20
A		Total	1216-23-70
11	Roha	Div	85-19-80
12	Roha	Kharkhardi	139-85-30
13	Roha	Belkhar	17-43-50
14	Roha	Sonkhar	69-07-30
15	Roha	Nhave	381-77-40
16	Roha	Navkhar	41-17-30
17	Roha	Kutal	44-22-60
B		Total	778-73-20
A+B		Total	1994-96-90

Proposal for Development of Bulk Drug Park in Raigad District of Maharashtra State

Details of the Area

Geographical Area of 17 villages in Murud and Roha Talukas of Raigad District is 4309 Hectares. Out of which 1995 Hectares Area is already notified for acquisition.

Out of proposed 1995 Hectares Area - 321 Hectors is Government Land and 1674 (38.84%) Hectares is Private Land.

Cultivation details of Private Sector (1674 Hectares) are as under			
Sr. No.	Details	Area (In Hectares)	% (Against total village area of 4309 Hectares)
1	Area under cultivation	971	22.53
2	Varkas / Potkharab Area	703	16.31

Note : Cultivation mainly consists of Rice.

Proposal for Development of Bulk Drug Park in Raigad District of Maharashtra State

- **No Villages will be relocated.**
- **Reimbursement of the acquired land for development –** Along with the reimbursement of the land used for park 10 % more developed land will be given to PAP which can be used for Commercial, Industrial or Residential purpose. The People affected by the Project can use this land for commercial purposes enabling them a source of permanent income.
- **Preference** for skilled employment - Locals will be given preference for jobs.
- **Skill Development Programme - A Skill Development Centre** will be established for the skill development of the locals.
- **No Impact on Local fishing Business**: The effluent treated water will be disposed 10 kms in the sea and there would be no impact on the business of the local fishermen.
- **Strengthening of Villages through Corporate Social Responsibility (CSR) -** Strengthening of Civil Amenities in the village and implementation of new welfare schemes for the locals will be implemented through Corporate Social Responsibility (CSR) fund of the companies established in the Bulk Drug Park.
- **Total Investment and Employment-** The investment of 30,000 Cr in this project is expected and it will generate employment to approximately **75,000** people.

Proposal for Development of Bulk Drug Park in Raigad District of Maharashtra State

Schemes for Conservation of Environment

- **Rain Water Harvesting** is proposed among the amenities of the park.
- Integrated facilities are proposed for the industry level waste collection, sorting, processing, recycling and disposal.
- Encouraging the adoption of sustainable / eco-friendly pathways for environmental protection in industries developed in the park.
- Development of risk management systems for prevention and management of all types of emergencies and safety measures to deal with any natural calamities and disasters.

Proposal for Development of Bulk Drug Park in Raigad District of Maharashtra State

Schemes for Conservation of Environment

- Encouraging the use of less invasive methods to reduce carbon emissions.
- Implementation of Environmental and Health Risk Management Plan (EHRMP).
- Environmental Impact Assessment (EIA) and Social Impact Assessment (SIA) will be conducted
- Construction of Central Wastewater Treatment Plant (CETP) with capacity of **70 MLD.**
- Solid Waste Management Plant
- 10% open space will be kept in the Organization premises which will be used for plantation of trees (Green Belt) .

Thank You

Environment (Protection) Rules, 1986 amended (Third Amendment of 2022)

Environment Notification G.S.R.804(E), dated 03rd November 2022

Whereas, the Environment (Protection) Amendment Rules, 2022 were published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), *vide* notification number G.S.R. 138 (E), dated the 18th February, 2022 inviting objections and suggestions from all persons thereby within a period of sixty days from the date on which copies of the Official Gazette containing the said notification were made available to the public;

And Whereas, copies of the Official Gazette containing the said notification were made available to the public on the 18th February, 2022;

And Whereas, objections and suggestions received from all persons and stakeholders in response to the said notification have been duly considered;

Now therefore, in exercise of the powers conferred by sections 6 and 25 of the Environment (Protection) Act, 1986 (29 of 1986) read with sub-rule (3) of rule 5 of the Environment (Protection) Rules, 1986, the Central Government hereby makes the following rules further to amend the Environment (Protection) Rules, 1986, namely: -

1. Short title and commencement

(1) These rules may be called the **Environment (Protection) Third Amendment Rules, 2022.**

(2) They shall come into force from **1st July, 2023.**

2. In the Environment (Protection) Rules, 1986, in the Schedule I,-

(a) in serial number 88-,

(i) item "A. Emission Standards" and entries relating thereto, the following shall be substituted, namely:-

"A. Emission Standards:

The emission limits for new engines used for power generating set (hereinafter referred to as Genset) applications up to 800 kW Gross Mechanical Power, namely:

(i) Diesel engines;

(ii) Engines based on dedicated alternate fuels;

(iii) Engines based on Bi-fuels run either on Gasoline or on any one of the alternate fuels;

(iv) Engines based on Dual Fuel run on Diesel and any of the alternate fuels;

(v) Portable Generator sets (PI engines below 19kW and up to 800 cc displacement) run on Gasoline fuel, dedicated alternate fuels and Bi-fuel run either on Gasoline or on any one of the alternate fuels;

1. The emission limits for new engines up to 800 kW used for Genset shall be effective from 1st July, 2023 as specified in the Table 1 and Table 2 below subject to the General Conditions contained therein, namely:

TABLE 1

Emission limits for Genset engines up to 800 kW Gross Mechanical Powered by All CI engines and PI engines > 800 cc engine displacement.

Power Category, kW	NOx	HC*/**	NOx +HC*/**	CO	PM		Smoke (light absorption coefficient)	
	CI/PI	CI/PI	CI/PI	CI/PI	CI	PI	CI	PI
	g/kWh						m-1	
P ≤ 8	-	-	7.5	3.5	0.30	-	0.7	-
8 < P ≤ 19	-	-	4.7	3.5	0.30	-	0.7	-
19 < P ≤ 56	-	-	4.7	3.5	0.03		0.7	
56 < P ≤ 560	0.40	0.19	-	3.5	0.02	-	0.7	-
560 <P ≤ 800	0.67	0.19	-	3.5	0.03	-	0.7	-

TABLE 2

Emission limits for portable Genset up to 19 kW powered by PI engines (up to 800 cc engine displacement)

Category Engine Displacement (cc)	CO	NOx +HC */**
	g/kWh	
Up to 99	< 250	<10
> 99 and up to 225	< 250	<08
> 225 and upto 800	< 250	<06

The abbreviations used in Table 1 and Table 2 are as follows:

(i) NOx – Oxides of Nitrogen;

(ii) HC– Hydrocarbon;

(iii) CO – Carbon Monoxide;

(iv) PM – Particulate Matter;

(v) CI-Compression Ignition engines;

(vi) PI- Positive Ignition engines;

(vii) * HC stands for THC for diesel and gasoline;

(viii) ** HC for alternate fuels shall be as defined in System and Procedure for Generator set.

2. Test cycle for constant speed and variable speed application shall be as described in System and Procedure for Genset.

3. Smoke shall not exceed prescribed limit value throughout the operating load points of the test cycle.

Note: (i) The test shall be done on engine dynamometer for all CI engines and PI engines (above 800 cc displacement);

(ii) the test shall be done on resistive load bank for Portable Gensets (up to 19 kW and up to 800 cc engine displacement) powered by PI engines;

(iii) the emission limits are applicable to both constant speed and variable speed gensets and genset engines are used primarily to operate an electrical generator or alternator to produce and supply electric power for other applications in place of power from electric grid;

(iv) portable genset combines an electrical generator and a prime mover engine to form a single piece of equipment. This combination engine-generator set can be moved, pulled and not attached to earth, by a person and not build permanently into a structure such as power house or station and satisfy the following conditions namely,-

(a) power output is up to 19 kW and up to 800 cc engine displacement;

(b) power by PI air cooled engine;

(c) it is on Hand-cart mounted units.

(v) the test procedure for measurement of gross power and the tolerances shall be as per procedure laid down in System and Procedure for Genset;

(vi) administrative and test procedure for measurement of emission of visible and gaseous pollutant and particulate matter shall be as per procedure laid down System and Procedure for Genset;

(vii) Table 1 and Table 2 emission limits shall be applicable for Type Approval Test and Conformity of Production Test as carried out by authorised certifying agencies;

(viii) Frequency of Conformity of Production test and selection procedure shall be as per procedure laid down in System and Procedure for Genset;

(ix) engine Durability Period and Deterioration Factor: Deterioration factor is applicable to all CI and PI engines above 19 kW power category only;

(a) engine manufacturer may choose for an engine test laid down in System and Procedure for Genset as mentioned in Table 3 given below:

TABLE 3

Category (Power Band)	Emission durability period (hours)	Engine Category
>19 ≤ 56 kW (constant speed Engines)	3000	PI and CI
>19 ≤ 56 kW (Variable speed Engines)	5000	PI and CI
> 56 kW (All engines)	8000	PI and CI

(b) as an alternative to use a service accumulation schedule to determine deterioration factors, engine manufacturers shall use the assigned multiplicative deterioration factors for engine families using exhaust after-treatment system as per the Engine Capacity mentioned in Table 4 given below:

TABLE 4

Engine Category	CO	HC	Nox	PM
CI	1.3	1.3	1.15	1.05
PI	1.3	1.3	1.15	-

(c) Additive Deterioration Factors shall be specified by manufacturer with the supportive document as specified System and Procedure for Genset for each pollutant in an engine family approval application for CI engines and PI engines not using any exhaust after-treatment system;

(d) manufacturers shall request type approval certification for shorter or longer useful life for an engine family and the test agency can approve a shorter or longer useful life in hours of engine operations but not in years.

4. Engines rely on the external devices and/ or reagent in order to reduce emissions, shall ensure the correct operation of NOx control measures through Onboard Diagnostics as per procedure laid down in System and Procedure for Genset.

5. Emission of ammonia over the test cycles for engines equipped with Selective Catalytic Reduction shall not exceed a mean value of 25 part per million (ppm) for engine power category less than or equal to 56 kW and 10 ppm for engine power category above 56 kW.

6. Engines rely on the use of any external devices and /or exhaust after treatment devise to reduce particulate matter emissions, shall ensure the correct operation of particulate matter control measures.

7. PI engines rely on the use of any external devices and /or exhaust after treatment device to reduce NOx emissions, shall ensure the correct operation of NOx control measures, as per procedure laid down in System and Procedure for Genset.

8. The NOx reduction reagent shall conform to standards determined in System and Procedure for Genset.

9. Specifications of test fuels for Type approval and Conformity of Production tests shall be as defined in System and Procedure for Genset and one emission compliance tests shall be carried either on commercially available fuel or with reference fuel as declared by the manufacture during type approval test application and the same to be followed during Conformity of Production compliance tests.

10. Stack height for Genset shall be governed as per Central Pollution Control Board guidelines.

11. Electronically controlled compression Ignition engines and dual fuel engines shall be within the control area regulated in System and Procedure for Genset and shall not exceed more than two times the limit values of the emissions specified in Table 1.";

(ii) item "C. General Conditions," and the entries relating thereto the following shall be substituted, namely:-

"C. General Conditions:

1. Applicability.- These General Conditions shall apply to all new engines for power generation application and products manufactured, assembled or imported to India, operating at constant or variable speed as the case may be:

   Provided that these rules, shall not apply to-

   (a) engine or product, assembled or manufactured or imported, as the case may be, for the purpose of export outside India, or;

   (b) engine or product intended for the purpose of sample limited to four in number and to be exported back within six months of completing the sample testing and not for sale in India.

   (c) engine or product, assembled or manufactured or imported, as the case may be, for the purpose of research and development testing which shall be scraped or re-exported.

2. Requirement of certification.- Domestic manufacturer, importer or assembler of engines for power generation up to 800 kW and engine displacement > 800 cc and of portable Gensets up to 19 kW and engine displacement up to 800 cc, shall obtain Type Approval from authorised certifying agency and also comply with Conformity of Production test of their product(s) for the emission limits which shall be valid for the next Conformity of Production year or the date of implementation of the revised norms specified above, whichever is earlier.

   Explanation. – The term Conformity of Production year covers the period from 1st July of calendar year to 30th June of the following calendar year.

3. Sale, import or use of engine or product not complying with these rules.- No person shall sell, import or use an engine and genset for power generation application which is not having a valid Type Approval certificate and certificate of Conformity of Production referred to in General Condition 2.

4. Requirement of conformance labelling shall be as mentioned in System and Procedure for Genset.

5. Nodal Agency. – The Central Pollution Control Board shall be the nodal agency for implementation of these rules.

   (a) In case of difficulty in implementation of these rules, the matter shall be referred to the nodal agency.

(b) shall constitute a Standing Committee to advise it related to the implementation of these rules.

6. Authorised agencies for certification. – (a) Automotive Research Association of India, Pune (Maharashtra); (b) International Centre for Automotive Technology, Manesar (Haryana); and (c) Indian Institute of Petroleum, Dehradun (Uttarakhand) are authorised to carry out or witness such tests as they may deem necessary, for giving certificates of Type Approval and Conformity of Production for engines and Gensets for power generation application: -

7. Compliance and testing procedure.-

(1) the Compliance and Testing Procedure, as published by the Central Pollution Control Board shall be followed by all concerned,

(2) the authorised agencies for certification shall submit the testing and certification details in respect of the emission to the Central Pollution Control Board annually.

8. Engine components or parts identification.- All the details of engine components or parts responsible for the emission performance shall be clearly marked in English language.

9. Safety code of practices for alternate fuels shall be as defined in System and Procedure for Genset.

10. Fuel system components certification for alternate fuels shall be as defined in System and Procedure for Genset.

11. The Central Pollution Control Board, Commission for Air Quality Management, State Pollution Control Boards or Pollution Control Committee may issue more stringent norms taking account to local condition of the area.

12. Transition provisions for Gensets and Genset engines manufactured as per earlier norms shall be as defined as follows:

(a) Last date of manufacturing of engine system as per earlier norms shall be 30th June 2023. For PI engines it shall be 31st July 2023.

(b) Last date of manufacturing of Gensets as per earlier norms shall be 31st December 2023.

(c) Last date of manufacturing of PI Gensets as per earlier norms shall be 31st August 2023.";

(b) serial number 95 and the entries relating thereto shall be omitted;

(c) in serial number 95 A,-

(i) item "A. Emission Limits" and the entries relating thereto shall be omitted;

(ii) item "C. General Conditions" and the entries relating thereto shall be omitted;

(d) in serial number 95 B,-

(i) item "A. Emission Limits" and the entries relating thereto shall be omitted;

(ii) item "C. General Conditions" and the entries relating thereto shall be omitted;

(e) in serial number 95 C,-

(i) item "A. Emission Limits" and the entries relating thereto shall be omitted;

(ii) item "C. General Conditions" and the entries relating thereto shall be omitted.

F.No.Q-15017/05/2012-CPW

Naresh Pal Gangwar, Addl. Secy., Ministry of Environment, Forest and Climate Change, New Delhi

Note: *The principle rules were published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), vide number S.O.844(E), dated the 19th November, 1986 and lastly amended, vide notification G.S.R. 682(E), dated the 5th September, 2022.*

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Draft notification to further amend the Environment (Protection) Rules, 1986 - reg.

Environment Notification G.S.R.805(E), dated 04th November 2022

(Published in the Gazette of India on 7th November, 2022)

DRAFT NOTIFICATION

In exercise of the powers conferred by sections 6 and 25 of the Environment (Protection) Act, 1986 (29 of 1986), the Central Government hereby makes the following draft rules, as required under sub –rule (3) of the rule 5 of the Environment (Protection) rules 1986, for the information of the public likely to be affected thereby; and notice is hereby given that the said draft notification shall be into consideration on or after the expiry of a period of sixty days from the date on which copies of the Gazette containing this notification are made available to the public.

Any person interested in making any objections or suggestions on the proposals contained in the draft notification may forward the same in writing, for consideration of the Central Government within the period specified above to the Secretary, Ministry of Environment, Forest and Climate Change, Indira Paryavaran Bhawan, Jor Bagh Road, New Delhi – 110 003, or send it to the email address: mscb.cpcb@nic.in and sonu.singh@gov.in

1. Short title and commencement.

(1) These rules may be called the **Environment (Protection) Amendment Rules, 2022.**

(2) They shall come into force after six months from the date of publication of final notification in the Official Gazette.

2. In the Environment (Protection) Rules, 1986, in Schedule-I, after serial number 116 and the entries relating thereto, the following serial number and entries shall be inserted, namely: -

S. No.	Industry	Parameter	Standards
(1)	(2)	(3)	(4)
"117	Hot Mix Plant	Particulate Matter Concentration (mg/Nm^3) in stack emission	
		Batch type Hot Mix Plant	150
		Drum type Hot Mix Plant	300

Notes:

i. The minimum stack height for Hot Mix Plant shall be calculated as: Stack height (H_s) = $14(Q)^{0.3}$, where, Q is the SO_2 emission rate in kg/hr.

ii. Only approved fuel prescribed by SPCBs/ PCCs shall be used.

iii. Dust emission from material handling shall be contained with water sprinkling or by covering the points of dust emission.

iv. The internal roads, working platform, loading and unloading areas in premises should be paved and kept clean all times.

v. The Noise Pollution (Regulation & Control) Rules, 2000 under the Environment (Protection) Act, 1986 to be followed and workers shall be provided with personal protective equipments.

vi. The green belt should be developed along the periphery.

vii. Use of Recycled Asphalt Pavement (RSP) shall be allowed in the aggregates.

viii. Any process rejects or left over of the hot mix should be recycled in the process.

ix. The site shall be reinstated at the end of operation phase i.e. after dismantling the plant.

x. SPCBs/ PCCs may decide the size & capacity to permit hot mix plants based on available technology and prevailing environmental conditions.

xi. The HMP shall be installed from the following siting criteria (New HMPs)

a. 1 km from boundary of cities and towns,

b. 0.5 km from habitation,

c. 0.2 km from National or State Highways (from Centre Line),

d. 0.5 km from Schools/Colleges and temples,

e. 1 km from Hospital, court and tourist spot.

xii. In case of existing hot mix plants not meeting above siting criteria, the unit should provide minimum 6 m high compound wall of GI sheets along plot periphery.

xiii. The hot mix plant should be equipped with appropriate air pollution control devices as mentioned below so as to ensure optimum efficiency to achieve the standards:

a. Drum Type: Cyclone/multi-clones with wet scrubber

b. Batch Type: Multi-clones with bag filters

F. No. Q-15017/14/2018 – CPW

Naresh Pal Gangwar, Addl. Secy., Ministry of Environment, Forest and Climate Change, New Delhi.

Note: *The principle rules were published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i) vide number S.O.844(E), dated the 19th November 1986 and last amended vide notification number G.S.R. 682 (E), dated the 5th September 2022.*

IDMA's National President in the Constitution of High Level Committee under the chair of Hon'ble Minister for Chemicals & Fertilisers to oversee the progress of setting up of Bulk Drug Parks to align with the overall objectives of the scheme - reg.

Office Memorandum F.No. 31026/58/2020-Policy, dated 10th November, 2022

To

i. Drugs Controller General of India, CDSCO,
ii. Joint Secretary, Drug Regulations, DoHFW,
iii. ACS / Principal Secretary, Industry Department, Government of Gujarat,
iv. ACS / Principal Secretary, Industry Department, Government of Himachal Pradesh,
v. ACS / Principal Secretary, Industry Department, Government of Andhra Pradesh,
vi. CEOs / MDs of State Implementing Agencies,
vii. President, IPA,
viii. President, IDMA,
ix. President, BDMAI,
x. President, OPPI,
xi. JS (NIPER) with the request to nominate two representatives from any NIPERs having knowledge of various technologies of Bulk Drug Production,
xii. IFCI / PMA,
xiii. All Scheme Steering Committee Members.

1. In order to make the country self-reliant in Bulk Drugs (APIs/KSMs and Drug Intermediates) and keeping in mind the strategic objectives of drug security for the country, the Department of Pharmaceuticals is implementing the ***Scheme for Promotion of Bulk Drug Parks,*** which is an intrinsic part of the efforts of Govt of India towards Drug Security.

2. Under the scheme, three Bulk Drug Parks in the State of Gujarat, Himachal Pradesh and Andhra Pradesh are being supported in the form of financing of common infrastructure facilities/projects. The objective is to create a robust ecosystem for the manufacturing of Bulk Drugs in the country and also reduce the manufacturing cost significantly, by providing easy access to standard testing & infrastructure facilities.

3. While the Scheme Steering Committee will continue to monitor the Scheme at operational level, there is a need to set up a **High Level Committee** with industry representatives and technical experts to ensure that the design, investments and infrastructure in the parks are aligned with the strategic objectives of the scheme. The Department of Pharmaceuticals has, thus, constituted a High Level Committee to monitor the progress of the parks with the following compositions: -

i.	Hon'ble Minister of Chemicals and Fertilizers	:	Chairman
ii.	Hon'ble Minister of State (Chemicals & Fertilizers)	:	Deputy Chairman
iii.	Secretary, D/o Pharmaceuticals	:	Member
iv.	Drugs Controller General of India, CDSCO	:	Member
v.	Joint Secretary, Drug Regulations, DoHFW	:	Member
vi.	ACS / PS, Industry Department, Govt of Gujarat	:	Member

vii.	ACS / PS, Industry Department, Govt of Himachal Pradesh	:	Member
viii.	ACS / PS, Industry Department, Govt of Andhra Pradesh	:	Member
ix.	CEOs / MDs of State Implementing Agencies	:	Members
x.	President of IPA	:	Member
xi.	President of IDMA	:	Member
xii.	President of BDMAI	:	Member
xiii.	President of OPPI	:	Member
xiv.	Two representatives from NIPERs	:	Members
xv.	Joint Secretary, D/o Pharmaceuticals	:	Member Secretary

4. The State of Gujarat, Himachal Pradesh and Andhra Pradesh will present the details of design, strategy of selection of industrial units along with the list of bulk drugs going to be manufactured in the parks, well before the allotment of plots to ensure that through the scheme, the intended objectives of domestic manufacturing of critical bulk drugs is achieved.

5. The Terms of Reference of this Committee are as follows: -

i. To monitor the implementation of bulk drug parks, for ensuring the production of the bulk drugs required for strategic goal of drug security.

ii. To facilitate alignment of investments in the Bulk Drug parks with pharmaceutical industry requirements and public health needs.

iii. To facilitate transfer of technology and other interventions required to achieve the above objectives

6. The Committee, may co-opt other experts as and when required. The meeting should at least meet once in three months.

7. This issues with the approval of Hon'ble Minister, Chemicals and Fertilizers.

Dr. N. Yuvaraj, Joint Secretary to the Govt. of India, Ministry of Chemicals and Fertilizers, Department of Pharmaceuticals, New Delhi.

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Soon, 300 drug formulations to have mandatory bar codes on packages

The Union health ministry had issued a draft gazette notification regarding the same in June seeking comments and feedback from the public

"A bar code or QR code will authenticate whether a particular drug is original or not," the official added

To curb the menace of spurious medicines, the government is finalising the process of mandating pharmaceutical companies to print bar code on the packages of 300 drug formulations so that information such as manufacturing licence and batch number can be accessed upon scanning.

The amendments to Drugs and Cosmetic Rules, 1945 which, once approved, will come into force from May next year.

"A sizable of the drugs mentioned in the list are mostly bought over the counter exposing people to the possibility of consuming counterfeit medicines. This amendment aims to prevent supply of fake medicines and ensure improvement in public healthcare," an official source told PTI.

"A bar code or QR code will authenticate whether a particular drug is original or not," the official added.

The Union health ministry had issued a draft gazette notification regarding the same in June seeking comments and feedback from the public.

Based on the comments and further deliberations, the ministry is in the process of finalising it.

Manufacturers of 300 drug formulation products as specified in the Schedule H2 of the Rule 96 of Drugs and Cosmetics Act will be required to print or affix bar code or quick response code on its primary packaging or secondary package label that store data or information legible with software application to facilitate authentication.

The stored data or information shall include particulars such as unique product identification code, proper and generic name of the drug, brand name, name and address of the manufacturer, batch number, date of manufacturing and expiry and manufacturing license number.

In the first phase, 300 drugs from top pharma brands having around 35 per cent of the total market share will be brought under this ambit and by December next year, all drugs may be covered.

The drugs include Allegra, Amlokind, Azithral, Betadine, Calpol, Ceftum, Combiflam, Dolo, Dulcoflex, Ecosprin, Gelusil, Jalra, Lantus, Manforce, Meftal Spaz, Shelcal, Human Mixtard, Pan 40, Otrivin, Pantocid, Rantac, Stamlo, T-bact ointment and unwanted kit and Volini spray.

The Drugs Technical Advisory Board (DTAB) in a meeting held in November 2021 had recommended introduction of bar code or QR code in the top 300 brands of drug formulations.

Source: Business Standard, 05.11.2022

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A big boost to drug discovery

Health Ministry recently issued a notification amending ND&CT Rules 2019, to include provisions for deemed approval for various steps involved in the clinical trial for new drugs

In what can be a big boost to the drug discovery and development process in the country, the Union Health Ministry has recently issued a final notification amending the New Drugs and Clinical Trials (ND&CT) Rules 2019, to include provisions for deemed approval for various steps involved in the clinical trial for new drugs, including registration of ethics committees, conducting clinical trials and manufacturing new drugs for test or analysis or clinical trials. Undoubtedly, India is emerging as a major

hub for clinical research as ND&CT Rules, 2019 has been able to offer clarity in guidelines for Indian clinical trial subjects to actively participate in new Covid-19 vaccine trials.

Besides, diverse patient population pool as compared to global patient population is also helping the country in witnessing development of clinical research. Clinical trials protocol has today become more streamlined with the coming up of ND&CT Rules, 2019 involving a lot of regulatory, economic, skill and subject enrollment interventions and protocols. ND&CT Rules 2019 are being fruitful in providing guidance on running clinical trials smoothly in accordance with approved protocol from ethics review boards and regulatory authorities. Now, the government has further amended the ND&CT Rules to make it more industry-friendly. The Ministry, on January 21, 2022, had published a draft notification, seeking the stakeholders to submit objections and suggestions and the objections and suggestions received from the public on the proposed amendment have been considered by the central government before finalising the notification.

As per the amended in the ND&CT Rules, in Rule 8, sub rule 3(ii), a provision has been inserted as per which if there is no communication received from the Central Licensing Authority (CLA), i.e the office of the Drugs Controller General of India, to the applicant within the 45 working days period, the registration of Ethics Committee shall be deemed to have been granted by the CLA and such registration shall be deemed to be legally valid for all purposes and the applicant shall be authorised to initiate clinical trial in accordance with these rules.

The applicant who has taken deemed approval under this amended provision should, before initiating the functions of the Ethics Committee, inform the CLA in Form CT-02A and the CLA will, on the basis of this information, take on record the Form CT-02A which will become part of the official record and will be called deemed registration of the CLA. The next provision to be inserted is under Rule 22, Sub-Rule (2), wherein if there is no communication from the CLA to the applicant within the 90 working days period, the permission to conduct all clinical trial will be deemed to have been granted by the CLA and such permission shall be deemed to be legally valid for all purposes and the applicant shall be authorised to initiate clinical trial in accordance with these rules. In Rule 24, a provision to be added under which if there is no communication from the CLA to the applicant within 90 working days period, the permission to conduct all clinical trials shall be deemed to be legally valid for all purposes and the applicant shall be authorised to initiate clinical trials in accordance. In yet another boost to drug discovery in the country, the government has made another amendment in Rule 34, Sub-Rule (2), as per which a provision is added that if no communication has been received from the CLA to the applicant within the 90 working days period, the permission to conduct bioavailability or bioequivalence (BA/BE) study of the new drug or investigational new drug shall be deemed to have been granted. A Sub-Rule, (2A) is proposed to be added so that the applicant who has taken deemed approval shall, before initiating BA/BE study of the new drug or investigational new drug, inform the CLA in Form CT-07A and the CLA shall on the basis of the said information take on record the Form which will become part of the official record and shall be called deemed approval of the CLA.

In Rule 53, in Sub-Rule (1) and (2), a provision will be inserted under which if no communication has been received from the CLA to the applicant within the period of 90 working days, the permission to manufacture new drugs or investigational new drugs for clinical trial or bioavailability or bioequivalence study or test and analysis shall be deemed to have been granted by the CLA and it shall be deemed to be legally valid for all purposes and the applicant shall be authorised to manufacture the new drug or investigational new drug for the said purpose, after submitting a Form CT-11A.

Similarly, under the Rule 60, Sub-Rule (1)(ii), if no communication has been received from the CLA to the applicant within the period, to manufacture unapproved active pharmaceutical ingredient for development of pharmaceutical formulation for test or analysis or

clinical trial or bioavailability and bioequivalence study shall be deemed to have been granted by the CLA and such permission shall be deemed to be legally valid for all purpose and the applicant shall be authorised to manufacture the new drug or investigational new drug for said purposes in accordance with these Rules. In Rule 60, the Sub-Rule (2)(ii) shall also be amended, stating that in case of rejection, the applicant may request the CLA to consider the application within a period of sixty days from the date of rejection of the application on payment of fee as specified in the sixth schedule and submission of required information and documents. Definitely, the Union Health Ministry's initiative will help fast-track the drug discovery and development process to the marketing stage in the country. (The author is a freelance journalist with varied experience in different fields)

Source: Sreeja Ramesh, Bizz Buzz, 07.11.2022

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SANKALP: An opportunity for pharma MSMEs to get workforce trained on GMP

Govt has recently approved the financial assistance for 7,500 workmen employed with pharma MSMEs to re-skill/upskill on 360 degree aspects of good manufacturing practice (GMP)

Under its Skill Acquisition and Knowledge Awareness for Livelihood Promotion (SANKALP) project, the Union Ministry of Skill Development and Entrepreneurship has recently approved the financial assistance for MSME pharma units to get their manufacturing workforce trained on good manufacturing practice (GMP). SANKALP, a programme of the Ministry of Skill Development with loan assistance from the World Bank, is aiming to improve short term skill training qualitatively and quantitatively through strengthening institutions, bringing in better market connectivity and inclusion of marginalised sections of the society. The Skill Development and Entrepreneurship Ministry has approved the financial assistance for 7500 employees and workmen employed with MSME companies in pharma clusters pan India to re-skill/ upskill on 360 Degree aspects of GMP. Nominated employees can therefore avail of these online upskilling modules, fully funded by the government.

SANKALP was launched on January 19, 2018 and will be in force till March 2023. There are three programs offered under the SANKALP Project for re-skilling and upskilling of MSME workforce in the life sciences sector. These include 360 Degree GMP for production machine operators, 360 Degree GMP for manufacturing assistants and 360 Degree GMP for packaging assistants.

The central government's initiative in this regard comes after the relentless efforts of the Life Sciences Sector Skill Development Council (LSSSDC) which had submitted a representation to the Skill Development and Entrepreneurship Ministry seeking financial assistance for MSME pharma units to get their manufacturing workforce trained on GMP following feedback from the pharmaceutical industry associations about the financial inability of the MSME pharma companies to use 360 Degree GMP programs in paid model.

LSSSDC is an industry led, national level vocational education awarding body, which has been working relentlessly for bridging the skill gap in life sciences sector including pharma, biotechnology and contract research. In 2020, LSSSDC in consultation with industry leaders and experts, have developed and launched Good Manufacturing Practice Training Programs covering 360 Degree aspects of GMP requirements for employees and workmen working in key job roles in a manufacturing unit.

These programs were based on the skill gap trends identified in various regulatory audits like USFDA, UKMHRA, WHO and State FDAs over the last three years. During the pandemic of Covid-19, realizing the advantage of technology intervention, these programs were developed as online modules which provided the flexibility of implementation keeping the quality and standardization of programs intact. LSSSDC had partnered with nominated Indian industry experts and a German Federal Agency, GIZ, for development of these programs.

Of course, the Central government's skilling programme and its partnerships with the pharma industry will bolster access to high quality industry ready workforce. It will accelerate implementation of a digital workplace strategy capable of driving the new dimensions in employment opportunities. This skilling programme will be reoriented to promote sustainability and employability. In view of the continuous changes worldwide in areas like newer infections, virus mutations and other diseases, it is

absolutely necessary that continuous skilling of people is needed to sustain newer needs and remain employable.

This becomes very essential in the pharma sector because India is steadily becoming global pharmacy for all essential medications. It is on the basis of representation of LSSSDC that the Ministry of Skill Development and Entrepreneurship under its initiative SANKALP has approved the financial assistance for pharma MSMEs helping them get their employees trained on GMP. It is obvious that the LSSSDC understood that the medium and small size employers are not able to meet the rigorous re-skilling and up-skilling demand for its operator and assistants level workforce due to a financially stressed economy.

To participate in the SANKALP Project for re-skilling or upskilling of MSME workforce in life sciences sector, interested companies need to provide valid Udyam Certificate to LSSSDC; ensure access to LSSSDC team for basic employee data required for enrollment and allow LSSSDC to take Aadhaar based attendance during the training program; ensure no salary deduction for employee/ worker during the upskilling program duration, and wherever possible provide computers for delivery of upskilling program to its employees/ workers. Overall this SANKALP project is an opportunity for MSME pharma units to get their workforce trained on GMP. (The author is a freelance journalist with varied experience in different fields)

Source: Sreeja Ramesh, Bizz Buzz, 09.11.2022

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Fresh push for APIs under PLI scheme

Chinese domination in APIs has left Indian drug manufacturers susceptible to supply chain shocks. Mint

The government has extended the last date for applications for manufacturing Active Pharmaceuticals Ingredients (APIs) under the PLI scheme after the sops it offered failed to create the expected response, people aware of the development said.

China's dominance in APIs, an essential input for drug development of even the most basic kinds such as painkillers, has left New Delhi susceptible to supply chain disruptions, including from repeated lockdowns in China, which is the largest world's largest manufacturer and exporter of APIs.

"For 7 [kinds of] APIs, for which we don't have people (applications) yet, we are again calling for application. And the last date for applying is 21 November. We understand that PLI 2.0 is going as per the plan and the aim is to cover all the major pharma products under PLI pharma. As of now, it is too early to say anything about which PLI pharma scheme is going well because none of them have crossed the production year," said a government official on condition of anonymity.

The Department of Pharmaceuticals rolled out three PLI schemes—bulk drugs with an outlay of ₹6,940 cr, medical devices (₹3,420cr) and pharmaceuticals (₹15,000 cr) to help cut dependency on China.

However, the experts said the subsidy offered by the government was not enough to attract the investment required to begin large scale manufacturing. "As far as bulk drugs are concerned, about 14 projects have been commissioned with an investment of ₹612 cr. The incentive rates that we are offering is 20% for the first year, 15% for the fifth year and 5% for sixth year," another official said. "Many items imported from China are in form of raw materials including APIs, drug formulations and parts of machinery which are used for producing finished goods for exports. China accounted for over 43% of the total pharma imports worth $4,066 mn between Apr -Sept this year. But India exported pharma products worth $12,727 mn during the same duration," the official added.

Sanjeev Jain, MD, Akums Drugs & Pharmaceuticals said: "The scheme is expected to promote the production in the country and increase the value addition in exports as well as create a positive impact on the pharmaceutical market revenues in the times to come. However, it's too early to see direct impact on revenue as of now."

Trade experts said India used to be self- sufficient in API production but cheaper alternatives from China resulted in the closure of those manufacturing units. "It is after covid-19 and Russia-Ukraine war that a lot of countries have realised the consequence of over-dependence on China for critical items like semi-conductors and APIs. India used to be self-sufficient in making APIs but cheaper alternatives resulted in the shutting down of manufacturing in India. Getting those back will not just happen due to the subsidy offered. An entire ecosystem to support manufacturing of critical items will be needed," a trade expert said. As per the CII, Chinese active ingredients are about 20% to 30% cheaper than Indian products and incentives ranging up to 20% under PLI could help bridge the gap.

Queries emailed to department of pharmaceutical spokesperson and ministry of commerce remained unanswered till press time.

Source: Ravi Dutta Mishra & Priyanka Sharma, HT Mint, 08.11.2022

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PLI scheme will gain momentum in next 2 years, says Chief Economic Advisor

CEA Anantha Nageswaran says it will expand and pick up steam in other areas as well

V Anantha Nageswaran, Chief Economic Advisor

The PLI (Production Linked Incentive) scheme is likely to gain more momentum and would expand to more sectors thereby giving further thrust to growth. According to Dr V Anantha Nageswaran, Chief Economic Advisor.

The PLI scheme announced in 2020 and 2021, is currently implemented in two or three areas . However, it is likely to gather steam moving forward. "PLI is for the medium and long term; it is about creating capacity within India to become a global leader, to attract supply chains into India and to facilitate China-plus-one to happen. The PLI scheme is likely to gain momentum. Right now, it is happening in two or three areas-mobile phones, pharmaceuticals and chemicals – but it has to pick up steam in other areas as well and hopefully in the next two years it will happen," Nageswaran said addressing the annual session of Indian Chamber of Commerce virtually on Monday.

The PLI scheme was conceived by the government to scale up domestic manufacturing capability, accompanied by higher import substitution and employment generation. According to him, the country's medium-term growth outlook is good as balance sheet is good, corporates are willing to invest, manufacturing activity continue to expand and digital infrastructure is becoming more and more important in access to finance, leading to formalisation.

RURAL CONSUMPTION UP

There are signs of improvement in rural consumption as two-wheeler sales have been picking up. There has been a recovery in employment rate and the balance-sheets of both banks and corporates have shown improvement. "The non-performing assets have come down and the banking sector is well recapitalised and ready to lend. In fact, it is already lending," he said. Talking of some steps that need to be taken, he said India should allow the rupee to depreciate gradually in the short term and go for judicious use of forex reserves. It is important to build supply chain resilience and augment forex reserves in order to be well prepared for any contingency that may arise during 2023, he said.

Source: Business Line, 07.11.2022

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60TH IDMA ANNUAL PUBLICATION 2022

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- **Import of Bulk Drugs and Intermediates (All Countries) during the year 2020-21 and from April 2021 to December 2021**
- **Export of Drug Formulations and Biologicals (All Countries) during the year 2020-21 and from April 2021 to December 2021**
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Note: *GST will be charged extra, if applicable

Contact: **Publications Department**

INDIAN DRUG MANUFACTURERS' ASSOCIATION

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