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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. 34 08 to 14 September 2022

INDIAN PHARMACOPOEIA COMMISSION:

PARLIAMENT NEWS:

INTERNATIONAL NEWS:

NATIONAL NEWS:

Celebrating the 2nd National Pharmacovigilance Week from 17th - 23rd September 2022

National Coordination Centre, Indian Pharmacopoeia Commission, is pleased to announce the official celebration of "2nd National Pharmacovigilance Week" from 17th to 23rd September 2022 to be celebrated every year on these days which will go a long way in reaching common masses to sensitize them about the importance of reporting Adverse Drug Reaction to improve patient safety.

This is an annual event. The theme for this year's 2nd National Pharmacovigilance Week is **"Encouraging reporting of ADRs by Patients".**

Healthcare professionals including physicians, nurses, pharmacist and others are the backbone of the healthcare system who contributes for patient safety. Hence, Indian Pharmacopoeia Commission has decided to celebrate "National Pharmacovigilance Week" on the occasion of patient safety day which with an aim to reach out to healthcare professionals' general public about the importance of reporting adverse drug reaction.

NCC-PvPI on behalf of the Ministry of Health & Family Welfare, Govt of India, urges all the Healthcare Professionals/Marketing Authorization Holders/ Professional Bodies/ Academic Institutions and other stakeholders to celebrate it by organizing activities like Conferences/Debates/Poster-Oral Presentations/ Quiz Contests/Essay Writing Competitions etc. in the area of Pharmacovigilance at your respective organizations.

● ● ●

In Rajya Sabha & In Lok Sabha

In Rajya Sabha

Institution of IPR Development

Rajya Sabha Unstarred Question No. 1482.

Shri Ayodhya Rami Reddy Alla:

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

(a) the details of share of patents filed by domestic entities out of total share of patents filed in India;

(b) whether Government has plans to create an exclusive apex level Institution for IPR Development to harness the full potential of IPRs in fuelling social and economic growth, if so, the details thereof, if not, the reasons therefor; and

(c) whether Government has considered labelling products with 'patent pending' to acknowledge their credibility and authenticity and increase their market value in the interim time while the patent gets approval, if so, the details thereof, if not, the reasons therefor?

Answered on 29th July, 2022

A. (a): In Financial Year 2021-22, out of the total 66440 patents filed in India, 29500 patents were filed by Domestic entities. In current Financial Year up to June 2022, out of the total 18007 patents filed in India, 8473 patents have been filed by Domestic entities. (b): Government has already established a national center of excellence for training, management, research, education in the field of Intellectual Property (IP) Rights, namely Rajiv Gandhi National Institute of Intellectual Property Management (RGNIIPM) at Nagpur.

(c): The existing Patents Act, 1970 already provides that on and from the date of publication of the application for patent and until the date of grant of a patent in respect of such application, the patent applicant shall have the like privileges and rights as if a patent for the invention had been granted on the date of publication of the application. However, the applicant is not entitled to institute any proceedings for infringement until the patent has been granted.

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

In Lok Sabha

Anti-Dumping Duty on Chemicals

Lok Sabha Unstarred Question No. 1692

Shri Jayant Sinha:

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

(a) the details of anti-dumping duty imposed on imported chemicals in India, year-wise since 2014;

(b) the details of the countries from which each of these chemicals are imported; and

(c) the details of ongoing investigations about the dumping of certain chemicals such as mono ethylene glycol and toluene di-isocyanate?

Answered on 27th July, 2022

A. (a) to (b): The Central Government, i.e., the Ministry of Finance, on the recommendation of the Directorate General of Trade Remedies (DGTR), Department of Commerce, has imposed the anti-dumping duty on the imports of various chemicals/ petrochemicals since 2014, the list of which is at Annexure-I.

(c): DGTR vide its final finding dated 24th June, 2022 has recommended continuation of anti- dumping duty in the sunset review investigation concerning imports of "Toluene Di-isocyanate, originating in or exported from China PR, Japan and Korea RP to the Ministry of Finance.

The anti-dumping investigation concerning imports of "Mono Ethylene Glycols" from Kuwait, Saudi Arabia and USA was initiated by DGTR vide its notification dated 28th June, 2021 and the same is in progress.

ANNEXURE-I

Anti-Dumping Duty In Force On Imports Of Chemicals/ Petrochemicals Imposed Since 2014

S.No.	Product	Country (ies) involved
1.	Sodium Nitrite-I	China PR
2.	Certain Rubber Chemicals-I	China PR, EU
3.	Acetone	EU, South Africa, & USA
4.	Phosphoric Acid	Korea RP
5.	Paranitroaniline	China PR
6.	Methylene Chloride	EU, USA
7.	Meta Phenylene Diamine (MPDA)	China PR
8.	Sodium Citrate	China PR
9.	2-Ethyl Hexanol	EU, Indonesia, Korea RP, Malaysia, Chinese Taipei and USA
10.	N-Butanol	EU, Malaysia, Singapore, South Africa and USA
11.	Methyl Acetoacetate	China PR, USA
12.	Toluene Di isocyanides (TDI)	China PR, Japan, Korea RP
13.	Ammonium Nitrate	Russia, Indonesia, Georgia, and Iran
14.	Sodium Chlorate	Canada, China PR, EU
15.	Sulphonated Napthalene	China PR
16.	Dimethylacetamide	China PR, Turkey
17.	MIPA	China PR
18.	Phosphorous pentaoxide	China PR
19.	Saturated Fatty Alcohols	Indonesia, Malaysia, Thailand
20.	Zeolite-4A	China PR
21.	Saccharine	Indonesia
22.	Chlorinated Polyvinyl Chloride Resin (CPVC) - whether or not further processed into compound	China PR, and Korea RP
23.	Toluene Di-isocyanate (TDI) having isomer content in the ratio of 80:20	European Union, Saudi Arabia, Chinese Taipei and UAE
24.	1-Phenyl-3-Methyl-5-Pyrazolone	China PR
25.	Aniline	China PR
26.	Ciprofloxacin hydrochloride	China PR
27.	Phthalic Anhydride	China PR, Indonesia, Korea RP, Thailand
28.	Natural Mica based Pearl Industrial Pigments excluding cosmetic grade	China PR
29.	Aceto Acetyl Derivatives of aromatic or heterocyclic compounds also known as Arylides	China PR
30.	Untreated Fumed Silica	China PR
31.	Sodium Hydrosulphite	China PR and Korea RP
32.	HFC Components	China PR
33.	Silicon Sealants	China PR
34.	HFC Blends	China PR
35.	“N,N-Dicyclohexyl Carbodiimide (DCC)”	China PR

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

E-Commerce

Lok Sabha Unstarred Question No. 1835

Shri Ramesh Bidhuri:

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

(a) whether the Government has taken any steps for streamlining and regulating e-commerce industry in the country;

(b) if so, the details thereof;

(c) whether any policy has been framed by the Government in this direction; and

(d) if so, the details thereof?

Answered on 27th July, 2022

A. (a) to (d): Government has implemented several legislative and policy measures for streamlining and regulating e-commerce industry in the country. Some of these measures are FDI Policy; Foreign Exchange Management Act, 1999; Consumer Protection Act, 2019; Competition Act, 2002; Central Goods and Services Tax (CGST) Act, 2017; Information Technology Act, 2000; Payment and Settlement Systems Act, 2007; Companies Act, 2013; Copyright Act, 1957 etc.

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

Medical Ethics

Lok Sabha Unstarred Question No. 2255

Shri E. T. Mohammed Basheer:

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

(a) whether it has come to the notice of the Government that professional Conduct, Etiquette and Ethics in medical profession are not being strictly adhered to;

(b) if so, the details thereof; and

(c) whether the Government proposes to take appropriate action to check unethical practices and ensure that health ethics are strictly adhered to and if so, the details thereof?

Answered on 29th July, 2022

A. (a) to (c): The erstwhile Medical Council of India (MCI) formulated Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002, to prescribe standards of Professional Conduct, Etiquette and Ethics for registered medical practitioners. Any act of violating the provision of the said Regulations amounts to professional misconduct. The National Medical Commission Act, 2019 empowers the appropriate State Medical Councils or Ethics and Medical Registration Board (EMRB) of the Commission, to take disciplinary action against a doctor for violation of the provision of the aforesaid Regulations. When complaints are received against the violation of code of ethics for doctors, such complaints are referred by EMRB (previously by erstwhile MCI) to the concerned State Medical Councils where the doctors/medical practitioners are registered.

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

Production and Export of Important Medicines

Lok Sabha Unstarred Question No. 2298

Shri Subbarayan K.:

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

(a) whether it is a fact that the pharma sector in India is growing well and is a major producer and exporter of important medicines like antibiotics, antimalarial, anti-TB drugs, Paracetmol etc.;

(b) if so, the details thereof along with the present position of India in the production and export of these medicines;

(c) whether it is a fact that India was making 70 per cent of the active pharma ingredients (API) or bulk drugs by 1990, but a major part of these bulk drugs are presently being imported and mostly from China;

(d) if so, the details thereof;

(e) whether the Government has any plan to make inputs and intermediates for chemical and fertilizers based APIs in the country and therefor reduce the critical dependence on imported inputs for making medicines in the country; and

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

Answered on 29th July, 2022

A. (a) to (b): Yes, Sir. The Indian Pharmaceutical industry is the 3rd largest in the world by volume. India exported pharmaceuticals worth Rs. 1,75,040 crore in the financial year 2021-22, including Bulk Drugs/ Drug Intermediates. The quantity and the value of the drugs exported during the last five years is as under: -

Export of Drugs and Pharmaceuticals		
	Quantity (MT)	Value (In Rs Cr)
2017-18	665934	1,06,038
2018-19	674084	1,28,028
2019-20	524757	1,40,537
2020-21	642718	1,74,064
2021-22	1075906	1,75,040

Source: *DGCIS, Ministry of Commerce and Industry.*

(c) to (d): India is one of the major producers of Active Pharma Ingredients (API) or bulk drugs in the world. India exported Bulk Drugs/ Drug Intermediates worth Rs. 33,320 crore in financial year 2021-22. However, the country also imports various Bulk Drugs/ APIs for producing medicines from various countries including China. Most of the imports of the Bulk Drug/APIs being done in the country are because of economic considerations and also, China is one of the largest producers of KSMs and APIs in the world.

The quantity and the value of Bulk Drug and Drug Intermediates exported from India to other countries and imported from other countries including China during the last three years is as under: -

	Export to all countries		Imports from all countries		Imports from China	
Year	Quantity (MT)	Value (In Rs Cr)	Quantity (MT)	Value (In Rs Cr)	Quantity (MT)	Value (In Rs Cr)
2019-20	271544	27533	364433	24172	220875	16443
2020-21	324331	32857	390476	28529	256609	19403
2021-22	453130	33320	400642	35249	264582	23273

(e) to (f): The Government strives to minimize country's dependence on imports and to give fillip to indigenous manufacturing. In order to make the country self-reliant in APIs and drug intermediates, the Department of Pharmaceuticals is implementing the following three schemes: -

(i) The 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, with a financial outlay of Rs. 6,940 crores and the tenure from FY 2020-2021 to FY 2029-30, provides for financial incentive for 41 identified products. A total of 51 applicants have been selected under the scheme.

(ii) The Production Linked Incentive Scheme for Pharmaceuticals, with a financial outlay Rs. 15,000 crores and the tenure from FY 2020- 2021 to FY 2028-29, provides for financial incentive to 55 selected applicants for manufacturing of identified products under three categories for a period of six years. The eligible drugs under this scheme include APIs.

(iii) The Scheme for Promotion of Bulk Drug Parks, with a financial outlay of Rs. 3,000 crores and the tenure from FY 2020-2021 to FY 2024-25, provides for financial assistance to three States for establishing Bulk Drug Parks.

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

"Antiretroviral Therapy Drugs"

Lok Sabha Unstarred Question No. 2221

Shri Pradyut Bordoloi

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

(a) whether shortage of Antiretroviral Therapy (ART) Drugs used by HIV/AIDS patients has been reported from various States during the current year 2022, if so, the details thereof including duration of shortage; State/UT-wise particularly in the North east region;

(b) the number of ART Centres and number of patients seeking antiretroviral therapy during the last five years, State/UT-wise and year-wise;

(c) whether the Government is aware that stopping of free ART supply in some States/UTs and policies

to reimburse the expenditure incurred to patients based on receipts may compel patients to drop out of treatment, if so, the details thereof;

(d) the reasons for which responsibility of ART drug procurement has been passed on from National AIDS Control organization (NACO) to State/UT Governments;

(e) whether the Government has assessed the difficulties being faced by the State/UT Governments with procurement and funding of ART drugs; and

(f) if so, the details thereof along with steps taken/ proposed to be taken by the Government to resolve such difficulties?

Answered on 29th July, 2022

A. (a) to (f): India provides free antiretroviral (ARV) medicines of HIV/AIDS for lifelong treatment of around 14.8 lakh People Living with HIV (PLHIV) through 681 Anti-Retroviral Treatment (ART) centres under its National AIDS and STD Control Programme (NACP), which is fully funded by the Government of India. The National AIDS Control Organisation centrally procures ARV medicines for PLHIV as per national guidelines. The details of number of ART centres under NACP and number of patients on ART during last five years is given at Annex-1.

There is adequate stock of ARV medicines nationally for around 95% PLHIV in India who are on various 1st and 2nd line ARV regimens. For treatment of PLHIV, Dolutegravir-based ARV regimens are globally acclaimed as the best and safest ARV with minimal side effects and most of the PLHIV in India are on the single pill Dolutegravir-based regimen (Tablet TLD: Tenofovir+Lamivudine+Dolutegravir), for which there is around 3 months' stock nationally.

The ARV stock status is monitored stringently by NACO. There is no reported stock out for ARV drugs at the state level.

If there is occasional anticipated shortage issue at some ART centres, then proactive steps are taken to ensure uninterrupted supply of ARV drugs to all PLHIV through immediate relocation from nearby ART centres or other States. Further, State/District AIDS Control Societies (SACS/DACS) under State Governments are authorized to do emergency local procurement of ARV drugs (as per requirement, & as an interim measure) from their budgeted Grant-in-aid under NACP. Sufficient budget is allocated under the head "ARV for exceptional cases" for all 36 SACS under Annual Action Plan by NACO for emergency local procurement of ARV medicines and there is no need for purchase of ARV medicine by PLHIV or its reimbursement thereof.

Annex 1: Details of ART Centres and PLHIV Alive on ART

S. No.	States/ UTs	As on March 2018		As on March 2019		As on March 2020		As on March 2021		As on June 2022	
		ART centre	PLHIV On ART	ART centre	PLHIV On ART	ART centre	PLHIV On ART	ART centre	PLHIV On ART	ART centre	PLHIV On ART
1	Andaman & Nicobar Islands	1	106	1	113	1	125	1	127	1	151
2	Andhra Pradesh	40	1,77,273	40	1,84,336	40	1,92,693	40	1,90,243	53	2,01,739
3	Arunachal Pradesh	1	96	1	135	1	169	1	183	1	252
4	Assam	6	5,846	6	6,752	7	7,819	7	7,880	9	9,736
5	Bihar	17	46,047	19	53,259	20	60,544	20	63,448	28	70,601
6	Chandigarh	2	5,804	2	6,476	2	6,480	2	6,478	2	5,047
7	Chhattisgarh	5	12,235	5	13,092	5	14,798	8	15,216	8	17,261
8	Delhi	11	27,250	11	30,565	12	33,376	12	32,663	12	35,349

9	Dadar & Nagar Haveli and Daman and Diu	–	–	–	–	–	–	–	–	1	284
10	Goa	2	2,884	2	2,980	2	3,058	2	3,027	2	3,159
11	Gujarat	30	62,752	30	67,517	34	71,499	36	71,711	44	75,650
12	Haryana	1	11,059	7	10,614	7	15,371	7	16,085	15	23,883
13	Himachal Pradesh	6	3,959	6	4,219	6	4,544	6	4,606	6	4,978
14	Jammu & Kashmir	2	2,350	2	2,610	2	2,841	3	2,925	3	3,214
15	Ladakh										
16	Jharkhand	8	9,471	8	10,766	8	11,897	12	12,130	13	13,597
17	Karnataka	64	1,55,411	64	1,65,445	65	1,71,288	68	1,69,830	71	1,73,718
18	Kerala	10	12,919	10	13,839	10	14,445	10	14,713	15	15,379
19	Madhya Pradesh	18	22,133	18	25,193	18	29,183	19	29,733	25	33,670
20	Maharashtra	90	2,37,796	89	2,47,095	91	2,57,391	92	2,53,636	95	2,61,061
21	Manipur	13	12,483	13	12,879	13	13,216	13	13,366	13	13,795
22	Meghalaya	1	1,777	2	2,324	4	2,745	4	3,047	4	3,943
23	Mizoram	6	7,412	6	8,568	6	9,870	12	11,365	14	13,122
24	Nagaland	8	7,290	8	8,093	9	9,772	12	10,082	12	10,940
25	Odisha	15	17,142	15	19,127	15	20,944	15	21,692	16	23,158
26	Puducherry	1	1,193	1	1,237	1	1,262	1	1,252	1	1,263
27	Punjab	12	27,697	13	32,544	13	38,424	19	40,344	22	49,609
28	Rajasthan	24	37,092	24	41,408	24	45,209	35	46,514	35	51,721
29	Sikkim	1	170	1	184	1	207	1	218	1	277
30	Tamil Nadu	55	1,12,778	55	1,17,712	55	1,21,650	55	1,20,911	55	1,23,173
31	Telangana	22	73,198	22	80,579	23	83,517	23	83,490	23	88,955
32	Tripura	3	1,186	3	1,389	3	1,759	3	2,061	3	3,108
33	Uttar Pradesh	38	67,855	38	77,608	38	86,303	44	90,857	52	98,933
34	Uttarakhand	3	3,575	3	4,062	3	4,468	5	4,459	6	4,751
35	West Bengal	19	35,680	19	40,233	19	43,261	20	44,084	20	47,694

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

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PDG welcomes Indian Pharmacopoeia Commission to pilot for global expansion

The Pharmacopoeial Discussion Group (PDG), which brings together the European Pharmacopoeia (Ph. Eur.), the Japanese Pharmacopoeia (JP) and the United States Pharmacopeia (USP), with the World Health Organization (WHO) as an observer, is delighted to welcome the Indian Pharmacopoeia Commission (IPC) as a participant in the PDG pilot for global expansion. This announcement follows the decision to launch a pilot for expansion of membership taken at the 2021 PDG Annual Meeting ("PDG prepares pilot for global expansion of membership") and that represented a critical first step in the PDG's commitment to expanding the recognition of harmonised pharmacopoeial standards with a view to achieving global convergence. The one-year pilot for expansion is scheduled to start as of the PDG Annual Meeting to be held virtually in October 2022.

Global pharmacopoeias that were interested in participating in this pilot had been invited to submit their applications, which were then evaluated based on objective entry criteria. For full transparency towards the PDG stakeholders, these criteria ("PDG Entry Criteria") and the detailed framework for the pilot phase ("PDG Pilot Framework") can be found on the websites of the three PDG pharmacopoeias, as was announced in the press release following the interim PDG meeting in June 2022 ("Pharmacopoeial Discussion Group videoconference meeting").

After reviewing each application, the PDG agreed by consensus to start the pilot phase with the IPC, the only applicant that met all the requirements in the entry criteria for the pilot. The PDG would like to thank the other applicants for their interest in the pilot and will remain in touch on potential collaborative opportunities in the future with the aim of achieving greater convergence of global pharmacopoeial standards. This includes continuing to share PDG publications (i.e. draft texts for public consultation and final sign-off texts) with non-PDG pharmacopoeias in order to support convergence of these texts beyond the PDG. The PDG also continues to welcome comments from other pharmacopoeias on its draft texts.

The established PDG members will use the lessons learned from the one-year expansion pilot to further refine the Group's working methods and, at the end of the pilot, will identify any changes necessary to ensure that the PDG continues to perform efficiently, prior to a broader rollout.

The PDG looks forward to welcoming the IPC to the expansion pilot in October 2022, and working together on providing strong, science-based harmonised pharmacopoeial standards.

Source: EMA Newsroom, EDQM Strasbourg, France, 09.09.2022

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Nip This Pharma Threat in the Bud

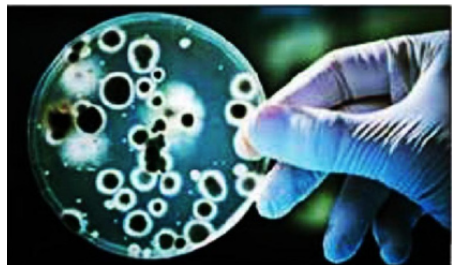

Steve Brooks

Often hailed as the pharmacy of the world, the booming pharmaceutical sector of India has more than doubled its share in exports over the past decade. India accounts for 60% of vaccines and 20% of generic medicines globally. During the Covid-19 pandemic. the sector supported many countries with medication and vaccines. The industry has unlocked growth for the Indian economy, enabling better employment opportunities, improved health and quality of life. However, the looming threat of antimicrobial resistance (AMR) holds the potential to undo years of progress made by the pharma sector.

In 2019, AMR was directly responsible for over 1 million deaths, and an additional associated 5 million deaths. This was much more than the deaths caused by malaria and HIV collectively that year. Humans and animals do drive AMR in the environment from untreated wastewater in healthcare facilities, municipal waste-water and farms, and untreated effluents from pharmaceutical manufacturing may contribute to the spread of environmental AMR when discharged into the water streams.

Together, these drivers subsequently increase the build-up of AMR in humans and animals due to the interconnectivity between ecosystems. The spread of AMR not only has ramifications on health but also impacts economic and developmental goals, including those on sanitation, poverty and well-being. Multilateral organisations like the World Health Organisation (WHO), United Nations Environment Programme (UNEP) and fora like G7 have emphasised curtailing the various drivers of AMR. With the inclusion of UNEP in the global quadripartite to curtail AMR, there has been a renewed emphasis on limiting it. In India, the Centre and some state governments like Andhra Pradesh, Kerala and Madhya Pradesh have also developed action plans to arrest AMR spread.

The National Action Plan on AMR and the Andhra Pradesh's State Action Plan have also called for stringent limits for antibiotic residues from farms, healthcare facilities, factories and pharma manufacturing units. However, in the absence of strict limits for antibiotic residues, several cases of antibiotic pollution in rivers of pharma hubs


Spot the problem early

like Telangana and Himachal Pradesh have been reported. Since its inception, the AMR Industry Alliance (AMRIA) has been striving to develop safe discharge values for various antibiotics. Recently, with the help of the British Standards Institution (BSI). AMRIA formulated the Antibiotic Manufacturing Standards (AMS) to reduce the risk from antibiotic manufacturing effluents. AMS requires the manufacturer to develop an environmental management system and risk-based approach to assess and control effluents along with implementing predicted no-effect concentrations (PNEC) criteria.

With a certification scheme that will provide independent verification that an antibiotic is made in accordance with the requirements of the standard in the pipeline, widespread adoption of these standards can usher in a new era of environmental transparency, accountability and responsibility in antibiotic manufacturing. Sustainable manufacturing must be supplemented with sustainable procurement practices to help revamp the global pharma supply chain.

Countries like Norway, Sweden and Britain are providing market incentives to promote sustainable antibiotic manufacturing. While Norway's antibiotic procurement policy offers 30% weightage to environment-friendly production, the Swedish government uses environmental criteria in pharma procurement. With countries providing first-mover benefits to manufacturers with greener practices. Indian manufacturers should ensure their competitive advantage by embracing them.

While some industry members can take the lead by self-regulating, a robust monitoring framework along the lines of the AMS and certification scheme anticipated in early 2023 that can be widely adopted is the need of the hour. Also, with SME manufacturers concentrating most of the pharma sector in India, GoI needs to step in to facilitate the adoption of risk assessment. That means manufacturers quantify antibiotic losses to the environment and understand where and how best to reduce such emissions.

Where necessary, low-cost technologies can significantly reduce the discharge from antibiotic manufacturing. Undertaking collaborative and cohesive measures for regulating the discharge of effluents from pharma manufacturing sites is a prerequisite in ensuring the elimination of AMR from the environment.

The writer is adviser: AMR Industry Alliance

Source: Economic Times, 12.09.2022

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Redesigning of Commerce department underway, govt to set up 'trade promotion body' to promote trade: Piyush Goyal

Los Angeles [US], September 11 (ANI): Union Minister for Commerce and Industry Piyush Goyal on Saturday said that the redesigning of the Commerce Department is under process and the Ministry will come up with a plan after thoroughly studying the received reports suggesting the new structure.

Union Minister for Commerce and Industry Piyush Goyal (Photo/ANI)

"We are in the process to redesign the structure of the Commerce Ministry and one of the ideas in front of us is to set up a 'trade promotion body', similar to 'Invest India'. It is a facilitation unit that will promote trade from India, for India," Goyal said while addressing a media briefing.

Responding to a question on when can 'Trade Promotion Body' –which is aimed to drive overall promotion strategy, export targets, and execution– come into force, Goyal said, "We have just received the reports suggesting the new form of the Commerce Ministry, we will now go through the process of studying the report in great detail and then come up with the overall plan."

The Union Minister said that there were a number of suggestions on some roles that government could do to connect ideas and entrepreneurs from here with potential partners or stakeholders in India.

"We have two initiatives, 'Invest India' and 'Startup India Team' which support startups in India, connecting with the investors both in India and abroad," he said.

The Union Minister said that the partnership between the Indian diaspora and India will truly help fast-track India's journey to a developed nation. "It's great to see the energy that our diaspora has across the west coast, they want to contribute to India's development," he added.

According to an earlier statement from the Commerce Ministry, the Department of Commerce is set to undergo transformative changes towards evolving into a 'future ready' establishment of the Government with scaling up, strengthening, and infusion of 'new age' capabilities leading to an ecosystem which can achieve USD 2 trillion exports by 2030.

As part of the restructuring exercise, a dedicated trade promotion body would be set up to devise an overall strategy to achieve targets and make it future-ready," Goyal had said earlier.

He said that the focus will be on strengthening negotiations capability at the World Trade Organisation (WTO) and for bilateral free trade agreements; centralisation and digitisation of trade facilitation processes and rehauling the data analytics ecosystem.

"Indian trade and commerce will not only be a strong element in India's march to prosperity, towards becoming a developed nation in the Amrit Kaal but also play an extremely important role in serving the needs of the whole world," he added.

Goyal, while releasing 'The Department of Commerce Restructuring Dossier' had said that his ministry is preparing for greater multilateral and bilateral engagement with other countries and the objective is to raise India's share in global exports and to create jobs.

Goyal said restructuring of the entire department of commerce aims at preparing India to become a key global player in world trade.

He further said the restructuring rests on 5 major pillars: Increasing India's share in global trade, assuming the leadership role in multilateral organisations, the democratisation of trade, creating 100 Indian Brands as Global Champions, and setting up Economic Zones in India to strengthen the manufacturing base and attract greater investments to India.

In February this year, a review exercise by Commerce and Industry Minister Piyush Goyal called for revamping of the Department of Commerce, fortification, and consistent strengthening of trade and investment promotion bodies including the Directorate General of Foreign Trade (DGFT).

With several emerging opportunities owing to shifts in global trade dynamics like rapid growth of services and disruptive potential of climate change, the Ministry felt the need to proactively develop exports, build India's brand in global trade and undertake constant monitoring of exports to ensure the achievement of targets on time.

The revamping of the Commerce Department is also aimed at further building on its strategic direction and aspirations for the next decade and moving from inherent traditional roles to new roles by re-engineering the operation model with enhanced 'new-age' capabilities. In line with this, the revamped Department will have a more coherent trade promotion strategy with clear targets and execution accountabilities.

There will be a strengthened negotiation ecosystem with the right expertise and robust end-to-end processes with clearly defined focus areas and institutions. An optimal mix of talent with specialists and generalists sourced from across private and government sectors to create an agile setup responsive to market opportunities and exporter needs via interlinkages across bodies is in the works.

According to a project report on the designing of a 'future ready' Department of Commerce, a dedicated 'trade promotion body' to drive overall promotion strategy, export targets, and execution is proposed to be set up. A stronger active role for missions in trade promotion for market intelligence leads generation and localized research has been envisaged. Strengthening negotiations via multi-skilled negotiation teams and separation between bilateral and WTO negotiations has been envisioned.

It has also been proposed to set up a 'trade remedies review committee' including the Ministry of Commerce and Industry, Ministry of Finance, and line ministries for transparency in investigations outcomes. Centralization and digitization of trade facilitation processes have been recommended to drive ease of compliance and scheme administration. Rehauling the data and analytics ecosystem via centralized data management and embedded analytics capabilities in the Department of Commerce has been proposed. (ANI)

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Source: The Print, 11.09.2022

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PLI extension to more sectors on anvil

Discussions underway to bring certain electronic components, pharma and medical devices under the production-linked incentive (PLI) scheme

New Delhi: There are demands to extend production-linked incentive (PLI) scheme to more sectors such as certain electronic components, pharma and medical devices, and discussions are underway in the government on these proposals, a senior government official said.

Discussions are also going on to bring PLI scheme for toys, furniture, bicycles and containers. The objective of the scheme is to make domestic manufacturing globally competitive, create global champions in manufacturing, boost exports and create jobs. The government last year rolled out the scheme with an outlay of about Rs 2 lakh crore for as many as 14 sectors, including automobiles and auto components, white goods, textiles, advanced chemistry cell (ACC) and speciality steel.

"So, from Rs 1.97 lakh crore, there are savings from some sectors. So against those savings, things are being planned. Proposals are under consideration," the official said. Demand for including sectors like certain electronic components, toys, furniture, bicycle, and containers has come against the backdrop of the government's move to cut imports and boost domestic manufacturing. The strategy behind the scheme was to offer companies incentives on incremental sales from products manufactured in India, over the base year.

Source: Bizz Buzz, 13.09.2022

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International regulatory convergence key for accessibility, affordability of medicines

Hyderabad: About 100 regulators from more than 50 countries will share a common platform to discuss international regulatory convergence to promote accessibility and affordability of quality medicines. This convergence will save time and resources of the drug companies in going through the approval process

separately in each market, said Ravi Uday Bhaskar, Director General, Pharmexcil.

The Ministry of Commerce and India's national regulatory body for cosmetics, pharmaceuticals and medical device Central Drugs Standard Control Organisation are hosting the eight edition of International Exhibition for Pharma and Healthcare (IPHEX) from Sept 21 to 24. It will be hosted at India Expo Centre in Noida.

This is the first time that healthcare regulators from several countries are coming together to discuss about the regulatory enablers for fast tracking approvals and regulatory preparedness for healthcare emergencies. The Drugs Controller General of India will lead the discussion along with State and Central regulators. This conclave will provide an opportunity to the Indian industry to interact with the international regulators, he said.

The three-day event will focus on India sourced generic drugs, global expectations, learnings from Covid, accessibility, affordability and equitable distribution of Covid vaccines and therapeutics, migrating to risk-based inspections and others.

Dr Chava Satyanarayana, Founder and Chief Executive Officer of Laurus Labs Limited and IPHEX Chairman, said Indian pharma companies and vaccine makers demonstrated resilience during the Covid. It is contributing to the healthcare through the supply of quality, affordable generic medicines to nearly 200 countries and is now 'Pharmacy of the World'. About 350 Indian exporters are exhibiting their products. About 700 overseas buyers are expected to visit the exhibition.

NOSCH Labs Director and Pharmexil Committee of Administration Member Dodda VVS Reddy was also present at the event.

Source: Telangana Today, 12.09.2022

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Several antibiotics, other drugs may get cheaper

Several antibiotics, nicotine replacement therapy products, painkillers, drugs to treat chronic diseases are likely to get cheaper as government inches closer to announcing the National List of Essential Medicines (NLEM) on Tuesday.

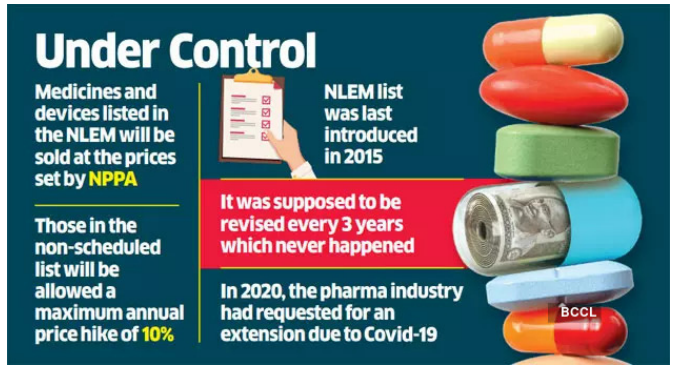
Medicines and devices listed in the NLEM must be sold at the prices set by National Pharmaceuticals Pricing Authority (NPPA), while those in the non scheduled list are allowed a maximum annual price increase of 10%. The revision of the NLEM aims to ensure that antibiotics are available when needed, and that the right antibiotics are prescribed for the right infections.

The revised list has been formulated with a new method, a departure from the existing practice

The NLEM list was last introduced in 2015. It was supposed to be revised every three years which never happened. In 2020 the pharma industry requested for an extension due to Covid-19. Last year, the Indian Council of Medical Research (ICMR) submitted a revised NLEM list to the health minister in September.

However, the health ministry re-initiated the exercise of reviewing the drugs which has now been finalised," said the same person. Commonly used drugs which are proposed last year to be brought under price control include anti-diabetes drugs such as teneligliptin and insulin glargine, anti-tuberculosis drugs bedaquiline and delamanid, antiparasitic ivermectin and rotavirus vaccine.

The committee on the National List of Essential Medicines (NLEM) headed by Balram Bhargava, former



secretary, department of health research and director-general of the Indian Council of Medical Research decided on those medicines that should be available in adequate numbers and assured quality. For the medicines included in NLEM, manufacturers are required to sell their product equal to or lower than the ceiling price fixed using a formula set by the government.

A ceiling price calculation is based on the simple averaging of the market prices of different brands of medicines having a market share of at least 1 per cent.

The revised list has been formulated with a new method, a departure from the existing practice, where not all essential drugs will find their prices capped. The Standing National Committee on Medicines, was tasked with preparing the shortlist which medicines should be available in adequate numbers and assured quantity. Under the earlier mechanism, the health ministry prepared a list of drugs eligible for price regulation, following which the department of pharmaceuticals under the ministry of chemicals and fertilisers incorporated them into Schedule 1 of the Drug Price Control Order. The National Pharmaceutical Pricing Authority then fixed the prices of drugs.

Source: Teena Thacker, ET Bureau, 13.09.2022

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National List of Essential Medicines (NLEM) 2022 - Released

The list has been prepared after consultation with 350 experts. A total of 140 meetings took place before the list was finalised.

Dr Mansukh Mandaviya releasing the National List of Essential Medicines 2022. Photo credit: Twitter/@mansukhmandviya

Union Minister for Health and Family Welfare Dr Mansukh Mandaviya on Tuesday released the National List of Essential Medicines (NLEM) 2022. The list includes 384 medicines, 8 more than the last list which was issued in 2015. There were 376 medicines in the list that was issued in 2015. While 24 medicines have been removed from the list, there are 34 new medicines that have found a place on the latest list.

Mandaviya, after releasing the list, said that several drugs will now become more affordable. "Several antibiotics, vaccines, anti-cancer drugs and many other important drugs will become more affordable & reduce patients' out-of-pocket expenditure," he tweeted.

The list has been prepared after consultation with 350 experts. A total of 140 meetings took place before it was finalised.

(Member can visit https://www.zeebiz.com/india/news-essential-medicines-list-india-nlem-2022-released-4-cancer-medicines-included-check-complete-list-of-384-drugs-198692 to view The list of 384 medicines included in the National List of Essential Medicines (NLEM) 2022)

Source: Ambarish Pandey, ZeeBiz WebDesk, 13.09.2022

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