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IDMA BULLETIN

VOL. NO. 53 | ISSUE NO. 15 (PAGES: 36) | 15 TO 21 APRIL 2022 | ISSN 0970-6054 | WEEKLY PUBLICATION

INDIAN PHARMA - GLOBAL HEALTH CARE

INDIAN DRUG MANUFACTURERS' ASSOCIATION

HIGHLIGHTS

LIMITLESS DEDICATION. THAT LEADS TO UNQUESTIONABLE PURITY.

Dear Partner,

It goes without saying that Signet provides excipients only of the highest quality and purity, from global leaders like Pfanstiehl, Galactic and Novo Nordisk Pharmatech A/S.

Pfanstiehl brings over ten decades of experience being at the forefront of the pharmaceutical as well as biotechnology sectors, specialising in high purity and low endotoxin ingredients and intermediates. Galactic are global leaders in the production of lactic acid and mineral lactates, offering purity and quality in equal measure across their products. While Novo Nordisk Pharmatech A/S have been the premier supplier of the finest and safest quaternary ammonium compounds, for over 65 years.

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- L-Arginine Hydrochloride
- L-Histidine Hydrochloride Monohydrate
- L-Histidine • Sodium Succinate Anhydrous
- Sodium Succinate Hexahydrate

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FEF BENZALKONIUM CHLORIDE SOLUTION

FEF CETRIMIDE

FEF CETYL TRIMETHYL AMMONIUM BROMIDE

GALACTIC

GALACID PHARMA 90 (Lactic acid)

GALAFLOW SL PHARMA (Sodium Lactate)

GALAXIUM PEARLS PHARMA (Calcium Lactate Pentahydrate)

Signet

The Complete Excipients Company

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IDMA BULLETIN

Vol. No. 53 **Issue No. 15** **15 to 21 April 2022**

IDMA ACTIVITIES:

GOVERNMENT COMMUNICATIONS:

FSSAI MATTERS:

CUSTOMS MATTERS:

DGFT MATTERS:

PARLIAMENT NEWS:

NATIONAL NEWS:

Methylcobalamin is a DEFINITE approved food ingredient as per FSS Regulations, 2016 (Amendment 6th September 2021) as well as FSS Regulations, 2022

Dear Member,

The controversy on methylcobalamin's status seems unending. Inorder to allay fears and remove controversy the below circular has been prepared by **Dr. R K Sanghavi**, Chairman – Nutraceutical Committee, IDMA for Members information and reference.

Regards,

Daara B Patel
Secretary- General, IDMA

To,
All Food Business Operators
IDMA – Members

The new FSS (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose and Prebiotic and Probiotic Food) Regulations, 2022 supersede the FSS Regulations, 2016 and any amendments made thereunder and are intended to be applicable and imply from 1st April 2022.

As in the earlier 2016 gazette The Food Safety and Standards Act (FSS), even the FSS (Nutra) 2022 Regulations does not specifically mention Methylcobalamin under the applicable Schedule - I for Health Supplements (HS). In this latter schedule there appears the standardized list of Nutrients (vitamins, minerals, amino acids and other nutrients) and includes two tables [first table listing vitamins (A) and minerals (B) and the other second table having the names of standardized amino acids, other nutrients and nucleotides]. Under the same Schedule - I table for vitamins and minerals the Serial No 6 mentions Vitamin B_{12} and specifies cyanocobalamin (i) and hydroxycobalamin (ii). This has unfortunately been implied by the FBOs that other than these two forms of Vitamin B_{12} the rest all (which includes Methylcobalamin) are unapproved and even deemed banned!! **This is completely false** as there is an implicit footnote (1) below the table listing Vitamins and Minerals which states –

*"Note 1 – Suitable esters, **derivatives** and salts of vitamins and salts and chelates of minerals may be used."*

It is a medical reality that Methylcobalamin is a derivative of Cyanocobalamin. All of the B_{12} forms are reduced to the core cobalamin molecule inside the cytoplasm and then the converted 2 active forms of B_{12}- Methylcobalamin (90%) and Adenosylcobalamin (10%) -irrespective of the form of B_{12} ingested, are released from the mitochondria into the blood [Gams RA, Ryel EM & Ostroy F. Protein-mediated uptake of vitamin B12 by isolated mitochondria. Blood 1976; 47(6): 923-930].

J Phys Chem B. 2019 Jun 6;123(22):4663-4672. doi: 10.1021/acs.jpcb.9b01969. Epub 2019 May 23.

Photochemical Spin Dynamics of the Vitamin B 12 Derivative, Methylcobalamin

Valentina Lukinović, Jonathan R Woodward, Teresa C Marrafa, Muralidharan Shanmugam, Derren J Heyes, Samantha J O Hardman, Nigel S Scrutton, Sam Hay, Alistair J Fielding, Alex R Jones

Abstract (Abridged)

Derivatives of vitamin B12 are six-coordinate cobalt corrinoids found in humans, other animals, and microorganisms. By acting as enzymatic cofactors and photoreceptor chromophores, they serve vital metabolic and photoprotective functions. Depending on the context, the chemical mechanisms of the biologically active derivatives of B12-methylcobalamin (MeCbl) and 5'-deoxyadenosylcobalamin (AdoCbl)-can be very different from one another.

THUS, METHYLCOBALAMIN IS AN UNDISPUTED VITAMIN B_{12} DERIVATIVE AND THEREFORE QUALIFIES AS AN APPROVED INGREDIENT FORM FOR INCORPORATING IN PRODUCTS INSTEAD OF THE CONVENTIONAL CYANOCOBALAMIN.

It needs to be emphasized here that Cyanocobalamin is a synthetic form of Vitamin B_{12} that's not found in nature; however, Methylcobalamin is a naturally occurring form and its food sources include fish, meat, eggs and milk.

Methylcobalamin is legitimate and an approved ingredienteven as per FSS Regulations, 2022 as a standardized derivative of Vitamin B_{12}. Being natural, the FBOs are providing a more bioavailable form of Vitamin B_{12}which is critical for facilitating health of blood and nerve cells and to help make DNA (deoxyribonucleic acid), the genetic material in all of body's cells.

The Nutraceutical Committee of the Indian Drug Manufacturers' Association (IDMA) has been in the forefront in ensuring acceptance of important ingredients including Methylcobalamin as standardized by FSSAI. The footnote text (wordings) were also suggested by Chairman of IDMA's Nutraceutical Committee and accordingly,based on the same, the earlier gazette notification dated 6th September 2021 [F. No. Stds./03/ Notification (Nutra)/FSSAI – 2017] authorizing the incorporation of derivatives of vitamins (such as Methylcobalamin) in Nutraceutical products was issued. Hence, it is urged that the Food Business Operators (FBOs) override and firmly confront any ill-informed, misguided Food Safety Officer (FSO) who approaches and questions Methylcobalamin's status as a permissible food ingredient in marketed / manufactured FSSAI products such as Health Supplements and Nutraceuticals. We need not anymore be disturbed by stray circulars such as File No.4(12)2016/Gujarat/Enf/FSSAI (dated 31st October 2019) issued by responsible regulators be it from the State or even Central office of FSSAI especially since it is mentioned in the FSS Regulations, 2022 that these new regulations aim to 'remove ambiguity and bring more clarity' and also'supersede FSS Regulations, 2016 and any amendments made thereunder'.

Thus, being natural and thereby more preferred, FSSAI needs to give due recognition to Methylcobalamin and accordingly it has never ever been banned via any circular / notification / order. **Moreover, FSSAI has even specifically mentioned that derivatives of vitamins are permitted as footnote under the Schedule-I of FSS (Nutra) Regulations, 2022 and this automatically gets Methylcobalamin the status of an approved ingredient – being a Vitamin B_{12} derivative.**

All FBOs must take cognizance of facts rather than fret and fume, or be confused, over baseless and erroneous information being circulated by those less well-versed with regulations, including the wrong interpretations by FSOs or Enforcement Directorate operatives at state-levels.

Best future for the Methylcobalamin-containing products – a critical form essential for fostering healthy Vitamin B_{12} status amongst consumers.

DR R K SANGHAVI

CHAIRMAN – Nutraceutical Committee

IDMA Congratulates Dr Rajesh Gupta for Being Nominated as Non Official Member of the HP State Pollution Control Board

IDMA Congratulates Dr Rajesh Gupta, Director, Dallas Formulations Private Limited, Executive Committee Member, IDMA and President, Himachal Drug Manufacturers Association for being nominated as Non Official Member of the HP State Pollution Control Board Representing the Interest of Industry Sector as per Government Notification no. STE-A (1)-4/2001-Loose dated 13th April 2022 (as reproduced below).

ENVIRONMENT, SCIENCE & TECHNOLOGY DEPARTMENT

NOTIFICATION

Shimla-2, the 13th April, 2022

No. STE-A (1)-4/2001-Loose.— In supersession of this Department Notification of even number dated 18 October 2016, the Governor Himachal Pradesh, in exercise of powers conferred under Section 4(2) (c) and Section 4 (2) (d) of the Water (Prevention and Control of Pollution) Act,1974, is pleased to nominate the following Non-Official and other Members of the H.P. State Pollution Control Board for a period of three years, with immediate effect in public interest:

Members of Local Authorities under Section 4(2) (c):

1. Smt. Deepali Jaswal, Mayor, Municipal Corporation, Mandi
2. Smt. Reena Devi, President, Municipal Council, Nalagarh, Distt. Solan
3. Smt. Nirmal Kaur, President, Municipal Council, Paonta Sahib, Distt. Sirmaur
4. Shri Jitender Sharma. President, Municipal Council, Sundernagar, Distt. Mandi
5. Shri Rahul Chaudhary, Councilor, Paonta Sahib Village and Post Office Gorkhuwala Tehsil Paonta Sahib Distt. Sirmaur.

Non-Official Members representing interest of Agriculture, Fishery or Industry or Trade under Section 4 (2) (d):

1. Dr. Som Dev Sharma (Agriculture Sector) President, Bhartiya Kisan Sangh, H. P. C/o Shri Rajeev Dhiman (SDO BSNL) Village Garheri Brahmana, P.O. Jhaniyari Distt. Hamirpur.

राजपत्र, हिमाचल प्रदेश, 19 अप्रैल, 2022 / 29 चैत्र, 1944 351

2. Shri Rajesh Gupta (Industry Sector) President, Himachal Drug Manufacturer Association, 153, 1st Floor, Motia Palaza, Near Toll Barrrier, Baddi, Distt. Solan-173205.

3. Shri Roop Lal (Fishery Sector) President, Fisheries Cooperative Society, Bilaspur

The Non-Official Members shall be entitled to TA/DA as prescribed by the State Government in this behalf from time to time.

By order,

PRABODH SAXENA, IAS,
Addl. Chief Secretary (Env., Sci.&Tech).

INDUSTRIES DEPARTMENT
Section-A

Invitation to IDMA's MSME member companies to participate in the 12th edition of KOREA PHARM & BIO 2022, scheduled to be held in KINTEX-II, Seoul, South Korea during JUNE 14-17, 2022

Indian Drug Manufacturers' Association (IDMA) & Kyungyon Exhibition Corporation, South Korea invite IDMA's MSME member companies to participate in the 12th edition of **KOREA PHARM & BIO 2022,** scheduled to be held in KINTEX-II, Seoul, South Korea during **JUNE 14-17, 2022**.

IDMA has submitted an application to MSME Ministry to organize Indian National Pavilion in the aforesaid exhibition by which exhibitors from MSME categories can avail reimbursement of up to 100% on booth cost and economy class airfare for 1 person from the exhibiting company as per the guidelines.

KOREA PHARM has been the most preferred platform for the last 8 years for Indian exporters of Pharmaceuticals, APIs, Intermediates, Natural Ingredients. PHARMEXCIL has been a regular participant by organizing national pavilion. **PHARMEXCIL has confirmed participation of 20+ exhibitors for this year as well.**

The exhibition, organized by Kyungyon Exhibition Corporation, is the oldest Exhibition focused on Pharmaceuticals and Pharmaceutical Ingredients. This is the only Exhibition supported by Ministry of Food & Drug Safety, and Korea Pharmaceuticals & Bio-Pharmaceuticals Manufacturers Association. KOREA PHARM & BIO 2022 will be co-held with 6 other exhibitions with participation expected to have 1,500 exhibitors.

EXHIBIT PROFILE : Pharmaceuticals, Pharmaceutical Ingredients, APIs, Bulk Drugs, Intermediates, Excipients, Bio-Pharmaceuticals, Functional Ingredients, Natural Extracts.

Participation Cost: Rs. 2.70 lakh / 9 sqm Standard Booth
Corner Booth to be charged at Rs. 2.75 lakh
To be paid to IDMA

Participants from Non-MSME categories are welcome to participate but financial subsidies from MSME Ministry is not possible.

To register your participation, please send your Udyam Registration Certificate and Participation Cost to IDMA by **April 30, 2022**. Please hurry up as limited booths available.

CONTACTS

Exhibition & MSME Reimbursement related Queries:
Mr. Susanta Mahapatra / md@3smg.in / 91-9971988322
IDMA: Mr. Melvin Rodrigues / actadm@idmaindia.com / 91-9821868758

Requesting all IDMA MSME Members to participate and take benefit from this Exhibition.

Looking forward to your usual excellent support and prompt action.

Thanking you,

With Best regards,

Daara B Patel, Secretary - General

Donations to maintain the continuous supply of Medical Supplies to Sri Lanka and Maintenance of Medical Supplies supply chain of Sri Lanka

As you are all aware our neighbouring country Sri Lanka is under unprecented financial / economical crisis.

You are also aware that Dr. Lohitha Samarawickrema, President of NCPM, (National Chamber of Pharmaceutical Manufacturers), Sri Lanka and Indian Drug Manufacturers' Association signed the MoU along with Mr. Deepnath Roy Chowdhury, National President, IDMA (Year 2017-2018) and Mr. Daara B. Patel, Secretary General, IDMA on 18th May 2018.

We have received a request from Sri Lankan authorities courtesy Dr. Lohitha Samarawickrema, the President-NCPM Sri Lanka, for suppling emergency medicines for the people of Sri Lanka. The detailed correspondence and list of medicines is attached for your perusal and information. We are sure you will rise to the occasion and do the best in support for our brothers and sisters in Sri Lanka.

Director MSD can be contacted through his official email - dmsd@msd.gov.lk)

All required details are available at https://www.msd.gov.lk/index.php/donation

Request all members who have the required approvals to be generous and help for this noble cause.

Thanks and Regards,

Daara Patel
Secretary - General

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njhiyNgrp) 0112698507 , 0112694033
Telephone) 0112675449 , 0112675280

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website) www.health.gov.lk

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ஔடத உற்பத்திகள்இ வழங்குகைகள் மற்றும் ஒழுங்குறுத்துகை இராஜாங்க அமைச்சு
State Ministry of Production, Supply and Regulation of Pharmaceuticals

To all respected doners,

Donations to maintain the continuous supply of Medical Supplies to Sri Lanka

The State ministry of Production, Supply and Regulation of Pharmaceuticals and its institutions are completely responsible for procuring, distribution, and regulation of pharmaceuticals, consumables, and all kinds of medical supplies for all healthcare institutions in Sri Lanka.

The State ministry is utilizing the maximum production capacity of the local production and has also initiated to utilize the Indian Credit Line to the maximum effect to purchase medical supplies for Sri Lanka. But due to the prevailing foreign reserve crisis it has been extremely difficult to maintain the supply chain of most of lifesaving drugs which are not produced at Sri Lanka and could not be imported through the Indian credit line.
The state ministry would like to thank you for your generosity for coming forward to help us to maintain the Medical Supplies supply chain. We would like to inform following facts for all potential doners.

1. Your donations could be send as funds (in USD) as well as in goods.

2. A sperate Working Committee has been appointed to coordinate this activity, to direct you and to utilize donations to the maximum effect. The working committee is chaired by the Director of the Medical Supplies Division (MSD).
3. For USD donations
   The Sate Ministry is awaiting official approval of the Finance Ministry to open a foreign currency account to collect your donations to support Medical Supplies Supply Chain. A sperate online payment gateway is also requested . We hope to inform the progress and its details as soon as we obtain the official approvals.

4. For Goods – The quality and safety of the donated medical supplies are paramount. Therefore these need to be approved by the NMRA (National Medicinal Regulatory Authority) if they do not pocess the NMRA approval. And they need to be distributed considering the national interest. Medical Supplies demand is dynamic and estimates change time to time. Therefore, all donations in goods need to be approved by the Director MSD and coordinated by the National Working Committee. That will not only ease the custom clearance procedures, importing procedures as well as NMRA procedures but also will be able to distribute through the National System to the most needed places.
   (Director MSD can be contacted through his official email - dmsd@msd.gov.lk)
   All required details are available at https://www.msd.gov.lk/index.php/donation

5. Your donations sending from the official channel is expected to be audited and monitored by the Auditor Generals Department of Sri Lanka to avoid any sort of waste.
6. We have imposed these procedures to make this process completely transparent, avoid any possible irregularities, any delays and waste / malpractice.

We as the State Ministry are fully committed to direct you and handle your donations to in accordance to the current legal procedures, guild lines, regulations and best practices.

While thanking for your genericity, we would be extremely grateful if you could adhere to the official pathway for maximum security, transparency and to obtain the maximum out come you expect to achieve.

Thank you,

Dr. R.M.S.K. Rathnayake
Secretary
State Ministry of Production, Supply and Regulation of Pharmaceuticals

NMRA Instructions for facilitation of clearance of donations of medical products*

Need 3 documents .,

1. Letter from the receiver of the donation.
This letter should include
× Name of the product
× Manufacturer (If possible)
× Clearing agent in Sri Lanka

2. Performa or commercial invoice
This should include
× Invoice number
× Manufacturer details
× Quantity
× Nominal value

3. Scanned image of outer pack/ label of the product
If you are arranging through local agents try to get already NMRA registered products.

If the donations are arranged from overseas please try to get products registered in recognized regulatory bodies such as US FDA, EMA., MHRA, TGA Australia.

For any queries please contact Dr Saveen Semage, CEO, NMRA on 0710818548.

You can send documents and requests to dg@nmra.gov.lk or directly hand over to CEO's office NMRA.

Rathnayake

Dr. R.M.S.K. Rathnayake
Secretary
State Ministry of Production, Supply and Regulation of Pharmaceuticals

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State Ministry of Production, Supply and Regulation of Pharmaceuticals

Admiral (Prof.) Jayanath Colombage,
Ministry of Foreign Affairs
Republic Building,
Sir Baron Jayathilake Mawatha,
Colombo 01

Maintenance of Medical Supplies supply chain of Sri Lanka

The State ministry of Production, Supply and Regulation of Pharmaceuticals and its institutions are completely responsible for procuring, distribution and regulation of pharmaceuticals, consumables, and all kinds of medical supplies for all healthcare institutions in Sri Lanka.

The State ministry is utilizing the maximum production capacity of local production and has also initiated to utilize the Indian Credit Line to the maximum effect to purchase medical supplies for Sir Lanka.

There is a considerable amount of vital medical supplies such as orthopedic implants, anti-cancer drugs, reagents and consumables used at Blood banks, HLA testing, HIV-AIDS testing reagents and Laboratory reagents are imported from, USA, Europe and Australia. Due to the prevailing foreign reserve crisis it has been extremely difficult to maintain the supply chain of above mentioned extremely important medical supplies imported from Europe. (the list is attached herewith)

We would be extremely grateful if you could assist State Ministry to coordinate with foreign missions and any other interested donors to maintain the medical supplies which are not manufactured in Sri Lanka and could not be imported using the Indian credit line.
Your kind consideration regarding this will be important to maintain the medical supplies supply chain in Sri Lanka.

Rathnayake

Dr. R.M.S.K. Rathnayake
Secretary
State Ministry of Production, Supply and Regulation of Pharmaceuticals

List of Urgent Pharmaceuticals

No	New SR NO	Item	Unit	Monthly Requirement
1	205801	Streptokinase Inj. 1.5M.U.	Vial	50
2	602401	Anti Rabies serum 1,000I.U./5ml	Vial	4,167
3	404901	Disposable, IV giving sets	Set	700,000
4	600201	Anti Rabies (TC)vaccine	Vial	50,000
5	1501401	Suxamethonium chloride inj.100mg/2ml	Amp	10,000
6	1501901	Dantroline sodium inj. 20mg vial	Vial	29
7	801	Morphine sulphate Tab 10mg	Tab	70,000
8	802	Morphine sulphate Tab. 15mg	Tab	12,500
9	807	Morphine sulphate Inj. 15mg	Amp	50,000
10	808	Morphinesul.Inj.(Presvat.free) 2mg/2ml	Amp	350
11	1102	Pethidine hydrochloride Inj.75mg	Amp	15,000
12	1201	Remifentanil Inj. 1mg in1mlamp/vial	Amp	600
13	100804	Flucloxacillin Syr.125mg/5ml 100ml	Bot	12,500
14	100902	Co-amoxiclav Tab. 625mg	Tab	2,500,000
15	101403	Cefuroxime Tab. 500mg	Tab	375,000
16	101404	Cefuroxime Syr.125mg/5ml,100ml bot.	Bot	500
17	101503	Cefotaxime Inj . 500mg vial	Vial	12,500
18	101703	Ceftriaxone Inj. 500mg	Vial	27,500
19	101704	Ceftriaxone Inj. 1g	Vial	145,833
20	101902	Cefepime Inj. 1g vial	Vial	833
21	102001	Imipenem Inj. 500mg	Vial	25,000
22	102101	Meropenem Inj. 500mg vial	Vial	66,667
23	102102	Meropenem Inj. 1g vial	Vial	150,000

24	102502	Gentamicin Sulphate Inj.80mg/2ml ampoule	Amp	35,000
25	102701	Netilmicin Inj. 100mg/2ml	Vial	500
26	103502	Vancomycin Inj. 1g Vial	Vial	4,000
27	104801	Dapsone Tab. 50mg	Tab	22,610
28	105101	Clofazimine Cap/Tab 100mg	Cap	3,000
29	105701	Ofloxacin Tab. 200 mg	Tab	20,000
30	105801	Levofloxacin Tab. 500mg	Tab	15,000
31	105802	Levofloxacin Inj. 500mg vial	Vial	7,500
32	107101	Fluconazole Cap. 50mg	Cap	90,000
33	107102	Fluconazole Inj. 200mg in100ml	Vial	3,500
34	107103	Fluconazole Cap. 200mg	Cap	3,500
35	107401	Amphotericin Inj. 50mg Vial	Vial	208
36	107403	Liposomal Amphotericin B injection 50mg for I.V. use	Vial	2,083
37	108301	Linezolid Injection 600mg/300mL	Bag	3,446
38	108302	Linezolid tablet 600mg	Tab	2,000
39	108401	Colistimethate Sodium Injection 1,000,000 IU vial	Vial	11,047
40	200102	Digoxin Inj. 500 mcg/2ml	Amp	400
41	200302	Furosemide (Frusemide) Inj.20mg/2ml	Amp	208,333
42	200601	Adenosine Inj. 6mg/2ml	Amp	583
43	201201	Carvedilol Tab. 6.25mg	Tab	2,083,333
44	201401	Esmolol HCl Inj. 100mg/10ml	Vial	13
45	201502	Labetalol HCl Inj. 100mg/20ml	Amp	2,333
46	201602	Metoprolol Tartrate inj. 5mgin 5ml	Amp	83
47	201901	Sildenafil Tab. 50mg	Tab	125,000
48	202001	Sodium nitroprusside Inj. 50mg	Vial	42
49	203702	Verapamil HCl Inj. 5mg/2ml	Amp	1,250
50	203801	Nicorandil Tab. 10mg	Tab	3,333,333
51	203901	Dobutamine Inj. 250mg/20ml	Vial	12,500
52	204201	Ephedrine Inj. 30mg/1m amp.	Amp	15,000
53	204401	Noradrenaline Inj. 4mg/2ml	Amp	100,000
54	204601	Heparin Inj. 25,000 I.U/5ml	Vial	25,000
55	204701	Enoxaparin Inj.40mg/0.4ml PF.Syringe	PF.Syr	66,667
56	204702	Enoxaparin Inj.60mg/0.6mlPF.Syringe	PF.Syr	83,333
57	205701	Alteplase 20mg vial	Vial	75
58	207301	Alprostadil 500mcg Inj.ampoul	Amp	50
59	300102	Diazepam Tab. 5mg	Tab	634,983
60	300104	Diazepam rectal solution5mg/2.5ml	Tube	333
61	301101	Flupenthixol decanoate Inj.40mg/2ml	Amp	3,750
62	302001	Risperidone Tab.2mg	Tab	2,083,333
63	302801	Sertraline tablet 50mg	Tab	833,333
64	302902	Venlafaxine HCl Cap. E.R. 75mg	Cap	541,667

65	303103	Ondansetron Inj. 8mg in 4mlampoule	Amp	75,000
66	303403	Tramadol Inj. 100mg/2ml Amp.	Amp	8,333
67	303501	Sumatriptan Tab. 50mg	Tab	583
68	303703	Phenytoin Sodium Tab. 100 mg	Tab	1,000,000
69	303704	Phenytoin sodium Inj. 250mgin 5ml	Amp	4,000
70	303801	Carbamazepine Tablet 100mg	Tab	125,000
71	304001	Sodium Valproate Tab. 100mg	Tab	1,000,000
72	304002	Sodium valproate Tab. 200mg	Tab	5,833,333
73	304201	Clobazam tablet 5mg	Tab	208,333
74	304202	Clobazam Tab.10mg	Tab	416,667
75	304501	Topiramate Tab. 25mg	Tab	416,667
76	304502	Topiramate Tab. 50mg	Tab	416,667
77	305001	Co-careldopa Tab. 25/100mg	Tab	625,000
78	305002	Co-Careldopa Tab. 25/250mg	Tab	466,667
79	305201	Benztropine Inj. 2mg/2ml	Amp	150
80	305402	Disulfiram Tab.250mg	Tab	16,667
81	305801	Duloxetine(hydrochloride)20 mgCapsule	Cap	100,000
82	305901	Levetiracetam Tablet 500 mg	Tab	500,000
83	305902	Levetiracetam Tablet 250mg	Tab	291,667
84	306101	Melatonin tablet 3mg	Tab	16,667
85	306801	Alprazolam tablet 0.25mg	Tab	62,500
86	306802	Alprazolam Tablet 0.5mg	Tab	58,333
87	400701	Potassium Chloride Tab. 600mg	Tab	833,333
88	400702	Potassium chloride Injection 15 % in 10ml Ampoule	Amp	39,167
89	401005	Sodium chloride IV infusion 0.9% 1000ml collapsible bag	Bag	3,917
90	401104	Dextrose for IV use 50%, 50ml	Vial	66,667
91	401701	Calcium gluconate 10%, Inj.10ml	Amp	25,000
92	402201	Protein hydrolysate Inj. 100ml	Bot	1,000
93	402202	Protein Hydrolysate Inj.10% w/v in 500ml bottle	Bot	833
94	402702	Thiamine HCl Inj. 100mg/2ml	Amp	33,333
95	402802	Pyridoxine HCl Tab. 25mg	Tab	166,667
96	403101	Alfacalcidol Cap. 250ng	Cap	2,750,000
97	403201	Phytomenadione Tab 5mg	Tab	7,500
98	403202	Phytomenadione Injection1mg/0.5ml	Amp	25,000
99	403501	Hydroxocobalamine Inj. 1mg/1ml	Amp	11,667
100	404001	Epoetin inj. 2000 IU PF.Syr	PF.Syr	16,667
101	404002	Epoetin Inj.4000IU PF.Syr	PF.Syr	116,667
102	404004	Epoetin injection 10,000 IUVial / Pre-filled syringe	PF.Syr	4,000
103	404602	Deferiprone Cap.500mg	Cap	900
104	404801	Desferrioxamine Inj. 500mg	Vial	37,500
105	405301	Hum. Albumin Solu. 20%, 50ml	Bot	33,333

106	405302	Albumin solution (human) 5%,250ml	Bot	833
107	405401	Calcium 500mg+Vitamin D3250IU Tab	Tab	250,000
108	405801	Eltrombopag Tablet 50mg	Tab	4,167
109	406202	Calcium polystyrene sulphonate15g-17g powder sachet	Sachet	10,000
110	406702	Cholecalciferol capsule/tablet1000 IU(25 mcg)(Colecalciferol)	Cap	200,000
111	406703	Cholecalciferol tablet 5000 IU (Colecalciferol)	Tab	16,667
112	407201	Total Parenteral Nutrition in500ml ¿1,500ml collapsible bag	Bag	2,083
113	500104	Salbutamol Inj.5mg/5ml	Amp	500
114	500205	Fluticson+SalmetrolInha.250/25md,120d	Inhal	75,000
115	500706	BeclamethazoneInha.250mcg/md,200d	Inhal	35,000
116	501304	Chlorpheniramine MaleateInj.10mg/1ml	Amp	20,000
117	600101	Tetanus toxoid vaccine0.5ml(SD) amp	Amp	66,667
118	600401	Meningococcal Vaccine singledose vial	Vial	333
119	600501	Pneumococcal Vaccine singledose vial	Vial	625
120	602501	Anti Rabies human Ig 300I.U.	Vial	417
121	603201	Human immunoglobulin for IVuse, 1g	Vial	1,667
122	603202	Human Immunoglobulin for IVuse 2.5g-3.0g Vial.	Vial	1,833
123	603205	Human immunoglobulin for IVuse 5-6g	Vial	7,500
124	700601	Bipha.Isoph.Insulin(Human)Inj. 30/70	Vial	150,000
125	700701	InsulinIsophane(human)1,000IU/10ml	Vial	4,167
126	700801	Insulin Soluble (Hu) Inj.1,000IU/10ml	Vial	10,000
127	701103	Thyroxine tablet 25mcg	Tab	400,000
128	701301	Propylthiouracil tablet 50mg	Tab	20,833
129	701401	Fludrocortisone tablet 0.1mg	Tab	16,667
130	701603	Dexamethasone Tablet 4 mg	Tab	15,000
131	701604	Dexamethasone Tablet 8 mg	Tab	11,667
132	701702	Prednisolone Tablet 1mg	Tab	25,774
133	701804	Methylprednisolone IV Inj.500mg	Vial	2,500
134	701805	Methylprednisolone IV Inj. 1gVial	Vial	3,333
135	702401	Hydroxyprogesterone Inj.250mg/1ml	Amp	1,667
136	703001	Tetracosactrin Inj.250mcg/1ml	Amp	167
137	703202	Somatropin for Iinj. 2IU-30IU	IU	25,000
138	703401	Vasopressin Inj. 20 I.U./1mlampoule	Amp	1,833
139	703502	Alendronate sodium tablet 70mg	Tab	45,833
140	800401	Domperidone tablet 10mg	Tab	9,169,471
141	800501	Metoclopramide tablet 10mg	Tab	85,000
142	800701	Ranitidine HCl Inj. 50mg/2mlamp	Amp	100,000
143	800802	Omeprazole cap. 20mg	Cap	21,459,513
144	800803	Omeprazole sodium Inj. 40mg	Vial	100,000
145	801001	Mesalazine tablet 400mg	Tab	15,000

146	801201	Bisacodyl tablet 5mg	Tab	250,000
147	801401	Iso-Os.bowel clens.prep.(PEG 58g-60g+Elect)	Sachet	12,000
148	900101	Ciprofloxacin Eye drops0.3%, 5ml vial	Vial	41,667
149	900201	Fusidic acid Eye Drop 1%(S.R.)	Vial	12,500
150	901801	Acetazolamide Tab. 250mg	Tab	100,000
151	902101	Fluorescein sodium Inj.10%,5ml vial	Vial	250
152	902401	Perflurodecalin 5ml vial	Vial	83
153	902502	Silicone oil 1000/CST 10ml Bot.	Bot	208
154	903001	Brinzolamide eye drops 1%,5mlvial	Vial	6,667
155	903201	Nepafenac ophthalmic susp.0.1%,3ml vial	Vial	3,750
156	904101	Moxifloxacin ophthalmicsolutn. 0.5%,5ml	Vial	11,667
157	904302	Tobramycin 0.3% +Dexamethasone 0.1% eye drops,10ml dropperbottle	Bot	667
158	1000201	Gentamicin sulphate Ear/Eye Drops 0.3% w/v in 10ml dropper bottle	Vial	10,038
159	1000401	Clotrimazole 1%+Lignocaine 2%Ear drops 10ml vial	Vial	667
160	1000601	Betamethason Eye/Ear/Nasaldrop 0.1%,5ml	Vial	5,833
161	1000801	Ofloxacin ear drops 0.6%, 5ml	Vial	250
162	1001701	Betamet +Neomy. Eye,Ear,NasalDrop. 5ml	Bot	3,333
163	1002001	0.2% Chlorhexidine Mouth Wash100ml bottle	Bot	8,333
164	1100101	Paraffin, liquid	ml	2,416,667
165	1100102	Paraffin,yellow soft	g	22,833,333
166	1100103	Paraffin ,White Soft	g	3,333,333
167	1100301	Urea Crystals	g	83,333
168	1100401	Pure Coconut oil	ml	250,000
169	1100601	Dithranol Powder	g	417
170	1101101	Calamine Powder	g	41,667
171	1101301	Crotamitone Cream 10% 20g tube	Tube	417
172	1102201	Silversulphadiazine Cream1%,500g	Jar	1,667
173	1103101	Selenium sulphide lotion2.5%,60ml bot	Bot	2,500
174	1103401	Permethrin cream 5%, 15g tube	Tube	10,000
175	1103601	Cetrimide powder 500g tin	Tin	833
176	1103801	Chlorhexidine solution4% w/v, 500ml bot	Bot	1,667
177	1104001	Hydrogen perox. sol.6%400ml-500ml bot.	Bot	2,917
178	1105001	Tretinoin cream 0.025% 15g tube	Tube	6,826
179	1105501	Ortho-phthaladehydedisin.soln. 0.55%w/v	ml	125,000
180	1106601	Acitretin Capsule 10mg	Cap	8,333
181	1200201	Chlorambucil Tablet 2mg	Tab	2,500
182	1200502	Melphalan injection 50mgpowder with solvent	Vial	23
183	1201103	Doxorubicin hydrochloride injection 2mg/ml 25ml vial	Vial	1,500
184	1201601	Capecitabine Tablet 500mg	Tab	83,333

185	1201701	Cytarabine Inj. 100mg/5ml vial	Vial	250
186	1201703	Cytarabine injection1g in 10ml vial	Vial	500
187	1202101	Mercaptopurine Tablet 50mg	Tab	13,333
188	1202401	Vincristine sulphateinjection 1mg vial	Vial	1,917
189	1202501	Vinblastine Sulphate Inj 10mgvial	Vial	167
190	1202701	Etoposide Capsule 100mg	Cap	400
191	1202703	Etoposide Capsule 50mg	Cap	100
192	1202801	Lecucovorin Tab 15mg(Folinic acid)	Tab	2,000
193	1202803	Lecucovorin Cal.Inj10mg/ml,5mlvial	Vial	4,583
194	1202804	Lecucovorin Cal.Inj.15mg / 2ml ampoule/vial(folinic acid)	Amp	3,750
195	1203201	Asparaginase 10,000IU vial	Vial	100
196	1203402	Temozolomide capsule 250mg	Cap	400
197	1203901	Procarbazine Capsule 50mg	Cap	200
198	1204401	Imatinib Mesilate Cap 100mg	Cap	45,833
199	1204403	Imatinib mesilateCap/Tab 400mg	Cap	20,833
200	1204901	Paclitaxel injection 30mg/5mlvial	Vial	8,333
201	1204904	Paclitaxel injection260mg	Vial	750
202	1205001	Irinotecan injection 40mg/2ml	Vial	250
203	1205201	Azathioprine tablet 50mg	Tab	208,333
204	1205403	Cyclosporin capsule 100mg	Cap	12,500
205	1205404	Cyclosporin Syrup 100mg in 1ml, 50ml bottle	Bot	38
206	1205601	Tacrolimus capsule 0.5mg	Cap	83,333
207	1205602	Tacrolimus capsule 1mg	Cap	375,000
208	1205701	Rituximab injection100mg/10ml vial	Vial	583
209	1205702	Rituximab injection500mg/50ml vial	Vial	750
210	1206101	Filgrastim Inj 300mcg in0.5ml/1ml, PFS/vial	Vial	14,167
211	1206301	Lenalidomide capsule 5mg	Cap	7,500
212	1206501	Megestrol acetate tablet 40mg	Tab	625
213	1206701	Anastrozole tablet 1mg	Tab	166,667
214	1207301	Goserelin acetate implant3.6mg	Implnt	1,167
215	1207402	Octreotide Inj. 50mcg,1ml amp	Amp	6,667
216	1207901	Exemestane tablet 25mg	Tab	5,167
217	1208501	Abiraterone acetate tablet250mg	Tab	22,917
218	1210101	Mesna injection 200mg in 2ml	Vial	2,500
219	1300102	Ergometrine maleate inj.500mcg/1ml amp	Amp	2,917
220	1300202	Oxytocin injection 5 I.U. /1ml amp	Amp	141,667
221	1300301	Dinoprostone vaginal tablet3mg	Tab	5,000
222	1300603	Potassium citrate oral solution 200ml bottle	Bot	33
223	1300702	Sodium Citrate oral Solution500mg/334mgper 5ml ,100ml bot	Bot	33
224	1301201	Clotrimazole pessaries 100mg	Pessa	5,000

225	1301502	Tamsulosin capsule 0.4 mg	Cap	500,000
226	1301801	Tolterodine tablet 1mg	Tab	4,167
227	1301802	Tolterodine sustained release capsule 2mg	Cap	5,000
228	1302401	Estrogen vaginal cream 0.01%, 15g tube	Tube	333
229	1400306	Diclofenac sodium Supp.100mg	Supp	58,333
230	1400901	Leflunomide tablet 10 mg	Tab	150,000
231	1401001	Allopurinol tablet.100mg	Tab	300,000
232	1500201	Ketamine HCl Inj. 200mg/20ml	Vial	1,000
233	1500401	Etomidate inj. 20mg/10ml vial	Vial	292
234	1500701	Sevoflurane 250ml bottle	Bot	750
235	1500902	Midazolam inj. 5mg/1ml amp	Amp	75,000
236	1501101	Atracurium besylate inj.25mg/2.5ml	Amp	83,333
237	1501201	Pancuronium bromide inj.4mg/2ml	Amp	583
238	1501301	Vecuronium bromide Inj. 10mgvial	Vial	2,917
239	1501501	Neostigmine injection0.5mg/1ml amp	Amp	2,500
240	1502003	Bupivacaine 0.5%+Glucose 8% in 4ml inj	Amp	22,917
241	1502104	Lidocaine spray10% ,50mlbottle	Bot	333
242	1502201	Lignocaine 2% + Adrenalin inj. 30ml vial	Vial	15,000
243	1502301	Lignocaine with Prilocaine cream 5g tube	Tube	583
244	1502501	Rocuronium bromide inj. 50mg/5ml vial	Vial	225
245	1600201	Acetylcysteine injection2g/10ml amp	AMP	8,000
246	1600401	Methionine tablet 500mg	Tab	1,000
247	1600501	Dicobalt edetate inj.300mg/20ml amp	Amp	1
248	1600801	Dimercaprol inj. 100mg/2ml amp	Amp	0
249	1601001	Pralidoxime chloride inj.1g/20ml	Amp	2,000
250	1601101	Dehydrated ethanolInj.(96.8w/w) 5ml amp	Amp	2
251	1601201	Methylene blue inj. 1% w/v10ml amp	Amp	250
252	101703	Ceftriaxone Inj. 500mg	Vial	27,500
253	101704	Ceftriaxone Inj. 1g	Vial	145,833
254	101902	Cefepime Inj. 1g vial	Vial	833
255	102001	Imipenem Inj. 500mg	Vial	25,000
256	102502	Gentamicin Sulphate Inj.80mg/2ml ampoule	Amp	35,000
257	102701	Netilmicin Inj. 100mg/2ml	Vial	500
258	103502	Vancomycin Inj. 1g Vial	Vial	4,000
259	105802	Levofloxacin Inj. 500mg vial	Vial	7,500
260	108302	Linezolid tablet 600mg	Tab	2,000
261	108401	Colistimethate Sodium Injection 1,000,000 IU vial	Vial	11,047
262	200102	Digoxin Inj. 500 mcg/2ml	Amp	400

263	201401	Esmolol HCl Inj. 100mg/10ml	Vial	13
264	201602	Metoprolol Tartrate inj. 5mgin 5ml	Amp	83
265	203702	Verapamil HCl Inj. 5mg/2ml	Amp	1,250
266	203801	Nicorandil Tab. 10mg	Tab	3,333,333
267	207301	Alprostadil 500mcg Inj.ampoul	Amp	50
268	405302	Albumin solution (human) 5%,250ml	Bot	833
269	405801	Eltrombopag Tablet 50mg	Tab	4,167
270	500104	Salbutamol Inj.5mg/5ml	Amp	500
271	800701	Ranitidine HCl Inj. 50mg/2mlamp	Amp	100,000
272	1206501	Megestrol acetate tablet 40mg	Tab	625
273	108301	Linezolid Injection 600mg/300mL	Bag	3,446

PRESENTATION

Strengthening of Pharmaceutical Industries Scheme (SPI) From FY 21-22 to 25-26 by DoP

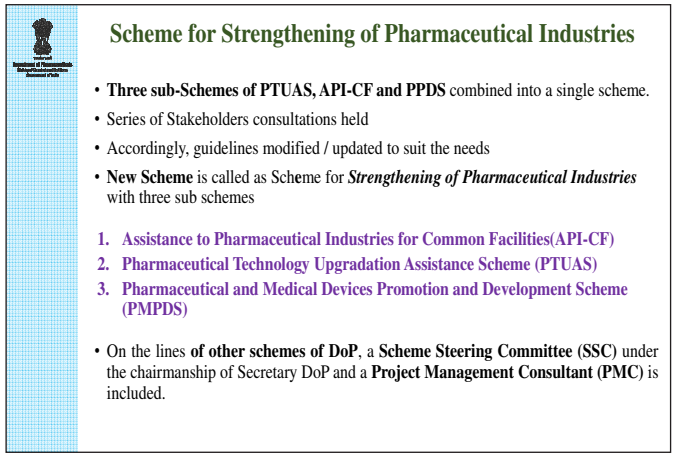
Dear Members,

An interactive/discussion session on the Scheme "Strengthening of Pharmaceuticals Industry" of Department of Pharmaceuticals with MSME Associations was held on 16.04.2022 through VC under the Chairmanship of Joint Secretary (Pharma). The Presentation made by Department of Pharmaceuticals on Strengthening of Pharmaceutical Industries Scheme (SPI) From FY 21-22 to 25-26 is reproduced below for members reference and information.

Regards,

Daara B Patel

Secretary- General, IDMA



Scheme for Development of Pharmaceutical Industries

Two sub-Schemes under SPI scheme:

1. Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS)

- To facilitate Small and Medium Pharma Enterprises (SMEs) to upgrade their plant and machinery to World Health Organization (WHO) - Good Manufacturing Practices (GMP) standards, to enable them to make world-class high-quality drugs and become globally competitive and markets leaders.
- Out of 6790 SMEs in manufacturing bulk and API drugs, only 2006 are WHO GMP certified and more than 4500 remain outside WHO-GMP.
- No units approved so far.

2. Assistance to Pharmaceutical Industry for Common Facilities (API-CF)

- Financial assistance is provided for creation of Common Facilities, such as Common Testing Centre, Training Centre, R&D Centre, Central Effluent Treatment Plan (CETP), Common Logistic Centre, etc.
- Projects approved so far till FY 20-21 –three.

3

Scheme for Strengthening of Pharmaceutical Industries – Projected financial outlay

	Projected Financial Outlay (Rs. in crore)	
Financial Year	Assistance to Pharmaceutical Industry for Common Facilities (API-CF)	Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS)
2021-2022	10.30	0
2022-2023	36.60	53.60
2023-2024	61.90	104.30
2024-2025	54.10	120.70
2025-2026	15.50	21.50
Total	178.40	300.10

Scheme for Strengthening of Pharmaceutical Industries - Scheme Steering Committee -

Composition

- Secretary, DoP – Chairperson
- Financial Adviser, DoP-Member
- Drug Controller General of India-Member
- Joint Secretary (Schemes), DoP-Member
- Representative of Ministry of MSME-Member
- Director / Dy Secretary (Schemes), DoP –Convener

The SSC may **invite persons with domain knowledge** in Pharma, Medical Device or finance to take part in SSC meetings

Responsibilities

- To provide direction for effective implementation of the Scheme.
- To evaluate & recommend proposals for approval.
- To monitor the implementation of the scheme.
- To take decisions on any deviations in approved projects
- To take all decisions required for successful implementation of the Scheme, including recommending the modifications, required in guidelines of scheme.
- It shall meet at least **once in 3 months**.

Scheme for Strengthening of Pharmaceutical Industries - Project Management Consultant -

PMC

- The SSC would engage an agency (PMC) through a competitive bid process,
- With experience in
  - developing, financing or executing the cluster development / technology up gradation projects
  - or
  - interest subvention / capital subsidy schemes.
- PMC will be a bridge between the SSC and the beneficiary
- Enable expeditious implementation of the projects in a **systematic, professional and transparent manner**.

Responsibilities

- Assist SSC in selecting beneficiaries by issuing Request for Proposal (RFP) and formulating criterion for selection.
- Examine proposals and evaluate them as per guidelines and put up before SSC for approval.
- Creating awareness in and among industry.
- Execution of Approved projects by formulating agreements, guiding the beneficiaries.
- Devising a robust monitoring and evaluation mechanism to ensure timely execution of projects.

- PMC to develop **a portal** for the implementation of all three schemes
- **Monthly & Quarterly reporting format** will be part of above portal.
- PMC to **share reports** of sanction and disbursement of incentive and other related information to DoP.

1. Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS)

Objective: To facilitate Micro, Small and Medium Pharma Enterprises (MSME) of proven track record to upgrade their technology to meet **WHO-GMP** or **Schedule M** standards

Intended Beneficiaries: Micro, Small and Medium Enterprises of pharma sector

Incentive under the scheme

- **Interest subvention up to 5%** (6% in case of units owned by SC/ST) on reducing balance basis

or

- **Capital subsidy of 10%,** on loans upto maximum limit of Rs.10 Cr with a minimum repayment period of 3 years
- At least 50% of total sanctioned loan amount has to be on components eligible under the Scheme
- Loan proposals will not be allowed to avail of benefits under any other Technology Up-gradation Scheme of GoI or States or any other autonomous institutions/PSUs or Boards of either Central or State Government

1. Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS) - Indicative list equipment covered as approved by DCGI

Eligible Activity	Formulation Plant	API/Intermediate/ Bulk Drug Plant
Up gradation of HVAC (Heating, Ventilation, and Air Conditioning) system to WHO norms i.e. HEPA (High-Efficiency Particulate Air filters)	√	√
Stability testing chambers.	√	√
All equipment & instruments for operating a Microbiology laboratory including autoclaves, incubators, biosafety cabinets, colony counters, HVAC systems	√	√
All lab scale and pilot scale manufacturing equipment required for R&D development – formulation/bulk.	√	√
State-of- art lab equipment for testing as per Pharmacopeia other than IP not limiting to NMR, HPLC, HPTLC, IR Spectrophotometer, Atomic Absorption Photometers, GC, Electrophoresis and Dissolution apparatus.	√	√
Water management and purification systems including Steam systems.	√	√
Automatic particle counters for sterile areas	√	√
Laboratory information management system	√	√

1. Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS)

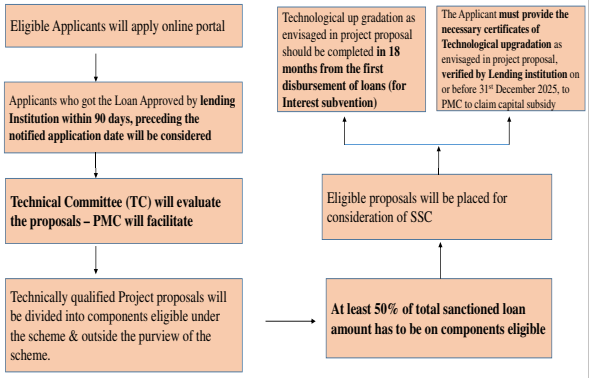
- Applications to be received by PMC **on a rolling basis** till 29th February 2024 subject to availability of budget.
- Applications must be made to PMC **within 90 days of loan** sanction
- PMC will obtain **technical recommendation** of a Technical Committee
- PMC will also verify loans from lending banks
- Projects will be sanctioned on **first come first sanction** basis.
- Project proposals will divided into components eligible under the scheme and those which are outside the purview of this scheme
- Incentive will be given on **approved project cost**.

- Only machinery and electronic Management Information System (MIS) required for technological up gradation of the plant.
- Procurement of only new machinery will be permitted i.e only machinery bought after the date of sanction of loan.
- Guidelines to mention the Machinery.

1. Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS)

- **Capital Subsidy**: Application must be sent to the lending institution for verification on or before 30th September 2025.
- Applicant must provide the necessary verified certificates of Technological Upgradation on or before 31.12. 2025 to claim subsidy.
- Technological up gradation **to be completed in 18 months** from the date of first disbursement of loans for interest subvention.
- No 1st instalment of interest subvention will be paid after 31st March 2024.
- **Interest subvention amount** to be directly credited to **lending Institution**.
- In case of Credit linked capital subsidy, the **subsidy amount** will be paid directly to **bank account of the applicant**

1. Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS) - Implementation process & Timelines



1. Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS)

Physical and Financial Outlay

Financial Year	Physical Outlay		Financial Outlay (Rs. in crore)	
	New Project	Cumulative	Grant-in-Aid	Professional Services
2021-2022	0	0	0	0
2022-2023	150	150	52.50	1.10
2023-2024	270	420	102.20	2.10
2024-2025	0	320	118.30	2.40
2025-2026	0	100	21.00	0.50
Total	**420**	**-**	**294.00**	**6.10**

- **PMC to submit the outstanding demand to DoP/SSC quarterly i.e. first week of April, July, October and January in every financial year.**

2. Assistance to Pharmaceutical Industries for Common Facilities (API-CF)

Objective: To strengthen the existing pharmaceutical clusters' capacity for their sustained growth by creating tangible assets as "Common Facilities".

Intended Beneficiaries: Manufacturing units in Pharma clusters, atleast 5 members are required to come together to form a Special purpose vehicle (SPV).

Incentive under the scheme:

- 70% of the approved project cost or **Rs 20 cr**., whichever is less.
- In case of Himalayan States & States in NE Region, the grant-in-aid would be Rs. **20 Cr** per Cluster or 90% of the project, whichever is less.

Contribution by SPV

- Minimum of 30% of the approved project cost to be contributed by SPV
- No duplication of funding for the same component/ intervention.
- SPVs may dovetail funds from other sources, provided there is no duplication of funding for the same component/ intervention.
- Resource raised through such dovetailing will be in addition to the 30% contribution of the SPV.

2. Assistance to Pharmaceutical Industries for Common Facilities (API-CF)

The cost of project shall include

- cost of land,
- building,
- internal infrastructure,
- administrative & management support expenses including salary of CEO, engineers, other experts and staff during project implementation period,
- preliminary expenses,
- machinery & equipment,
- miscellaneous fixed assets and
- other support infrastructure such as water supply, electricity and margin money for working capital.

list of eligible activities

The illustrative list in order of priority is as under:

- Research and Development Labs
- Testing Laboratory for Pharma Products
- Effluent Treatment Plants
- Logistic Centers
- Training Centers
- Other allied activities can be taken up based on recommendations of SSC.

Grant-in-Aid from DoP **will not be utilized towards** land component of the project or construction of rest house, administrative buildings or any other building and as categorized as **non-essential construction** for the technical requirements of project.

2. Assistance to Pharmaceutical Industries for Common Facilities (API-CF)

Project proposal to have :

- Business plan including Gap Analysis and proposed operations of the Common Facility.
- Final projections and financial viability report.
- Identification of impediments and bottlenecks
- Action plan for enhancing competitiveness and positioning the cluster on a self-sustaining trajectory of growth.
- Implementation schedule

The project proposal to have technical recommendation from competent technical body.

- **In-principle approval** will be granted who submit a **complete project proposal with technical recommendation** and have availability of land.
- A project will be accorded **final approval** by the **SSC within 6 months** of in principle approval.

2. Assistance to Pharmaceutical Industries for Common Facilities (API-CF)

Instalments

Instalment	% of Funds	Remarks/Pre-requisite
1st	30	• Mobilization advance against an Indemnity Bond, on final approval of the project by SSC.
2nd	30	• Against the production of Bills • 60% utilization of 1st instalment • Proportionate expenditure incurred by the SPV.
3rd	30	• Against the production of Bills • 100% utilization of 1st instalment • 60% utilization of 2nd instalment • Proportionate expenditure incurred by the SPV.
4th	10	• SPV has mobilized • Spent entire sanctioned Grant-in-Aid • Spent its full share

Outlay

Financial Year	Physical Outlay		Financial Outlay (Rs. in crore)	
	New Project	Cumulative	Grant-in-Aid	Professional Services
2021-2022	0	2	10.00	0.30
2022-2023	5	7	35.50	1.10
2023-2024	5	10	60.00	1.90
2024-2025	0	5	52.50	1.60
2025-2026	0	0	15.00	0.50
Total	**10**	-	**173.00**	**5.40**

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GOVERNMENT COMMUNICATIONS

Appointment of Dr Atul Goel as DGHS - reg.

To
Dr. Atul Goel, Director Professor (General Medicine), LHMC, New Delhi.

1. Consequent upon attaining the age of 62 years by Dr. Sunil Kumar, Additional DGHS (who was holding the charge of DGHS on officiating basis), Dr. Atul Goel, Director Professor (General Medicine), from Teaching Sub-cadre of CHS, presently posted in LHMC, New Delhi is hereby appointed as Director General of Health Service (DGHS) on officiating basis with full financial and administrative powers for smooth functioning of the office of Dte. GHS with immediate effect and until further orders.
2. No additional remuneration shall be paid to Dr. Atul Goel for holding the post of DGHS on officiating basis.
3. This issues with the approval of the Competent Authority.

F. No.A.40020/02/2022-CHS.IV

Vivek Narayana, Under Secretary,
Govt. of India,
Ministry of Health and Family Welfare,
Nirman Bhawan,
New Delhi.

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Declaration with respect to Veg or Non-Veg logo for source of ingredient including additives on the food label - reg.

F.No.RCD-15001/6/2021-/Regulatory-FSSAI (E-1475), dated 5th April 2022

To

1. *Commissioner of Food Safety of all States/UTs*
2. *Directors, all Regional Office of FSSAI*
3. *All Central Licensing Authorities*
4. *CITO - for uploading on the website.*

1. Reference is drawn to FSSAI Order of even No. dated 22.12.2021 vide which it was inter alia stated that the **declaration regarding Non-Veg or veg food is mandatory irrespective of the percentage of any ingredient in the food.**

2. In continuation to above, it is further clarified that the obligation upon the Food Business Operators (FBOs) to make disclosure with regard to the article of food being vegetarian or non-vegetarian as stipulated under Clause 2.2.2 (4) of FSS (Packaging & Labelling) Regulations, 2011 is independent of, and not subject to the provisions of Sub-Clause 2.2.2 (2) (d) of the said Regulations. The exemption in the Sub-clause 2.2.2 (2) (d) is only with regard to declaring the sub-components of compound ingredients in the list of ingredients which are less than 5%.

3. Consequently, the FBO shall have to declare the Non-Vegetarian logo in case any individual constituent ingredient of the compound ingredient is of non-vegetarian in origin, irrespective of the percentage of compound ingredient of the food.

4. In view of above, the Commissioners of Food Safety of all States/UTs and all the Regional Directors of FSSAI are directed to ensure strict enforcement of the Clause 2.2.2 (4) of FSS (Packaging & Labelling) Regulations, 2011 in accordance with the above clarification and sensitize all the manufacturing FBOs under your respective jurisdictions while giving wider publicity to the above clarification to make the public aware about the same.

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

Inoshi Sharma, Executive Director, Regulatory Compliance, Food Safety and Standards Authority of India (A Statutory Authority established under the Food Safety and Standards Act, 2006), Regulatory Compliance Division) FDA Bhawan, Kotla Road, New Delhi.

Trade notice from Brihan Mumbai Custom Brokers Association on Delay in filing of EGM due to errors at JN Customs – reg.

(Drawback Pendency Report : LEO given on or before 10.04.2022)

Rs in Crores

Site ID	Site Name	No. of SBs in Queue							No. of SBs whose PFMS Staus is not Accepted	No. of Not Processable SBs	Not Processable DBK Amount
		EGM	EGM ERROR	SAMPLE	DBK AC	DBK SUP	SCROLL IN	QUERY REPLY			
INNGP6	Nagpur - ICD / CFS	117	24	0	3	14	36	33	60	234	.87
INNGRB	Nepalgunj Road - Border	100	0	0	101	82	18	378	11	489	7.83
INNJP6	DABGRAM - ICD / CFS	63	2	0	0	0	77	0	36	101	.08
INNML1	New Mangalore - Sea Port	698	74	0	2	15	32	83	191	1046	7.18
INNPT1	Nagapattinam - Sea Port	0	0	0	0	0	0	0	0	0	0
INNSA1	Jawaharlal Nehru (Nh - Sea Port	26003	105875	2641	1299	7695	37621	17128	39961	191608	789.12
INNSK6	Nasik - ICD / CFS	427	3	0	0	100	153	0	113	543	.21
INNTVB	THOOTHIBARI LCS - Border	0	0	0	0	0	0	0	0	0	0
INOKH1	Okha - Sea Port	0	0	0	0	0	0	0	0	0	0
INOMU1	Old Mundra Port - Sea Port	24	2	0	0	274	110	0	26	52	.05
INPAN1	Panaji Port - Sea Port	0	0	0	0	0	0	0	0	0	0
INPAV1	Pipavav (Victor) Por - Sea Port	626	45	33	2	111	593	185	191	1080	8.6
INPBD1	Porbandar - Sea Port	39	1	0	0	54	9	0	3	43	.05
INPBLB	KAMARDWISA LCS - Border	0	0	0	0	0	0	0	0	0	0
INPKR6	ICD PALI, REWARI - ICD / CFS	0	3	0	0	6	31	0	3	6	.09
INPMP6	Pimpri - ICD / CFS	0	0	0	0	3	0	1	0	1	0
INPNK6	KLPPL PANKI - ICD / CFS	578	19	93	55	257	114	424	93	1207	14.68
INPNP6	Babarpur - ICD / CFS	0	0	13	0	0	37	0	60	73	.63
INPNQ4	Pune - Air Cargo	1	0	0	0	2	2	0	11	12	0
INPNTB	Panitanki(Naxalbari) - Border	1063	0	0	321	288	631	1	0	1064	0
INPNY1	Pondicherry - Sea Port	0	0	0	0	0	0	0	0	0	0

Amendments in Chapter 5 of the Handbook of Procedures 2015-20, related to Export Promotion Capital Goods Scheme to reduce 'Compliance Burden' and enhance 'Ease of doing Business' – reg.

Public Notice No.03/2015-2020, dated 13th April, 2022

In exercise of powers conferred under Paragraph 1.03 of the Foreign Trade Policy (FTP) 2015-2020, as amended from time to time, the Director General of Foreign Trade hereby makes the following amendments in Chapter 5 of the Handbook of Procedures (2015-20) with immediate effect. These amendments are applicable for EPCG authorizations issued under FTP 2015-20.

S. No.	Para No.	Existing provision	Revised provision
1.	**5.14(c)**	**5.14 Block-wise Fulfilment of EO** (c) Where EO of the first block is not fulfilled in terms of the above proportions, except in cases where the EO prescribed for first block is extended by the Regional Authority subject to payment of composition fee of 2% on duty saved amount proportionate to unfulfilled portion of EO pertaining to the block, the Authorization holder shall, within 3 months from the expiry of the block, pay duties of customs (along with applicable interest as notified by DOR) proportionate to duty saved amount on total unfulfilled EO of the first block.	**5.14 Block-wise Fulfilment of EO** (c) Request for extension of Export Obligation period of first block shall be submitted within 6 months from the date of expiry of first block EO period along with composition fee of 2% on duty saved amount proportionate to unfulfilled portion of EO pertaining to the block. RA may consider the request for extension of block wise EO period, received after 6 months, but within 6 years from date of issue of authorization, with a late fee of Rs. 10,000/- per authorization. Application made beyond 6 years, for extension of block-wise EO period for regularization purpose, shall also be considered by RA concerned, with an additional late fee of Rs. 5,000/- for each year per authorization. 'This late fee is in addition to the composition fee that may be payable on account of shortfall in export obligation. Where EO of the first block is not fulfilled in terms of para (a) above, except in cases where the EO prescribed for first block is extended by the Regional Authority, the Authorization holder shall, within 6 months from the expiry of the block, pay duties of customs (along with applicable interest as notified by DOR) proportionate to duty saved amount on total unfulfilled EO of the first block.
2	**5.15**	**5.15 Monitoring of Export Obligation** Authorisation holders shall submit to RA concerned by 30th April of every year, report on fulfillment of export obligation by secured electronic filing using digital signatures/ or hard copy thereof.	**5.15 Annual reporting of' EO fulfillment** Authorisation holders shall submit to the RA concerned by 30th June of every year, a report on fulfillment of export obligation through online. Such a report shall contain details such as Shipping bill/GST invoice number, date of export/supply,

			description of product exported/supplied and FOB/ FOR value of export/supply for both specific as well as average export obligation. Any delay in filing such an annual report shall be regularised on payment of Rs. 5000/- late for each financial year per authorisation.
3.	**5.16(a)**	**5.16 Automatic Reduction/ Enhancement upto 10% Duty saved amount and pro rata Reduction/ Enhancement in export obligation** (a) in excess of the duty saved amount indicated on the authorization by not more than 10 %, the authorization shall be deemed to have been enhanced by that proportion. Customs shall automatically allow clearance of such goods without endorsement by RA concerned. The authorization holder shall furnish additional fee to cover excess imports effected, in terms of duty saved amount, to RA concerned, within one month of excess imports taking place. Export obligation shall automatically stand enhanced proportionately. RA concerned may also accept the additional fee to cover the excess imports effected, in terms of duty saved amount, if the same is furnished beyond one month but within two years of the excess import taking place, subject to payment of composition fee of Rs. 5000/- per authorisation.	**5.16 Automatic Reduction/ Enhancement upto 10% Duty saved amount and pro rata Reduction/ Enhancement in export obligation** (a) in excess of the duty saved amount indicated on the authorization by not more than 10 %, the authorization shall be deemed to have been enhanced by that proportion. Customs shall automatically allow clearance of such goods without endorsement by RA concerned. The authorization holder shall furnish additional fee to cover excess imports affected, in terms of duty saved amount, to RA concerned, at the time of application for EODC. Export obligation shall automatically stand enhanced proportionately.
4	**5.17(d)**	**5.17 Extension in Export Obligation Period.** (d) Request for extension in EO Period shall be made to RA within 90 days from the date of expiry of original EO Period. However, RA may consider the request for extension received up to 180 days with additional composition fee of Rs. 5,000.	**5.17 Extension in Export Obligation Period.** (d) Request for extension in EO Period shall be made to RA concerned within 6 months from the date of expiry of original EO Period. However, RA may consider the request for extension received after 6 months, but within 8 years from date of issue of authorization, with a late fee of Rs. 10,000/-. Application made beyond 8 years, for extension of EO period from 6 to 8 years for regularization purpose, shall also be considered by RA concerned, with an additional late fee of Rs. 5,000/- for each year per authorization. This fee is in addition to the composition fee that may be payable on account of shortfall in export obligation. However, EO extension, beyond 8 years from date of issue of authorisation, shall not be allowed by RA under this provision.

5.	**5.19 A**	**5.19A - Maintenance of Annual Average Export Obligation** The excess exports done towards the average export obligation fulfillment of an EPCG authorization during a year can be used to offset any shortfall in the Average EO done in other year(s) of the EO period or the block period as the case may be provided Average EO imposed is maintained on an overall basis, within the block period or the EO period as applicable.	**5.19A - Maintenance of Annual Average Export Obligation** The excess exports done towards the average export obligation fulfillment of an EPCG authorization during a year can be used to offset any shortfall in the Average EO done in other year(s) of the EO period or the block period as the case may be, provided Average EO imposed is maintained on an overall basis, within the EO period.
6	**5.22**	**5.22 Redemption** (a) Authorisation holder shall apply for redemption in ANF 5B with documents prescribed therein as a proof of EO fulfillment. (b) On being satisfied, RA concerned shall issue a certificate of discharge of export obligation to the EPCG authorisation holder and forward a copy to Customs Authorities with whom BG/LUT has been executed.statement giving details of the documents submitted by the authorisation holder towards evidence of EO fulfillment shall also be enclosed with the certificate.	**5.22 Export Obligation Discharge Certificate (EODC)** (a) Authorisation holder shall apply for EODC in ANF 5B with documents prescribed therein as a proof of EO fulfillment. (b) On being satisfied, RA concerned shall issue EODC to the EPCG authorisation holder and a copy of which will be foronline, for further action by Jurisdictional Customs Authorities with whom BG/LUT has been executed. Where EODC is granted to the EPCG authorisation holder based on online application, a copy of EODC will be forwarded online to ICEGATE for further action by Jurisdictional Customs Authorities with whom BG/LUT has been executed.
7.	**5.23 (a)**	**5.23 Regularization of Bonafide Default and Exit from EPCG Scheme** (a) In case, EPCG authorisation holder fails to fulfill prescribed export obligation, he shall pay Customs Duty along with applicable interest as prescribed by Customs Authority. Such facility can also be availed by EPCG authorisation holder to exit at his option. The authorisation holder will have the option to furnish valid duty credit scrips, issued under Chapter 3 or Chapter 5 of FTP, for payment of the Customs duty component	**5.23 Regularization of Bonafide Default and Exit from EPCG Scheme** (a) In case, EPCG authorisation holder fails to fulfill prescribed export obligation, he shall pay Customs Duty/taxes/Cess along with applicable interest as prescribed by Customs Authority, Such facility can also be availed by EPCG authorisation holder to exit at his option.

Effect of this Public Notice: With a view to enhance ease of doing business and reduce the compliance burden, certain provisions of Chapter 5 related to the Export Promotion Capital Goods Scheme of the Handbook of Procedures (2015-20) are amended for EPCG authorizations issued under Foreign Trade Policy (2015-20).

File No.18/79/AM-21/P-51

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

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In Lok Sabha & In Rajya Sabha

In Lok Sabha

International Cooperation with MSMEs

Lok Sabha Unstarred Question No. 3472

Shri Unmesh Bhaiyyasaheb Patil:

Dr. Sujay Radhakrishna Vikhe Patil:

Dr. Shrikant Eknath Shinde:

Shrimati Aparupa Poddar:

Shri Rajendra Dhedya Gavit:

Dr. Heena Gavit:

Dr. Krishna Pal Singh Yadav:

Q. Will the Minister of **MICRO, SMALL AND MEDIUM ENTERPRISES** be pleased to state:

(a) the details of schemes run by the Government to encourage international cooperation between various countries and the MSMEs in the country with a particular focus on MSMEs in Maharashtra, West Bengal & Madhya Pradesh;

(b) the number of MSMEs that have been certified/ rated under Zero Defect and Zero Effect (ZED) Model out of 22,222 MSMEs; and

(c) the number of MSMEs supported for gap analysis, handholding, consultancy etc. out of 7368 MSMEs till date; and

(d) the details of particulars of these processes like handholding, consultancy etc. and the manner in which these are undertaken?

Answered on 24th March 2022

A. (a) To encourage international cooperation between various countries and the MSMEs in the country, Ministry of Micro, Small and Medium Enterprises(MSME) is implementing International Cooperation Scheme, a Central Sector Scheme. The scheme is in operation since its inception in 1996. The Scheme facilitates Indian MSMEs for their participation in international exhibitions, trade fairs, buyer seller meet and for holding international conferences and seminars which are in the interest of MSME sectors. The purpose of this scheme is enhancing the competency of MSMEs, capturing new markets for their products, exploring & enhancing exports, exploring new technologies for increasing manufacturing capacity, generation of employment etc. As per scheme guidelines, financial assistance is provided on reimbursement basis to the State/ Central Government organizations, industries/ enterprises Associations and registered societies/ trusts and organizations associated with promotion and development of MSME sector. The details of expenditure incurred and no. of MSMEs assisted under the scheme during last 3 years are as under:-

Year	Expenditure (Rs. in crore)	No. of MSME benefited	No of events supported
2018-19	4.80	590	46
2019-20	6.90	586	52
2020-21	1.80	102	15

(b): The total registrations under ZED Scheme: 23948 MSMEs Out of 23,948 registrations, the following are the status of MSMEs undergone ZED model:

Site Assessment carried out: 503 MSMEs

- Bronze certified: 131 MSMEs
- Silver certified: 132 MSMEs
- Gold certified: 62 MSMEs
- Diamond certified: 04 MSMEs
- No rating: 174 MSMEs

(c) & (d): In regard to Gap Analysis, Handholding, Consultancy, etc., component under the scheme was not initiated during FY 2016-17 & 2017-18 under the erstwhile ZED Scheme. Further, the erstwhile ZED Scheme has been renamed as “MSME Sustainable (ZED)”, and its guidelines is under approval stage.

Minister of State for Micro, Small And Medium Enterprises (Shri Bhanu Pratap Singh Verma)

Global Market

Lok Sabha Unstarred Question No.3484

Shri Dayanidhi Maran:

Q. Will the Minister of **MICRO, SMALL AND MEDIUM ENTERPRISES** be pleased to state:

(a) whether the steps are being taken by the Government to help MSMEs exhibit and showcase their products in the global market if so, the details thereof along with the list of programmes underway and the funds allocated for the purpose;

(b) whether the Government has conducted any study or consulted with stakeholders and domain experts on the impact of online retail of MSME products and if so, the details thereof;

(c) whether the Government has conducted any study on the impact of Covid-19 on MSMEs specialising in heritage and indigenous arts and crafts and if so, the details thereof; and

(d) the steps being taken by the Government to promote or develop an online marketplace and digital retail infrastructure for MSMEs specialising in heritage and indigenous arts and crafts?

Answered on 24th March 2022

A. (a): To support MSMEs reach out to customers across the world, Ministry is implementing International Cooperation Scheme (ICS) facilitating participation of the MSMEs in International Exhibitions, Trade Fairs, Buyer-seller meets abroad, etc to exhibit and showcase their products. A provision of Rs. 90.00 crore has been made for the financial cycle (2021-22 to 2025-26) under IC Scheme. Details of guidelines of the Scheme are available at the website of the Ministry www.msme.gov.in.

(b) & (c): The adverse impact of Covid-19 pandemic has been felt on the economy including on the MSME sector. The Ministry of MSME on 7th September, 2021 assigned a study to Small Industries Development Bank of India (SIDBI), the terms of reference of which inter-alia included assessment of losses suffered by the MSME sector due to Covid-19 pandemic. The said study was based on the survey conducted by SIDBI taking a random sample pool comprising 1,029 MSMEs spread across 20 States and 2 Union Territories. The report of the study submitted on 27th January, 2022, reveals that 67 percent of the respondent MSMEs were temporarily closed for upto a period of 3 months.

(d): A comprehensive B2B Portal- MSMEmart.com is being operated by the National Small Industries Corporation (NSIC) as a one stop digital solution to all business needs of MSMEs across all sectors and provide next generation services to MSMEs to make them competitive in global market. Further, KVIC is also implementing an e-commerce portal ekhadiindia.com to promote sale of khadi and village industry products online.

Minister of State for Micro, Small and Medium Enterprises (Shri Bhanu Pratap Singh Verma)

Closed MSMEs

Lok Sabha Unstarred Question No. 3663

Shri Kalyan Banerjee:

Q. Will the Minister of MICRO, SMALL AND MEDIUM ENTERPRISES be pleased to state: the action proposal of the Government to restart the closed MSMEs during the last three years and the budgetary allocation made during 2022-23 in this regard?

Answered on 24th March 2022

A. (a): The Government has taken a number of measures for promotion, development, and for enhancing the competitiveness of MSME sector, including restarting the closed MSMEs. Some of them, announced as a part of the economic package under Aatma Nirbhar Bharat Abhiyan, includes the following :-

(i) Rs. 20,000 crore Subordinate Debt for MSMEs.

(ii) Emergency Credit Line Guarantee Scheme (ECLGS) for Businesses, including MSMEs.

(iii) Rs. 50,000 crore equity infusion through Self Reliant India Fund.

(iv) New revised classification of MSMEs based on composite criteria of investment in Plant & Machinery or equipment and Turnover.

(v) No Global tenders for Government procurements upto Rs. 200 crore.

In addition, the Government has announced the following initiatives for MSMEs in the Budget 2022-23:-

(i) Udyam, e-Shram, NCS and ASEEM portals to be interlinked for credit facilitation, skilling and recruitment.

(ii) Emergency Credit Line Guarantee Scheme (ECLGS) to be extended up to March 2023 and its guarantee cover to be expanded by Rs. 50,000 crore, with the additional amount being earmarked exclusively for the hospitality and related enterprises.

(iii) Credit Guarantee Trust for Micro and Small Enterprises (CGTMSE) scheme to be revamped with required infusion of funds to facilitate additional credit of Rs. 2 lakh crore for MSEs and expand employment opportunities.

(iv) Roll out of Raising and Accelerating MSME Performance (RAMP) programme with an outlay of Rs. 6,000 crore over 5 years.

The budgetary allocation made to Ministry of MSME during 2022-23 is Rs. 21,422.00 crore.

Minister of State for Micro, Small and Medium Enterprises (Shri Bhanu Pratap Singh Verma)

In Rajya Sabha

Impact on Indian Trade Due to Economic Sanctions on Russia

Rajya Sabha Starred Question No. 242

Shri Vaiko:

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

(a) in view of economic sanctions and punitive measures imposed on Russia by the USA and other Western countries, whether Government has examined the impact of such sanctions;

(b) if so, the details thereof; and

(c) the extent to which the implications of such sanctions would affect the Indo-Russia trade, the details thereof?

Answered on 25th March 2022

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

Statement Referred to in Reply to Parts (a) to (c) of Rajya Sabha Starred Question No. 242 For Answer on 25th March, 2022 Regarding "Impact on Indian Trade Due to Economic Sanctions on Russia".

(a) to (c): The impact can be assessed only after the situation stabilizes. However, Department of Commerce is holding regular consultation with all stakeholders to find out the impact on bilateral trade between India and Russia.

The Minister of Commerce and Industry (Shri Piyush Goyal)

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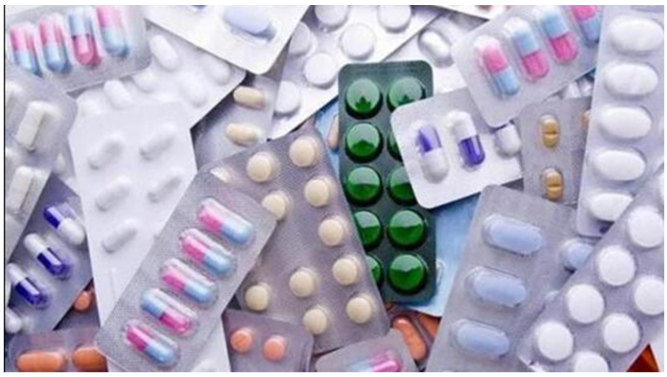
Covid lockdown in China begins to choke Himachal's pharma hub

Over the past month, prices of medicines have doubled and there has been a 50% increase in the rates of packaging material



The lockdown in China's commercial capital of Shanghai to contain the spread of Covid-19 has disrupted the supply of raw material to Himachal Pradesh's pharmaceutical hub in the Baddi-Barotiwala and Nalagarh industrial belt, the biggest pharma hub in Asia.

The indefinite lockdown in China's commercial capital of Shanghai to contain the spread of Covid-19 has disrupted the supply of raw material to Himachal Pradesh's pharmaceutical hub in the Baddi-Barotiwala and Nalagarh industrial belt, the biggest pharma hub in Asia leading to the doubling of cost of active pharmaceutical ingredients (API) and packaging material in the past month.

The prices of several medicines have doubled, such as Paracetamol, which was available for ₹300 a kg in March and now costs ₹700 a kg. There has been a 50% increase in the price of PVC (polyvinyl chloride used for packaging) from ₹110 to ₹190 a kg. The rate of aluminium, also used in packaging medicines, has increased from ₹300 to ₹625 a kg in a month. Cefixime trihydrate, the ingredient used for manufacturing of antibiotics, cost about ₹8,500 a kg in March, but its price has increased to ₹13,000 a kg now.

67 ingredients sourced from China

Himachal Pradesh is the country's third-largest drug producer in terms of volume. It imports 65% of its requirement of raw material or intermediates from China. Raw material from China is used in making antibiotics, Paracetamol, drugs to treat diabetes and cardiovascular diseases. There are 67 such ingredients that are sourced from different locations in China. They include B12, B1, B6 and vitamin E and fermentation process-based APIs.

Both active and inactive ingredients come together to form any medication. The API is the portion of a drug that has therapeutic effects on the body, the chemical compound that makes one feel better. Inactive ingredients are the non-medicinal, but important and necessary, components of the drug.

Big demand but imports on slide

The pharma hub, which produces primary life-saving, anti-inflammatory and anti-viral medicines that are also exported, fears that further delay in shipments from Shanghai and Shenzen could lead to a shortage of raw material.

"There is a big demand for API but imports are on a slide, leading to the shortage. It's worrisome for the pharma industry," says Rajesh Gupta, the president of the Himachal Pradesh Drug Manufacturers Association (HPDMA).

"The worst thing to happen to the stock market and any economy is supply chain disruption. I was seeing the satellite image of ships docked at Shanghai port. Get ready for a massive supply chain shock. A huge cost impact is expected in the shipping world soon. Specifically, due to the shortage of containers," he said.

The Himachal Drug Manufacturers Association (HDMA) has urged the Government of India to set up an API-monitoring cell for regulating prices of bulk drugs. The BBN industrial belt has about 650 pharma units. The ₹40,000-crore drug industry in Himachal Pradesh accounts for every second drug produced in the market.

"If the lockdown in China is prolonged, it can have an adverse effect on the manufacturing of pharmaceuticals drugs," said State Drug Controller Navneet Marwaha.

Despite the Covid-19 induced lockdowns, the pharma units of Himachal Pradesh kept up the pace to manufacture emergency medicines required for treating patients.

Source: Gaurav Bisht, Hindustan Times, 21.04.2022

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Leapfrogging into the future of Indian pharma

The Indian pharmaceutical industry ranks third worldwide for production by volume and caters to 20% of the global demand in the generic market in terms of volume.(AP)

Over the last two decades, the Indian pharma industry has grown leaps and bounds driven by its strength in the global generics space to the extent of being conferred the stature of becoming the pharmacy of the world. The Indian pharmaceutical industry ranks third worldwide for production by volume and caters to 20% of the global demand in the generic market in terms of volume. With a strong network of 3,000 drug companies and approximately 10,500 manufacturing units spread across the length and breadth of the country, India offers a unique competitive advantage in the global pharmaceutical industry. Having said that, for Indian pharma to rise up in the global pharma order, focusing on certain aspects are vital, this includes, building a conducive environment for spurring domestic manufacturing and exports, as well as encouraging innovation through an increased research and development (R&D) push.

The pandemic accelerated pharma industry's reimagination drive and the industry demonstrated remarkable collaboration across the board and stood in solidarity to abate the threat to human life. Our industry embraced a technology-driven approach and harnessed data to unlock new growth opportunities and imbibed pivotal lessons.

With its distinctive capabilities in product development, manufacturing process and strong distribution muscle, today, India's pharmaceutical exports are utilised in almost 206 countries across the world and in FY 21, the exports from the industry stood at $24.44 billion. It is a long march for India to create a global dominance in the pharmaceutical industry and to achieve this, some of the aspects that I believe are crucial in this regard are:

The changing landscape of the domestic pharma industry: India's domestic pharmaceutical market has seen a year on year growth of 9.8%, the shift from being importers to exporters of quality drugs has been made possible by deploying initiatives that strengthened our quality management systems and embedded a culture of quality within the organisation. Increasingly, pharma companies are seeking newer avenues for expansion - biologics, therapeutic drug development and digital tools, but we are still lagging in incremental innovation, development of new molecular entities (NMEs) and active pharmaceutical ingredient (API) R&D.

India has some high-quality academic institutions; yet it is not a scientific or research power. For India to be fully successful as a global scientific and intellectual force, it needs research universities and industry-oriented research focus along with adequate policy/ infrastructure to drive commercialization of the research. We will need to highlight these areas.

The Government has been providing an enabling environment by launching notable initiatives to promote indigenous manufacturing of API and formulations, production linked incentive scheme to boost manufacturing of critical API/key starting materials, promotion of generic medicines by the Jan Aushadi initiative. These interventions are step in the right direction and their timely and effective implementation will help in building competitiveness of the Indian pharma industry.

Unlocking the future growth pillars: While there is no inherent lack of talent and workforce, the lack of a stable pricing and policy environment limits the growth of the sector. All the stakeholders involved must work collaboratively on developing a plan to produce economically feasible drugs and products which are supported by proper clinical trials and regulatory decision.

The pandemic highlighted the need for a robust Indian manufacturing base of products. Pharmaceutical pricing is an important consideration for all countries, especially in the context of manufacturing essential medicines, affordable to the entire population. The Government support through introduction of new initiatives and policies has helped create an enabling environment for R&D, manufacturing, and marketing of safe, quality and affordable medical products.

Indian companies now have an unprecedented opportunity to partner with global players across a wide range of activities, from contract manufacturing and

licensing arrangements to franchising and joint venture opportunities.

Today, digitisation is causing a quantum shift in India's health care ecosystem. It has also played a crucial role in bringing about operational efficiencies, managing supplies and enabled more meaningful and convenient engagements with stakeholders. From a value-add point of view, we see digital as a tool that will empower every stakeholder in the healthcare ecosystem.

The unfolding of the consumerisation story in India has revealed a paradigm shift in mindset from illness to wellness and self-care among patients. Pharma companies need to play a significant role in this curative-behavioural change by equipping patients with the right set of tools, devices and treatment options to guide from awareness to their adherence journey.

In the patient funnel, diagnostics is another key area the industry need to prioritise. Building solutions around the care continuum from easy and early diagnostics to efficient treatment and monitoring should be focused on. Apart from that, funding innovative methods to bring about newer and better opportunities for healthcare management should be encouraged at all levels.

Driving innovation across the ecosystem: From an overall innovation perspective, pharma/health care companies are looking at innovation from various lenses to play a more valuable role within the healthcare ecosystem moving forward. As an industry that has the patient at the centre of 'care', we can improve access to health care with the use of analytics and big data. The industry can shift the paradigm of innovation, creating optimised business models to benefit patients and pharma companies alike.

It is time for us to take note of advanced tools and emerging technologies powered by advanced analytics, robotics and automation that have the potential to revolutionise every element of pharma-manufacturing within the next few years. Adoption of Industry 4.0 is enabling a revolution in manufacturing, with pharmaceutical companies globally adopting technologies such robotics, augmented/virtual reality with great success. Touchless factories are paving the way for a future-fit organisation with minimised scope for errors, increased throughput and reduced timelines

India must also increase its thrust on developing new and improved drugs, biologics, medical devices, diagnostics, and vaccines. This will provide further impetus to the quality, accessibility and affordability of medicinal products through innovation and stringent regulatory supervision.

There is a strong need to create collaborative synergy between academia, industry, research laboratories and regulators along with a conducive policy framework to foster innovations. Through the collective effort of the stakeholders and supportive policy changes, India is well poised to position itself as a provider of safe and high quality medicines across the globe.

(The article has been authored by Samina Hamied, executive vice-chairperson, Cipla and vice-president, Indian Pharmaceutical Alliance)

Source: Hindustan Times, 19.04.2022

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Govt eyes innovative products to raise credit flow to pharma companies

Synopsis "Sector specific issues of pharmaceuticals companies will be taken up by this group, including credit requirement, faster loan clearances and streamlining of procedures," said an official aware of the matter.

The government is eyeing innovative credit products such as funds against Intellectual property rights (IPR) as it looks to increase flow of credit to the pharmaceuticals sector. It has set up a working group to look into financing issues of the sector.

Besides representation from the finance and chemicals and fertilizers ministries, the group will have officials from leading pharma firms and banks including the State Bank ofIndia. "Sector specific issues of pharmaceuticals companies will be taken up by this group, including credit requirement, faster loan clearances and streamlining of procedures," said an official aware of the matter.

The pharma industry's demands include simplification of loan application, collateral-free loans, inclusion of pharma industry in micro, small and medium enterprises (MSME) segment and need for schemes such as Credit Guarantee Fund Trust for Micro and Small Enterprises (CGTMSE) for pharma and ancillary units. "Some of these suggestions are being deliberated on, including innovative credit products like funds against IPR," said the official.

The government has identified pharma as a champion sector and has approved a production-linked incentive (PLI) scheme worth ₹15,000 crore for high value products in pharmaceuticals. There is a separate scheme for setting

up parks for bulk drugs. The pharma sector accounts for about 1.72% of the country's GDP. India's pharma industry is the world's third largest by volume and 14th largest in terms of value. A senior bank executive said the government is looking at various sectors to address issues related to credit and to push lending in the productive sectors of the economy.

Source: Dheeraj Tiwari, ET, 19.04.2022

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A modern traditional option for healthcare

The establishment of the World Health Organisation (WHO) Global Centre for Traditional Medicine (GCTM) is a major step that could help achieve the 2030 goal of universal healthcare. Nearly 80% of the world's population relies on traditional medicine. Despite that, there has been little effort to base traditional medicine in evidence and data.

Much of traditional medicine is based on received knowledge and home remedies. Faith and transgenerational anecdotal evidence have been its mainstay, remedies a free market for anyone with persuasive skills. The WHO GCTM is a concrete step to change this by working on four strategic areas: evidence and learning; data and analytics; sustainability and equity; and innovation and technology to optimise the contribution of traditional medicine to global health. Ensuring that traditional medicine in rooted in evidence, data and analytics will give it equal footing with modern medicine systems. A solid evidence base for traditional medicine will help countries integrate it as appropriate into their health systems. The collaborative nature - 32 memoranda of understanding (MoUs) with universities and research centres across WHO member countries - of the centre will make this possible. Traditional medicine must not remain the option for those who do not have access to modern medicine or the ignorant.

Health systems are about maintaining health, preventing disease, diagnosing and treatment. The goal is to create a system with universal access and acceptability, based in science, which uses technological advances, focuses on well being, prevention, diagnosis and treatment by deploying the best available solutions, be they 'traditional' or 'modern' medicine. With its strong base in traditional medicine, India is a natural home for this endeavour.

Source: The Economic Times, 21.04.2022

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