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INDIAN DRUG MANUFACTURERS' ASSOCIATION

HIGHLIGHTS

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- Maize Starch • Potato Starch • Wheat Starch

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- NEOSORB (Sorbitol) • XYLISORB (Xylitol)

CYCLODEXTRINS

- KLEPTOSE (Betacyclodextrin)
- KLEPTOSE HPB (Hydroxypropyl Betacyclodextrin)

MODIFIED STARCHES

- LYCATAB (Pregelatinized Starch)
- GLYCOLYS (Sodium Starch Glycolate)
- TACKIDEX (Dextrin)

SPECIALTY PRODUCTS

- LYCOAT • PEARLITOL FLASH • STARLAC
- NUTRIOSE

SUGARS AND SOLUBLE FIBRES

- GLUCIDEX (Maltodextrin)
- Dextrose • Dried Glucose Syrup

LUBRICANTS

- Magnesium Stearate

VEG SOFT GEL SYSTEM

- LYCAGEL VS 720
- LYCAGEL VS 720 PREMIX

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Patenting by Design

Dr. Gopakumar G. Nair, Editor, Indian Drugs

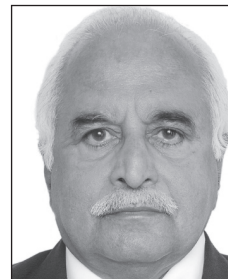
Dear Reader,

Grant of patent is largely based on the prior and clear understanding of the patentability criteria more by the inventors than the applicants. Any perceived invention must meet the basic requirements of novelty and inventive step. Novelty is easy to target as it requires only the absence of any exact replica of the perceived invention in prior art or any public domain including prior patents or patent applications. However, the inventor is often at a loss to identify the inventiveness or non-obviousness in a potential project for patenting, because there is a vast information-base or prior art data to be scanned or screened to ensure that the perceived invention is not likely to be obvious to a person skilled in the art. In patent practice, major group of applicants including large government organizations often come up with complaints that their patent applications are often “rejected”, “refused”, “abandoned” or lapsed. Very often, when an FER (First Examination Report) is received from the Controller of the Patent Office, the objections or observations are perceived as discouraging innovations. To overcome these problems, it is essential that all researchers and inventors need to get fully trained and equip themselves to conduct prior art searches to ensure novelty and inventive step.

It is also essential for researchers to understand various aspects of Intellectual Properties. Copyrights, Designs and Trademarks are different from Patents. Often Industrial Designs are confused with Patents. Designs are only for external or ornamental appearance and have no technology content, while Patents are inherently technology related in contents. If the technical elements are patentable and can be protected as such, they can either be applied for a patent or may alternately be protected privately (without publication) as a trade secret. However, trade secrets may not be possible to be protected eternally unlike patent inventions which are granted protection for 20 years from date of application in specific geographical jurisdictions.

The ultimate goal for an inventor or patent applicant should not only be to meet patentability criteria or conduct a patentability search. Every good invention requires patent protection which should only be a means to

Dr. Gopakumar G. Nair is a Ph.D in Organic Chemistry (1966) from National Chemical Laboratory, Pune (Pune University). He was a Post-Doctoral fellow at IIT Bombay, Powai (1967) before joining the Pharma Industry. He was Director of Bombay Drug House P. Ltd., later Chairman of BDH Industries Ltd. as well as CMD of Bombay Drugs & Pharma Ltd., which was merged with Strides Arcolab Ltd. in 2001. Dr. Nair served IDMA as office bearer for many years from 1972 onwards and was Chairman of various Committees for nearly 4 decades. He was the President of IDMA in 1999/2000. Currently, Dr. Nair is the Chairman of the IPR Committee in IDMA.



Having moved into the Intellectual Property field, he was the Dean of IIPS (Institute of Intellectual Property Studies) at Hyderabad in 2001/2002. Later, he set up his own boutique IP firm, Gopakumar Nair Associates, as well as Gnanlex Hermeneutics Pvt. Ltd., having done his LL.B. from Mumbai University. He has done his LL.M. from Jindal Global Law School in 2022. He is also CEO of Patent Gurukul and President of Bharat Education Society, Kurla, Mumbai, managing many educational institutions in and around Mumbai.

commercialization or licensing out for taking to the market place for public benefit. As such, a PNIS (Patent Non-Infringing Status) and FTO (Freedom to Operate) search is also essential to be conducted to ensure that the patented invention is not hindered by infringement litigation in its journey to the market place.

It is time that every researcher and potential inventor has to become patent literate and also get trained in prior art search. Patents are a matter of law and facts. As such, it is also advisable for innovative researchers to get themselves familiarised with nuances of law or jurisprudence, if not become trained in law formally. IPR related law training courses are conducted by WIPO, NALSAR and others including RGNIPM, Nagpur (under the aegis of the IP Office, India).

Courtesy: Indian Drugs, Editorial, 59 (11), November 2022

A Report on IDMA Annual Interactive Session, Chapter West Bengal

Executive Committee Meeting of Indian Drug Manufacturers' Association followed by the **Annual Interactive Session** was organized by the West Bengal State Board on Thursday, 17th November, 2022 at the Ball Room, The Oberoi Grand, Kolkata.

The Inaugural programme started with the IDMA Anthem followed by the National Anthem.

The session was attended by 162 participants including delegates, guests and dignitaries.

In the inaugural session Mr. Probhas Bondhu Chakraborty, Hon. Jt. Secretary, IDMA, Chapter West Bengal welcomed all and outlined the details of the programme. Mr. Siddhartha Paul, Hon. Secretary, Chapter West Bengal introduced the guests and individually welcomed all of them.

Dr. Viranchi Shah, National President, IDMA in his **PRESIDENT'S ADDRESS** made a structured presentation on the current affairs, future trends in the Pharma Industry along with action plans to deal with the problems and seize the opportunity to grow the pharmaceutical industry from USD 50 billion to USD 500 Bn by 2047, on the 100th year of Indian Independence.

Mr. Daara B Patel, Secretary General, IDMA in his address requested the audience to increase the membership strength and congratulated the State Board for successfully organizing such a wonderful programme.

Dr. Sanjoy Mitra, Managing Director, SMSRC Pvt. Ltd., Kolkata made an interesting presentation on "Indian Pharma Market in post Covid Era-Rx perspective". He

stressed on the importance of building brands to drive and sustain the business consistently. His observation, on small and mid-size companies who continued to perform or recovered faster during and post covid periods were the ones who had relatively better quality of brands within their portfolio, was well substantiated with various examples and analytics.

Panel Discussion on **Strategy for Business Growth**, though the last event of the session was the most interesting one as it captivated the audience with pertinent questions being asked to the panelists who shared their deep insights from their wide experience and knowledge acquired in the process of leading their companies in the path of exceptional growth. The panelists from the industry were Mr S V Veeramani, CMD Fourrts (India) Laboratories, Mr Mehul Shah, MD Encube Ethicals, Mr Nirav Mehta, Director Corona Remedies. Dr Sanjoy Mitra, MD SMSRC Pvt Ltd., management consultant for strategic marketing in pharmaceuticals as the fourth panelist shared his understanding of obstacles to growth and how to avoid them. The panelists responded well to all the questions while clarifying different issues that came up during the session. The panel discussion was moderated by Mr Deepnath Roy Chowdhury, Past National President whose questions were intelligently framed to provoke the panelists share their experience spontaneously.

The delegates present participated enthusiastically and were greatly benefited through the various clarifications provided by the eminent speakers.

Mr. Shiv Sagar Tiwari, Chairman IDMA, Chapter West Bengal delivered the formal vote of thanks.

Glimpses of the Event



E C Meeting



Welcome address



National President's speech



The Dias



The Panelists



The IDMA Group



The Audience



Vote of Thanks

Ministry of Health and Family Welfare announces the Extension of Tenure of Dr V G Somani, DCG(I)

Notification S.O. 5398(E), dated 21st November, 2022

In pursuance of the provisions of clause (b) of rule 21 of the Drugs Rules, 1945, the Central Government hereby appoints Dr. Venugopal Girdharilal Somani, holding the charge of Drugs Controller (India) in the Central Drugs Standard Control Organisation, Ministry of Health and Family Welfare, to be the licensing authority till the 15th

February, 2023 or till the next incumbent joins the said post or until further orders, whichever is earlier.

F. No. A.12025/03/2022-DRS

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



NOW AVAILABLE ! IDMA-APA GUIDELINES / TECHNICAL MONOGRAPHS

TECHNICAL MONOGRAPH NO. 1
STABILITY TESTING OF EXISTING DRUGS SUBSTANCES AND PRODUCTS

TECHNICAL MONOGRAPH NO. 3
INVESTIGATION OF OUT OF SPECIFICATION (OOS) TEST RESULTS

TECHNICAL MONOGRAPH NO. 5
ENVIRONMENTAL MONITORING IN CLEANROOMS

TECHNICAL MONOGRAPH NO. 7
DATA INTEGRITY GOVERNANCE

TECHNICAL MONOGRAPH NO. 2
PRIMARY & SECONDARY CHEMICAL REFERENCE SUBSTANCES

TECHNICAL MONOGRAPH NO. 4
PHARMACEUTICAL PREFORMULATION ANALYTICAL STUDIES

TECHNICAL MONOGRAPH NO. 6
CORRECTIVE/PREVENTIVE ACTIONS (CAPA) GUIDELINE

TECHNICAL DOCUMENT NO. 8
QUALITY 4.0 DIGITAL TECHNOLOGY OF THE FUTURE

Copies are available at IDMA Office, Mumbai. We do not mail any publications against VPP payment. All payments to be made in advance as Cheque/DD/RTGS/NEFT in favour of "INDIAN DRUG MANUFACTURERS' ASSOCIATION" at Mumbai.

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Relaxation on Global Tender Enquiry (GTE) under Rule 161(iv) of General Financial Rules (GFRs) 2017

Dated the 25th November, 2022

OFFICE MEMORANDUM

Attention is invited to this Department's OM No. F.12/17/2019-PPD dated 15.05.2020 and 28.05.2020 regarding amendment in Rule 161(iv) of General Financial Rules (GFRs) 2017 stipulating that no Global Tender Enquiry (GTE) shall be invited for tenders upto Rs. 200.00 crore or such limit as may be prescribed by this Department from time to time, without prior approval from the competent authority i.e. Secretary (Coordination) , Cabinet Secretariat.

2. In this context, in view of request of Ministry of Health & Family Welfare (MoH&FW), it has been decided that 90 (67+23) Drugs/Medicines listed at Annexure-A will be exempted from the instructions issued by this department vide OMs No. F.12/17/2019-PPD dated 15.05.2020 & 28.05.2020 regarding GTEs. This exemption will be valid for all the tenders issued for such drugs/medicines till 31.03.2023.
3. This issues with the approval of Finance Secretary.

No.F.4/1/2022-PPD(pt.)

Usha Rani
Under Secretary (Procurement Policy)
Procurement Policy Division,
Department of Expenditure,
Ministry of Finance, Government of India

List of 90 (67+23) drugs/medicines exempted from the instructions of Department of Expenditure (DoE) issued vide OMs No. F.12/17/2019-PPD dated 15.05.2020 & 28.05.2020 regarding Global Tender Enquiry.

List of 67 Drugs

S.no	Name of the Medicine and Strength
1	Abemaciclib 150mg Tablet. .
2	AFLIBERCEPT 40 MG
3	Apidra Solostar
4	ATEZOLIZUMAB 840 MG/ 1.2MG
5	Avelumab injection: 200 mg/10 mL (20 mg/mL) solution in single-dose vial
6	BASILIXIMAB 20 MG
7	Biphasic Insuliin Aspart Inj-
8	Brolucizumab solution for injection 120 mg/ml(vial + filter needle)
9	Ceritinib Tab/Cap- Each Hard Gelatin Tab/Cap to contain: Ceritinib 150mg
10	CETUXIMAB 100 MG
11	CETUXIMAB 500 MG
12	Creon 10000
13	DARATUMUMAB 100 MG 400mg
14	DEGLUDEC 100 I.U./ML INSULIN, PREFILLED PEN 3 ML.
15	Desflurane Anaesthetic Liquid (SUPRANE)

16	Detemir Insulin 100iu/ml 3ml Pen	27	Human Papillomavirus- Each 0.5ml to contain: Human Papillomavirus Quadrivalent (6, 11, 16, 18) Vaccine, Recombinant & 0.5ml
17	DULAGLUTIDE 0.75 MG (BRAND-TRULICITY 0.75MG) 1.5	28	Idursulfase injection : 6 mg/3 mL (2 mg/mL) in single-use vial
18	Dulaglutide Inj- Each 0.5 ml to contain: 1.5 mg of Dulaglutide, Citric Acid Anhydrous [0.07mg], Mannitol [23.2 mg], Polysorbate 80 [0.10 mg], Trisodium Citrate Dehydrate [1.37 mg] Water for injection	29	Imiglucerase injection: 400 units of imiglucerase as a lyophilized powder in a single-dose vial.
19	DURVALUMAB 120 MG/ 500MG	30	INJ AVELUMAB 200 MG
20	Each Tab/Cap contain: Alpelisib 150mg	31	INJ PANITUMUMAB 100 MG (BRAND:INJ. VECTIBIX)
21	Each Tab/Cap contain: Olaparib 150mg	32	INJ PEMBROLIZUMAB 100 MG, 420
22	Emicizumab Inj- Each Vial Contains : Emicizumab 30mg For Sub Cut Injection (R-DNA Origin), Each Vial Contains : Emicizumab 60mg For Sub Cut Injection (R-DNA Origin)	33	INJ PERTUZUMAB 420 MG (BRAND:PERJETA)
23	FACTOR EIGHT BYPASSING ACTIVITY - Containing : Factor Eight Bypassing activity, Anti- Inhibitor-Coagulant Complex. 500 IU.	34	INJ. INSULIN ASPART 100IU/ML-3 ML PENFILL.ONE PEN AND 20 NEEDLES FREE WITH EVERY 20 CATRIDGES
24	Golimimumab (r-DNA Origin)- Each Single Use Pre-Filled Syringe to contain: Golimumab 50mg/0.5ml Component [Amount Per Dose (Mg)]: Golimumab (CNTO 148) -50mg, Sorbitol -20.5mg, L-Histidine - 0.44mg, Polysorbate 80 - 0.075mg, Water For Injection - 0.5mg	35	Inj. Insulin Degludec 70% + Insulin Aspart 30% 100 IU/ml., 3 ml. Cartridge (RYZODEG PENFILL.)
25	GOSERELIN 10.8 MG SR INJ (BRAND: ZOLADEX) 3.6	36	Inj. Liraglutide 18 mg per pen, 1 needle free per pen
26	HUMAN COAGULATION FACTOR VII INJ - Each vial to contain: Human Recombinant Coagulation Factor VII activated (r-DNA origin) 1mg, Each vial to contain: Human Recombinant Coagulation Factor VII activated (r-DNA origin) 2mg	37	INJ. MEPOLIZUMAB POWDER FOR SOLUTION 100 MG
		38	Inj. Secukinumab 150 mg(Scapho)
		39	Inj. Thyrotropin alfa 1.1 mg (THYROGEN)
		40	Insulin Analogue of 50% Insulin Aspart + 50% longer acting analogue 100 iu/ml.
		41	INSULIN GLULISINE INJECTION(MONOCOMPONENT INSULIN GLULISINE) 100I.U./ML,3ML CARTRIDGE WITH ONE NEEDLE FREE OF COST PER CARTRIDGE AND ONE COMPATIBLE DEVICE FREE OF COST PER TWENTY CARTRIDGES.

42	Insulin Inj-Each Cartridge to contain: 25% Lispro And 75% LisproProtamine Suspension (100 IU/ml) [Monocomponent Insulin, Recombinant DNA Origin] & 3ml Cartridge Each Cartridge to contain: 50% Lispro And 50% LisproProtamine Suspension (100 IU/ml) [Monocomponent Insulin, Recombinant DNA Origin] & 3ml Cartridge
43	Intravitreal Dexamethasone Implant- Each inj to contain: Intravitreal Dexamethasone 0.7mg
44	Laronidase injection: 2.9 mg/5 mL (0.58 mg/mL) of laronidase in a single-dose vial
45	Levonorgestrel- Each Sterile Intrauterine System to contain: Levonorgestrel 52mg (Levonorgestrel 20 Microgram / 24 Hours Intra Uterine Delivery System)
46	LYNPARZA
47	Mepolizumab Inj- Each Vial to contain: Mepolizumab 100mg
48	Methoxy Polyethylene Glycol Epoetin-Beta- Each PFS to contain: Methoxy Polyethylene Glycol Epoetin-Beta 100mcg, Methoxy Polyethylene Glycol Epoetin- Beta- Each PFS to contain: Methoxy Polyethylene Glycol Epoetin-Beta 50mcg, Methoxy Polyethylene Glycol Epoetin- Beta- Each PFS to contain: Methoxy Polyethylene Glycol Epoetin-Beta 75mcg
49	Midostaurin Tab/Cap- Each Tab/CapContains:Midostaurin 25mg
50	NIVOLUMAB 100 MG INJ (BRAND:OPDYTA), Each 4 ml Vial to contain: Nivolumab 40mg
51	Obinutuzumab Inj- Each Vial to contains: Obinutuzumab 1000 mg

52	PERITONEAL DIALYSIS FLUIDS 1.5% - Each 100ml to contain: Dextrose Anhydrous 1.5gm, Sodium Lactate 448mg, Na Cl 538mg, Ca Cl 25.7mg, Mg Cl 5.08mg & 5Ltr Bag, Peritoneal Dialysis Fluids 1.5%- Each 100ml to contain: Dextrose Anhydrous 1.5gm, Sodium Lactate 448mg, Na Cl 538mg, Ca Cl 25.7mg, Mg Cl 5.08mg & 2Ltr Bag, PERITONEAL DIALYSIS FLUIDS 2.5% - Each 100ml to contain: Dextrose Anhydrous 2.5gm, Sodium Lactate 448mg, Na Cl 538mg, Ca Cl 25.7mg, Mg Cl 5.08mg & 2Ltr Bag
53	Pertuzumab Inj- Each 14ml Vial to contain: Pertuzumab 420mg (30mg/ml)
54	RAMUCIRUMAB 100 mg&500 MG(BRAND- CYRAMZA)
55	Ryzodeg penfil
56	Secukinumab Inj- Each 1 ml to conatin: Secukinumab 150mg, Sucrose 92.43mg, L-Histidine / L- Histidine Hcl Monohydrate 4.656 mg, Polysorbate 80 - 0.60mg.
57	Tab./ Cap. (Netupitant 300 mg. + Palanosetron 0.5 mg.) (AKYNZEO CAPS.)
58	TUOJEO SOLOSTAR 1.5ML PEN(INSULIN GLARGINE INJECTION 300IU/ML)THREE NEEDLES FREE WITH ONE PEN
59	TUROCTOCOG ALFA 500 I.U. INJECTION
60	VERTEPORFIN 15 MG
61	Ceftazidim 2gm + Avibactam 500mg Inj.

62	Crizotinib Tab/Capsule (250 Mg)
63	Tab. Dacomitinib Monohydrate 30 mg.(Tab Dacoplice 30 Mg.)
64	Isavuconazole 100 mg caps.

65	Liraglutide 18 mg
66	Ceftaroline 600 mg/vial
67	Palbociclib 75 mg/100mg/125 mg

List of 23 Drugs

S.no	Name of the medicine & Strength
1	AFATINIB 20 MG TAB 30 MG, 40MG
2	ALECENSA 150 MG
3	AXITINIB TAB/CAP 5 MG
4	CANAGLIFLOZIN+METFORMIN TAB/CAP-
5	ELTROMBOPAG TABLETS 25 MG, ELTROMBOPAG TABLETS 50 MG (REVOLADE 25/50 MG)
6	EMPAGLIFLOZIN 10 MG+LINAGLIPTIN 5 MG TAB/CAP
7	EMPAGLIFLOZIN 10 MG+ TAB (BRAND:JARDIANCE)25,
8	INVOKANA (CANAGLIFLOZIN 100 MG TABLETS)
9	LINAGLIPTIN 2.5 MG + METFORMIN 500 MG TAB/CAP
10	NILOTINIB 150 MG TAB (BRAND:TASIGNA)200MG
11	OSIMERTINIB 80 MG
12	RECOMBINANT ANTI HEMOPHILLIC FACTOR-VIII

13	RECOMBINANT ANTIHEMOPHILLIC FACTOR-VIII
14	RIBOCICLIB TABLET/CAPSULE 200 MG (BRAND KRYXANA)
15	RUXOLITINIB 15 MG, 5 MG, 20 MG TABLET (BRAND JAKAVI)
16	SACUBITRIL 24 MG+VALSARTAN 26 MG TABLET, 49/51 MG, 97/103 MG (VYMADA 100 MG)VILDA
17	SAXAGLIPTIN TABLETS 2.5 MG, SAXAGLIPTIN TABLETS 5 MG
18	SAXAGLIPTIN & METFORMIN HYDROCHLORIDE EXTENDED RELEASE TABLETS
19	SUNITINIB MALATE TAB/CAP
20	TAB.BARICITINIB 2 MG, 4 MG
21	TAB.PAZOPANIB 400 MG. (TAB. VOTRIENT 400 MG.)
22	TAGRISSO 80 MG (OSIMERTINIB 80 MG)
23	VOTRIENT 200 MG 400





Availability of Govt. Funds

Government Key Initiatives, Funds and Departments

Easy availability of capital is essential for entrepreneurs at the early stages of growth of an enterprise.

Mukesh Chandra Kestwal

Program Head – Innovation Hub & Govt. Engagement
Headstart Network Foundation

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We are trying to create an ecosystem which is based on the mantra
'of the youth, by the youth, for the youth'

Hon'ble PM Shri Narendra Modi



Mukesh Chandra Kestwal, Headstart Network Foundation, © 2022

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Some of Ongoing Applications For Startups

Organization Name	Last Date	Website	Fund Limit
Startup India Seed Fund	Rolling Basis	https://seedfund.startupindia.gov.in/	50 Lakh
Small Farmers' Agri-Business Consortium	Rolling Basis	http://sfacindia.com/Equity_grant.aspx	15 Lakh
Atal New India Challenge (ANIC), Women Entrepreneurship Focus	31 Dec 2022	https://www.aim-challenges.in/	1 Cr
USOF, ELECOM TECHNOLOGY DEVELOPMENT FUND,	30 Dec 2022	https://usof.gov.in/	10 Cr
AgriEncs Grand Challenge, MeitY	28 Nov 2022	https://www.meity.gov.in/content/inviting-applications-agriencs-grand-challenge	15 Lakh
DCIS, Department of Telecommunication	20 Dec 2022	https://dcis.dot.gov.in	50 L to 10 Cr
Frontier Tech Solutions, UNICEF Innovation Fund	09 Jan 2023	https://www.unicefinnovationfund.org/apply/fron-tier-tech-solutions	80 Lakh
Fund of Fund, BIRAC, DBT	05 Jan 2023	https://www.birac.nic.in/desc_new.php?id=989	07 Cr
Technology Innovation Fund (TIF) (TIH-IoT Technology Development Program 2022)	20 Dec 2022	https://www.tih.iitb.ac.in/tih-iot-technology-development-program-2022-2/	50 Lakh
Aarohan* - TIH-IoT Seed Support Program 2022	Rolling Basis	https://www.tih.iitb.ac.in/tih-iot-seed-support-program-2022	50 Lakh

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Government Agencies

Enabling the Startup Ecosystem

Organisation Name	Website
Department of Science and Technology, Ministry of Science and Technology	https://dst.gov.in/
Startup India	https://www.startupindia.gov.in/content/sih/en/search.html?roles=GovernmentBody&page=0#
Atal Innovation Mission	https://aim.gov.in/
Office of Principal Scientific Officer	https://www.psa.gov.in/ https://www.istem.gov.in/ https://manthan.gov.in/
Software Technology Park of India (STPI)	https://stpi.in/
National Science & Technology Entrepreneurship Development Board (NSTEDB)	https://www.nstedb.com/
Ministry of Electronics and Information Technology (MeitY)	https://www.meity.gov.in/
MSME	https://msme.gov.in/
National Innovation Foundation	https://nif.org.in
Global Innovation and Technology Alliance	https://gita.org.in/
Department of Bio Technology	https://dbtindia.gov.in/
Technology Development Board	http://tdb.gov.in/

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BENEFITS OF GOVT. GRANTS

- Non-repayable: outright gifts, not loans
- Wide range of categories
- Resources available
- No limit to the number of grants
- No hidden costs or fees
- Can apply anytime (based on timeline)

These are some of benefits. However, based on grants you are applying, terms may differ.

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WHO CAN APPLY

Individual

Startups

Incubators

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MINISTRY FOR FUNDS

- > Department of Science & Technology (DST)
- > Department for Promotion of Industry and Internal Trade (DPIIT)
- > Council of Scientific & Industrial Research (CSIR)
- > Atal Innovation Mission
- > Ministry of Electronics and Information Technology (MeitY)
- > Department of Electronics and Information Technology (DeiTY)
- > Department of Biotechnology (DBT)
- > Small Industries Development Bank of India (SIDBI)
- > Ministry of Micro, Small and Medium Enterprises (MSME)
- > Ministry of Communications and Information Technology (MCIT)
- > Software Technology Parks of India (STPI)
- > National Skill Development Corporation (NSDC)
- > National Bank for Agriculture and Rural Development (NABARD)
- > Micro Units Development and Refinance Agency Ltd. (MUDRA)
- > Science and Engineering Research Board (SERB)
- > Biotechnology Industry Research Assistance Council (BIRAC)

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Department of Science & Technology (DST)

- > Science and Technology of Yoga and Meditation (SATYAM)
- > NIDHI-PRomoting And Accelerating Young And ASpiring Innovators & Startups (NIDHI- PRAYAS)
- > National Science & Technology Management Information System (NSTMIS)
- > Centre For Augmenting WAR With COVID-19 Health Crisis (CAWACH)
- > NIDHI-Accelerator - Fast Tracking A Start-Up Through Focused Intervention
- > NIDHI- Seed Support System (NIDHI-SSS)



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Department for Promotion of Industry and Internal Trade (DPIIT)

- > Startup India
- > Invest India
- > AGNI
- > Startup India Seed Fund Scheme (SISFS)



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Council of Scientific & Industrial Research (CSIR)

- Promoting Innovations In Individuals, Startups And MSMEs (PRISM)



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Atal Innovation Mission

- Atal Incubation Center
- Atal Tinkering Laboratories
- Atal Research & Innovation for Small Enterprises (ARISE)
- Atal New India Challenge (ANIC)



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Ministry of Electronics and Information Technology (MeitY)

- Scheme To Support IPR Awareness Seminars/Workshops In E&IT Sector
- Technology Incubation And Development Of Entrepreneurs (TIDE) 2.0
- Department of Telecommunication



Ministry of Electronics and Information Technology
Government of India

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Department of Electronics and Information Technology (DeiTY)

- Multiplier Grants Scheme (MGS)
- Support for International Patent Protection in Electronics & Information Technology (SIP-EIT)
- Electronic Development Fund (EDF) Policy
- Modified Special Incentive Package Scheme (M-SIPS)
- Scheme to Support IPR Awareness Seminars/Workshops in E&IT Sector

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Ministry of Communications and Information Technology (MCIT)

- Support For International Patent Protection In Electronics & Information Technology (SIPEIT)
- Aspire - Scheme for promotion of innovation, entrepreneurship and agro-industry



Department of Telecommunications
Ministry of Communications
Government of India

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Small Industries Development Bank of India (SIDBI)

- Stand Up India
- 4E (End to End Energy Efficiency)
- COVID-19 STARTUP ASSISTANCE SCHEME (CSAS)
- Sustainable Finance Scheme
- SIDBI Make in India Soft Loan Fund for Micro Small and Medium Enterprises (SMILE)
- Startup assistance Scheme



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Ministry of Micro, Small and Medium Enterprises (MSME)

- Aspire Scheme For Promotion Of Innovation, Entrepreneurship And Agro-Industry
- Various Other Startup, Incubation Fund



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Department of Biotechnology (DBT)

- E-YUVA
- Biotechnology Ignition Grant Scheme (BIG)
- Small Business Innovation Research Initiative (SBIRI)
- BIRAC Incubators SEED Fund
- Rapid Grant for Young Investigator (RGYI)



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Software Technology Parks of India (STPI)

- Software Technology Park (STP) Scheme
- CHUNAUTI - NextGen Startup Challenge Contest



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National Skill Development Corporation (NSDC)

- Udaan Training Programme For Unemployed Youth Of J&K



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National Bank for Agriculture and Rural Development (NABARD)

- Dairy Entrepreneurship Development Scheme
- Biotechnology Venture Fund
- SEAF Agribusiness Fund
- Tata Capital Innovations Fund
- India Opportunities Fund
- Omnivore Capital Trust



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Micro Units Development and Refinance Agency Ltd. (MUDRA)

- Pradhan Mantri Mudra Yojana (PMMY)



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Science and Engineering Research Board (SERB)

- Technology Development Programme (TDP)
- Ayurvedic Biology Program
- Industry Relevant R&D
- High Risk-High Reward Research



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Biotechnology Industry Research Assistance Council (BIRAC)

- SPARSH (Social Innovation programme for Products: Affordable & Relevant to Societal Health)
- Industry Innovation Programme on Medical Electronics (IIPME)
- Biotechnology Industry Partnership Programme (BIPP)
- Biotechnology Ignition Grant (BIG)



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#startupindia

2016

Startup India Seed Fund
(Duration 5 years)

Startups Incubators

Target Estimated in 4 years



INR 945 cr

3600 Entrepreneurs
300 Incubators

Sector Agnostic

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2015

ASPIRE

(Scheme for Promotion of Innovation, Rural Industries and Entrepreneurship)

(Duration 1 to 2 years)

Startups

Incubators

Components:

- Livelihood Business Incubation (LBI)
- Technology Business Incubation (TBI)
- Start-up Promotion through Small Industries Development Bank of India (SIDBI)

Target Estimated in 2019-20

INR 200 cr

80 LBI 20 TBI

75000 Skilled Entrepreneur

Agro Industry

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2016

ATAL Innovation Mission

(Duration 5 years)

Individual

Startups

Incubators

AIM Framework :

- Atal Tinkering Labs (10 lakhs for 5 years)
- Atal Incubation Centres (10 cr for 5 years)
- Atal Research & Innovation for Small Enterprises (ARISE) (50 lakhs for 9 - 12m)

Target Completed

INR 1000 cr

350 collaborations


8700 ATIs (10K+ estimated)

10,000 mentors

Sector Agnostic

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2015

MUDRA Yojana

(Micro Units Development & Refinance Agency Ltd.)


(Duration 7 years)

Individual

Startups

MUDRA Products :

- Shishu (50,000)
- Kishore (50,000 - 5 lakhs)
- Tarun (5 lakhs - 10 lakhs)



Target Estimated in 2021-22

INR 69571 cr

Sectoral Development

Financial Literacy

Institution Development

Non-corporate, Non-farm small/micro Enterprises

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Ministry of Skill Development And Entrepreneurship

2017

Skill Development and Entrepreneurship (Duration 5 years)

Individual

Startups

Incubators

Initiatives

- Pradhan Mantri Kaushal Vikas Yojana 3.0
- Jan Shikshan Sansthan
- Udaan (For J & K graduates and post graduates)
- National Skill Certification and Monetary Reward Scheme (STAR)

Target Estimated

INR 4951 cr

Sectoral Development
Financial Literacy
Institution Development

Non-corporate, Non-farm
small/micro Enterprises

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NABARD

2017

Dairy Processing and Infrastructure Development Fund (Duration 10 years)

Individual

Startups

Target Estimated for 3 years

INR 8004 cr

95 lakh milk producers
50000 villages
28,000 Milk Cooling units

Dairy MSME

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Ministry of Electronics and Information Technology Government of India

2015

Support for International Patent Protection in Electronics & Information Technology (SIP-EIT) (Duration 5 years)

Startups

Target Estimated

INR 15 lakhs per Invention


International Patent Protection

Applied at any stage

MSME
ICTE Sectors

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2018

Multiplier Grants Scheme (MGS)

(Duration 2-3 years)

Startups


Incubators

INR 36 cr
2 cr to 4 cr per startup

Increase in number of Entrepreneurs by R&D Lab interaction

Computer Sciences & Information Technology

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2019

NIDHI- Seed Support System (NIDHI-SSS)

(Duration 2-3 years)

Startups

INR 10 cr
25 Lakhs to 100 Lakhs per startup

Development and commercialization of innovative technologies/products/services

All Science Disciplines

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Conclusion

These initiatives have been introduced for the development of the Indian startup ecosystem. India seems to be heading towards the golden era of entrepreneurship.

*India, heading towards becoming a **Global R&D Hub***

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What PM has to say on it?



"I see startups, technology & innovations as exciting and effective instruments for India's transformation"

Narendra Modi
Hon'ble Prime Minister of India

NPPA fixes price of 272 new drugs in the first six months of 2022-23

The drug price regulator has fixed prices of 272 drugs and reviewed the price of one combination drug during the first six months of the current financial year, besides extending its price control measures on the Covid-19 related products, according to the Department of Pharmaceuticals (DoP).

The National Pharmaceutical Pricing Authority (NPPA) has fixed the retail prices of 77 new drugs under the revised Schedule I of the National List of Essential Medicines (NLEM), 2015 during the month of September, 2022.

Including these, the cumulative retail price fixation during the six months from April 1, 2022 to September 30, 2022, was for 272 drugs, said the Department in a latest monthly review.

During the period, the Authority has also extended the price fixation on liquid medical oxygen (LMO) and oxygen inhalation (medicinal gas) in cylinder, and the ceiling prices fixed on heparin injection 1000 IU/ml and 5000 IU/ml, till December 31, 2022.

The Authority has also issued 12 preliminary notices to companies based on the monitoring and enforcement activities and an amount of Rs. 23.85 lakh was recovered towards overcharged amount during the month of September, said the Department.

According to a statement by Bhagwanth Khuba, minister of state for chemicals and fertilisers, in August, 2022, NPPA has fixed the ceiling prices of 890 scheduled formulations of medicines under NLEM, 2015 till June 30, 2022. In addition, NPPA has fixed retail price of 2,023 new drugs under DPCO, 2013 till June. Besides, NPPA has also capped the trade margin of non-scheduled formulations of 42 anti-cancer medicines under 'Trade Margin Rationalization' approach as a pilot for proof of concept, wherein price of more than 500 brands of medicines were reduced up to 90%, he added.

During the six months, the NPPA has also revised the price of Pune-based Emcure Pharmaceuticals' HIV drug combination darunavir 800 mg + ritonavir IP 100 mg tablet upwards, following a review order from the DoP.

NPPA has fixed the retail price of darunavir 800 mg + ritonavir IP 100 mg, as Rs. 197.55 per tablet, through an notification in November 8, 2019, while the same combination of Hetero Healthcare Ltd in November 2, 2018 was fixed at Rs. 212.91 per tablet based on the

recommendation of the multidisciplinary committee (MDC) of experts.

The company approached the DoP following this and received a favourable order in June, 2021. DoP in its order observed that the NPPA could have used the retail price of Rs. 212.91 per tablet for Hetero Healthcare, while filing the retail price for Emcure Pharmaceuticals. After further communications from the DoP and deliberations, the NPPA notified the price of each darunavir ethanolate equivalent to darunavir 800 mg and ritonavir IP 100 mg tablet manufactured by Hetero Labs Ltd and marketed by Emcure Pharmaceuticals, will be Rs. 212.91.

Source: *Pharmabiz*, 01.11.2022



RoDTEP. FinMin may allow expansion of export promotion scheme but funding is a problem

Pharma, chemicals, steel could get benefit of input duty remission but onus may be on Commerce Ministry to manage resources



The Finance Ministry is ready to consider allowing pharmaceuticals, steel, organic chemicals and inorganic chemicals to benefit from the popular export promotion scheme—Remission of Duties and Taxes on Exported Products (RoDTEP)—but it may not be keen to allocate more resources for it, sources said.

“If the RoDTEP scheme gets extended to the four previously excluded schemes, it is the Commerce Ministry which may be asked to provide the resources from the allocation already made for the scheme. This would be a challenge as the available amount may not be enough to accommodate more claimants but the Finance Ministry has indicated that it would be difficult to come up with more funds,” a source tracking the matter told *businessline*.

The RoDTEP scheme, announced on January 01, 2021 with the simultaneous withdrawal of the popular Merchandise Export from India Scheme (MEIS), refunds exporters the embedded duties/taxes that are not rebated under other schemes. These include value added tax (VAT) on fuel used in transportation, mandi tax, duty on electricity used during manufacturing, etc.

The MEIS had to be withdrawn as it was not compatible with WTO norms because of lack of transparency in calculation of reimbursement rates.

The RoDTEP scheme, which covers almost 8,000 tariff lines, providing duty remission at rates ranging from 0.3 per cent to 4.3 per cent, excluded some major items such as steel, pharmaceuticals and chemicals.

LACK OF FUNDS

After months of persuasion by the industry bodies, the government now seems to be ready to include these sectors in the scheme but lack of funds could be a serious impediment.

“The Finance Ministry allocated around ₹13,800 crore this fiscal for RoDTEP scheme. Now, this amount can barely take care of the existing claimants. It will be very difficult to provide for the new sectors from this fund. The Finance Ministry has to allocate more funds or the Commerce Ministry can explore if it is possible to channelise funds from some other scheme,” the source said.

With India’s exports taking a severe beating in October 2022, falling around 16.5 per cent (year-on-year), and world trade expected to grow by just 1 per cent next year, the Centre is looking at ways to provide support.

Exporters are hoping that the government will sort out the issue of funding and extend the RoDTEP scheme soon, the source said.

Source: Amiti Sen, Business Line, 27.11.2022



Pharma exports rise by 4.22% to \$14.57 billion during April-October in current fiscal

USA, Canada and Mexico (NAFTA countries), Europe and Africa account for 67.5% (nearly \$5 billion) of the total exports

Pharmaceutical exports from India registered a growth of 4.22% to reach \$14.57 billion during the April-October period despite a negative trend last month, according to a senior official of an export promotion body under Government of India.



Udaya Bhaskar, Director General of Pharmaceuticals Export Promotion Council of India (Pharmexcil) which is an organisation under the Ministry of Commerce, said he was hopeful of ending the current fiscal at around \$27 billion as against \$24.62 billion during the last financial year.

“There was a dip (-0.32%) in July and (-5.45%) and there was 8.47% positive growth in September. I am optimistic that it will be revived in the coming months and may touch USD 27 billion at the end of the fiscal,” Mr. Bhaskar told PTI.

During the same period last fiscal, the exports fetched \$13.98 billion.

USA, Canada and Mexico (NAFTA countries), Europe and Africa account for 67.5% (nearly \$5 billion) of the total exports.

“Our exports in the category of vaccines are in a very bad shape. Despite the above and Russia-Ukraine war factors, we are on a positive side,” he further said.

In October, exports fell by 5.45% to \$1.95 billion.

India’s overall exports contracted by 16.65% to \$29.78 billion in October 2022 as compared to the last year’s period, according to data released by the Ministry of Commerce recently. During April-October 2022, exports recorded a growth of 12.55% to \$263.35 billion.

Mr. Bhaskar said strengthening of dollar against the currencies of some of the key countries has also resulted in decline in exports during October besides the sanctions resulting from the Russia-Ukraine war.

“For example, Nigeria is one of the top five markets for Indian pharma exports. The continuous depreciation of Nigerian Naira against the US Dollar has forced that country to go slow on imports,” the official further said.

Union Health Minister Mansukh Mandaviya, in a recent tweet, said India has emerged as a global pharma powerhouse under Prime Minister Narendra Modi’s rule.

Exports of pharma production grew to over \$90,32,000 crore during April-October period from nearly ₹38,000 crore in the same period in 2013 up by 137.7%, the Minister said tagging an infographic.

Source: HT Mint, 28.11.2022



China Plus One strategy: Indian API firms start to reap benefits

The pandemic stricken supply disruptions and the extant geopolitical tensions have benefited Indian active pharmaceutical ingredient (API) players the most, claims the industry.

As multinationals (MNCs) pursue a China Plus One strategy to derisk dependency on the world's second biggest economy, Indian players are steadily emerging a clear favourite.

Says Siddharth Mittal, chief executive officer and managing director (MD) of Biocon, "Our customers want an alternative source, assuming Indian companies also offer at the same price.

More and more customers are seeking a long term derisk and shunning off Chinese reliance.

We are also taking steps to ensure we can lock in vendors who don't want to buy from China." This process will, however, be long drawn out.

The company has to qualify a new API (for its product) before it can completely switch over (to a new source).

"From a development point of view, our APIs qualify, but commercialisation will take a while.

We see a high single digit growth in our API business," says Mittal.

Likewise, Manish Dhanuka, MD, Orchid Pharma, says: "Bearing in mind the geopolitical situation, buyers from the West want to derisk their supply chain from China's and are looking towards India to fill this gap. Orchid has succeeded in developing customers who wanted to mitigate this risk." Meanwhile, Chinese costs have been increasing, claims its local industry.

"China has steadily been increasing the prices of APIs and intermediates.

A typical example is China controlled Penicillin G. India imports about 8,000 million tonnes per annum of this key raw material for antibiotics.

In the past few years, the price has shot up from about \$14 to \$34 per kilogram," says Dhanuka.

Therefore, with increasing Chinese prices and its global dominance in the antibiotics API market, Indian manufacturers must become competitive internationally.

"The monopoly of Chinese manufacturers has them dictating worldwide supply and prices.

It is crucial for India to have a fully backward integrated supply chain for lifesaving drugs," he adds.

Indian players have, in fact, started supplying to China as well. "Chinese drug regulator National Medical Products Administration has raised the drug standards of China to the level of the West.

Many homegrown Chinese players are unable to meet these standards, opening the door to companies like Orchid Pharma, that have been selling in the US markets for decades, to supply their products to China as well," says Dhanuka.

Another leading API maker Glenmark Life Sciences noted in its 2021-22 annual report that wages in China have risen to a much higher level than India's since 2007 due to a shift in demographics and economic reforms.

"India's manpower costs are currently lower than China's, and this cost effective skilled labour supply advantage is expected to continue in the future.

The cost of labour in China has more than doubled, from 5.2 per cent of the total direct manufacturing cost to 10.6 per cent, while in India, it has decreased from 6.1 per cent to 5 per cent (2015 data)," it said in the annual report.

In 2020, an estimated 40 per cent of all factories in China had closed, resulting in supply disruptions and higher costs.

This is when the global formulation makers realised the importance of derisking their dependence on China and reshuffle their API import source.

An industry source in the Indian API industry says, "It may not be a priority for European and US formulation makers to diversify the source immediately, but adding India to their list is on everyone's mind.

This is a relatively protracted process, but there has been a significant move towards this direction in the past year or so." Dishman Carbogen Amcis, a leading API and contract manufacturing player based out of Gujarat that



has plants across the world, including China, said in its annual report that the “Covid outbreak and China Plus One strategy being pursued by global MNCs have only affirmed the position of India as the most preferred destination for outsourcing research and development and manufacturing due to its proven track record of high quality research capabilities, in addition to its competitive cost structure”.

“Indian API companies have been the biggest beneficiary due to the pandemic led supply chain disruption and the anti China sentiment and stand to gain significant market share in the years to come.

There has been an increasing trend of backward integration in the industry for input materials, thereby reducing import dependence,” said Dishman.

The global API market was estimated to be around \$181.3 billion in 2020 and is expected to grow at a compound annual growth rate of 6.2 per cent to reach about \$259.3 billion by 2026.

Source: Sohini Das, Business Standard, 27.11.2022



API import from China may fall 25% in next 5 yrs'

New Delhi: It seems the government’s initiative to reduce dependency on China for active pharmaceutical ingredient (API) has started yielding results as pharma majors have moved towards API manufacturing in the country under the aegis of Product Linked Incentive (PLI) scheme, which was approved by the Union Cabinet in February 2021.

India currently imports about 70 per cent of API from China.

However, given the current market sentiment, India’s dependency on China for API import may get reduced by

20-25 per cent in the next five years as pharma majors have taken it a challenge and working on a mission mode to bring down API import, opined Rajeev Singh Raghuvanshi, who is Secretary of Indian Pharmacopoeia Commission (IPC) that functions under the Ministry of Health and Family Welfare.

While talking to Millennium Post, Raghuvanshi said, “It’s a fact that production of API is not an overnight game. It would increase gradually. The best part is that the government has cleared its intent by starting PLI schemes in this regard, which has been taken by the industry in a positive way.”

“Definitely, money has its role in the growth of any project, but the important part of PLI scheme is that the government has given a positive signal to the industry as all three PLI schemes in this sector have mobilized pharma industry a lot towards API manufacturing,” he said, adding that the government has put fuel in the fire and now it’s the responsibility of the companies to make it happen.

However, Raghuvanshi also stressed that pharma business should not be seen from the profitability mindset. “There is a need to be more sensitive towards pricing of life-saving drugs as apart from profitability, there are several other social factors connected with this sector.

“ It’s worth mentioning that the Indian pharma sector is the third largest in the world by volume and 14th largest in terms of value. India contributes 3.5 percent of total drugs and medicines exported globally. Despite all these, India is significantly dependent on import of basic raw materials such as bulk drugs that are used to produce the finished dosage formulations.

The objective of the PLI scheme is to attain self-reliance and reduce import dependence in critical key starting materials (KSMs), drug intermediates and API.

Source: Dharendra Kumar, Millenniumpost, 29.11.2022





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