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# IDMA BULLETIN

VOL. NO. 53 | ISSUE NO. 32 (PAGES: 68) | 22 TO 30 AUGUST 2022 | ISSN 0970-6054 | WEEKLY PUBLICATION

## INDIAN PHARMA - GLOBAL HEALTH CARE

INDIAN DRUG MANUFACTURERS' ASSOCIATION

**REGISTER NOW FOR VRIDDHI**
**S1 ~ Founder's Mentality ~ organized by IDMA and BAIN & COMPANY**

**on Friday, 16th September 2022**

**at Hotel The Trident, Nariman Point, Mumbai from 8.30 am to 5.00 pm**

*(Details on Page: 4)*

**Special offer from DIA to IDMA Members for DIA-USFDA-PMDA-TGA-CDSCO:Advanced Manufacturing Workshop**

**on 12th & 13th September 2022**

**from 3.00 p.m. to 7.00 p.m. (Virtual)**

*(Details on Page: 14)*

## HIGHLIGHTS

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**CELLULOSE ACETATE PHTHALATE**
**CELLULOSE ACETATE BUTYRATE (CAB)**
**BIOSUSTANE SAIB**

SOLVAY

**DSS** (Docusate Sodium 100%)
**DSS GRANULAR** (DSS 85%)
**DSS 50%**
**ANTAROX F 127** (Poloxamer 407)

SSB STROEVER SCHELLACK BREMEN

**SSB PHARMA** (Shellac)
**SSB AQUAGOLD**
(Shellac Aqueous Coating System)

Signet
*The Complete Excipients Company*

*A Publication of*
**Indian Drug Manufacturers' Association**
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# IDMA BULLETIN

**Vol. No. 53** **Issue No. 32** **22 to 30 August 2022**

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## PATENT MATTERS:



## GOVERNMENT COMMUNICATIONS:



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# REGISTER NOW FOR VRIDDHI S1 ~ Founder's Mentality ~ organized by IDMA and BAIN & COMPANY on Friday, 16th September 2022 at Hotel The Trident, Nariman Point, Mumbai from 8.30 am to 5.00 pm

The Indian Drug Manufacturers' Association (IDMA) is pleased to invite you to the **first session (S1) of "Vriddhi",** an insights-exchange series envisaged with the objective of supporting Indian pharmaceutical companies to expand their vision by embracing **founder's mentality** and making PE work to their advantage. **IDMA has partnered with Bain & Company**, one of the world's most respected management consulting firms, to design and deliver Vriddhi. The program schedule is attached for your reference.

Vriddhi S1 is being organised at **The Trident Hotel, Nariman Point, Mumbai on Fri, Sep 16, 2022, 08:30 to 17:00 IST.** The event is expected to draw in-person participation of 70-80 promoter and Vice-President and above professional leaders from the industry.

Registration Form: **https://forms.gle/G67ua71bxWyyHivj9**

**The registration fees is 6,000 INR + taxes per person** and includes cost of breakfast, lunch, and evening high-tea. ***For every 3 registrations from a company, the 4th registration will be complimentary***. If you have more than one (1) person attending, you are requested to fill the form for every individual. **The Platinum, Diamond, and Gold sponsors for the IDMA Diamond Jubilee (60th Year) Celebrations have one (1) registration complimentary** to reciprocate their long-standing and generous patronage to IDMA.

IDMA has obtained **special rate of 9,000 INR + taxes per night per room** including buffet breakfast at The Trident. Please convey through this form on your desire to make a reservation - IDMA team will facilitate it.

**IDMA Bank Transfer Details for Registration Fees Payment of 7,080 INR (6,000 INR + 18% GST)**

Account Holder's Name: **Indian Drug Manufacturers Association**

Current Account Number: **76080200000242**

Bank: **Bank of Baroda**

IFSC Code: **BARB0DBWORL**

Branch: **Worli, Mumbai 400 018**

We look forward to receiving your participation and hosting you. Best wishes.

Sincere Regards,

| **Dr. Viranchi Shah** | **Shri Mehul Shah** | **Shri Daara Patel** |
|---|---|---|
| *National President* | *Honourary General Secretary* | *Secretary General* |

*RSVP: Mr. Melvin Rodrigues (Senior Manager, IDMA) - actadm@idmaindia.com and +91 9821868758.*


## Industry Partners

NORDEN a coesia company — Associate Partner

KÖRBER — Lead Partner

SPINCO BRINGING TECHNOLOGY, ENABLING SCIENCE. — Associate Partner



## Speakers

**Karan Singh**
*Managing Partner*
Bain & Company

**Vivek Gambhir**
*Chief Executive Officer*
boAt

**Rajesh Vedak**
*Managing Director & President*
Körber India

**Parijat Ghosh**
*Partner*
Bain & Company

**Kshitij Sheth**
*Director*
ChrysCapital

**Manish Gaur**
*Managing Director*
Multiples PE



## Speakers

**Pankaj Patwari**
*Managing Director*
Advent International

**Sunil Thakur**
*Partner*
Quadria Capital

**Dharmesh Shah**
*Managing Director*
BDR Pharmaceuticals

**Mehul Shah**
*Managing Director*
Encube Ethicals

**Nirav Mehta**
*Executive Director*
Corona Remedies

**Sanjiv Navangul**
*Managing Director & CEO*
Bharat Serums and Vaccines



## Reasons to Attend Vriddhi S1

**Receiving insights and approaches** on growth strategies and raising or managing private equity investments

**Networking** with some of the respected pharmaceutical, private equity, and management consulting leaders in a closed-door setting

**Shaping narrative and fostering collaboration** on technology advancement and best practices.



## Schedule

| | | |
|---|---|---|
| 08:30 | 09:30 | Arrival and Registration including Breakfast |
| 09:30 | 10:00 | **Inaugural Session** |
| 10:00 | 11:00 | **Founder's Mentality and Micro-battles** {Presentation and Q&A}<br>Karan Singh, *Managing Partner - Bain & Company* |
| 11:00 | 11:45 | **Case Study: Transformation Journey** {Presentation and Fireside Chat}<br>Vivek Gambhir, *CEO - boAt* and *ex.MD & CEO - Godrej Consumer Products* |
| 11:45 | 12:00 | Break |
| 12:00 | 12:30 | **The Digital Future of the Pharmaceutical Industry**<br>Rajesh Vedak, *Managing Director & President - Körber India* |
| 12:30 | 13:30 | **Private Equity: A Source of Competitive Advantage** {Presentation and Q&A}<br>Parijat Ghosh, *Partner - Bain & Company* |
| 13:30 | 14:15 | Lunch |



## Schedule

| | | |
|---|---|---|
| 14:15 | 15:15 | **Raising External Capital and Working with PE Investors** {Discussion}<br>Kshitij Sheth, *Director - ChrysCapital*<br>Manish Gaur, *Managing Director - Multiples PE*<br>Pankaj Patwari, *Managing Director - Advent International*<br>Sunil Thakur, *Partner - Quadria Capital*<br>Parijat Ghosh, *Partner - Bain & Company* (Moderator) |
| 15:15 | 16:15 | **Importance of Founder's Mentality and Navigating the Future** {Discussion}<br>Dharmesh Shah, *Managing Director - BDR Pharmaceuticals*<br>Mehul Shah, *Managing Director - Encube Ethicals*<br>Nirav Mehta, *Executive Director - Corona Remedies*<br>Sanjiv Navangul, *Managing Director & CEO - Bharat Serums and Vaccines*<br>Karan Singh, *Managing Partner - Bain & Company* (Moderator) |
| 16:15 | 16:25 | **Vote of Thanks** |
| 16:25 | 17:00 | High-Tea |



## Conveners

**Dr. Viranchi Shah**
*National President* - IDMA
*Director* - Saga Laboratories

**Karan Singh**
*Managing Partner*
Bain & Company

**Mehul Shah**
*Hon. General Secretary* - IDMA
*Managing Director* - Encube Ethicals

**Parijat Ghosh**
*Partner*
Bain & Company

**Daara Patel**
*Secretary General* - IDMA



I look forward to welcoming you at Vriddhi S1 on Fri, Sep 16, 2022 in Mumbai.

*Thank you. Best wishes.*

IDMA — BAIN & COMPANY

**The Indian Drug Manufacturers' Association (IDMA) and Bain & Company**
are pleased to invite you to the first session (S1) of

# Vriddhi

*An insights exchange series for pharmaceutical entrepreneurs to expand their vision by embracing founder's mentality and making private equity work to their advantage.*

on **Fri, Sep 16, 2022, 08:30 to 17:00 IST** at **The Trident, Nariman Point, Mumbai.**

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**Associate Partner**

# 7th National Conference on Pharma & Allied Industry - PHARMA CONFEX 2022 at Ahmedabad Management Association (AMA), Ahmedabad, Gujarat on 26th August 2022 organized by Saket Projects Ltd.



***Address by Guest of Honour, Mr Daara B Patel, Secretary-General, IDMA on Indian Pharma Sector – Post Covid Emergence on the Global Landscape***

Good Morning Respected Dignitaries, the organizers of Saket and my dear friends,

Greetings from our National President, Dr. Viranchi Shah and from all the Members of Indian Drug Manufacturers' Association (IDMA).

It gives me immense pleasure to be here with you after almost 4 years and address this august gathering at the 7th National Conference on Pharma & Allied Industry - PHARMA CONFEX 2022 at Ahmedabad Management Association (AMA), Ahmedabad.

The current pandemic has brought the entire world to its knees and the whole world has observed the adverse catastrophe of this Global Pandemic. We are in the middle of a once-in-a-century crisis that has spread across the world in a matter of months. The pharmaceutical industry has moved quickly into a crisis mind-set, managing people's problem, protecting the business, and trying to be part of the solution. The theme for today's CONFEX is suitably titled **Indian Pharma Sector – Post-Covid Emergence on the Global Landscape.**

For far too long, the pharma industry has been labelled as slow to respond to environmental changes. The Covid-19 pandemic has come with an almost equal share of woes and opportunities for the industry.

On a positive note, the industry has taken advantage of the pandemic and we have demonstrated our skills to change adversities into opportunities. Digitalization has played a vital role.

**We are pleased to inform you that India has emerged as a "first responder" to the global crisis**

India has played a humongous role during the two-year-long running COVID-19 pandemic. India supplied 'Made-in-India' vaccines to at least 98 countries.

INDIA supported the world during Covid-19 Pandemic by supplying:

- Vaccines – 98 countries
- Medicines
  1. Hydroxychloroquine – 53 countries
  2. Remedisivir – 11 Lakh injections to more than 100 countries
  3. Favipiravir – 18 countries
  4. Anti-viral medicines like Famciclovir, Tocilizumab, Itolizumab, Doxycycline + Ivermectin, etc.

- Sanitizers
- PPE Kits
- Oxygen in bulk containers to Hospitals
- Laudable initiatives for Repurposing of Drugs for use against Covid-19

**During 2020, the New Normal had taught us to change as follows:**

- ✓ Work From Office
- ✓ Work From Home
- ✓ Work From Anywhere

**Digital is an idea whose time has come.** Despite these trying times, the pharmaceutical industry has triumphed and now we have learned to live with the New Normal that we all have experienced during this Covid-19 Pandemic throughout the last two years. Most of the Healthcare & Pharma Companies have learnt to adapt to this New Normal. The companies who have not adapted to the New Normal – Digitalization, will have to catch up with the rest of the pharma companies or will have to lag behind in their development.

**Earlier the rule was Perform or Perish now it is Digitize or Diminish.**

Today, the pharma industry business is normal and is progressing very well. There is an increase in demand of medicines. The future may not see patients having to go to Hospitals / Doctors every time they fall ill. The doctor's medicine and his magical tools will be going to patients through electronic devices.

At an industry-level, the changes will likely be more sweeping with more focus on network optimization, patient-centricity, and new demands on capacity and efficiency.

**Pandemic & increase in Production capacity utilization**

It was a thrilling experience working together with Government Officials, their staff & Industry Associations, working in tandem 24x7 for the benefit of the patients not only in India but the entire world. All this helped us to increase the production capacity utilization from 20% in March 2020 to 80+% in June 2020.

Thinking of the impact of Covid-19 on the future of the pharma industry in its entirety, we would say it is a blessing in disguise. Those who have identified opportunities amid this pandemic have reaped huge benefits.

As most of you would be aware, Indian Drug Manufacturers' Association (IDMA) was formed in the year 1961; 60 glorious years of service to the Nation.

IDMA has been the engine leading the Indian Pharmaceutical Industry to greater heights and glory and ensuring near self-sufficiency of affordable quality medicines for our people and also globally.

IDMA has a membership of 1100 plus members and is the apex national body of Pharmaceutical and API manufacturers in our country. IDMA is the only Association comprising of small, medium and large scale pharmaceutical manufacturers situated throughout the length and breadth of our country and is rightly known as the **"Voice of the National Sector"**. IDMA has eight State Boards pan India and Gujarat State Board is the biggest and most vibrant State Board. The importance of Gujarat in the Indian Pharma Industry has increased over the recent years …

1. Our Honourable Prime Minister, Shri Narendra Mody Ji is from Gujarat
2. Dr. Mansukh Mandaviya Ji, our Honourable Minister of Health & Family Welfare and Chemicals & Fertilizers is from Gujarat
3. And our own IDMA's National President – Dr. Viranchi Shah is from Gujarat

It is necessary to strike the right balance and being sufficiently agile to rapidly respond to fast-changing environment.

In line with this, companies are setting specific goals to meet their internal objectives for improved customer service, profitability and growth, focusing especially on enhanced innovation & diversity with agility and speed.

Today, the pharmaceutical industry is valued at $44 Billion and is expected to grow to $600 Billion by 2047 at 11% CAGR. It is an opportune time that SMEs pursue a greater share in the growth story of the industry. This can most likely happen when we invest ahead of time in growth, quality, risk, and compliance management. The Government of India had launched a series of policy measures in recent past - Atmanirbhar Bharat, Pradhan Mantri Jan Aushadhi Pariyojna, Ayushman Bharat, and Production Linked Incentive Schemes. More encouragement and impetus are expected in near future

through OTC policy, Research Linked Incentive Schemes, Pricing and Decriminalisation reforms.

IDMA congratulates and appreciates the efforts of the Government Specially Dr. Mansukh Bhai Mandaviya, our Honourable Minister who launched New Schemes to Strengthen the Indian Pharmaceutical Industry (SPI) on 21st July 2022. These new schemes will help the industry to enhance its quality, technology & infrastructure upgradation & capacity building and encourage collaboration between various stakeholders for the overall development of the pharma sector.

IDMA applauds this excellent initiative of the Government which is an excellent opportunity for our Pharma Industry.

IDMA is committed in our "Seva for Sampoorna Swasthya" to the entire world with supply of safe, efficacious, and reliable medicines. In this endeavour, we are working with the union government, various state governments, regulators, fellow industry associations like the Indian Pharmaceutical Alliance (IPA), Organisation of Pharmaceutical Producers of India (OPPI) and other stakeholders to secure resources and support for the growth of IDMA member companies. Various state governments are also offering industry-friendly policies to usher investments in their respective geographies, source latest technology, generate employment, and increase overall prosperity.

Two critical uncertainties will frame how the industry will emerge post-COVID. The first one is the depth and the duration of Covid-19 disruptions. The other fact is how bold the stakeholders are, and their willpower and ability to align with the new world order.

In a favourable bookend scenario of hope, we could see a short sharp contraction followed by a rapid return to normalcy. The behaviour of retail stakeholders - pharmacists, doctors, and patients - has changed significantly, even in this scenario.

Expect fast updates in telemedicine and digital health along with enlightened regulatory actions, openness, and new funding. At the minimum, we see a higher risk sensitivity leading to an increased focus on the resilience of today's global and geographical vulnerable value chains.

Supply chain leaders and managers will expect the lessons learned to be applied to creating a resilient and agile supply chain that can with stand any disruptions and quickly respond to the crisis. They will also need to understand and quantify risk exposure and develop contingency plans for each disruption scenario. Moreover, when potential future disruptions are identified, manufacturers need to quickly analyse a range of scenarios, assess impact, and make rapid and informed decisions to minimise the impact.

As you are aware, IDMA is the National Association representing the interest of manufacturers in India. The latest happenings in the Indian Pharma Industry is with regards to the Notification stipulating printing of QR codes with specified information on packaging of Active Pharmaceutical Ingredients (APIs). This would become effective from 1st January, 2023. IDMA members, mostly Small & Medium Enterprises, have expressed apprehensions on the utility of the proposed notification and a number of questions have been raised by them.

In view of the apprehensions, IDMA is of the opinion that QR code labels are not providing any additional details that will help in improving quality or tracing of APIs sold in India. In fact, all information to be provided in QR code can clearly be read on the current label written in English or that label can be expanded to include additional data. So to summarize, our members fail to see how adding QR code labels would provide any new benefits. On the contrary, we find that it will increase compliance and costs exorbitantly by making Small and Medium-scale manufacturers perform an additional task of creating labels.

On 22nd August 2022, IDMA made a Representation on the Draft of New Drugs, Medical Devices and Cosmetics Bill, 2022. The legislative changes during last 50 years and the implementation of the legislation especially, during last 20 years have shown an emphasis on penal measures. For example, there have been several instances of considering a Not of standard quality drug even for minor out of specification results as criminal offence punishable with imprisonment and fine etc. by invoking the clause of Spurious/ Adulterated Drugs. Due to such over emphasis on penal measures, the key element of Corrective and Preventive Action [CAPA] in quality management system for the purpose of quality upgradation has been overlooked.

The tool of prosecution to deal with out of specification [NSQ] drugs is not used by any international regulatory agency and is dealt with through administrative and departmental actions leading to implementation of Corrective and Preventive Action [CAPA].

**IDMA feels that there is a Need for new approach.** After Constitution of a Committee to draft entirely a new Act, it was expected that this opportunity will be used to bring about radical changes in the framework of law that would focus on the philosophy of implementation that is not based on using punitive measures as a first choice of action and lays an emphasis on adoption of technical and science based measures for implementation of the regulation.

IDMA and other industry associations have requested from time to time for this new approach and were expecting decriminalization of violations specially for not of standard quality drug and of rules under the Act. Having requested this New Approach, we would like to place on record that IDMA is committed to promote quality excellence in the industry to ensure that medicines of the highest quality are made available to the patients.

**RoDTEP (Refund of Duties and Taxes on Exported Products)** - Joint representation was sent by BDMA, IDMA, IPA, FOPE and Pharmexcil to Hon'ble Smt. Nirmala Sitharaman, Minister of Finance requesting her to announce RoDTEP rates for pharma industry as well.

As we emerge from the pandemic, companies will need help to lay the right foundation for such a rapid digitisation journey. The development of artificial intelligence (AI) and machine learning (ML) and data analytics are major advances in this field, enabling companies to learn more about audits and connections with their entire value chains.

As Charles Darwin said in his book, "On the Origin of Species" about his scientific theory of Natural Selection "It is not the strongest of the species that survive nor the most intelligent, but the one most responsive to change."

As a responsible industry Association, IDMA members are committed to adding smiles to the faces of the ailing population, adding productive years to their lives, and improving the quality of their life, and we do so with the lowest possible cost as compared to anywhere else in the world. An era when the world is facing serious disruption due to health crises, our role becomes even more important.

**We want to tell the World**

You Ask We Manufacture

The Day is not far when the World will say

**If it is medicines it is**

**INDIA**

**Jai Hind**

**Jai Gujarat &**

**Jai Ho Indian Pharma Industry**

Thank You


*Dr H G Koshia, Dr. Milind Joshi & Mr. Daara Patel at Saket Projects Event - 7th National Conference on Pharma & Allied Industry - PHARMA CONFEX 2022*

# Shri Piyush Goyal inaugurates "Conclave on Public Procurement (Preference to Make in India) Order, 2017"

## Our TRP in public procurement is: Trust, Reliability and Prosperity of the nation - Shri Goyal

## Shri Goyal urges industry to play role of whistleblower and bring malpractices to the notice of government

## Government is keen to use Artificial Intelligence in GeM to make it more effective- Shri Goyal

## BIS will engage with Indian Industry to ensure use of Indian standards in various sectors of manufacturing - Shri Goyal

Union Minister of Commerce and Industry, Consumer Affairs, Food and Public Distribution and Textiles, Shri Piyush Goyal today inaugurated the "Conclave on Public Procurement (Preference to Make in India) Order, 2017" at Vanijya Bhawan, New Delhi to sensitise stakeholders about the Order.

Addressing the conclace, Shri Goyal said we need to take collective resolve to become a developed nation by 2047, one of the 5 Prans stated by Shri Narendra Modi in his Independence Day Address. We really need to push the envelop and work hard to ensure prosperity reaches to last person in the bottom of pyramid, he added.

Shri Goyal urged industry to play role of whistleblower in instances of wrong declaration in terms of indigenization of products put up on GeM. This would help in transparency in procurement process, which encourages domestically made goods and services, he added. Shri Goyal further said we are undertaking this exercise in full public glare because under PM's vision we have to strive for full transparency in our working.

Shri Goyal remarked that our TRP in public procurement is: Trust, Reliability and Prosperity. He mentioned that Government is keen to use Artificial Intelligence in GeM procurement process to make it more effective and sought industry cooperation to that end.

Recalling one of the 5 Prans given by PM Shri Narendra Modi in his Independence Day Address, Shri Goyal spoke about getting rid of colonial mindset and stated that BIS will engage with Indian Industry to ensure use of Indian standards in various sectors of manufacturing.

Urging industry to continue engagement with Government, he asked them to share if they are facing any issues of harrasment. These would be openly addressed, he stressed.

The Minister expressed confidence in the capability of the local industry and congratulated them for their active participation in this growth journey. Seeking suggestions from the industry, he said proactive participation of the industry will truly help realise our goal of Sabka saath sabka vikas, sabka vishwas and sabka prayaas.

Appreciating the forward looking approach of DPIIT and Officials for their openness to engage with industry, Shri Goyal reiterated commitment of the government to working together with the Industry for a better future.

The "Public Procurement (Preference to Make in India) Order, 2017 (PPP-MII Order, 2017)" has been issued pursuant to Rule 153 (iii) of General Financial Rules, 2017 as an enabling provision to promote local industry by providing them preference in public procurement.

The Order is applicable on procurement of goods, services and works by Central Ministries/Departments, their attached/ subordinate offices, autonomous bodies controlled by the Government of India, Government companies, their joint ventures and Special Purpose Vehicles.

*Source: PIB Delhi, 23.08.2022*

● ● ●

CORPORATE AFFAIRS MATTERS

# Physical Verification of the Registered Office of the Company

**Notification G.S.R.____ (E) dated 18th August, 2022**

In exercise of the powers conferred under section 3, section 4, sub-sections (5) and (6) of section 5, section 6, sub-sections (1) and (2) of section 7, sub-sections (1) and (2) of section 8, clauses (a) and (b) of sub-section (1) of section 11, sub-sections (2), (3), (4), (5) and (9) of section 12, sub-sections (3), (4) and proviso to sub-section (5) of section 13, sub-section (2) of section 14, sub-section (1) of section 17, sub-sections (1) and (2) of section 20 read with sub-sections (1) and (2) of section 469 of the Companies Act, 2013 (18 of 2013), the Central Government hereby makes the following rules further to amend the Companies (Incorporation) Rules, 2014, namely:-

**1. Short title and commencement**

(1) These rules may be called the Companies (Incorporation) Third Amendment Rules, 2022.

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

**2. In the Companies (Incorporation) Rules, 2014, after rule 25A, the following rule shall be inserted, namely:-**

"25B. Physical verification of the Registered Office of the company.-

(1) The Registrar, based upon the information or documents made available on MCA 21, shall visit at the address of the registered office of the company and may cause the physical verification of the said registered office for the purposes of sub-section (9) of section 12, in presence of two independent witness of the locality in which the said registered office is situated and may also seek assistance of the local Police for such verification, if required.

(2) The Registrar shall carry the documents as filed on MCA 21 in support of the address of the registered office of the company for the purposes of physical verification and to check the authenticity of the same by cross verification with the copies of supporting documents of such address collected during the said physical verification, duly authenticated from the occupant of the property whereat the said registered office is situated.

(3) The Registrar shall take a photograph of the registered office of the company while causing physical verification of the same.

(4) The report of the physical verification shall be prepared in the following format namely:-

Report on Physical Verification of the Registered Office of the Company:

1. Name and CIN of the company:-
2. Latest address of the registered office of the company as per MCA 21 record:-
3. Date of authorisation letter issued by the Registrar of Companies: -

4. Name of the Registrar of Companies:-

5. Date and Time of visit for physical verification of the registered office:-

6. Location details along with Landmark:-

7. Details of the person available, if any at the time of the visit-

   (i) Name:-

   (ii) Father's Name:-

   (iii) Residential address:-

   (iv) Relationship with the company, if applicable:-

8. Remarks if any:-

9. Documents attached:-

(i) Copy of the agreement/ownership/rent agreement/ No Objection Certificate of the registered office of the company from owner/ tenant/ lessor:-

(ii) Photograph of the registered office:-

(iii) Self Attested ID-Card of the person available, if any:-

(iv) Any other document(s):-

Date:

Place: Signature

Name and Designation of the official with official address.

(5) Where the registered office of the company is found to be not capable of receiving and acknowledging all communications and notices, the Registrar shall send a notice to the company and all the directors of the company, of his intention to remove the name of the company from the register of companies and requesting them to send their representations along with copies of relevant documents, if any, within a period of thirty days from the date of the notice before taking further actions in accordance with the provisions of section 248 of the Act.".

**File No. 1/13/2013-CL-V, Vol. IV**

*Manoj Pandey, Joint Secretary, Government of India, Ministry of Corporate Affairs, New Delhi.*

Note: The principal rules were published in the Gazette of India, Extraordinary, Part-II, section 3, sub-section(1) *vide* number G.S.R.250(E), dated the 31st March, 2014 and last amended, *vide* number 291 (E), dated the 8th April, 2022.

● ● ●

# Special offer from DIA to IDMA Members for DIA-USFDA-PMDA-TGA-CDSCO: Advanced Manufacturing Workshop on 12th & 13th September 2022 from 3.00 p.m. to 7.00 p.m. (Virtual)

Dear Member,

We are indeed pleased to inform you that the U.S. Food and Drug Administration (USFDA) India Office and the Drug Information Association's (DIA) India Office would be hosting a 2 - day workshop (VIRTUAL) on regulatory policies, guidance and support for the adoption of advanced manufacturing technologies.

We are thankful to DIA for offering a special rate to all IDMA members who would be attending the workshop.

**Special Rate : 5000 INR + 18% GST per registration**

Since this is a special offer DIA has requested members to register manually in their system and we request you all to provide the details to be shared in the below format :

| Sr. No | Salutation | First Name | Last Name | Designation | Email id | Contact number | Address |
|---|---|---|---|---|---|---|---|
| | | | | | | | |

Also if there are 5 people from a single company DIA is offering a special group rate :

**For 5 paid registrations : 2 additional complimentary passes = 5 + 2 = total 7 registrations**

**The details will have to be provided in the same format as above.**

DIA will provide the invoice for payment via a bank transfer.

**Program flyer from DIA** is reproduced below for your reference.

The USFDA India Office has requested IDMA Members to join this workshop and reap benefits from the same.

We request our members to kindly register at the earliest with a copy to the **IDMA Secretariat – admin@idmaindia.com**

Thanks & regards,

**Daara B Patel**
Secretary – General

# DIA-USFDA-PMDA-TGA-CDSCO

## Advanced Manufacturing Workshop

*"Embracing The Future: Regulatory Considerations And Industry Perspectives On Advanced Manufacturing"*

SEPTEMBER 12-13, 2022 , 3pm - 7pm IST | FORMAT: VIRTUAL

### PROGRAM COMMITTEE

**Sarah McMullen**
Country Director
USFDA India Office

**Natalie Mickelsen**
Deputy Director
USFDA India Office

**Kristan Callahan**
Acting International Relations Specialist
USFDA India Office

**Gregory Smith**
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USFDA India Office

**Thomas O'Connor**
Deputy Director
Office of Testing and Research
Office of Pharmaceutical Quality, USFDA

**Yong Wu**
Quality Assessor
Office of Pharmaceutical Manufacturing Assessment
Office of Pharmaceutical Quality, USFDA

**Manuel Osorio**
Senior Scientist for Emerging Technologies & Medical Countermeasures
Center for Biologics Evaluation and Research (CBER), USFDA

**Yoshihiro Matsuda**
Senior Scientist (for Quality)
Pharmaceuticals and Medical Devices Agency (PMDA)

**Sau (Larry) Lee**
Deputy Director of Science
Office of Pharmaceutical Quality (OPQ)
USFDA

The U.S. Food and Drug Administration (USFDA) India Office and the Drug Information Association's (DIA) India Office will host a 2 -day workshop on regulatory policies, guidance and support for the adoption of advanced manufacturing technologies featuring USFDA, Pharmaceuticals and Medical Devices Agency (PMDA), Therapeutic Goods Administration (TGA), Central Drugs Standard Control Organization (CDSCO) and Industry representatives.

This comprehensive program offers a unique opportunity to hear from multiple regulators on current perspectives on advanced manufacturing technologies. The Regulators will speak on various initiatives taken by the respective agencies and the ways in which they are facilitating the adoption of advanced manufacturing technologies. Pharmaceutical industry representatives will discuss advanced manufacturing technologies, the advanced manufacturing landscape in India, and share views on current opportunities and challenges. Each day will conclude with a panel discussion with the relevant speakers.

### Objective

The objective of this workshop is to share agencies' thinking on this topic, industry's adoption of this topic and facilitate an active dialogue to encourage a better understanding of regulatory expectations. The workshop will focus on the need for accelerating the adoption of advanced manufacturing technologies, regulatory support and various initiatives from the regulatory agencies. Workshop participants will have opportunities for questions and answers with industry experts and regulatory agency representatives.

### KEY TOPICS

- Overview of the Advanced Manufacturing Technologies Program
- Regulatory Resources for Advanced Manufacturing Technologies
- Process Analytical Technologies (PAT)
- ICH Q13
- Indian landscape for Advanced Manufacturing Technologies
- Indian Industry Experience

**For further information, please reach out to:**
**Kanchan Patel** | +91 9820621844 | Kanchan.Patel@diaglobal.org

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DIA Global Center: Washington, DC, USA | Basel, Switzerland | Beijing/Shanghai, China | Horsham, PA, USA | Mumbai, India | Tokyo, Japan

## **AGENDA** | DAY 1 | Sep 12th, 2022

| | |
|---|---|
| 15:00-15:10 | **Welcome & Housekeeping** |
| | **Session 1** |
| 15:10-15:40 | **Opening Remarks** |
| | **Sarah McMullen**<br>USFDA India Office (INO)<br>Country Director<br><br>**S. Aparna**<br>Secretary<br>Department of Pharmaceuticals<br><br>**V G Somani**<br>Drug Controller General of India<br>CDSCO |
| | **Session 2** |
| 15:40-16:10 | **Experience in Pharmaceutical Innovation: Perspective on US FDA Advanced Manufacturing Initiatives** |
| | **Thomas O'Connor**<br>Deputy Director<br>Office of Testing and Research Office of Pharmaceutical Quality<br>USFDA |
| 16:10-16:20 | Tea / Coffee Break |
| | **Session 3** |
| 16:20-16:50 | **Center for Biologics Evaluation and Research Efforts for Advanced Manufacturing** |
| | **Manuel Osorio**<br>Senior Scientist for Emerging Technologies & Medical Countermeasures<br>Center for Biologics Evaluation and Research (CBER)<br>USFDA |
| | **Session 4** |
| 16:50 –17:20 | **PMDA perspective on Continuous Manufacturing** |
| | **Yoshihiro Matsuda**<br>Senior Scientist (for Quality)<br>Pharmaceuticals and Medical Devices Agency (PMDA) |
| | **Session 5** |
| 17:20-17:35 | Q&A |
| 17:35-17:45 | Tea / Coffee Break |
| | **Session 7** |
| 17:45-18:15 | **Advanced Techniques for Process Intensification & Continuous Manufacturing** |
| | Manjinder Singh<br>Senior Director<br>Cipla |
| | **Session 8** |
| 18:15-18:45 | **Panel Discussion** |
| | **Session 9** |
| 18:45-19:00 | Closing Remarks |

## **AGENDA** | DAY 2 | Sep 13th, 2022

| | |
|---|---|
| 15:00-15:10 | **Welcome & Housekeeping** |
| | **Session 1** |
| 15:10-15:40 | **TGA Efforts for Advanced Manufacturing** |
| | **Karen Loft**<br>TGA |
| | **Session 2** |
| 15:40-16:10 | **Considerations for Process Analytical Technology (PAT) Implementation for Continuous Manufacturing: A Regulatory Perspective** |
| | **Yong Wu**<br>Quality Assessor<br>Office of Pharmaceutical Manufacturing Assessment Office of Pharmaceutical Quality<br>USFDA |
| | **Session 3** |
| 16:10–16:20 | Q&A |
| 16:20–16:30 | Tea / Coffee Break |
| | **Session 4** |
| 16:30-17:00 | **USP Efforts for Advanced Manufacturing** |
| | **Dennis Hall**<br>Vice President-Manufacturing Services<br>United States Pharmacopoeia |
| | **Session 5** |
| 17:00-17:30 | **Experience on Adoption of Continuous Manufacturing** |
| | **Rajeev Rehani**<br>Executive Vice President & Head – API R&D<br>Dr Reddy's Laboratories |
| 17:30-17:40 | Tea / Coffee Break |
| | **Session 6** |
| 17:40-18:10 | **Various ways to implement continuous manufacturing in pharmaceutical development and production** |
| | **Robin Meier**<br>Scientific Director<br>L.B. Bohle Maschinen und Verfahren GmbH |
| | **Session 7** |
| 18:10-18:40 | **Panel Discussion** |
| | **Session 8** |
| 18:40-19:00 | Closing Remarks |

**DIA-USFDA-PMDA-TGA-CDSCO : Advanced Manufacturing Workshop: "Embracing The Future: Regulatory Considerations On Advanced Manufacturing"** **Event I.D. 22660 | 12-13 September, 2022 | Virtual Meeting**

MEETING MANAGER(S):
**Kanchan Patel**
cell: +91 9820621844 | kanchan.patel@diaglobal.org

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|---|---|---|---|
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| **INDUSTRY MEMBER** | 4000 | 720 | 4720 ❑ |
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| **STUDENT** | 1000 | 180 | 1180 ❑ |
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**Vinita Shetty** | Finance Manager
vinita.shetty@diaglobal.org
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cell: +91 9769764645

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# Why India Needs to Urgently Invest in its Patent Ecosystem?

EAC-PM/WP/1/2022

## WHY INDIA NEEDS TO URGENTLY INVEST IN ITS PATENT ECOSYSTEM?


*August 2022*

*Sanjeev Sanyal and Aakanksha Arora*

Table of Contents



*Sanjeev Sanyal is Member, Economic Advisory Council to PM (EAC-PM) and Aakanksha Arora is Deputy Director, EAC-PM.* *This paper has been published as a part of EAC-PM paper series for information and public debate. The contents of the paper including facts and opinions expressed are sole responsibility of the authors. EAC-PM or Govt of India does not endorse the accuracy of the facts, figures or opinions expressed therein. We would like to place on record our sincere appreciation to several people who helped us by providing useful information, suggestions and comments for this paper- Dr Bibek Debroy, Mr. Rajendra Ratnoo, Ms. Shruti Singh, Dr. Unnat P. Pandit, Dr. Dinesh P. Patil, Mr. Sukhdeep Singh, Mr. P K Pandey, Mr. Rahul Matthan, Mr. Lal Ratnakar, Mr. Shri Ram Kannaujia.*

**Executive Summary**

An evolved Intellectual Property Rights regime is the basic requirement for a knowledge-based economy. Technological innovation and scientific research require a robust patenting system. India is seeing a surge in start-ups and unicorns, and an efficient IPR system is an essential prerequisite for a healthy startup ecosystem. In this paper, we focus on analyzing India's performance in terms of patents and trademarks.

There have been significant improvements in the patent application process in the last few years, such as simplification of procedures, allowing expedited examination to various categories of applicants, electronic delivery of certificate, facility for video-conferencing etc. Similarly, there have been procedural improvements for trademark applications such as automatic allotment of applications to examiners, automating of renewal etc. The results of these reforms are visible in terms of higher filings and grants of both trademarks and patents.

As a result, there has been an increase in the number of patent applications up from 45,444 in 2016-17 to 66,440 in 2021-22. Similarly, the patents granted in India have gone up from 9,847 to 30,074 during the same time period. Simultaneously, there has been an increase in the share of residents in the applications from less than 30 percent in 2016-17 to 44.5 percent in 2021-22.

Despite these improvements, note that India lags behind its global peers. In 2020, the number of patents filed in India was 56,771, merely 4 percent of China where 14.97 lakh applications were filed and 9.5 percent of US where 5.97 lakh applications were filed in the same year. Similarly, the patent granted in India were 26361 as compared to 5.3 lakh in China and 3.5 lakh in US. Moreover, in India, it takes about 58 months on average to dispose of a patent application as compared to about 20 months in China and 23 months in US.

The analysis in this paper suggests that the major cause of this delay is the shortage of manpower in the patent office. Only 860 people were employed in the patent office in India at the end of March 2022, including both examiners and controllers, as compared to 13704 in China and 8132 in US. Thus, approximately, 1.64 lakh applications were pending at the controller level as on 31st March 2022.

Apart from the shortage of manpower, the paper identifies certain other procedural issues in the patent application process. First is the lack of fixed timelines for various steps, for instance there is no fixed timeline for filing an opposition against any patent application, leading to delays. Second, there are some cumbersome compliance requirements like submitting information pertaining to processing of foreign patent applications which is not important now in case of PCT applications, as India is a member of WIPO Centralized Access to Search and Examination where consolidated information related to status of PCT applications in large number of jurisdictions is already available. Apart from this, we discuss the option of bringing in utility model of patents, outsourcing the administrative part of process and improvements in portal and filing system to provide a push to the overall patenting ecosystem in India.

In terms of trademark activity as well, there has been a substantial increase in filing and registration over the last few years. Filing of applications increased from about 2.8 lakhs in 2016-17 to 4.5 lakhs in 2021-22. Most of the trademark applications are from Indians, with less than 3 percent foreign applications. India has moved up in position in terms of size of trademark activity, reaching the fifth place in the number of applications in 2020. China is the largest office for trademark applications with 93.4 lakh applications and US is at the second position with 8.7 lakh applications in 2020.

India is one of the fastest in giving the first examination report for trademark applications and even the time for final disposal/registration is on average 12-18 months in cases where no opposition is filed, which is comparable to China and US. Thus, under normal circumstances, the Indian trademark system works reasonably well. The delays happen in case an opposition is filed against the trademark application. The hearing is scheduled in accordance with the chronological order of the applications filed and the opposition proceedings are disposed of by the officers authorised for this purpose, who are mostly Assistant Registrar and above. The waiting time is long and it takes somewhere between 5 to 10 years for such applications to be processed.

The delays in opposition cases happen mainly due to a shortage of manpower, especially at the senior level. Even the sanctioned posts are not filled and there are a lot of vacancies, more so at senior levels. There are currently only 12 people out of the sanctioned strength of 54 at the post of Assistant Registrar and above currently in the Trademark registry office. Even at the examiner level, India has 156 examiners, whereas China has 2000 and USA has 633 examiners respectively.

In addition to shortage of manpower, a few procedural issues in trademark application procedure are identified, resolving which can help provide a philip to the entire trademark system. For instance, our discussion with practitioners in the sector indicated that certain deadlines mentioned in the Trademark Rules 2017 are not strictly adhered to in practice leading to delays. The paper further identifies few places in the registration system, where no human intervention is required- for instance, giving notice of opposition, abandonment of application in case response to opposition notice has not been received in the stipulated time, etc and argues for putting in place an automatic process to reduce the processing time further.

To address the concerns in the patenting and trademark system, the first and most important step is to hire more manpower in the Office of Controller General of Patents, Designs & Trade Marks. As a rough guidance, the manpower in patent office needs to be increased from about 860 currently to 2800 in the next two years. In case of Trademark Registry office, the sanctioned posts should be filled immediately, which will increase the manpower from 168 currently to 289. Further, more people can be added in the next few years based on the requirement. It is important to note here that this office is a revenue surplus office, with revenue of almost 5 times that of cost in 2020-21 and increased expenditure to hire more people in the office will actually be a revenue generating activity. Hence, hiring more people should not be

delayed on account of financial reasons. In addition to this, changes to address the issues identified in the processes should also be carried out.

Moreover, the Office of Controller General of Patents, Designs & Trade Marks is currently a subordinate office of the Ministry of Commerce. There is a need to provide more autonomy to the office by providing more financial and staffing flexibility.

While we have taken into account several drawbacks in IP system in India, it should be noted that there have been various improvements in recent years and some of the criticism by international observers in not always tenable. It is important to therefore not accept external criticism as it is, but to study the matter from the first principles.

# I. Introduction

There are two main economic objectives of any system of intellectual property protection. The first is to promote investments in knowledge creation and business innovation by establishing exclusive rights to use and sell newly developed technologies, goods and services. Not providing such rights would mean that the economically valuable information could be appropriated without compensation by competitive rivals; hence institutions and individuals would be reluctant to invest money and effort into research and commercialisation of activities. The second goal is to promote the widespread dissemination of new knowledge by encouraging or requiring rights holders to place their inventions and ideas on the market. Intellectual Property Regime is key to the creation of a knowledge economy and nurturing the start-up ecosystem, technological innovation and scientific research.

In this paper, we discuss where India stands in comparison to its global peers in terms of patenting activity and trademark activity. We further identify issues where India lags and suggest solutions to address those issues.

# II. Where does India stand in terms of patenting

There has been a gradual increase in the filing and granting of patents in India. The number of patents filed in India has gone up from 39,400 in 2010-11 to 45,444 in 2016-17 to 66,440 in 2021-22 and the patents granted in India has gone up from 7,509 to 9,847 to 30,074 during the same time period (Table 1). Further, the number of patents application is increasingly coming from Indian residents rather than MNCs. The share of Indian residents in total applications has more than doubled in the last decade. The share of residents in patent applications increased from 20 percent in 2010-11 to around 30 percent in 2016-17 and further to 44 percent in 2021-22. For the first time in the last 11 years, the domestic patent filing has surpassed the number of patents filed by non-Indians at the Indian Patent office in last quarter (Q4) of 2021-2022. It is important to note that these improvements of the last few years are largely due to the process reforms[1] undertaken in the last 5 years. Consequently, India's ranking in Global Innovation Index has climbed 35 ranks, from 81$^{st}$ in 2015-16 to 46$^{th}$ in 2021.

[1] Some of the key changes include online processing of forms, new timelines for disposal of applications, hearing of patenting cases through video-conferencing for speedy and contact-less proceedings, certain category of inventors applying for expedited of examination (like startups, small entities, Government departments) etc.

**Table 1: Patent applications in India**

| | Indian | Non-Indian | Share of domestic applications |
|---|---|---|---|
| 2016-2017 | 13,174 | 32,270 | 29.0 |
| 2017-2018 | 15,377 | 32,477 | 32.1 |
| 2018-2019 | 16,968 | 33,691 | 33.5 |
| 2019-2020 | 20,838 | 35,429 | 37.0 |
| 2020-2021 | 24,279 | 34,224 | 41.5 |
| 2021-2022 (Prov.) | 29,514 | 36,926 | 44.4 |

*Source: Office of the Controller General of Patents, Designs & Trade Marks (CGPDTM)*

This may seem like remarkable progress when compared over time, however India lags far behind its global peers. The number of patents applied and granted in India is still a fraction compared to the patents granted in China, USA, Japan, and Korea. The number of patents filed in India is merely 3.8 percent of China and 9.5 percent of USA in 2020 (Table 2).

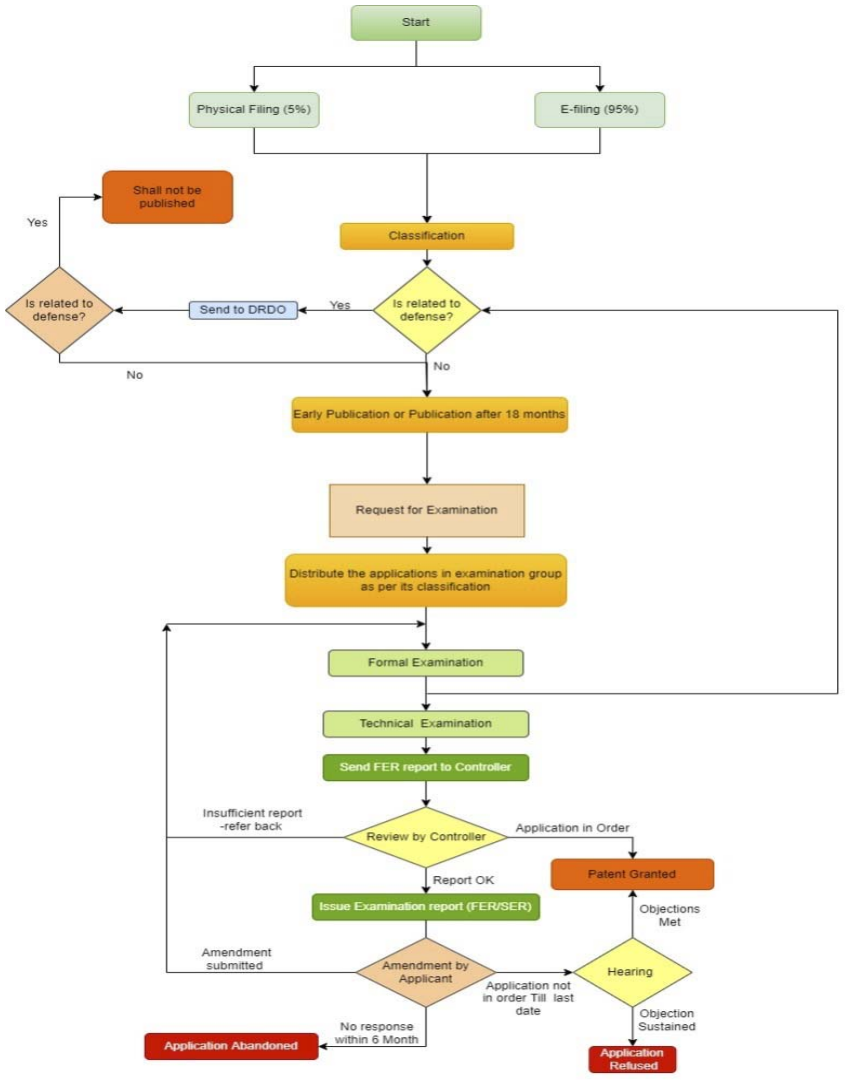
**Table 2: Patent applications and grants in India, China and US**

| Year | China | | United States of America | | India | |
|---|---|---|---|---|---|---|
| | Filing | Grants | Filing | Grants | Filing | Grants |
| 2016 | 13,38,503 | 4,04,208 | 6,05,571 | 3,03,049 | 45,444 | 9,847 |
| 2017 | 13,81,594 | 4,20,144 | 6,06,956 | 3,19,829 | 47,854 | 13,045 |
| 2018 | 15,42,002 | 4,32,147 | 5,97,141 | 3,07,759 | 50,659 | 15,283 |
| 2019 | 14,00,661 | 4,52,804 | 6,21,453 | 3,54,430 | 56,284 | 24,936 |
| 2020 | 14,97,159 | 5,30,127 | 5,97,172 | 3,51,993 | 56,771 | 26,361 |
| 2021 | - | - | - | - | 66,440 | 30,074 |

*Source*: *World Intellectual Property organization (WIPO) and Office of the Controller General of Patents, Designs & Trade Marks (CGPDTM) for India*

The National Intellectual Property Administration of the People's Republic of China (CNIPA) received close to 1.5 million patent applications in 2020. This is 2.5 times the amount received by the United States Patent and Trademark Office (USPTO). The USPTO – with 597,172 applications – ranked second, followed by Japan Patent Office (JPO) (288,472), Korean Intellectual Property Office (KIPO) (226,759) and European Patent Office (EPO) (180,346). Together, the top five offices accounted for 85.1 percent of the applications in the world in 2020, which is 7.7 percentage points higher than their combined share in 2010. This is mainly due to strong growth in China, whose share of the world total more than doubled during this period, from 19.6 percent in 2010 to 45.7 percent in 2020. Within these offices, the share of residents and non-resident applications vary widely. For example, only one in ten applications received in China was by non-residents in 2020 whereas the share was 54.8 percent in European Patent Office and 54.9 percent for US.

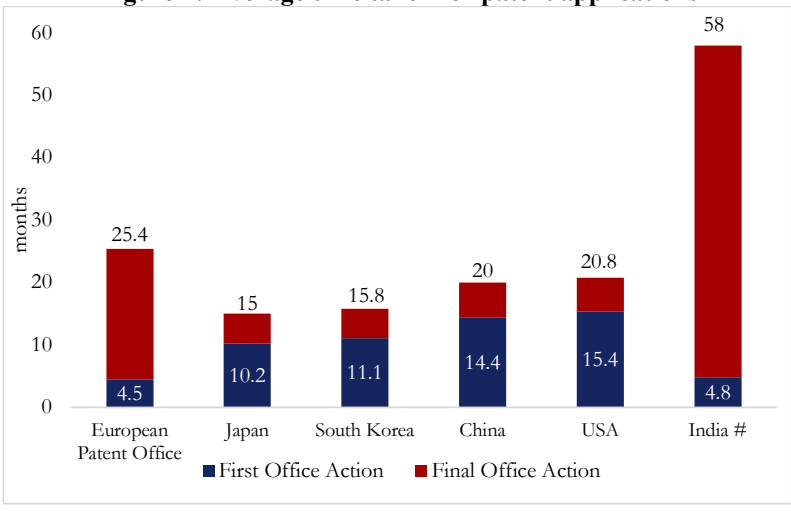
**Figure 1: Summary of Patent application process**




Not only the scale of patenting activity in India is smaller when compared to global leaders, the time taken for processing a patent application in India is also much higher. The Global best practice is disposal within 2 to 3 years, whereas in India, the average time taken is just under 5 years and is up to 9 years in some categories like biotech, and this is primarily due to the manpower shortage.

Once an application has been filed, it is published by the Controller within 18 months, until which the applicant can withdraw the application. After this, the application is processed for examination. The time taken for first office action has reduced drastically over the last few years. In fact, the average time taken for the first office action has reduced from 18 months in 2020 to 4.8 months now, which is the fastest in the world. But this has not improved the final outcome as major delays happen after that. The time for final disposal had decreased from 64 months in 2017 to 42 months in 2020, however it has started to increase thereafter and now stands at 58 months. In contrast, the average time taken for disposing of an application in China and US is 20- 21 months, which is almost 1/3rd of the time taken in India. The other 3 IP-5 offices, European Patent office, Japan and South Korea also process the application in 25.4, 15 and 15.8 months respectively (Figure 2).

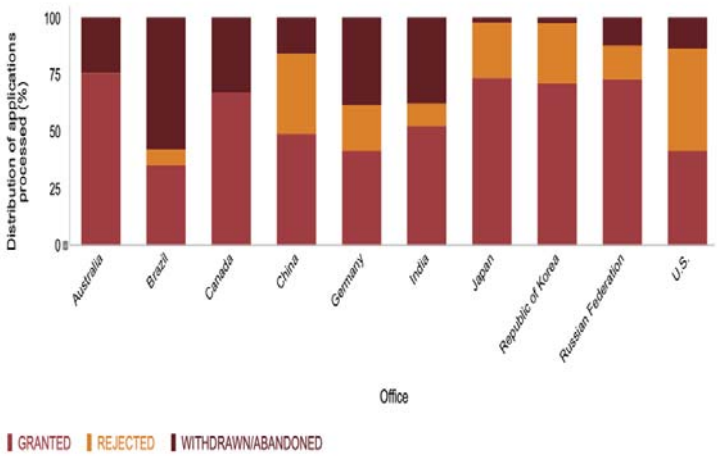
**Figure 2: Average time taken for patent applications**




*Source: WIPO for other countries and Office of the CGPDTM for India*
*Note: # Numbers for India is at the end of 2021-22 and for other countries is for 2020*

World Intellectual Property Organization (WIPO) in its annual report noted that the share of patent application withdrawn is one of the highest in India. Our discussion with people in the sector indicates that delays in the process are a major reason for this. The share of application withdrawn in India was about 66 percent in 2018, though numbers came down after some decline in processing time and some process simplification in processes was done. The withdrawal share reduced to 54 percent in 2019 and 38 percent in 2020, though it is still one of the highest in world and much higher than its global peers- US, Japan, Korea, China (Figure 3).

**Figure 3: Status of patent applications**




*Source: World Intellectual Property Indicators 2021 report*

# III. Issues in the patenting system

## III (A). Manpower shortage

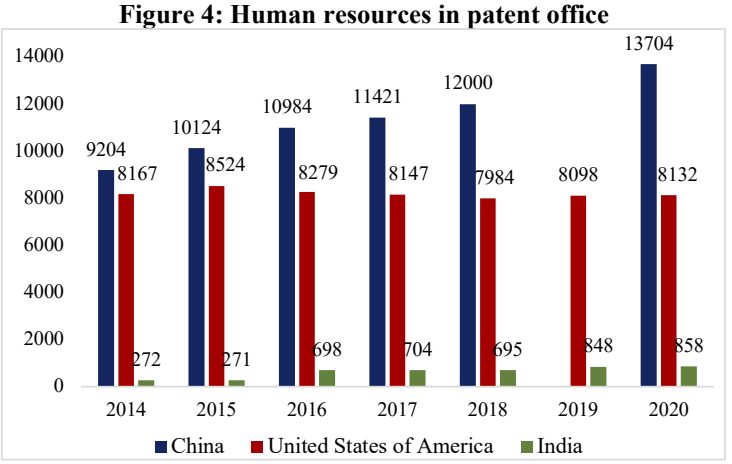
The major reason for delays is the lack of sufficient manpower in patent office. Though some additional workforce was added in the patent office in the last few years (Table 3) especially at the examiner level, it is very small when compared with China, US etc. (Figure 4).

**Table 3: Manpower in the patent office**

| Year | Examiners | Controllers |
|---|---|---|
| 2015-16 | 132 | 139 |
| 2016-17 | 564 | 134 |
| 2017-18 | 572 | 132 |
| 2018-19 | 449 | 246 |
| 2019-20 | 601 | 247 |
| 2020-21 | 611 | 247 |
| 2021-22 | 611 | 247 |

*Source: Office of CGPDTM*

**Figure 4: Human resources in patent office**

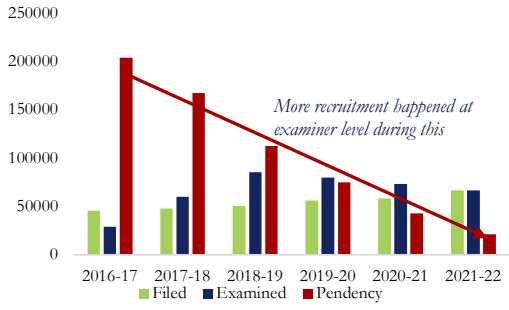



*Source: WIPO for China and US; Office of CGPDTM for India*
*Note: The number for China is not available for 2019.*
*In India, the manpower indicates sum of examiners and controllers.*

Since a greater number of people were added at the examiner level, the time taken for first office action and the pendencies at the first stage reduced drastically. In 2016-17, more than 2 lakh applications were pending at first examination level. Gradually, pendency reduced at the first examination level with more examiners available. However, there wasn't a commensurate increase in manpower at the controller level, this merely shifted the pendency from first examination level to the next stage. There are approximately 1.64 lakh applications pending at the controller level as of end March 2022 for which preliminary examination has already been done, up from 40 thousand in March 2017 (Figure 5).

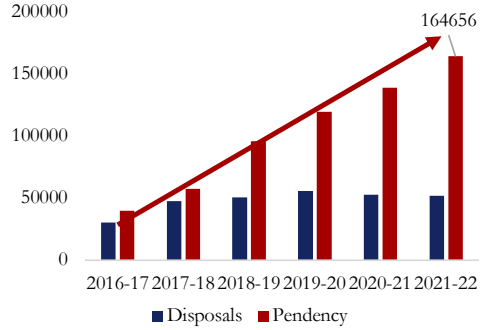
**Figure 5: Pendencies in patent office**

At examiner level
First Examination Level




*Source: Office of CGPDTM*
*Note: Pendency means unexamined applications*

At controller level
Final Examination (Disposal) Level




*Source: Office of CGPDTM*
*Note: Pendency at this stage means Preliminary Examined but pending for final examination and disposal*

Even the Parliamentary Standing Committee on Commerce's Review of Intellectual Property Rights Regime in India (2021) also noted that that is an urgent need to increase the manpower in patent office.

## III (B). Issues in the process

### III (B) (i). No fixed timelines for each step of the process

Apart from the shortage of manpower, another reason leading to delays in processing is the lack of fixed timelines for each step in the procedure. The lack of timelines for each step leads to various issues. For instance, Section 25(1) of the Patents Act 1970 provides that a pre-grant opposition can be filed by any person opposing the patent at any time after the patent application has been published and before the grant. There is no fixed time frame for this, leading to build-ups and delays. This provision is in some cases used by people for making frivolous complaints which keeps delaying the process[2].

Another example is that there is no time limit prescribed in the statute for controller to conduct a hearing to determine the validity of responses to the First Examination Report and any outstanding objections which may not have been adequately addressed by the applicant. It was found that this usually takes about 6-9 months. Additionally, the decision after the opposition hearing by the controller which should usually happen in 1 month typically takes about 3-4 months. However, these issues also arise due to shortage of manpower.

### III (B) (ii). Cumbersome compliance requirements

There are certain provisions of the Patent Act 1970 which lead to cumbersome compliance requirements on the applicants. For instance, some provisions require an applicant to keep submitting information relating to the prosecution of foreign patent applications in a periodic manner. This may have been an important requirement in the past, however, this is not required now for Patent Cooperation Treaty (PCT) applications as there are tools made available by WIPO, called WIPO CASE (Centralized Access to Search and Examination) which provide consolidated information for such applications related to the status of patent applications and related details in a large number of jurisdictions and India is already a part of this initiative.

[2] https://www.mondaq.com/india/patent/1092108/frivolous-pre-grant-oppositions-ipab39s-order-provides-guidelines-on-dealing-with-frivolous-pre-grant-oppositions

## IV. What needs to be done for patenting system?

### IV (A). Increase the manpower in the patent office

First of all, there is a need to immediately sanction additional posts at the controller level to clear the current backlog of 1.64 lakh applications (which have already undergone preliminary examination) as on end March 2022. Merely redistributing the existing manpower will not address the issue. Further, a substantial increase in manpower is required in the patent office in the next few years to be able to compete with our global peers in terms of scale of patent applications and the time taken to process them. As a rough estimate, the manpower in patent office should increase from existing 860 to about 2800 in the next two years.

In order to expand the available pool of trained workforce, a short certificate course (like a diploma) may be developed in collaboration with some academic/technical institutions that may be done concurrently with the existing graduation courses. Those who have done this course, after fulfilling the minimum qualification criteria, would then be eligible for hiring for the role of examiners on contractual basis. In addition to this, there is a need to build the career path of the employees in the patent office to attract good talent to the patent office. In this regard, there is a need to revisit the Modified Flexible Compensation Scheme (MFCS).

It is important to note that the Office of CGPDTM is a cash positive organisation and adding more manpower is revenue positive for Government (Figure 6). Bulk (approximately 60 percent) of the revenue of the Office of CGPDTM is received from the patents (Figure 7). Hence, financial reasons should not be thought of as a hindrance to adding more manpower in the patent office. In fact, due to addition of technical manpower, delay in grant of patents will be expedited which in turn add more revenue.

**Figure 6: Revenue and expenditure of Office of CGPDTM**

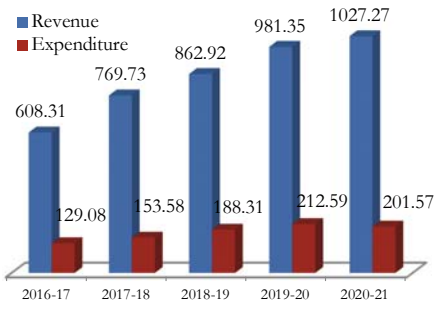
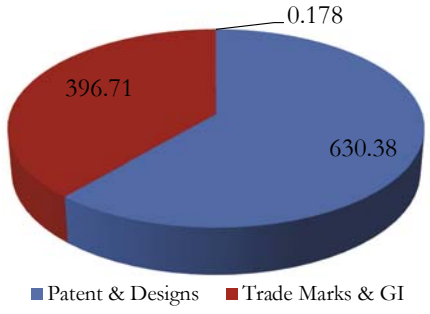



**Figure 7: Revenue in Office of CGPDTM in 2020-21**

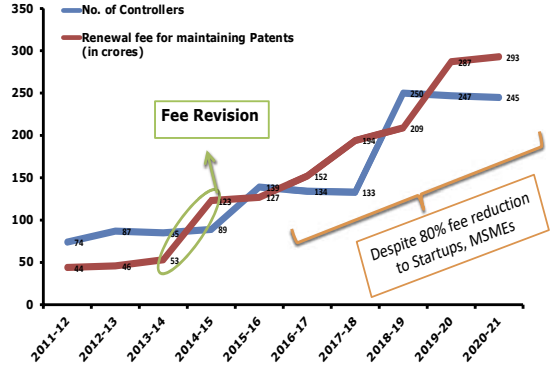


*Source: Office of CGPDTM*
*Note: Figures in Rs crore*

*Source: Annual report of Office of CGPDTM*
*Note: Figures in Rs crore*

The increase in manpower has already demonstrated a positive impact on revenue generated. For instance, an increase in controllers means more applications could be processed and hence the patent office received higher renewal fee for maintaining patents (Figure 8) despite large fee reductions for startups, MSMEs, etc.

**Figure 8: Number of controllers and renewal fee for patents**




*Source: Based on Annual Reports of CGPTDM*
*Note: Fee revision here indicates the increase in patent fees*

## IV(B). Solve the issues in the process

### IV (B) (i) Fixing timelines for various steps of the process

Lack of fixed timelines also leads to delays, hence an important step that needs to be taken to address the delays in processing of patent applications is that timelines need to be fixed for each step of the process. For instance, as mentioned in the previous section, a pre-grant opposition can be filed by any person opposing the patent application at any time after the application has been published and before grant. There is no fixed time frame for this, leading to build-ups and delays. Instead, there is a need to have fixed timelines. For example, as per 35(e) U.S. Code § 122, the time limit for any party to submit any material of potential relevance to the examination of the application is within 6 months after the date on which the patent application is first published under section 122 by the Office.

Another issue is that for various procedures, there are timelines prescribed in the rules, but they are not adhered to due to large pendencies owing to manpower shortage. For instance, as per

Rule 55 (5), the opposition hearing decision should be given within 1 month etc., however, in practice, is not followed in various cases due to shortage of manpower. Same is the case with various other steps.

An illustrative timeline which could be prescribed step-wise is provided in table 4 below. Though it is important to note that in practice, the timeline can be adhered to only after adequate manpower has been added.

**Table 4: Suggested timelines for the patent grant process**

| Steps | Suggested timelines |
|---|---|
| Once an application is filed, the time provided for publication is 18 months. After that the following steps have to be taken by the patent office. | |
| Reference to an examiner and issue First Examination report | 4 months |
| Time given to the applicant to give responses after FER has been issued | 3 months +3 months* |
| Controller must notify and conduct a hearing to determine the validity of responses to the FER and any outstanding objections which may not have been adequately addressed by the applicant. | 3 months |
| Any written submissions requested from applicant by controller | 15 days from hearing |
| Pre-grant opposition window | 6 months from issue of FER |
| Controller to notify applicant of objections | Should happen immediately |
| Preparing submissions and evidence by both applicant and party opposing the patent | 3 months |
| Opposition hearing | 2 months from submission of all pleadings by parties |
| Opposition Hearing Decision | 1 month |
| Grant: The patent is granted and published once (i) all FER responses are accepted and (ii) no pre-grant oppositions are pending | 1 month from completion of all proceedings |

Note: * 3 +3 months here mean that the applicant can submit the response in 3 months to the first examination report. Afterwards, the examiner can issue a subsequent examination report in case some aspects are left uncovered and then the applicant can then submit the response within 3 months. This can also help in reducing the number of cases going for hearing.

While there is a need to put fixed time limits to all the steps in the procedure, it is important to keep in mind that this should not lead to dilution of the any safeguard like pre-grant opposition. Specifically, in case of pharmaceuticals industry, where companies apply for new patents with minor changes in the composition etc. of the existing old drugs – dubbed "evergreening" of patents- pre-grant opposition plays an important role. This is a widely known issue. One solution to easy identification of compounds in the drugs to help prevent evergreening of patents that has been proposed is the use of International Nonproprietary Names (INN), however it has not yet been broadly used anywhere in the world. The future changes in the rules of pre grant opposition should take these challenges into account.

**IV (B) (ii). Remove the Cumbersome compliance requirements**

There are certain provisions of the patent acts which lead to cumbersome compliance requirements on the applicants. For instance, there are requirements on applicants to keep submitting information relating to the prosecution of foreign patent applications in a periodic manner leading to high compliance requirements.

Considering that now India is a part of WIPO Centralized Access to Search and Examination (CASE), such information can easily be accessed by the patent office for PCT applications. Hence, instead of this, the provision should be amended such that the controller can ask for specific information for these PCT applications which the applicant may submit. In fact, the use of information from WIPO CASE by the patent office should be promoted to get information about the patent application decisions in other important jurisdictions which will help expedite the national application.

## IV (C). Other improvements

**IV (C) (i). Consider bringing in utility model of patents**

A utility patent is a special form of patent right granted by a state to an inventor for a fixed time period where the eligibility requirements are less stringent and the term of protection is shorter and these are cheaper to acquire as well. These are essentially 'jugaad' kind of innovations done by amateur inventors. It secures protection for small innovations, which does not require the strict novelty and invention condition as required by patent law. This helps spur innovation, specifically for individual & small-scale innovators. Various countries in the world use this model. In 2020, 3 million utility patents were filed across the world.

A new legislation granting protection to incremental innovation through utility models can be considered to be brought about in India. This will also help push innovation done in Atal Tinkering Labs and Atal Incubation Centers under the Atal Innovation Mission as well by rewarding innovation done. India is already a hub of start-ups and small-scale enterprises, and utility patent model will promote incremental innovation in this category. Thus, there is a case for bringing in a utility patent model in India- which should be much cheaper than patents, provided at a much faster pace and has less stringent criteria for patentability.

**However, it is important to note that this should be made very clear that this is a separate patent category from the regular patents, so that it does not dilute the rigour of the existing system.** Again, this can only work after additional manpower is put in office so that the introduction of utility patent models does not result in further strain on the existing system.

**IV (C) (ii). Improvements in portal and systems for filing**

The processing system used in the patent office has been upgraded substantially over the years and there has been almost 95 percent movement of applications via the online mode. Even hearing is now being done in the online mode for a lot of cases.

Still, there is a significant scope of improving the overall system. Overall, the system needs to be made user-friendly to make it easier to use for applicants as well as examiners and controllers. It may be useful to outsource the whole IT system to a private player to get access to the latest infrastructure. A list of steps that could be taken for the improvement in the portal and filing systems is detailed in the Annexure.

**IV (C) (iii). Outsource the administrative process**

The administrative process of patent application process can be outsourced to a third party, like has been done in the case of passport office, so that the examiners and controllers can focus on the core technical work. Further, there is a case for extensive use of machine learning/automation of administrative steps so that the process can become more streamlined.

## V. Where does India stand in terms of Trademark activity

"Trade Mark" is defined in Sec. 2 (1) (zb) of The Trademarks Act, 1999 as "a mark capable of being represented graphically and capable of distinguishing the goods or services of one person from those of others".

There has been a substantial increase in trademark filing and registration in the last few years. Filing of applications increased from about 2 lakhs in 2013-14 to 4.5 lakhs in 2021-22. Simultaneously, the registrations increased from slightly less than 68 thousand in 2013-14 to 2.6 lakhs in 2021-22. Most of the trademark applications are from Indians, with less than 3 percent foreign applications in 2021-22 (Table 5). In fact, at most offices across the world, trademark applications are filed mainly by residents seeking protection within their domestic jurisdiction. In 2020, residents filing at their respective home or regional office accounted for 86.1 percent of global filing, with the remaining 13.9 percent associated with non- resident filings.

**Table 5: Trademark filing and registration**

| | TOTAL FILING | RESIDENT | NON-RESIDENT | TOTAL REGISTRATION | RESIDENT | NON-RESIDENT | OTHER DISPOSAL |
|---|---|---|---|---|---|---|---|
| 2013-14 | **200005** | 188927 | 11078 | **67796** | 60931 | 6865 | 39430 |
| 2014-15 | **210501** | 201938 | 8563 | **41583** | 37488 | 4095 | 42585 |
| 2015-16 | **283060** | 273034 | 10026 | **65045** | 59820 | 5225 | 145716 |
| 2016-17 | **278170** | 266814 | 11356 | **250070** | 226905 | 23165 | 47031 |
| 2017-18 | **272974** | 261033 | 11941 | **300913** | 281047 | 19866 | 176579 |
| 2018-19 | **323978** | 310156 | 13822 | **316798** | 297572 | 19226 | 236612 |
| 2019-20 | **334805** | 320702 | 14103 | **294172** | 278506 | 15666 | 165851 |
| 2020-21 | **431213** | 418446 | 12767 | **254513** | 241811 | 12702 | 43488 |
| 2021-22 | **447805** | 433997 | 13808 | **261406** | 251479 | 9927 | 60375 |

*Source: Controller General of Patents, Designs and Trade Marks*

It is important to note here that India reached the fifth highest place in the number of applications in 2020. For international comparison, WIPO in its reports recommends comparison by class count.[3] The trademark filing in the office of China (by class count) was 9.3 million followed by a count of 8,70,306 at the office of the U.S. (Table 6). These two top-

[3] A trademark application may refer to different classes of goods or services. Many offices use the Nice Classification, an international classification of goods and services for registering trademarks and service marks. Applications received at these offices are classified according to one or more of the 45 Nice classes (see www.wipo.int/classifications/nice). Some offices allow single-class filing only, meaning applicants have to file a separate application for each class. Others permit multi-class filings, enabling applicants to file a single application in which a number of classes can be specified. To improve international comparisons of the numbers of applications received, it helps to compare class counts across offices. Class counts are also used to make trademark registration internationally comparable. This method for comparing offices began in 2004, the first year for which complete class count data are available.

ranked offices were followed by the office of the Islamic Republic of Iran (541,750), the European Union Intellectual Property Office (EUIPO) (438,511) and the office of India (424,583).

**Table 6: Trademark filing in various countries (by class count)**

| | China | USA | India |
|---|---|---|---|
| 2013 | 18,78,389 | 4,41,059 | 2,00,392 |
| 2014 | 22,84,219 | 4,72,060 | 2,37,730 |
| 2015 | 28,68,581 | 5,17,105 | 2,89,730 |
| 2016 | 36,97,723 | 5,45,266 | 3,13,448 |
| 2017 | 57,39,679 | 6,13,902 | 2,83,574 |
| 2018 | 73,65,356 | 6,40,108 | 3,42,667 |
| 2019 | 78,33,010 | 6,72,644 | 3,67,768 |
| 2020 | 93,45,757 | 8,70,306 | 4,24,583 |

*Source: WIPO*
*Note: Number includes both residents and non-residents*

**Table 7: Trademark Granted (by class count)**

| | China | USA | India |
|---|---|---|---|
| 2013 | 10,20,257 | 2,73,940 | 61,975 |
| 2014 | 13,82,087 | 2,88,089 | 70,222 |
| 2015 | 22,39,412 | 3,11,925 | 86,304 |
| 2016 | 22,70,747 | 3,26,431 | 2,01,917 |
| 2017 | 28,17,571 | 3,61,748 | 3,39,753 |
| 2018 | 49,95,767 | 3,84,749 | 3,59,799 |
| 2019 | 64,05,623 | 4,39,484 | 3,23,006 |
| 2020 | 57,79,076 | 4,00,220 | 2,58,511 |

*Source: WIPO*
*Note: Number includes both residents and non-residents*

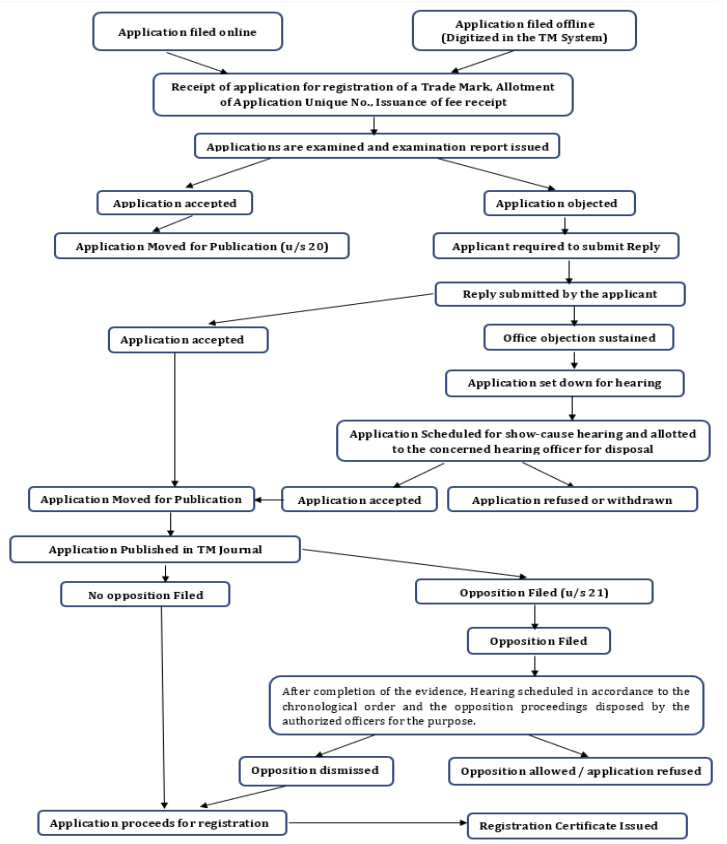
China (301.7 lakh) , followed by USA (26 lakh) and then India (24 lakh) have the highest number of trademarks in force as of 2020 (Table 8).

**Table 8: Trademarks in force (as of 2020)**

| | |
|---|---|
| China | 3,01,73,085 |
| United States of America | 26,05,916 |
| India | 24,09,005 |
| Japan | 19,73,640 |
| France | 15,72,726 |

*Source: WIPO*

**Figure 9: Summary of Trademark application process**




After the application is filed, each application is given a unique number and then allotted to examiners. Applications are then examined and an examination report is issued. As per the current situation, in India, the first stage examination of the application happens within 2-3 months, which is the fastest globally. After that, if the examiner has no objections and the application is accepted, it is moved for publication and a time of 4 months is provided for any objection to be raised by the public. In case no objection is received, the trademark is registered. So, this entire process of registration is finished in approximately 8-10 months. In case, there is any query or objection from examiners' side, a communication of examination report is sent to the applicant who has to submit a reply within 1 month. Post that, once the reply is submitted and is acceptable, the application is moved for publication and in case no objection is received in 4 months, the trademark is registered. However, in case the reply submitted by the applicant is not satisfactory, a show cause hearing is called. Also, in case there are some objections to

the application, the applicant can request a hearing in response to the examination report, which the Registrar must provide. No time limit has been prescribed for the completion of these steps in the existing rules. The notification of the date of hearing often takes several weeks. The hearing process also takes time given that in some cases multiple hearings are required. **Still, on average, in such cases, it takes about 18 months for the application to be processed. This is comparable to global peers.**

**The main issue arises when any opposition is filed.** Out of the total trademark applications, about 14-16 percent get opposed. Under the trademark rules, any person can give notice of opposition to the registration of a trademark to the Registrar within 4 months from the date of advertisement. After the opposition is filed, the notice of opposition is sent to the applicant, who then has to file a counter statement within 2 months pursuant to section 21(2) of the Trademarks Act[4]. After the submission of counterstatement/evidence by the applicant, the Registrar must then provide a copy of this counter-statement to opponent, who must respond with evidence within one month of receiving notice.

The hearing is scheduled in accordance to the chronological order of the applications filed and the opposition proceedings are disposed by the officers authorised for this purpose, which are mostly Assistant Registrar and above. In such cases, there is a long waiting time and **it takes somewhere between 5 to 10 years for such applications to be processed.**

**Box 1: Procedure of opposition**

1) **Opposition can be filed under Section 21** within 4 months from date of publication in Trademark Journal
2) **Notice of Opposition:** as per Rule 42 on form TM-O which shall be served to the applicant by the Registrar
3) **Counter Statement:** as per Rule 44 on form TM-O by applicant within 2 months of the receipt of Notice of Opposition
4) **Evidence in support of opposition:** as per Rule 45 within 2 months from service of Counter statement otherwise abandoned u/r 45(2)
5) **Evidence in support of Application:** as per Rule 46 within 2 months on receipt of opponent's evidence otherwise abandoned u/r 46(2)
6) **Evidence in reply by opponent**: as per Rule 47 within 1 month from receipt of applicant's evidence
7) **Further evidence** as per Rule 48: with leave of Registrar
8) **Hearing & Decision** as per Rule 50
   - After closure of evidence
   - Not more than 2 adjournments to each party.

[4] In case the applicant does not respond to the opposition query within 2 months, application is abandoned.

- Applicant not appearing on adjourned date: Application abandoned u/r 50(3)
- Opponent not appearing on adjourned date: opposition dismissed u/r 50(4)
- Decision in writing u/r 50(6) and Reasoned u/s 18(5)

# VI. Issues in Trademark system

## VI (A). Shortage of manpower

There is a shortage of manpower in Trademark Registry Office, more so at senior levels. The manpower in Trademarks Registry Office is even less than sanctioned posts and a lot of places are still lying vacant. For instance, there is not even a single Senior Joint Registrar against 2 sanctioned posts, only 1 Joint Registrar against 5 sanctioned posts, 8 Deputy Registrars against 15 sanctioned posts and only 3 Assistant Registrars against 32 sanctioned posts. At the senior examiner and examiner level as well, 43 out of 75 and 113 out of 160 posts are filled respectively (*Table 9*). Further, not all people hired at various posts are available for examination/hearing process. Some of them are involved in administrative roles as well, reducing the effective strength at disposal for trademark application related work even further.

**Table 9: Manpower in Trademark Registry Office in India**

| Post | 31st March | | | | | | 01.07.22 | Sanctioned strength as on date |
|---|---|---|---|---|---|---|---|---|
| | 2017 | 2018 | 2019 | 2020 | 2021 | 2022 | | |
| Sr. Joint Registrar | 0 | 0 | 0 | 0 | 0 | 0 | 0 | **2** |
| Joint Registrar | 0 | 0 | 3 | 1 | 1 | 1 | 1 | **5** |
| Deputy Registrar | 5 | 5 | 9 | 9 | 6 | 8 | 8 | **15** |
| Asst. Registrar | 10 | 14 | 7 | 7 | 7 | 4 | 3 | **32** |
| Sr. Examiner | 13 | 8 | 37 | 36 | 36 | 43 | 43 | **75** |
| Examiner | 48 | 95 | 68 | 65 | 60 | 62 | 113 | **160** |

*Source: Office of CGPDTM*

Since there was a shortage of examiners, some examiners were hired on a contractual basis since 2017 (*Table 10*). This increase in manpower at examiners due to hiring on a contractual basis helped in bringing down the time for issuing first examination reports to around 1-2 months. Though the contract of existing examiners ended on 30th June and has not been extended, hence as on 1st July 2022, there were no examiners on contract in Trademark Registry Office.

**Table 10: Examiner on contract in Trademarks registry**

| Post | 31st March | | | | | | 01.07.22 |
|---|---|---|---|---|---|---|---|
| | 2017 | 2018 | 2019 | 2020 | 2021 | 2022 | |
| Examiner on contract | 83 | 52 | 76 | 88 | 62 | 57 | 0 |

*Source: Office of CGPDTM*

The manpower in trademark registry office is inadequate when compared internationally. China has 2000 examiners, USA has 633 examiners and in contrast India has 156 examiners (*Table 11*).

**Table 11: Comparison of Manpower in Trademark registry Office**

| | Number of examiners |
|---|---|
| China | 2000 |
| USA | 633 |
| Europe | 254 |
| Japan | 161 |
| India | 156 |
| Korea | 141 |
| UK | 93 |

*Source: WIPO for other countries and Office of CGPDTM for India*

Since there is a huge shortage of manpower, specifically at senior level, only a small percentage of opposition cases are disposed of through hearing every year (*Table 12*).

**Table 12: Opposition disposals**

| | FILED | DISPOSED | |
|---|---|---|---|
| | | HEARING | THROUGH 21(2) |
| **2013-14** | 14099 | 8793 | 4053 |
| **2014-15** | 15267 | 9539 | 8174 |
| **2015-16** | 18409 | 11404 | 34850 |
| **2016-17** | 43450 | 10882 | 26177 |
| **2017-18** | 43450 | 10882 | 26177 |
| **2018-19** | 51961 | 21462 | 44951 |
| **2019-20** | 51969 | 35203 | 39203 |
| **2020-21** | 61963 | 8030 | 9602 |
| **2021-22** | 55825 | 6525 | 4748 |

*Source: Office of CGPDTM*

As a consequence, the applications where opposition is filed keep getting accumulated. At end June 2022, about 2.4 lakh applications were pending at opposition stage, with a total of about 2.8 lakh objections. Another 2.6 lakh applications are pending at showcause hearing stage (*Table 13*). Hence, 30 contractual hearing officers have been hired recently to expedite the work and tackle the pendency in applications.

**Table 13: Pendency of number of applications as of end June 2022**

| | |
|---|---|
| **EXAMINATION** | 101648 |
| **POST EXAMINED** | 193090 |
| **PENDING APPLICATION RECORD MANAGEMENT** | 63263 |
| **SHOWCAUSE** | 265666 |
| **OPPOSITION** | 239484 (Applications), 283044 (Oppositions) |

*Source: Office of CGPDTM*

## VI (A). Issues in process

### VI (A) (i). Compliance of rules and statutory deadlines as set by Trademark rules 2017

Our discussion with the people from the sector showed that some of the statutory deadlines set by Trademark Rules 2017 are not followed fully in practice, such as:

- The deadline for submission of reply as mentioned under Rule 33 of Trademark Rules 2017 is 30 days from the date of receipt of notification of the Examination report. However, replies are submitted after the deadline without status of the application being changed.
- In some cases, parties take more than prescribed time than mentioned in the Rule 45-47 of Trademark Rules 2017 for submission of evidence at times which delays the opposition process.
- The Rule 50 of Trademark Act, 2017 states that "provided that no party shall be given more than two adjournments and each adjournment shall not be more than 30 days". However, in practice, in some cases, more than 2 adjournments are filed and are granted by the Trademark Office.

# VII. What needs to be done for trademark system?

## VII (A). Increase the manpower in Trademark registry office

Lack of adequate manpower is the key issue creating issues in the process- despite providing the fastest first examination reports, the processing time of the applications increases to somewhere between 5-10 years in case there are objections/oppositions against any applications. This is because first, there is a considerable lag in the listing of an opposition hearing due to lack of manpower at Assistant Registrar and above, and secondly, even after the start of the hearing, multiple hearings are often conducted for the same opposition, which makes this process last several months. Hearings are often adjourned for months at a time due to lack of manpower as each Registrar in India has various matters on their docket in one day. In jurisdictions like the United States, hearings are often completed within one sitting since each official only has 2-3 matters on their docket. Hence, the key step to solve the problem of pendency of applications at the opposition stage is to hire more manpower.

As an interim measure, 30 contractual hearing officers have been hired recently. There is a need to immediately fill in the sanctioned seats, which will increase the manpower from 168

currently to 289. Further, the manpower needs to be scaled up going forward based on the requirement to cater to the increase in trademark filing in the coming years.

## VII (B). Solve the issues in the process

### VII (B) (i). Strict compliance of rules and statutory deadlines as set by Trademark rules 2017

Our discussion with the people from the sector showed that some of the existing statutory deadlines set by Trademark Rules 2017 are not followed fully in practice. An effort must be made to put in place a system so that the statutory deadlines are followed completely. However, it is important to note here that for this to work, adequate manpower needs to be added.

## VII (C). Other improvements

### VII (C) (i). Automation of some steps where no human analysis is required

No examination or human analysis/ intervention is required to provide opposition notice to the applicant and counter-statement to be submitted to the person who has opposed. In practice, serving notices by the Registrar to the applicant and opponent during the opposition process takes about 2-3 weeks in each instance. Hence a system for notice of opposition/counter-statement to be automatically mailed to the applicant/opponent will help save the processing time.

Similarly, in case response to the examination report or the response/evidence in reply of an opposition is not submitted in the stipulated time, there should be an automatic deemed abandonment of the application. On the registration of a trademark, the Registrar issues a certificate to the applicant in the prescribed form of the registration thereof, sealed with the seal of the Trade Marks Registry. No time limit has been prescribed for the completion of this step. Registration should happen immediately upon (i) 4 months lapsing from advertisement with no opposition; or (ii) completion of successful opposition hearings. Given that no further examination or human analysis or intervention is required at this stage, a process for automatic registration should be put in place so that registration can take place on the next working day of the completion of either of the above events. The automation of these steps will reduce the processing time of applications.

## VIII. Conclusion

There have been significant improvements in the patent and trademark application process in the last few years, the results of which are already visible in terms of higher filings and grants of patents and registration of trademarks and reduced processing times.

Despite the fact that the patent filed and granted have increased in the recent years, yet they are much lower when compared to the global peers- US, China. Moreover, the average time taken for disposing off a patent application in China and US is 20- 21 months, which is almost 1/3$^{rd}$ of the time taken in India. There are approximately 1.64 lakh patent applications pending at controller level as of end March 2022 for which preliminary examination has already been done.

Similarly, the trademark applications and registration has increased considerably over the years. India has become the fifth largest office in terms of filing trademark applications. Even in terms of processing, India is not far behind the global peers in cases where no opposition is filed against a trademark application. The issue arises in case any opposition is filed, where the applications take about 5-10 years for processing. At end June 2022, about 2.4 lakh trademark applications were pending at the opposition stage.

In both, patents and trademarks, the key issue is the shortage of manpower. Hence, the first step that needs to be undertaken is to increase the manpower immediately, with higher focus at the controller level in patents and with higher focus at the assistant registrar level and above in trademarks to clear the backlog/pendencies. Going forward, the manpower needs to be increased at all levels to keep in line with the increased filing trends and be able to compete with global peers. As a rough estimate, the manpower in patent office should increase from around 860 to 2800 in the next two years and in trademark office, the sanctioned posts should be filled immediately taking the manpower from 168 currently to 289. The hiring of more manpower should not be delayed on financial grounds as this is a revenue generating activity for the government. Also, a short certificate course (like a diploma) may be developed in collaboration with some academic institutions that may be done concurrently with the existing graduation courses. Those who have done this course, after fulfilling the minimum qualification criteria, would then be eligible for hiring for the role of examiners on contractual basis. Furthermore, to attract good talent, there is a need to build the career path of the

employees in the Office of CGDTPM. One option is to revisit the Modified Flexible Compensation Scheme.

Apart from increasing manpower, there is a need to address issues in the patent application process including fixing time for various stages of the process including for pre-grant opposition, and reducing compliance requirements. Further, there is a need to look at introducing utility model of patents, making various improvements in filing and IT systems, and outsourcing the administrative part of the process which can simplify and fasten the process.

In addition, there are few procedural changes that can be brought about to improve the overall trademark process as well. A system need to be put in place so that existing statutory deadlines mentioned in the Trademark Rules 2017 are strictly adhered to. Further, automation of some steps where possible will also increase the speed of processing.

Overall, it is important to note here that the key is to first increase the manpower as some of the other suggestions will work only if adequate manpower is put in place.

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**Annexure: List of suggested improvements in portal and systems for filing**

(i) Improvements in e-filling portal

- Filing of patent applications can be made simpler by introducing Aadhar based signature along with Digital Signature Certificate. This will particularly help small entrepreneurs, individuals etc.
- A proper helpdesk/chat bot can be created along with displaying some FAQs on the application process on the website for guiding applicants.
- A fee calculator can be made available on the e-filing portal so that the applicant can get a prior idea for required fees reducing the chance for errors and objections later on.
- Mandatory documents list before filing like in Passport application can be made available on the website. Mandatory documents check box at the time of filing will reduce the chance of missing something which later on leads to delays in processing.

(ii) Improvements in InPASS portal (search portal)

- InPASS can be made more user-friendly with an improved system for contextual search. A multilingual search option is also need of the hour.

(iii). Improvements to help precise classification and allotment

- This is a very crucial step as precise classification leads to the application being given to the intended examiner, otherwise the application keeps on getting reallotted among the officers before finally reaching the relevant examiner. Using IT tools and semantic analysis, it is possible to find a more relevant classification of the application.

(iv). Automation of formal examination

- The formal examination is mostly rule-based and is the examination on legal aspects. Example of formal application includes checks like whether application was filed on time, compliance of timelines for different forms, fees etc. A lot of this process can be automated and this will save a lot of time of the examiner and controllers and they can focus on technical aspects of the process.
- Formatting and segregation of uploaded documents: The documents should be uploaded in particular names. Segregating documents into various groups like formal forms, technical forms etc. will save a lot time of examiners.

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(v). Improvement in search tools

This search if any patent has been filed for the same or similar thing is the key work of examiners. The search has to be done for both patent literature and non-patent literature (for instance research papers etc.). There is a proper strategy for patent literature search, however no such strategy is available for non-patent literature. Nowadays most of the inventions are based on very new technology and non-Patent literature documents give more relevant citations for these. So, there is a need to have a proper search tool and access to all non-patent literature. This will help fasten the process at the amended application stage as well as the search can begin after the stage it had already been completed for.

(vi). Standardization of objections in report preparation

Creating a standard format for objections based on guidelines so that reports are generated in a unified format throughout the office will help in creating set quality of reports and fast disposal of applications by saving a lot of formatting efforts etc. The same thing is already implemented for International Search Authority applications.

(vii). Improvements in the Hearing process

- Hearing Video Conferencing (VC) license should be increased so that the disposal can be made quicker.
- No of people allowed in VC should be increased: A hearing involves participation from the controller, examiner, applicant, attorney and inventor. A pre and post-grant opposition further involve the opposing party and its attorney as well. Therefore, the number of people participating in a VC hearing needs to be increased.

(viii). Decision writing

- There is a need for having a uniform format for decision documents and reports.

(ix). Upgrade the IT-infrastructure

The current model is built on older technologies like .net and JSP which are less user-friendly and are slower. There has been an introduction of revolutionary technologies in IT in recent years. Shifting the module to advanced technologies like Node JS, HTML5 etc. will improve productivity and user experience.

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**References**


1) World Intellectual Property Indicators 2019
2) World Intellectual Property Indicators 2020
3) World Intellectual Property Indicators 2021
4) WIPO Statistics Database, September 2021
5) Annual Report 2019-20, The Office of Controller General of Patents, Designs, Trademarks and Geographical Indicators
6) Annual Report 2020-21, The Office of Controller General of Patents, Designs, Trademarks and Geographical Indicators
7) Parliamentary Standing Committee on Commerce's Review of Intellectual Property Rights Regime in India (2021)
8) WIPO Statistics Country Profiles


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● ● ●

# Ensuing Vietnam Medi- Pharm 2023 scheduled in May 10-13, 2023 at Hanoi - reg.

**F. No. 35022/8/2020-Policy, dated 18th August, 2022**

**1.** I am directed to refer to the above subject and to state that the Embassy of Vietnam in India has invited the Indian Pharma Industry to participate with the Indian Pharma Pavilion at Vietnam Medi-Pharm 2023 scheduled to be held from May 10-13, 2023 at Hanoi.

**2.** As informed by the Embassy, the Vietnam Medi-Pharm is an annual event hosted by the Ministry of Health, Vietnam and is one of the largest and prestigious medical shows in Vietnam. The event attracts a large number of local and international manufacturers, traders, distributors in the fields of medical, pharmaceuticals, hospitals, healthcare, dental, ophthalmology, chemicals, laboratory, beauty, medical tourism, opening up opportunities for cooperation and approaching advanced technologies in the world.

**3.** Trade and investment are one of the key pillars of the bilateral relationship between the India and Vietnam and India is one of the top 8th trading partners of Vietnam while Vietnam is 15th largest trading partner of India and fourth in Southeast Asia. The bilateral trade between India and Vietnam was about to reach US$ 13.2 billion in 2021 but it's much far below potential. In order to explore the two sides' trade and investment potential, the Vietnam Trade Office in India is in the process of connecting and linking up industries with India and Vietnam for trade and investment purposes.

**4.** In this regard, a brief note on the potentials of Vietnam Health Care Industry and business opportunities for Indian pharma industry in general medical equipment manufacturers, hospitals, medical tourism, dental, ophthalmology in particular along with a fair brochure are enclosed herewith for your perusal.

**5.** In view of above, Indian pharma and medical device industries may like to participate in the event. For any further information, Mr. Do Duy Khanh, first secretary of the Embassy and Ms. Kavita Rajesh, mobile number +91 9310046424, Email: in@moit.gov.vn; trade@vietnamembassydelhi.in are contact persons at Embassy of Vietnam at New Delhi.

**End: As above (1)**

*Venkat HA, Deputy Director,*
*Ministry of Chemicals and Fertilizers,*
*Department of Pharmaceuticals, New Delhi*

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# Vietnam's Growing Pharmaceutical Industry

- Vietnam's pharmaceutical industry is among the highest growth markets with over 98 million citizens making it an attractive market for investors.
- Despite this, the majority of domestic suppliers lack sufficient resources to fully exploit the market.
- Vietnam Briefing looks at opportunities as well as challenges for foreign investors when investing in the country's pharmaceutical industry.
- Vietnam's pharmaceutical market was valued at around US$10 billion in 2020, compared to US$5 billion in 2015. As per market research firm IBM, the size of Vietnam's pharmaceutical industry may reach US$16.1 billion in 2026.
- According to the Drug Administration of Vietnam, as of May 2019, Vietnam had about 180 pharmaceutical manufacturing enterprises and 224 domestic manufacturing establishments meeting GMP standards
- India is Vietnam's third largest supplier of pharmaceutical products, with an export turnover

of USD 198 million in the first nine months of 2020.

Vietnam's pharmaceutical market was valued at around US$10 billion in 2020, compared to US$5 billion in 2015. As per market research firm IBM, the size of Vietnam's pharmaceutical industry may reach US$16.1 billion in 2026. According to IQVIA, the industry also observed a 2 percent increase year-on-year, achieving a compound annual growth rate (CAGR) of 6 percent in the period 2018-2020.

**Local consumer trends**

Vietnam has a relatively large market size with a population of over 98 million and a life expectancy of approximately 76 years. Around 30 percent of the Vietnamese population that can afford relatively expensive western medicine is growing, equal to 30 million – the size of the entire Australian population. The industry also enjoys surrounding emerging markets with similar demands as Vietnam with a collective market size of 280 million including Thailand, Malaysia, Cambodia, Laos, and Singapore.

Vietnam's pharmaceutical industry is one of the highest growth markets in the region thanks to increasing economic growth, rising income per capita, and an aging population.

As per the World Bank, the number of Vietnamese people aged 65 and over, reached 7.6 million in 2020 accounting for nearly 7.9 percent of the country's total population. The General Statistics Office (GSO) forecasts that the number will reach 18.1 percent by 2049.

According to a report by the Vietnam Social Insurance Agency, in 2010, only 60 percent of Vietnam's population had health insurance, while in 2019, this figure was up to 90 percent. Another driving force for the pharmaceutical industry is the rapid urbanization rate. Vietnam's urbanization rate was at 37 percent in 2020 and in 2021 the urban population stood at approximately 36.6 million.

According to a study conducted by the EU-Vietnam Business Network (EVBN), 80 percent of individuals in Vietnam buy drugs from private pharmacies and self-medicate. Consumers are able to obtain drugs without a prescription, with common sources of information for decision-making when buying drugs being relatives or friends. Non-original and fake drugs can often find their way into pharmacies and clinics, hence buyers value brands known to them and advice from people close to them.

The pharmaceutical production and business system are expanding with about 250 manufacturing plants, 200 import-export facilities, 4,3000 wholesale agents, and more than 62,000 retail agents.

Major pharmaceutical companies in Vietnam are clustered in and around the capital Hanoi, Hai Duong province, Ho Chi Minh City, and some Southwest provinces including Can Tho City and Dong Thap province.

To meet increasing demand, many large pharmaceutical manufacturing enterprises such as HauGiang Pharmaceutical, Bidiphar, Imexpharm, and Pymepharco have been investing in upgrading factories, aimed at making breakthroughs in developing new domestic pharmaceutical products as well as improving the competitiveness with imported products.

Remarkedly, Hai Duong province has recently confirmed its cooperation with Indian partners on a large-scale pharmaceutical park. The pharmaceutical park project is expected to be worth US$10-12 billion invested by Indian businesses. The Pharmaceutical Park project covers more than 900 hectares of land area in Binh Giang and Thanh Mien districts, the largest of its kind in Hai Duong province.

For Hai Duong, the project will also help welcome international investors, especially those in hi-tech industries. For Vietnam as a whole, it signals the country's headway for future growth in the pharmaceutical industry.

**A potential market but underdeveloped industry**

Despite rapid growth, Vietnam's production capacity can only meet 53 percent of domestic pharmaceutical demand. In 2018, Vietnam's spent nearly US$2.8 billion on importing pharmaceuticals, and in 2021, that number jumped to US$4 billion according to GSO.

Major import markets include France, Germany, India, United States, South Korea, Italia, and Belgium with antibiotics being the leading import product.

| Vietnam's Pharmaceutical Imports | |
|---|---|
| **Year** | **Import Value** |
| 2018 | US$2.8 billion |
| 2020 | US$3.3 billion |
| 2021 | US$4 billion |

In addition, pharmaceutical R&D activities are lacking serious investment. While the government has prioritized advancing its domestic pharmaceutical industry, the country's capabilities are still limited to generic medicines (pharmaceuticals whose exclusive protection is expired), simple dosage forms, and functional foods.

Vietnam is also highly dependent on imported pharmaceutical materials, of which Chinese and Indian sources account for more than 85 percent. With its favorable tropical ecosystem, Vietnam has significant potential to grow medical plants, such as cinnamon.

However, the government still has no specific plans to develop large-scale medicinal plant growing areas at a national level. Some reputable local manufacturers have started developing their own medicinal plant farms, they only manage to meet a small amount of demand for production though.

Additionally, the input material is mostly imported from a few major markets, which has negatively affected the industry by increasing production costs and indirectly passing the cost onto the customers.

Such consequences were observed in late 2019 when the COVID-19 outbreak led to temporary shutdowns of many manufacturers in China and India, resulting in a shortage of pharmaceutical input ingredients in Vietnam.

Vietnam also lacks the appropriate supply chains to increase exports to more profitable regulated markets. Furthermore, many of the domestically produced and registered drugs may not comply with GMP (Pharmaceutical Inspection Co-operation Scheme Good Manufacturing Practice) standards observed in regulated markets, with 2-3 percent of drugs per annum failing to meet national quality standards.

**Opportunities**

Unlike the Chinese and Indian markets, local competition for innovative and complex treatments is not a threat to new investors as even major domestic manufacturers are still small and medium in size with limited capital, R&D resources as well as supply chains.

Therefore, with the right strategy, foreign pharmaceutical companies can benefit by involving in this early stage of the industry supply chains as there are yet to be large competitors in the market.

Investors can also take advantage of the preferential tariffs under agreements like the EU-Vietnam free trade agreement (EVFTA). EU investors are now allowed to establish a company to import pharmaceutical products and sell to local distributors or wholesalers. EU investors are also allowed to build warehouses and carry out clinical research and trials.

As per the EVFTA, Vietnam will also align with international standards on pharmaceuticals which means that products already certified in the EU will not require additional testing and certification in Vietnam, thus reducing time and costs in the Vietnamese market.

**Challenges**

One of the key challenges for foreign pharmaceutical businesses operating in Vietnam is that FDI logistic companies and foreign pharmaceutical companies are not permitted to distribute pharmaceutical products directly and must sell their products to domestic pharmaceutical distributors.

However, the distribution network is still fragmented, inefficient, and suffers from poor transparency. This system is subject to significant price distortion with hospital procurement involving bids that are 130-245 percent higher than the procurement price added with logistic costs.

Another challenge for MNCs operating in Vietnam is the potential delays in regulatory approval for new medicines. The Drug Administration of Vietnam remains the only branch of the Ministry of Health responsible for

managing and approving market authorization, assessing GMP, and releasing business and product licenses.

Therefore, initial reviews can be expected to take up to a year, while clinical trials can take up to at least three years, and assessment of stability data adds another year. Such a lengthy regulatory procedure may undermine the competitiveness of any foreign pharmaceutical enterprise that aims for further approval for the US and European markets while making it more challenging for these companies to recoup the investment.

Advertising is another area that should be of concern to pharmaceutical businesses in Vietnam. Advertising of over-the-counter drugs is allowed in Vietnam, but the advertising of prescription drugs is illegal. This could create problems for the public to find access to a drug.

**Market entry strategies**

In spite of all the barriers facing foreign producers, the best way to enter the market and become established in Vietnam is to find a local partner that has the ability to form connections with pharmaceutical distributors. Using this strategy, one can also eliminate some of the challenges faced with brand awareness due to the restrictions on advertising in Vietnam.

Finding a local company to start such a joint venture or an M&A is an important first step to entering the market in Vietnam.

Other market entry options include investing in the form of a drug importer, operating a manufacturing company through an M&A, and participating in pharmaceutical-related bidding packages of certain central and local state agencies. In our experience, an M&A is one of the best options to enter the Vietnamese market.

Though Vietnam has implemented steps to reduce its dependence on imports and develop its domestic industry, most drugs are still imported, including raw materials. This offers an opportunity for companies to become involved in the industry supply chains with the right market entry strategies.

**Takeaways**

The pharmaceutical industry in Vietnam is a promising market for growth in Asia with increasingly higher demand thanks to an expanding population, improved income, increasing urbanization, and environmental conditions.

Nevertheless, lack of proper development and investment are the main concerns for the country's pharmaceutical industry. In order to efficiently elevate the standards of the domestic pharmaceutical industry, Vietnamese companies and regulatory bodies will need to rely on a transfer of knowledge, skills, and resources from foreign partners.

Pharmaceutical companies also need to look to other suppliers besides major markets like China and India to ensure a sufficient supply of raw materials for production to meet the increasing demand.

New Delhi: Indian generic drugmakers have immense potential for growth in Vietnam which currently meets bulk of the domestic demand by importing medicines, Vietnam's domestic pharmaceutical industry is currently able to meet just 53 per cent of the country's demand, representing significant opportunities for Indian drugmakers as the country is among the leading global producers of generic medicines.

There is an enormous potential for Vietnam to purchase generic medicines from India, but the former is actively trying to get Indian pharmaceutical companies to manufacture in Vietnam instead of importing,"

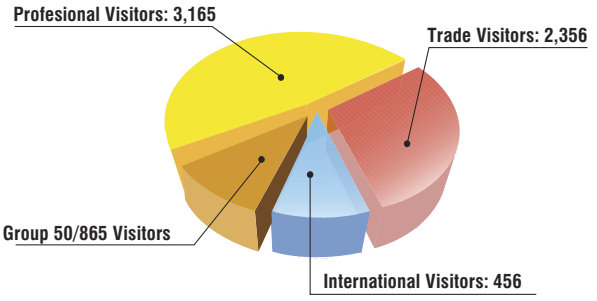
In addition to finished products, the country also provides raw pharmaceutical materials, and generic medicines for the Vietnamese market.

The medicines and raw materials imported from India are reasonably priced and meet the diverse needs of Vietnamese, especially those living in remote areas, Vietnamese pharmaceutical firms want to cooperate and call for investment from foreign companies, including those from India to attract capital, technology and high-quality human resources "Therefore, there is room for cooperation between Vietnamese and Indian businesses in the field,"



## SHOW ACHIEVEMENT IN 2022

**Visitors: 6,386**




### Statistic report:

| | |
|---|---|
| Total Exhibition Area (sqm) | 5,500 |
| Countries & Regions | 15 |
| Booths | 200 |
| Domestic | 155 |
| Foreign | 45 |
| Exhibitors | 150 |
| Domestic | 108 |
| Foreign | 42 |
| Satisfied | 81,8% |
| Commit to participate in 2023 | 88% |

### Introduction and display

- **Pharmaceuticals | functional foods**
  Material, pharma-chemicals, pharmaceuticals, Eastern, Southern, Middle pharmaceuticals
- **Medical equipment:**
  Surgical Equipment / Diagnostic Equipment / Rescue Equipment, Equipment for physical therapy and orthopedic surgery, Medical consumables / furniture and equipment / Medical protection products and consumable materials
- **Hospital | Clinic**
  Hospital – clinic / Project Equipment, furniture , Medical software, healthcare services
- **Dental | Ophthalmology**
  Medicines, Dental instruments, equipment, Ophthalmology instruments, equipment
- **Medical tourism:**
  Medical tourism service, high quality health care
- **Technology:**
  Early diagnosis technology, Vaccines: prevention, preventive medicine
- **Technical support equipment, health care products, Healthcare technology:**
  Mobility / assistive equipment, communication aid ...
- **Equipment for chemical and experiment:**
  Analysis and image processing Equipment / Equipment for Laboratory, The application of biotechnology, Technical & Medical Equipment / Equipment and products for treating water, waste medical.
- **Equipment and beauty products:**
  Cosmetic equipment, materials and beauty care products, massage & spa products and instruments...
- **Other equipment and products:**
  Teaching aids, mock-up for universities, colleges, Media, insurance, Medical magazines.

### Major Activities in 2023

- Specialized seminars, consultation/ Q&A regarding market information, pharmaceuticals, medical equipment, dentistry, bone grafts during the exhibition...
- Gratitude Raising awareness, consultant activities, disease prevention.
  Visit tours to hospital & pharmaceutical factories…
- Awarding the Certificates of Ministry of Health – Show Medal to Partners, Exhibitors.
- Consumer stimulus programs/ Lucky draw.


## General Information

**Time:** May 10 - 13, 2023

**Venue:** Friendship Cultural Palace,
91 Tran Hung Dao, Hanoi, Vietnam

**Opening hour:**

| | | |
|---|---|---|
| May 10, 2023: | Opening ceremony: | 09:00 - 10:00 |
| | Visitor: | 10:00 - 17:30 |
| May 11 - 12: | Visitor: | 09:00 - 17:30 |
| May 13: | Visitor: | 09:00 - 12:00 |

**Scale:**

- 12.000 sqm | 450 booths | 350 Exhibitors

**Visitors (estimated):**

- 12.000 local and international visitors
- More than 86% is professional visitors

**International Specialized Exhibition:**

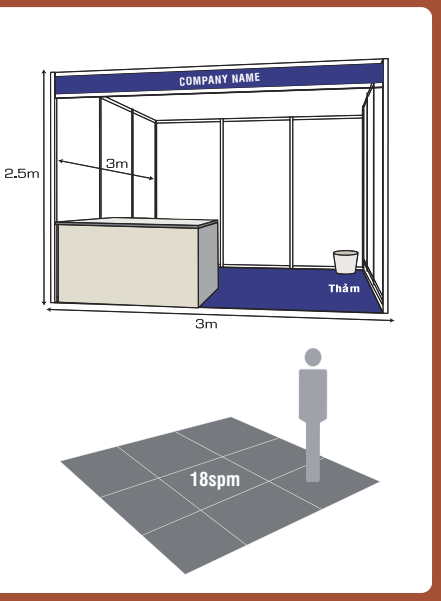
| | |
|---|---|
| The 12th International Dental | Vietnam Dental 2023 |
| The 16th Vietnam International Hospital | Vietnam Hospital 2023 |
| The 10th International Medical Tourism | Medical Tourism 2023 |
| Preventive Medicine Exhibition | VAPM 2023 |
| Rehabilitation, Eldercare, Healthcare Technology | REHAtex Vietnam 2023 |
| Innovative Care Conference and Exhibition | The Cares Vietnam 2023 |

## Participation procedure

- Return the application form, signed contact, transfer 50% of the deposits for total space rental fee in cash or by T/T to the organizer no later than 7 days from the signing day.
  The remaining amount should be paid 45 days before the opening day
- **Vietnam Medical Products Import and Export JSC**
  Account (USD):001.1.37.0076671
  VIETCOMBANK - Operation centre - 31- 33 Ngo Quyen Str., Hanoi
  SWIFT code: BFTV VNVX 001
- **Vietnam Advertisement and Fair Exhibition JSC**
  Account (USD): 0021371057051
  VIETCOMBANK HANOI - 11B Cat Linh Str., Hanoi
  SWIFT code: BFTV VNVX 002

**Standard booth (9sqm):**

Partition, fascia board with Exhibitors name in English, one information counter, two folder chairs, single phase socket (5A-220v), two fluorescent tubes, carpet floor one paper-disposed basket.




**Rawspace: The minimum area is 18sqm**

Exhibitors are required to design and build their own booths or pavilion. Raw space exhibitors have to send booth design to the Organizer approval before March 25, 2023

**Free Services:**

- Attending seminars, conferences, meetings...
- Trademark, product will be widely promoted
- To be provided with entrance badges, invitations for opening ceremony
- To be briefly introduced with company profile in the show catalogue
- Exhibits to be secured during closing time of the Exhibition
- Genaral cleaning security service to be provided

**Venue: Friendship Cultural Palace, 91 Tran Hung Dao, Hanoi, Vietnam**

**Sponsor for programs & activities:**

Various exclusive sponsor packages are available to maximize your brand and make yours stand out among others! Please contact us for further details.

**Sponsors: 2016 - 2022**

**Standing organizing board**

**Vietnam Medical products inport and Export JSC - VIMEDIMEX VN**
Add: 138 Giang Vo Str., Hanoi, Vietnam
Tel: (+84) 243 844 3462 * Fax: (+84) 243 845 9247
E-mail: planvimehanoi@gmail.com
Website: www.vimedimex.com.vn

**Vietnam Advertisement and Fair Exhibition JSC - VIETFAIR**
Add: Bien Phong Newspaper Bldg., 40A Hang Bai Str., Hoan Kiem Dist., Hanoi
Transaction office: 3rd Floor, No. 7, Tran Phu St., Dien Bien Ward, Ba Dinh Dist., Hanoi
Tel: (84) 24 3936 5566 E-mail: xttm@vietfair.vn
Website: www.vietfair.vn www.vietnammedipharm.vn

# Vietnam Medi-Pharm 2023

VIETNAM MEDI-PHARM Since 1994

Hospital · Dental · REHAtex Vietnam · CMEXPO · Medical Tourism

**Date: May 10 - 13, 2023**

**Venue: Friendship Cultural Palace - 91 Tran Hung Dao St., Hanoi, Vietnam**

## Application Form

Company (Exhibitor): .....

Authorized person name: .....

Position: .....

Address: .....

Tel: ..... Email: .....

Exhibit: .....

**We would like to book:**

**A. Space Requirements:**

❑ **Package standard booth** USD 2,880/unit of 9 sqms x ..... sqms = ..... USD

USD 2,500/unit of 6 sqms x ..... sqms = ..... USD

Each standard booth includes: space with carpet, partitions, 2 fluorescent tubes,1 electric socket point 220V/5A, 1 information counter, 2 chairs, company name in English on the fascia, 1 waste basket

❑ **Raw space (minimum 18 sqms indoor, 30 sqms outdoor):**

**Indoor:** USD 288 ..... sqms = ..... USD

**Outdoor:** USD 170 ..... sqms = ..... USD

**B. Advertising in the offical Exhibition cactalogue: (size 14.5 x 20.5)**

❑ **Cover Page 2, 3, 4:** **- Colour:** USD 1.200 x ..... page(s) = ..... USD

❑ **Inside full page:**

**- Colour:** USD 700 x ..... page(s) = ..... USD

**- B/W:** USD 500 x ..... page(s) = ..... USD

**Return the application form, signed contact, transfer 50% of the deposits for total space rental fee by T/T to the organizer no later than 7 days from the signing day. The remaining amount should be paid 45 days before the opening day**

**Please return this form to:**

**Vietnam Medical products inport and Export JSC - VIMEDIMEX VN**

Add: 138 Giang Vo Str., Ba Dinh Dist., Hanoi, Vietnam

VIETCOMBANK, Operation centre, 31-33 Ngo Quyen Str., Hanoi

Account No: 001.1.37.0076671 SWIFT code: BFTV VNVX 001

**VIETNAM ADVERTISEMENT AND FAIR EXHIBITION JSC (VIETFAIR)**

Bien Phong Newspaper Building – 40A Hang Bai – Hoan Kiem - Hanoi

At Vietcombank Hanoi, 11B, Cat Linh Street, Quoc Tu Giam Ward, Dong Da District, Hanoi, Vietnam

USD Acc no. : 0021371057051 SWIFT code: B F T V V N V X 002

**Date:**.....

**Signature with Company stamp**

**Standing organizing board**

VIMEDIMEX VN

**Vietnam Medical products inport and Export JSC - VIMEDIMEX VN**
Add: 138 Giang Vo Str., Ba Dinh Dist., Hanoi, Vietnam
Tel: (84) 24 3844 34 * Fax: (84) 24 3845 9247
E-mail: planvimehanoi@gmail.com
Website: www.vimedimex.com.vn

VIETFAIR

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Website: www.vietfair.vn www.vietnammedipharm.vn

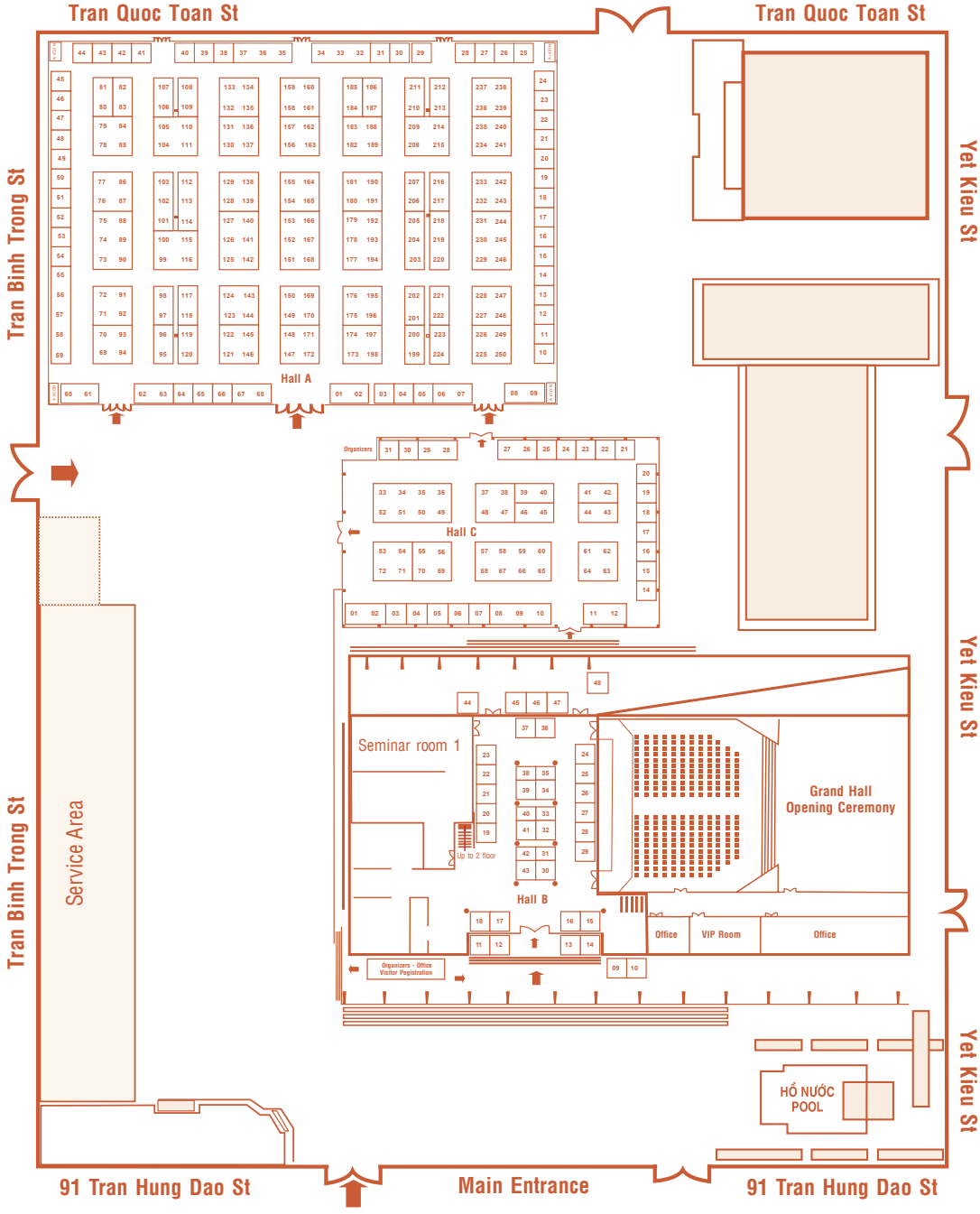
# Vietnam Medi-Pharm 2023

VIETNAM MEDI-PHARM
Since 1994

Hospital · Dental · REHAtex Vietnam · Medical Tourism

Date: May 10 - 13, 2023
Venue: Friendship Cultural Palace - 91 Tran Hung Dao St., Hanoi, Vietnam

## FLOOR PLAN



# In Rajya Sabha & In Lok Sabha

## In Rajya Sabha

## Generic medicines

### Rajya Sabha Unstarred Question No. 1056

### Shri Anil Desai:

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

(a) whether it is a fact that Government has taken several steps to popularise generic medicines, if so, the details thereof;

(b) whether there are sufficient PM Jan Aushadhi Kendras in all the States to provide these medicines to general public, if so, the details thereof; and

(c) whether these generic medicine are at par with medicines manufactured by other pharma companies, quality-wise?

### Answered on 26th July, 2022

**A.** (a): With an objective of making quality generic medicines available at affordable prices to citizens of the country, *Pradhan Mantri Bhartiya Janaushadhi Pariyojana* (PMBJP) was launched by the Department. Under the Scheme, dedicated outlets known as *Pradhan Mantri Bhartiya Janaushadhi Kendras* (PMBJKs) are opened to provide quality generic medicines at affordable prices. Prices of medicines sold through these outlets are 50%-90% less than that of branded medicines prices in the open market.

In order to enhance awareness about the Scheme, various media platforms like print, outdoor, TV & Social Media, etc. are being used regularly. Further, Pharmaceuticals & Medical Devices Bureau of India (PMBI), the implementing agency also organizes seminars and workshops across the country with PMBJK owners, doctors and other stakeholders. Further, for enhancing awareness about the scheme and promoting generic medicines 'Jan Aushadhi Diwas' is celebrated on 7th of March every year. This year a booklet on celebration of the 4th Janasushadhi Diwas was also circulated to all States/UTs for further dissemination and spreading awareness about the Scheme.

(b): Under the Scheme, till 30.06.2022, about 8,742 PMBJKs have been opened across the country. State/UT-wise list of PMBJKs is attached as **Annexure.**

(c) : Only quality Generic Medicines are sold through PMBJKs. In order to ensure quality of the products, PMBI procures medicines only from World Health Organization – Good Manufacturing Practices (WHO-GMP) certified suppliers. Apart from this, each batch of drug is tested at laboratories accredited by 'National Accreditation Board for Testing and Calibration Laboratories (NABL). Only after passing the quality tests, the medicines are dispatched to PMBJP *Kendras*.

**Annexure**

**Statement referred to in part (b) of the Rajya Sabha Unstarred Q. No. 1056 for answer on 26.07.2022 raised by Shri Anil Desai regarding Generic Medicines**

| State/UT- wise list of PMBJKs opened across the country till 30.06.2022 | | |
|---|---|---|
| **St. No.** | **Name of the State/UT** | **Number of PMBJK opened** |
| 1 | Andaman & Nicobar | 9 |
| 2 | Andhra Pradesh | 170 |
| 3 | Arunachal Pradesh | 28 |
| 4 | Assam | 96 |
| 5 | Bihar | 300 |
| 6 | Chandigarh | 7 |
| 7 | Chhattisgarh | 208 |
| 8 | Delhi | 382 |
| 9 | Goa | 10 |
| 10 | Gujarat | 511 |
| 11 | Haryana | 237 |
| 12 | Himachal Pradesh | 62 |
| 13 | Jammu and Kashmir | 212 |
| 14 | Jharkhand | 78 |
| 15 | Karnataka | 982 |
| 16 | Kerala | 990 |
| 17 | Ladakh | 2 |
| 18 | Lakshadeep * | 0 |
| 19 | Madhya Pradesh | 253 |

| | | |
|---|---|---|
| 20 | Maharashtra | 635 |
| 21 | Manipur | 32 |
| 22 | Meghalaya | 15 |
| 23 | Mizoram | 12 |
| 24 | Nagaland | 19 |
| 25 | Odisha | 356 |
| 26 | Puducherry | 20 |
| 27 | Punjab | 307 |
| 28 | Rajasthan | 137 |
| 29 | Sikkim | 3 |
| 30 | Tamil Nadu | 845 |
| 31 | Telangana | 170 |
| 32 | DNH & D&D | 35 |
| 33 | Tripura | 24 |
| 34 | Uttar Pradesh | 1175 |
| 35 | Uttarakhand | 218 |
| 36 | West Bengal | 202 |
| Grand Total | | 8,742 |

** Medicines are directly supplied to the administration of Union Territory of Lakshwadeep*

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

## Compliance of Court Orders Regarding Generic Medicine

### Rajya Sabha Unstarred Question No. 1064

### Dr. Ashok Bajpai:

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

(a) the details of the orders made by the Courts from time to time to promote the use of generic medicines in the country;

(b) the status of compliance with such orders of the Courts;

(c) whether Government is aware that despite the orders of the Courts and the relevant regulations of the Medical Council of India, generic medicines are not being prescribed by most medical practitioners; and

(d) if so, the details of the strategy of Government to address such non-compliance?

### Answered on 26th July, 2022

**A.** (a) to (d): Clause 1.5 of Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 prescribes that every physician should prescribe drugs with generic names legibly and preferably in capital letters and he/she shall ensure that there is a rational prescription and use of drug. Further, the erstwhile Medical Council of India (MCI) had issued Circulars dated 22.11.2012, 21.04.2017 and 18.01.2013 vide which all the Registered Medical Practitioners have been directed to comply with the aforesaid provisions.

The National Medical Commission Act, 2019 empowers the appropriate State Medical Councils or Ethics and Medical Registration Board (EMRB) of the Commission, to take disciplinary action against a doctor for violation of the provision of the aforesaid Regulations. When complaints are received against the violation of code of ethics for doctors, such complaints are referred by EMRB (previously by erstwhile MCI) to the concerned State Medical Councils where the doctors/medical practitioners are registered. States have been advised to ensure prescription of generic drugs and conduct regular prescription audits in public health facilities.

Practice of prescription audit is one of the prerequisites for getting certified under the National Quality Assurance Standards (NQAS).

Under National Health Mission (NHM), support is provided for provision of essential generic drugs free of cost in public health facilities. The support is not only for drugs but also for various components necessary for effective implementation of Free Drug Service Initiative viz. strengthening/setting up robust systems of procurement, quality assurance, IT backed supply chain management systems like Drugs and Vaccines Distribution Management Systems (DVDMS) developed by CDAC, warehousing, prescription audit, grievance redressal, Information, Education and Communication (IEC) training.

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

## In Lok Sabha

## Export/Import

### Lok Sabha Unstarred Question No. 1702(H)

### Shri Rakesh Singh:

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

(a) whether there has been an increase in imports and exports last month;

(b) if so, the details thereof;

(c) whether the proportion of import is less than export;

(d) if so, the details thereof including the reasons therefor;

(e) whether any remedial measures have been undertaken to reduce the trade deficit ascribed to imbalance in import export; and

(f) if so, the details thereof?

### Answered on 27th July, 2022

**A.** (a) & (b): The overall (merchandise plus services) exports increased from USD 52.8 billion in June 2021 to USD 64.9 billion in June 2022. The overall (merchandise plus services) imports increased from USD 52.9 billion in June 2021 to USD 82.4 billion in June 2022.

(c) to (f): The proportion of export and import in total trade is 44:56. The trade deficit is a function of import and export. Imports take place to meet the gap between domestic production and supply, consumer demand and preferences for various products. Many imports are inputs for further manufacturing in India and exports. For boosting exports government has taken the following measures recently:

(i) Foreign Trade Policy (2015-20) extended upto 30-09-2022.

(ii) Assistance provided through several schemes to promote exports, namely, Trade Infrastructure for Export Scheme (TIES) and Market Access Initiatives (MAI) Scheme.

(iii) Rebate of State and Central Levies and Taxes (RoSCTL) Scheme to promote labour oriented textile export has been implemented since 07.03.2019.

(iv) Remission of Duties and Taxes on Exported Products (RoDTEP) scheme has been implemented since 01.01.2021.

(v) Common Digital Platform for Certificate of Origin has been launched to facilitate trade and increase Free Trade Agreement (FTA) utilization by exporters.

(vi) 12 Champion Services Sectors have been identified for promoting and diversifying services exports by pursuing specific action plans.

(vii) Districts as Export Hubs has been launched by identifying products with export potential in each district, addressing bottlenecks for exporting these products and supporting local exporters/ manufacturers to generate employment in the district.

(viii) Active role of Indian missions abroad towards promoting India's trade, tourism, technology and investment goals has been enhanced.

(ix) Package announced in light of the COVID pandemic to support domestic industry through various banking and financial sector relief measures, especially for MSMEs, which constitute a major share in exports.

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

## Study on MSMEs

### Unstarred Question No. 1767.

### Shri Dayanidhi Maran:

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

(a) whether the ministry has conducted any study or analysis of the current fiscal health and recovery for Micro, Small Medium Enterprises (MSMEs) and if so, the details thereof;

(b) whether the Ministry has conducted any forensic audit of the impact of the schemes and beneficiaries who availed the stimulus package offered in the wake of the COVID-19 pandemic and if so, the details thereof;

(c) the details of the steps being taken by the Government to onboard MSMEs on digital platforms;

(d) the manner in which MSMEs are being supported to gain access to international markets; and

(e) the steps taken by the Government to remove barriers in credit flow for MSMEs?

### Answered on 27th July, 2022

**A.** (a) & (b)**:** As per information received from Ministry of MSME, the Ministry got a Study done by Small Industries Development Bank of India (SIDBI) to

assess the impact of change in MSME classification on the Sector and impact of Covid-19 pandemic. The study, inter alia, revealed that around 65 percent of the MSMEs surveyed, have availed the benefits under Emergency Credit Line Guarantee Scheme (ECLGS) and around 36 percent of the respondents (MSMEs) also availed loans under the Credit Guarantee Fund Trust for Micro and Small Enterprises scheme. Government has taken note of the points highlighted in the said report.

As informed by Department of Financial Services, Ministry of Finance, studies have been conducted to assess the impact of the support to MSMEs through ECLGS. These studies have found that under ECLGS, the loans were fairly easy to obtain, cost effective, helped to fulfill short term financial needs and eased the cash flow burden. The scheme has been successful in helping MSME sector to navigate through the crisis.

**(c) to (e):** Ministry of MSME has developed the Udyam portal for the registration of MSMEs. This portal has the provision for onboarding of MSMEs on TReDS platforms and GeM as on date.

Procurement and Marketing Support (PMS) Scheme is under implementation to benefit the MSMEs through promotion of new market access initiatives like organizing / participation in National / International Trade Fairs / Exhibitions / MSME Expo, etc. held across the country.

Besides, Government has announced the Aatma Nirbhar Bharat package for MSMEs in 2020. The package included: (i) Subordinate Debt for stressed MSMEs; (ii) Rs. 3 lakh crore Emergency Credit Line Guarantee Scheme (ECLGS) for business, including MSMEs, which has subsequently been increased to Rs. 5 lakh crore; (iii) Rs. 50,000 crore equity infusion through Self-Reliant India Fund; (iv) New revised criteria of classification of MSMEs; (v) New registration of MSMEs through 'Udyam Registration' for Ease of Doing Business; (vi) No global tenders for procurement up to Rs. 200 crore.

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

## FTA with EU

### Lok Sabha Unstarred Question No. 1698

### Shri Kotha Prabhakar Reddy:

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

(a) whether India and the European Union(EU) has resumed negotiations for a comprehensive Free Trade Agreement (FTA), a move aimed at strengthening economic ties between the two regions since 2014 onwards;

(b) if so, the details of the business/trade transacted with each European country, country and year-wise including the present status thereof?

### Answered on 27th July, 2022

**A.** a) : Yes, Sir. The India-EU FTA negotiations have resumed in June 2022.

b) : The year-wise bilateral trade between India and EU Countries is as under:

*(Values in USD Billion)*

| | | Export | | | Import | | | Total Trade | | |
|---|---|---|---|---|---|---|---|---|---|---|
| S. No. | EU Country | 2020-21 | 2021-22 | Apr- June, 2022 | 2020-21 | 2021-22 | Apr-June, 2022 | 2020-21 | 2021-22 | Apr- June, 2022 |
| 1 | GERMANY | 8.12 | 9.88 | 2.63 | 13.64 | 14.96 | 3.50 | 21.77 | 24.85 | 6.13 |
| 2 | BELGIUM | 5.24 | 10.08 | 2.62 | 6.94 | 9.95 | 2.72 | 12.18 | 20.03 | 5.34 |
| 3 | NETHERLAND | 6.47 | 12.54 | 4.61 | 3.32 | 4.48 | 1.50 | 9.79 | 17.02 | 6.10 |
| 4 | ITALY | 4.74 | 8.18 | 2.47 | 3.86 | 5.05 | 1.49 | 8.60 | 13.23 | 3.96 |
| 5 | FRANCE | 4.78 | 6.64 | 1.91 | 4.34 | 5.78 | 0.84 | 9.13 | 12.42 | 2.75 |
| 6 | SPAIN | 3.24 | 4.73 | 1.29 | 1.51 | 2.05 | 1.23 | 4.75 | 6.78 | 2.51 |
| 7 | POLAND | 1.65 | 2.72 | 0.68 | 0.71 | 1.12 | 0.31 | 2.36 | 3.85 | 0.99 |
| 8 | SWEDEN | 0.76 | 1.04 | 0.26 | 1.00 | 1.45 | 0.43 | 1.77 | 2.49 | 0.68 |

| | | Export | | | Import | | | Total Trade | | |
|---|---|---|---|---|---|---|---|---|---|---|
| S. No. | EU Country | 2020-21 | 2021-22 | Apr-June, 2022 | 2020-21 | 2021-22 | Apr-June, 2022 | 2020-21 | 2021-22 | Apr- June, 2022 |
| 9 | DENMARK | 0.76 | 0.94 | 0.26 | 0.59 | 0.89 | 0.21 | 1.34 | 1.83 | 0.46 |
| 10 | IRELAND | 0.56 | 0.69 | 0.15 | 0.41 | 1.14 | 0.58 | 0.98 | 1.82 | 0.73 |
| 11 | AUSTRIA | 0.45 | 0.56 | 0.22 | 0.62 | 0.83 | 0.20 | 1.08 | 1.39 | 0.42 |
| 12 | GREECE | 0.55 | 1.08 | 0.17 | 0.14 | 0.30 | 0.05 | 0.69 | 1.38 | 0.22 |
| 13 | PORTUGAL | 0.84 | 1.19 | 0.25 | 0.11 | 0.16 | 0.04 | 0.95 | 1.36 | 0.30 |
| 14 | FINLAND | 0.28 | 0.34 | 0.14 | 0.71 | 0.88 | 0.29 | 1.00 | 1.22 | 0.43 |
| 15 | CZECH REPUBLIC | 0.49 | 0.63 | 0.23 | 0.39 | 0.59 | 0.21 | 0.88 | 1.22 | 0.44 |
| 16 | ROMANIA | 0.37 | 0.59 | 0.22 | 0.19 | 0.26 | 0.07 | 0.57 | 0.86 | 0.29 |
| 17 | HUNGARY | 0.50 | 0.55 | 0.15 | 0.22 | 0.29 | 0.09 | 0.71 | 0.84 | 0.24 |
| 18 | SLOVENIA | 0.35 | 0.49 | 0.14 | 0.27 | 0.30 | 0.06 | 0.63 | 0.80 | 0.21 |
| 19 | CROATIA | 0.14 | 0.49 | 0.15 | 0.04 | 0.06 | 0.02 | 0.18 | 0.55 | 0.17 |
| 20 | LITHUANIA | 0.16 | 0.33 | 0.14 | 0.32 | 0.20 | 0.02 | 0.48 | 0.53 | 0.16 |
| 21 | MALTA | 0.32 | 0.48 | 0.19 | 0.02 | 0.02 | 0.03 | 0.34 | 0.50 | 0.23 |
| 22 | BULGARIA | 0.17 | 0.25 | 0.05 | 0.13 | 0.17 | 0.07 | 0.30 | 0.42 | 0.12 |
| 23 | SLOVAK REP | 0.16 | 0.17 | 0.05 | 0.04 | 0.10 | 0.02 | 0.19 | 0.27 | 0.07 |
| 24 | LATVIA | 0.10 | 0.13 | 0.04 | 0.05 | 0.13 | 0.06 | 0.15 | 0.27 | 0.10 |
| 25 | CYPRUS | 0.09 | 0.14 | 0.02 | 0.02 | 0.07 | 0.01 | 0.11 | 0.21 | 0.03 |
| 26 | ESTONIA | 0.05 | 0.06 | 0.03 | 0.06 | 0.07 | 0.02 | 0.11 | 0.13 | 0.05 |
| 27 | LUXEMBOURG | 0.01 | 0.01 | 0.01 | 0.03 | 0.07 | 0.01 | 0.04 | 0.08 | 0.03 |
| | **Total of EU Countries** | **41.36** | **64.96** | **19.08** | **39.72** | **51.40** | **14.07** | **81.08** | **116.36** | **33.15** |

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

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FEATURE

# We're at a turning point in the history of medicine

***Vas Narasimhan,**
***Reimaging medicine as CEO of Novartis***

Science and technology are advancing at an unprecedented pace, and we have more knowledge at our fingertips than ever before. They are leading to breakthroughs in healthcare and medicine—and only in stepping back and considering the full arc of human progress in medicine can we truly recognize the extraordinary moment we're in.

These developments come at an important time, as meeting the opportunity to improve human life remains more necessary than ever. Even today, the vast spectrum of disease remains largely untreated. We're currently only able to significantly impact less than 10% of the 7,000-8,000 diseases known to affect humans.

As science advances, so will the biopharmaceutical industry and the medicines we create—and if we innovate and work across sectors in the right ways, we'll translate that science into lasting, meaningful progress.

## A 120-year innovation arc

The modern biopharmaceutical industry came to form in the late 1800s, and for the better part of a century, we primarily used chemicals to modulate functions in the body. At the beginning, we still didn't fully understand the inner workings of cells or how diseases progressed.

Science and industry pushed forward, and as we learned more about the biology of health and disease, we created better, safer, more effective chemicals, today called small molecule drugs.

Then, roughly 40 years ago, science led to a breakthrough. Protein therapies and monoclonal antibodies allowed us to modulate the activity of specific proteins—a sea change in our ability to go after the exact molecular drivers of disease.

These were and still are central contributors to improving life expectancy and quality of life, and alongside traditional vaccines, they were essentially the only kinds of medicines brought forward by the industry in its first 120 years.

## Scientific progress at a historic pace

Today, we're probing human biology at its most fundamental levels, and coupled with technological advancements, we've created entirely new, unprecedented ways to intervene in disease. In just the past few years, multiple new types of treatments—a new generation of medicines—have been approved and are reaching patients, including RNA therapies, RNA vaccines, cell therapies, gene therapies, and radioligand therapies.

Juxtaposed against early advances in science, innovation's pace is dramatically accelerating. Just a few years after Emmanuelle Charpentier and Jennifer Doudna won the Nobel Prize in Chemistry for their work on CRISPR-Cas9, a method to edit DNA, we're exploring DNA and RNA gene and base editing to make new medicines. Its breakneck pace could shape an exciting future in which we could have an even greater impact on patients' lives.

### The journey of specificity

We're not just coming up with more treatment options and technologies—the science is getting more specific. As we understand more of the inner workings of our cells, we're able to correct the biological roots of disease more precisely.

Drugs from our industry's early days were generally nonspecific. Some went inside the cell, while some stayed outside the cell. In our current era, we're able to affect the inner machinery of the cell. *For the first time in the history of medicine, we have the ability to impact the entire continuum of cellular machinery—to interact with what is essentially the source code of the human cell.*

We'll likely be able to combine treatments across that continuum, mixing and matching modalities to find new solutions for the most intractable diseases. We're already able to combine radiotherapy and targeted therapies in a way that allows us to deliver ultra-precise radiation directly to tumors in some cancers. And many more exciting possibilities are on the horizon. Imagine if we could treat sickle cell disease by fixing the errant gene that causes it? Novartis is partnering with the **Bill & Melinda Gates Foundation** to not only realize that ambition, but also to find ways to ensure a breakthrough innovation like that, which could completely change the current treatment paradigm, would be accessible to patients in need, including the large patient population across sub-Saharan Africa.

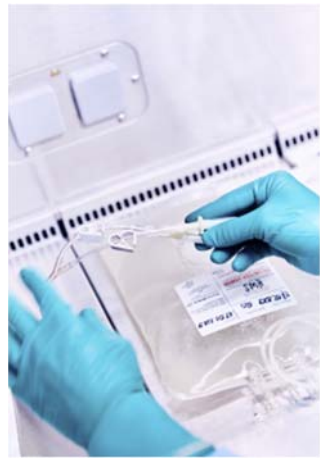
### Industry's next chapter: focus and expertise

As we look toward the healthier future within reach, we know *business is key to translating science into widespread human progress.* This is a longstanding truth underscored throughout the pandemic, and the leadership and innovation power of our industry will continue to benefit humankind.

In response to the rapid pace of innovation, we're seeing companies focusing and investing to ensure they can translate scientific advances into impacts people can feel in their everyday lives. Novartis, for example, has executed over $100 billion in transactions in the past four years to focus our company while building capabilities across advanced technologies in medicine.

The companies that will last and lead in this next chapter will be the ones who build unique capabilities across the entire organization, from R&D to advanced manufacturing. Because in most cases, the new medicines coming to the fore are tremendously complex. Not every company can reprogram disease-causing errors in a patient's cells or manufacture a single injection that corrects a faulty gene.

### A changing healthcare ecosystem



It's up to the biopharmaceutical industry to parse new technologies, figure out which advances work best for certain diseases and patient groups and, with effective collaboration across health systems and sectors, help ensure patients who need access have access to the latest biomedical innovations, regardless of geography, economic status, or anything else.

The pace of innovation risks outpacing the ability to deliver the newest medicines to patients. To meet the ecosystem where it is to facilitate both innovation and access will require new and closer collaborations with academia and government. We must collectively

bring our best to the work of reimagining medicine and ensuring health systems are prepared to deliver new kinds of medicines. It has and will continue to challenge our industry's approach to bringing medicines to patients, including novel approaches to pricing and more. This is something I hope to share more thoughts on soon.

**In it for the long haul**

As evidenced by the 120+ year innovation arc of our industry, this is a long-term endeavor. Progress will come both incrementally and in watershed moments that feel like progress has arrived all at once. Like all efforts to push the boundaries of our understanding of life, there will be failures that lead to important learnings along the way.

Nothing about this is easy. It requires courage for companies to change and do things that have never been done before. But we keep going. We invest, we learn, we become stronger, and we grow.

I believe companies who do this consistently will innovate and lead for decades, perhaps even centuries to come, and will ultimately have the greatest impact on humanity.

They won't just participate in the future of medicine—they will shape it.

**Courtesy:Vas Narasimhan, CEO Novartis is an author of this article. Views expressed are purely personal*

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NATIONAL NEWS

## Pricing regulator closely watching prices of diabetes drug going off patent

***Regulator looking to cap prices of Sitagliptin, Linagliptin and combinations***

*The National Pharmaceutical Pricing Authority (NPPA) has capped the prices of these two drugs in the range of Rs 16-25 per tablet.*

With more patients shifting to new gliptins (a category of diabetes drugs) as they go off-patent, the national pharma pricing regulator has moved quickly to cap prices of two diabetes molecules Sitagliptin and Linagliptin and their combinations.

Around nine per cent of India's 1.4 billion population has Type-2 diabetes, and this has crossed 11 per cent in few urban pockets. It is thus estimated that 100 million people in India have diabetes, but about half the Type-2 diabetes cases go undiagnosed.

Government sources reveal that the regulator is keeping a keen watch on diabetes drug prices, and also on the new category of drugs (gliptins and gliflozins) that are now going off-patent. "As generic brands enter the market, the competition is bringing the prices down. Thus patients, who could not afford these drugs earlier, are shifting. Therefore, it's necessary to keep a tab on the prices," said the official.

The National Pharmaceutical Pricing Authority (NPPA) has capped the prices of these two drugs in the range of Rs 16-25 per tablet. While Sitagliptin and its combinations (with metformin etc) have been capped between Rs 16-21 per tablet, for linagliptin and its molecules it has been capped at Rs 16-25 per tablet. Linagliptin, a BoehringerIngelheim drug, is set to go off-patent next year.

Sheetal Sapale, president-marketing, AWACS, a research and analytics firm explained that 5 per cent of Sitagliptin (plain doses) is captured already by generic brands within a month of this molecule going off patent. Around 27 players with 85 generic brands have already flooded the market, and over the next few months around 50 players with 100 sitagliptin and its combination brands are expected to hit the Indian market.

She says that prices have already crashed-–while the innovator price of Sitagliptin is Rs 36-45 per tablet, the generic brands are priced in the range of Rs 7-15. "The

generic brands are one-third of the innovator prices. And there is also a large price range among generic brands—the lowest priced one is half that of the highest priced generic brand," she adds.

While many patients who can afford it may prefer to stay with the innovator brand, this patent expiry may also generate fresh prescriptions. People who are now on basic treatment using an old class of sulphonylurea drugs, and who have not opted for gliptins due to affordability concerns, may now shift to gliptins. Already drugs in this space, such as vildagliptin, teneligliptin have gone off patent.

Sitagliptin (plain) has clocked a 54 per cent jump in volumes in July over June, according to AWACS data, while there has been a value growth of 14 per cent.

The overall anti-diabetes market has declined by one per cent during the past 12 months (up to July), but in July alone, there has been a value growth of 12.7 percent owing to this one drug going off patent.

The churn in the diabetes market started some years back when in 2015 Teneligliptin lost its patent around 2015 and Glenmark was the first Indian firm to launch the drug at a 55 per cent lower price. Following Glenmark's generic entry, several other players stormed the market leading to a price war. In December 2019, Novartis' novel drug vildagliptin lost its patent, following which a slew of generic brands entered the market, resulting in a sharp price drop of 70 percent within a month or so.

| Overall | Sitagliptin | Sitagliptin +Metformin combination | |
|---|---|---|---|
| Players | 27 | 27 | 27 |
| Brands | 85 | 34 | 36 |
| MSD (MRP/ tablet) | Rs 36-45 | Rs 20-23 | |
| Others | Rs 9-21 | Rs 12-21 | |

*Source: Sohini Das, Business Standard, 28.08.2022*

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## Pharma industry expects to report 7%-9% revenue growth in FY23: CRISIL

***The rating agency's estimates are based on a study of 184 drug makers that account for 55 per cent of the Rs 3.4 lakh crore-a-year sector revenue.***

Domestic pharma industry is expected to report moderate revenue growth of 7-9 per cent in the

current fiscal, due to headwinds in export sales in the regulated markets and high-base effect in the domestic formulations business, as per rating agency CRISIL. Operating profitability will shrink another 200-250 basis points (bps) after the 130 bps decline last fiscal due to continued pricing pressure in the US generics market, and high input and freight costs which offset moderate revenue growth, it said.

The rating agency's estimates are based on a study of 184 drug makers that account for 55 per cent of the Rs 3.4 lakh crore-a-year sector revenue.

CRISIL stated that the domestic formulations market is expected to grow 7-9 per cent this fiscal, on a 15 per cent growth last fiscal, led by a 6-8 per cent average price increase allowed by the National Pharmaceutical Pricing Authority in March 2022 and on the back of new product launches.

While the demand for Covid-19 induced drugs and vitamins is fading, a pickup in lifestyle-related chronic portfolio drugs and a few acute portfolio drugs, such as in the dermatology and ophthalmology segments, is likely to drive demand this fiscal, it added.

CRISIL Research Director Aniket Dani said the growth in US generics market will moderate given continued pricing pressure.

"The rupee's depreciation saves some blushes, though. Exports to other regulated markets could grow faster as global companies diversify geographically," he added.

*Source: BusinessToday.in, 23.08.2022*

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