

# IPGA TODAY

NEWSLETTER OF INDIAN PHARMACY GRADUATES' ASSOCIATION



June Issue 2022 RNI No. : DELENG/2013/51512



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- NEW DRUGS UPDATES
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- CIRCULARS & NOTIFICATIONS
- IPGA NEW MEMBERS
- IPGA WELFARE TRUST MISSION



**Dr. Atul Kr. Nasa**  
President-IPGA  
Managing Trustee-  
IPGA Welfare Trust  
Vice President-AIDCOC

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# From the Desk of the President

Dear Pharmacy Graduates,

Hopefully, all of you and your family members are safe and maintaining the norms of social distancing and taking precautions related to Covid-19. Our country has record-breaking vaccination drive and now we have completed a good number of booster dosing of the vaccines with good precautions, things are coming back to normal. During Covid times, IPGA did many activities and now many activities are carried out in physical mode by state branches, Women Forum and Students Forum. In this time, IPGA has done further expansion and started the Odisha and Chhattisgarh Branch and Local Chapters in Amroha, Uttar Pradesh and Ludhiana, Punjab. Further, IPGA CEC organized a CEC member meeting on 16<sup>th</sup> April 2022 in virtual mode and discussed many reforms of IPGA functioning. Further, it gives me immense pleasure to mention that IPGA has represented to UPSC, New Delhi to incorporate Pharmacy as an optional subject in the Civil Services Examination by UPSC. I would extend my invitation to all of you to join the 34<sup>th</sup> Annual IPGA Conference which is going to be held at D.Y. Patil Deemed to be University, Navi Mumbai on 24<sup>th</sup> – 25<sup>th</sup> September 2022. It is going to be organized by IPGA – Maharashtra Branch. Further, IPGA extend heartfelt congratulations to newly elected president of Pharmacy Council of India Dr. Montukumar M Patel. I am sure that this issue of IPGA Today will provide the detailed information to all of you on the various professional activities of our association conducted for the benefit of our community and society.

Stay Safe and Stay Healthy,

Dr. Atul Kr. Nasa





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## Journey of a Veteran Pharmacist:

# *Farewell as Editor-in-Chief: IPGA Today*



### **Journey of a Veteran Pharmacist: Farewell as Editor-in-Chief, IPGA Today**

Mr. Pawan Kr. Jaggi is a very familiar & respectable name in the pharmaceutical field. He has been a reliable source of information, knowledge, inspiration & motivation for pharma personnel of various fields, be it students, pharmacy teachers, industrial pharmacists, many medical legal practitioners, state & centre drug control officers, blood bank officials of innumerable patients or their caretakers, retail & wholesale chemists etc. He has left a positive vibe & sense of reverence for every soul he has touched. He is very lucky to have a very supportive family which helps him maintain a perfect balance between personal and professional life. He has many commitments which includes family business & many other professional activities.

Mr. Pawan Kr. Jaggi was born on 19-12-1952 in Delhi. His father Mr. C.L. Jaggi himself was a pharmacist & his friend, philosopher & guide. He motivated him to pursue career in Pharmacy.

Mr. Pawan Kr. Jaggi joined College of Pharmacy Pusa in 1970 to pursue Diploma in Pharmacy. At that time no other such college existed in & around Delhi & even this college offered only Diploma course of 2-years duration after schooling.

As the luck would have it, by the time he completed diploma course in 1972, College of Pharmacy was affiliated to Delhi University & a 4-year bachelor of Pharmacy course had just been initiated. On the basis of diploma, he was admitted to second year of B. Pharm. Throughout he was ranked First or second in class & was the eventual silver medallist in B. Pharm. 1975 batch.

Mr. Pawan Kr. Jaggi always remained in good books of his teachers due to his respectful, obedient behaviour & excellence in studies, active participation in in-door & out-door sports, essay competition, debates, quiz programmes and cultural programmes. He enjoyed merit scholarship throughout pharmacy education.

He reveres his teachers in pharmacy who brought the best out of him & he is still in personal touch with many of the teachers till date. During job also he continued his education side by side and went on to complete LLB from Delhi University in 1982

and Masters in Business administration (MBA) from IGNOU in 1992.

In professional front, after completion of B. Pharm., he joined a small volume parenteral Manufacturing unit in Delhi as manufacturing Chemist. During his four-year tenure, he performed his duties with a utmost sincerely & diligence, earning good name & fame for self and his organization.

In 1979 he cleared the UPSC written & Oral exam for the post of Drug Inspector in Delhi Government. He was ranked overall second amongst the three hundred plus aspirants vying for the coveted eight posts of Drugs Inspectors.

From August 1979 on joining Delhi Drugs Control Dept. Till 31st December 2012 when he eventually retired, he discharged every duty assigned to him with great enthusiasm, complete sincerity & honesty. Among other assignments, he was "Officer on Special Duty- Legal", In charge of Intelligence cell, First Appellate Authority under Right to Information Act. Before relinquishing office, he held the post of Licensing Authority & Head of Office in Drugs Control Dept. Delhi.

Like – the fruit bearing trees have to endure maximum stones pelted at them, he too had more than his fair share of adversities which he eventually overcome successfully & gracefully.

Immediately after retiring from Drug Control Department, Delhi, he was appointed as the "Chief Pharmacy Executive in Delhi Cancer Institute" in January 2013. He performed his duties graciously for the next six years before eventually calling it a day in Jan. 2019.

In addition, he was given the charge of Grievance officer. He streamlined all jobs and made work systematic. He co-ordinated various activities related to Pharmacy welfare of the patients and their caretakers.

He organised team of Pharma professional to carry on these duties thereafter also. A substantial number of patients and their family members benefitted immensely due to the benevolent & ever helping hand extended by him to one & all.

During his chequered career Pawan Kr. Jaggi received innumerable awards & accolades for his selfless attitude and unflinching dedication to Pharmacy profession.

Some of these are being listed below –

- i) Best Drugs inspector award 2002
- ii) IPGA Fellowship Award 2011
- iii) K.C. Chatterjee memorial Award 2014

- iv) IPGA lifetime Achievement Award 2016
- v) Pharma Ratan Award 2017

Mr. Pawan Kr. Jaggi has been associated with IPGA (Indian Pharmacy Graduates Association) for nearly five decades. He became life member of IPGA in 1973 right at the time of inception of this association during his study period. His life membership number is LM-05

He has held several IPGA posts from 2009 to 2021 and was till recently Editor in Chief of IPGA today newsletter. He is also founding member of IPGA Welfare Trust. For decades he has been fostering the IPGA Mission – “To improve the professional status of Pharmacy Graduates and to secure their rightful place in Pharmacy and Allied Professions”. He has jointly prepared a booklet for career guidance of Pharmacy students titled- “PHARMACY AS A CAREER”

As active member of IPGA and IPGA Welfare Trust he has been actively promoting IPGA aided lectures, seminars, exhibition, job fairs etc. in collaboration with Pharmacy Colleges / Universities various pharmacy institutes and industries.

Mr. Pawan Kr. Jaggi has been appointed by various Govt. departments as expert person of various committees for Pharmacy Profession related issues. He was a member of state Quality Assurance Cell as expert person for drafting standard operating procedures (SOPs) for pharmacies & Hospital.

He has proactively played his part as chairperson of Reception committee & other committees' member in successfully hosting IPCs in & around National Capital region in the years 2001, 2008, 2013, 2018.

He has been disseminating latest information on regulatory issues, clarification of legal terminologies etc. He is considered as a role model by Pharmacy students, faculty members, officers of central and state drug control officers etc. He has been instrumental in improvement of working of blood banks and Government approved Drug Testing Facilities in Delhi.

Mr. Pawan Kr. Jaggi has attained great stature as “TRAINER” is frequently summoned for imparting orientation, induction & refresher training to Drug Control officers of entire Central Drug Standard Control Organization (CDSCO) & state. He has been a regular visitor to National Institute of Pharmaceutical Education and Research (NIPER) for training Programmes, implementation and framing medical protocols in National Institute of Health and Family Welfare, Delhi.

In times of Pandemic, he has been involved regularly in conducting Webinars in collaboration in with various pharma universities/ institutes on topics related to pharmaceutical interest. The webinars were regularly attended by pharmacy students, faculty members, industrial pharmacists, regulatory

officials, marketing personnel etc.

Some of the topics of their lectures / webinars include –

1. Safe disposal of unused / expired medicines.
2. Overview of important laws related to drug industries
3. Regulation in twice of pandemic & lessons for the future.
4. Guidance Documents for handling of medicine by patients/ customers
5. Career opportunities in Regulatory Affairs.
6. Pharmacists' role in patient safety.
7. Career opportunities in the field of Pharmaceutical / medical science.
8. Licensing Requirements & procedure for Retail wholesale pharmacy in India.
9. CDSCO & its function.
10. Webinar on New Cosmetics Rules 2020.

Mr. Pawan Kr. Jaggi keeps a copy of Drug laws with him hard or soft copy whenever he travels & regards it like a holy book – Ramayana or Gita. He has developed expertise in interpretation of statutes, Drug related laws partly because of his legal background & partly due to sheer dedication & commitment towards profession.

He has been instrumental in suggesting many amendments in drug related rules & pharmaceutical monographs etc. His uncanny ability and expertise in communication skill has been very handy in his acumen to guide many of his office colleagues and assigned advocates in the proper manner for presenting a case, drafting appropriate replies to queries in several legal cases.

Mr. Pawan Kr. Jaggi has co-authored a book titled “Pharmaceutical Jurisprudence” also he has been an external examiner in regulatory affairs subject in Amity university & Jamia Hamdard university. He has been a member of Institutional Ethics Committee for clinical Trials in several Delhi Hospital like GTB Hospital, Delhi State Cancer Institute & Rajiv Gandhi Super Speciality Hospital. He has delivered lecture and chaired scientific sessions during IPCs in PAN India.

Mr. Pawan Kr. Jaggi is a strict vegetarian, teetotaler, very religious minded human being. After every lecture /presentation, he leaves his e. mail and mobile contact details for the audience to put forward any query related to the pharma profession in future also. He remained very prompt in replying to each query in spite of his busy schedule. He has dedicated five decades of his life for the benefit of profession of pharmacy and upliftment of the professional image of pharmacists. He is truly a Pharma Ratan. Entire fraternity of IPGA wishes Mr Pawan Jaggi a very happy, Healthy and prosperous life ahead. His contribution in making IPGA TODAY a big brand is worth appreciation.

Contents Contributed by: **Mr. Vinod Chhabra**

# WHO International Drug Monitoring Center

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## Introduction

The WHO international drug monitoring centre was established in 1968, the WHO program for international drug cooperation (WHO-PIDC) Monitoring (PIDM) is a tool that allows WHO member states to track and analyse new adverse reaction signals from data provided to the WHO global individual cases safety report database. Participate in the monitoring of drug safety, particularly in the identification of dangerous drugs.

- The WHO programming operations are overseen by UMC,
  1. which collects, assesses, and disseminates information from member countries on the advantage and disadvantages of drug effectiveness and hazards.
  2. working with members countries on research and development and practice of pharmacovigilance.
  3. Notifying member country NRA of potential drug safety issues via the WHO signal mechanism;
- Policy problems are handled at the WHO headquarters in GENEVA, SWITZERLAND.
- WHO PROGRAM INTERNATIONAL DRUG MONITORING REPORT adverse reactions to the drug. Individual case reports or ICRS, are used with pharmaceuticals. ICRS to the VIGIBASE global database.

was discovered that thalidomide, a drug, might cause limb deformities in babies if taken by women during pregnancy. This occurrence marked the modern starting point for a science devoted to patient concerns induced by drug usage. Pharmacovigilance is related to science and its activities.

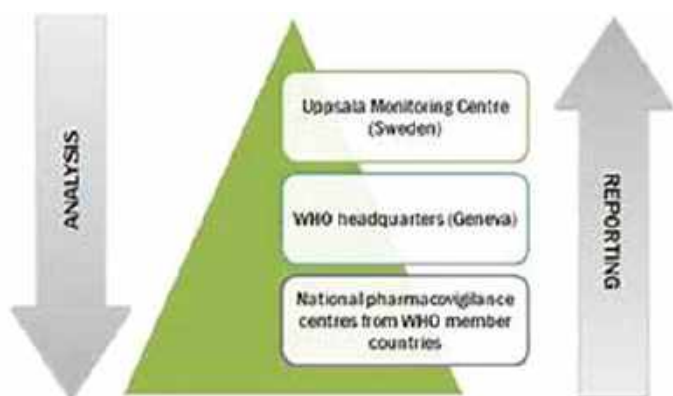
The WHO program goal is to ensure that early indications of previously diagnosed diseases are detected.

The unknown medication-related safety issue has been identified and is being investigated.

The 16-world health assembly (1963) adopted a resolution on the importance of prompt action in the dissemination of information on adverse drug reactions, which led to the establishment of the WHO pilot research project with ten countries to develop an international system for detecting the adverse reaction. the pilot project activities culminated in the current WHO International Drug Monitoring Centre, which has evolved to become global meteors of national pharmacovigilance centre in over 140 countries.

## WHO COLLABORATING CENTERS

- UMC SWEDEN
- MOROCCO
- THE NETHERLAND
- NORWAY
- INDIA



## HISTORY OF WHO INTERNATIONAL DRUG MONITORING CENTRE

In 1968, the first effective multinational drug monitoring cooperation began. The concepts arose as a result of the so-called thalidomide tragedy, which occurred in 1960 when it

## FUNCTIONS OF THE WHO PROGRAMME INTERNATIONAL DRUG MONITORING INCLUDE:

1. New adverse reaction is being identified and analyzed.
2. Exchange of information between WHO and National centre.
3. Periodical newsletters, guidelines, and books in the field of pharmacovigilance and risk management are published.
4. Utilize all clinical information management technologies, including ADR case reports. Eg: the WHO drug dictionary.
5. The adverse reaction terminology of the world health organization. Training and consulting services for national centers and countries creating a pharmacovigilance system.
6. Software for managing case reports that is tailored to the demands of national centre annual meetings for

## WHO Programme for International Drug Monitoring



representatives of the national centre where scientific research is presented as well as organizational issues are discussed.

### WHO Collaborating Centre the Uppsala Monitoring Centre (UMC):

- The Uppsala monitoring centre is located in Uppsala, Sweden.
- In 1978, the foundation was established.
- Sweden and the world health organization (WHO) have reached an agreement.
- It is an international governing board.
- WHO headquarters is in charge of policy.
- Self-sufficiency.
- Six members of the board, three from the government, and three from the world health organization.
- The program is handled by UMC, while WHO is in charge of policy.

### The program includes National Center:

Each participating country's Ministry of Health, or equivalent, establishes a National Center for pharmacovigilance, which is responsible for touching with WHO on pharmaceutical safety issues. WHO and its Collaborating Center (The Who Collaborating Center for International Cooperation) coordinate the network of country centers.

Uppsala, Sweden drug monitoring and more recently, the WHO collaborating center for Advocacy and training in pharmacovigilance.

Accra, Ghana, and Rabat, Morocco WHO Collaborating Center for pharmacovigilance. The Uppsala Monitoring Center, or UMC, is the name given to the facility in Uppsala. UMC is a foundation established by the Swedish government by a WHO agreement. According to the agreement, WHO headquarters is in charge of technical concerns and day-to-day operations.

Individual Case Safety Reports (ICSR) are received from

national centers in the WHO network, and UMC maintains a database of them.

Vigilance, the database, now has about 7 million descriptions (as of December 2011) which include vaccines, herbals, etc.

### The Advantages and Responsibilities of Membership:

When a country joins the program as a member. The national policies must be implemented. The benefits and responsibilities of membership are well understood among center workers.

The following are the primary advantages:

- Obtaining Vigibase access (containing worldwide medicine safety data).
- Early warnings regarding potential safety risks.
- Terminologies and software (tools for carrying out national pharmaceutical safety).
- Access to the international network and support guidelines and resources on pharmacovigilance practice (knowledge and expertise of member countries) in addition, each year, member of the WHO program gathers in a member nation for a meeting.

The annual conference of the National Pharmacovigilance Centers to share knowledge and ideas.

### Role of Uppsala Monitoring Center:

Uppsala Monitoring Center is one of five officially recognized collaborating centers, and it is in charge of all technical and scientific components of the project of the WHO global pharmacovigilance network.

It entails:

1. Analysing vigilance data and identifying potential safety issues as signals.
2. Conduct research.
3. Using debate and research to broaden the scope of pharmacovigilance as well as consultation.
4. Collect, evaluate and disseminate information from members countries about the benefits, drawbacks, and hazards of medication to enhance medical care and public health around the world.
5. Collaborate with other countries that are members.
6. Tools for data entry, management, retrieval, and analysis, such as big flow and vigilyze, are being developed and provided.

### Role of WHO in Pharmacovigilance:

- To find Adverse reactions that have not been detected in clinical trials program.
- Uppsala Monitoring Center, Sweden -collecting case reports.

- Jobs performed are:
  1. Detection and review of signals.
  2. Advisory and education.
  3. Research and development.

## Requirements for Participation in the WHO International Drug Monitoring Programme:

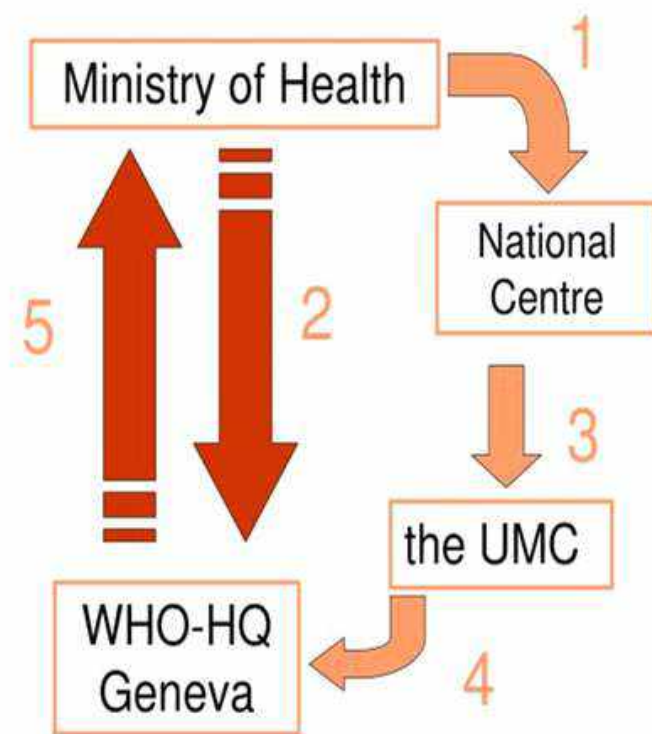
- A basic understanding of the methodology of spontaneous reporting: a country that joins the WHO program must have a system in place to collect individual case safety reports. The national program should have a reason for existing to ensure continuity of operations and access to appropriate staffing and technical facilities. By operating the program, management staff will gain the necessary expertise to interpret data from the spontaneous adverse reaction reporting system.
- A national pharmacovigilance center: the WHO program for international drug monitoring is only open to WHO member states. The competent national health authority appoints a national center to represent each state. The national center's administrative affiliation differs by country. the national center is usually related to the national drug regulatory body, but it can also be linked to a university, a hospital department, or a drug information service.
- Technical ability to meet WHO reporting requirements:

The WHO program for international drug monitoring's core asset is its adverse reaction database.

How to join the WHO Programme for International Drug Monitoring:

- An official application to join the WHO international drug monitoring program.  
The appropriate health authority shall send the program to WHO headquarters in Geneva.  
The country authority the institution and the person in charge should be identified in the application.  
In the WHO program, a person represents the country as a national center.  
From the time the formal agreement is signed, the country will be considered an Associate Member Country.  
A membership application has been received.  
The majority of the benefits are available to the Associate Member country.  
Full member country is supplied with service.
- UMC should receive a sample of at least 20 ICSRs gathered as a part of the National Pharmacovigilance Program. UMC can provide you with reporting instructions. Please keep in mind this step might be taken at

the same time or even before a formal meeting.  
The application is forwarded to the WHO. The example



report will be put through its pages.  
UMC employees should check for technical conformity with the reporting standard.  
The national centers will be notified of any deviation when the two are compatible, and UMC will notify WHO Headquarters if the report is received.  
The country that has applied will obtain confirmation of its admission to WHO from WHO Headquarters.  
The step involved in joining the WHO program are outlined in the program

## WHO Advisory Committee on the Medical Product Safety(ACSMOP):

- It was established in 2003 to provide WHO, including its collaborating centers for International Drug Monitoring (THE UMC), with recommendations on medicinal product safety
- It advises the WHO on the journal and specialized pharmacovigilance issues.
- The committee which has 12 members is made up of a WHO expert advisory panel for drug evaluation and drug policies and management, as well as relevant WHO clusters and expert advisory panels.
- Every year, ACSOMP meets to discuss current and emerging pharmacovigilance issues with a particular

focus on a public health issue

5. The ACSOMP meets for 1 year in GENEVA at the WHO headquarters.

## The Vigibase System Requires A National Support Center:



The national centers are responsible for the timeliness, completeness, quality of reports, etc. it helps in the pharmacovigilance center for signal detection and signal strengthening.

## Vigilyze

It is a signal detection and management tool that starts with insight from the member of WHO PIDM on how to use the medication more safely as a starting point for efficient quantitative signal identification? It aids in the management of National signals including quantitative assessment.

## Signal Detection

### What is Signal Detection at UMC?

The goal of signal detection is to identify and describe any potential harm to the patients as a result of their medication use. Signal detection is a core function of UMC

UMC monitor vigilance, the global database of reported drug side effects regularly for previously unrecognized or incomplete document side effect. With the millions of adverse events reports in vigilance, UMC uses a combination of computerized data mining methodology and clinical report interpretation to prioritize medicinal adverse effect combos. Simultaneously quantitative screening of scientific literature gave extra information that might be used to conduct more specific searches in vigilyze and access weather further inquiry into potential safety signals is required, international monitoring is done regular basis

## Clinical Assessment:

Medicine adverse effect combos that require further investigation are evaluated by UMC signal teams in a collaboration with external clinical specialists to determine the seriousness and impact of suspected side effects on public health and to combination for further investigation. To establish a signal, 1 more than 1 one case report is usually necessary, the evaluation of case series reporting the same adverse events, UMC uses the criteria which were devised by sir AUSTIN BRADFORD HILL in 1965, to analyze the causality of multiple case reports. After individual reports on possible side effects have been analyzed and summarized and systemic literature has been reviewed for additional data, a decision is reached as to whether the strength of the case warrants the formulation of signals.

## Reference:

1. <https://www.who.int/teams/regulation-prequalification/regulation-and-safety/pharmacovigilance>

**Lokmat Times**

## PCI proposes 'exit exam' for B Pharm degree holders

**Aim is to check knowledge of students before they get registered as pharmacists**

**MEHDOOB INAMDAR**  
AURANGABAD, NOV 30

If you think mere passing the four-year Bachelor of Pharmacy (B Pharm) course is enough for getting registered as pharmacists, you are wrong.

The Pharmacy Council of India (PCI) recently proposed to make 'exit examination' mandatory for registration as a pharmacist. Talking to this scribe, Dr Babasaheb Ambedkar Marathwada University (Bamu) vice-chancellor Pramod Yeole, who was recently appointed PCI president, said that the PCI had recently proposed to make 'exit examination' compulsory for B Pharm degree holders to check their knowledge before they enter the pharmacy industry.

**Exit Exam for D Pharm**

A similar examination for Diploma in Pharmacy (D Pharm) pass outs has been introduced since 2018. It is called as D Pharm Exit Examination Regulations (DPEER). Significantly, the PCI has prepared an action plan to upgrade pharmacy education to global standards. It also has plans to collaborate with foreign institutions and health care bodies for generating employment opportunities for Indian pharmacists. The PCI is soon going to launch a web portal for the registration and tracking of pharmacists.

**30 pc seats increased**

There are more than 3,500 diploma and undergraduate pharmacy colleges in the country with a total intake capacity of nearly 3-lakh students seats. In the last two years, the number of seats was increased by about 30 per cent.

He said the PCI had submitted a proposal to the union health minister to revamp the country's pharmacy education. Notably, the number of pharmacy colleges has increased in the last few years compared to engineering colleges. State-level pharmacy councils have been receiving complaints about candidates lacking basic knowledge even after completing an undergraduate degree in pharmacy, the VC said, adding that that is why the PCI had proposed giving 'exit examination' to B Pharm degree holders before issuing them a registration certificate, from this academic year.

# Safety Monitoring of Vaccines in Covid-19

Vanshika Yadav, Arti R. Thakkar

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## Overview of safety monitoring

In this current global situation of pandemic i.e., covid-19, the cases even reached more than 140 million as it is reported by WHO. The death even reached more than 3 million which leads to huge loss. Therefore, there is an urgent need of vaccines that need to be delivered to the population as it needs to be administered worldwide.

Vaccines is a biological preparation that improves immunity to a particular disease. As we know that no vaccine is completely safe and effective as it definitely causes some side effects or adverse effects which can be minor or major. So, to ensure the safety of patient that we are going to administered we need to follow proper rules and regulations that comes withing to check the proper functionality of vaccines and all the related adverse events so that it does not cause any serious health effect and may be toxic.

The vaccine safety is prime for public, manufacture, immunization providers and for the recipients of vaccines.

Importance of safety monitoring of vaccines are:

- It decreases the risk of death.
- Lower risk tolerance.
- Higher standard of safety.
- 

Methods that are generally used for monitoring vaccines safety can be:

- Pre- licensure
- Post-licensure

In the pre-licensure, mainly the studies are carried out on animals like mice, rabbits. Vaccines are tested in thousands of people before being licensed and on the market.

When vaccine is shown to be safe and effective in phase-III, then the manufacturer applies for a license from FDA. The FDA licenses the vaccine itself and licenses the manufacturing plant where the vaccine will be made.

During the application, FDA reviews the following :

- The clinical trial results.
- Product labelling
- Manufacturing plant
- Manufacturing protocol.

In post licensure monitoring, we generally look for the rare reactions which we don't find in each patient. It is rare and found only in 0.1% of population.

Phase-4 reactions studies can be an FDA requirement for licensure. These trials include tens of thousands of volunteers and may address question of long-term effectiveness and safety or examining the unanswered questions identifying in phase-3 phase. Manufacturer need to submit the samples of each vaccine lot and results of their own tests for potency and purity as per FDA before releasing then for public use. The adverse event classification can be: Vaccine induced, vaccine potentiated, programmatic error and coincidental.

But there are various methodological problems that came into way and some of them are as follows:

- Signal detection
- Assessment of causality
- Exposure
- Outcome
- Analysis, confounding and Bias.

Once, all the methodology for the vaccines have been completed further moved to, the reporting system, that is to the National Reporting system and jointly administered by CDC and FDA. This vaccine adverse event system was created in 1990, to unify the collection of all the reports of adverse events after the vaccination. Majorly look for the detection of new or rare events that comes with each new taken.

## Patient risk factors

In the safety monitoring of vaccines the immunization providers have a keen role i.e., vaccine storage and handling, vaccine administration, timings and spacing of vaccine doses, observation of precautions and contraindications, Management of vaccine side effects, Reporting of suspected side effects and even the communication about vaccine benefits and risks.

## Pre-clinical studies of vaccines

All medicines and vaccines undergo rigorous testing for safety and efficacy through clinical trials before they are authorized for use or for going into the market or enter into the market.

Vaccines are extensively tested through several different phases of trials that includes the foremost thing which is pre-clinical study of vaccine.

The identification and management of potential risks

associated with vaccines is the major concern are looking for. Vaccine pharmacovigilance aims to detect adversely events early to trigger accurate risks assessment and appropriate response to the problem. This ensures the minimization of negative effects to individuals. Major goal is to lessen the potential negative impact on immunization programmes.

### **Monitoring adverse vaccine reactions is a major safety component of pre-licensure clinical trials.**

The pre-clinical study use tissue culture or cell- culture systems and animal testing to assess the safety of the candidate vaccine and its immunogenicity, or the ability to provoke an immune response. Animals subjected to use includes mice and monkey. The preclinical study will give researchers an idea about the cellular responses that might be expected in human so that they can also go for a safe starting dose for the next phase of the clinical trials to note further any adverse or side effects for the safe method of administering the vaccine.

Researchers sometimes find it difficult to do the preclinical studies due to challenge studies with the animals, which means that they vaccinate the animals and then try to infect them with the target pathogen. Many candidate vaccines never progress as so far beyond this stage because they fail to produce the desired immune response. The preclinical studies often lasts 1-2 years and usually involves researchers in the private industry.

First the researchers or the sponsors or the private company needs to submit an application for an Investigational new drug IND to the U.S. food and Drug Administration. The sponsor describes the manufacturing and testing process, summarizes the laboratory reports, and describes the proposed study. An institutional review board, representing an institution where the clinical trial will be conducted or not. The FDA has 30 days to approve the application. Once the IND application, has been approved, the vaccine is subject to three phases of testing.

The next step will include the clinical trials with human subjects that includes phase-1 of the vaccine trials followed by phase-2 and phase-3. Then they are subjected to be approval and licensure for the following vaccines.

Once the IND application has been approved, working on the phase-1 of the clinical trials has started that includes the first attempt to assess the candidate vaccine in humans that involves a small group of adults, usually between 20-80 subjects. Depending upon that the vaccine for which age group that is if it will be for children, they are first be tested

on adults and then the gradually step for down the age of the test subjects until they reach their target.

This phase- trial may be non- blinded which is also known as open-label in which the researchers and perhaps subjects know that whether a vaccine or a placebo is used.

The goals of the phase-1 testing are to assess the safety of the candidate vaccine and to determine the type and extent of immune response that the vaccine provokes.

In a small minority, of phase-1 vaccine trials, researchers basically use the challenge model attempting to infect the volunteers with the pathogen after the experimental group has been vaccinated. The participants or the volunteers need to be monitored and conditions carefully controlled.

Phase-2 vaccine trials, basically includes, a larger group pf around several hundred individuals or the participants or the volunteers for the testing. In this, the individuals may belong to somehow a group of acquiring the disease. These trials are randomized and well controlled, and this includes a placebo group. The goals of this phase-2 trials, is to study the candidate vaccine safety, immunogenicity, proposed doses, schedule of immunizations, and the method of delivery.

Phase -3 vaccine trials, the candidate moves to the larger trial group, involving around thousands to ten thousand of people. These phase-3, tests are randomized and double blind and involves the experimental vaccine that is being tested against a placebo. The placebo is usually a saline solution, a vaccine for another disease or some other substances.

The goals of this phase-3, is to assess vaccine safety in a large group of people. Certain rare side effects might not surface in the smaller groups of subjects tested in earlier processes.

It is basically done to detect a significant difference for low-frequency event, the trials would be including around 60,000 subjects.

The vaccine efficacy has also been tested. These factors might include;

1. Does the candidate vaccine prevent disease?
2. Does it prevent infection with the pathogen?
3. Does it lead to the production of antibodies or other type of immune responses related to the pathogen?

The last steps would include the final approval and licensure which is to be done once a successful phase3 trial has been done completely. The vaccine developer will

submit a Biologics License Application to the FDA. Then, the FDA will inspect the factory where the vaccine will be made and approve the labelling of the vaccine.

After licensure, the FDA will continue to monitor the production of the vaccine, including inspecting facilities and reviewing the manufacturers tests of lots of vaccines for potency, safety and purity.

The FDA has the right to conduct its own testing of manufacturers vaccines.

Now, the POST-LICENSURE Monitoring of vaccines will be conducted.

The post licensure surveillance of vaccine safety is critical. The conditions and reasons for safety monitoring change follows licensure for a newly introduced vaccine. It is also known as post marketing surveillance.

Post-license vaccine safety studies can identify adverse events that were not detected in pre-licensure trials and to address questions that arose during pre-clinical phase. Post-licensure vaccine safety studies are conducted once a vaccine is on the market and used in the general population. However, design of post-licensure vaccine safety studies involves pragmatic and scientific decisions, which must be made while balancing diverse stakeholder opinions that includes industry sponsors, regulators, policy makers, health care administrators, insurers, institutional review boards, clinicians, staffs and patient as well who can have numerous and often conflicting demands.

Pharmacovigilance conducted after a product has been licensed and introduced for use in population of vaccine safety is critical. Pharmacoepidemiologic studies are essential in the post licensing surveillance of vaccines in order to evaluate the potential benefits and risks of vaccines used in common practice. Surveillance is required to detect rare or unanticipated vaccine adverse events and to ensure confidence in vaccination.

## **FDA NEW VACCINE APPROVAL PROCESS:**

After evaluation being done, FDA decides whether to approve (license) the vaccine for use in the United States. If FDA approves the vaccine, the company is permitted to market it in the United States for use in the population for which it is approved.

Usually, FDA follows the Path for vaccines from Research to FDA Approval:

- Research and Discovery
- Preclinical Research
- Clinical Trials

- Manufacturing
- FDA Review Staff
- FDA Inspections
- Biologics License Application (BLA)
- Vaccines and Related Biological Products Advisory Committee (VRBPAC)
- FDA Approval
- Prescribing Information and Labelling
- Vaccine Safety Surveillance
- Phase 4 clinical Trials
- Lot Release
- FDA Regulatory Research

**Research and Discovery-** scientists develop concepts for a vaccine based on how the virus or bacteria causes diseases in humans. They test their ideas in the laboratory.

**Manufacturing-** Vaccine manufacturing is complex. Manufacturers must develop a process to consistently and reliably produce thousands of vaccine doses. Before approval, the FDA works closely with vaccine manufacturers to develop the lot release protocol- a template of the tests that will be conducted for each lot (batch) of vaccine after approval.

**FDA Review Staff-** FDA carefully and thoroughly evaluates data and information about the vaccine. A typical FDA review team is comprised of physicians, chemists, statisticians, pharmacologists/toxicologists, microbiologists, experts in post marketing safety, manufacturing and facility investigators, as well as labelling and communications experts.

**FDA Inspections-** The FDA's expert investigators inspect manufacturing facilities to carefully examine and evaluate the process used to make the vaccine to determine compliance with FDA's requirements. Manufacturing facilities are inspected before a vaccine can be approved, and then on a routine basis following approval.

**Biologics License Application (BLA)-** After phase 3 clinical trials meet specified milestones and the manufacturer develops a commercial manufacturing process, the manufacturer submits a BLA to the FDA. A BLA may be hundreds of thousands of pages or more and includes preclinical and clinical data, and details of the manufacturing process and the facility.

**Vaccines and Related Biological Products Advisory Committee (VRBPAC):** Sometimes, the FDA seeks the input of the VRBPAC, a federal advisory committee, VRBPAC is a panel of outside, independent, scientific and public health experts. The FDA considers, but is not bound by, the VRBPAC's recommendations.

**FDA Approval:** The FDA evaluates hundreds of thousands of pages or more of data and manufacturing information as part of a BLA. If the FDA determines the vaccine is safe and effective for its intended use, that it benefits outweigh its risks for the people who are likely to get the vaccine, and the manufacturing process assures product quality and consistency, the FDA will “license” or approve the vaccine.

**Prescribing Information and Labelling:** Based on scientific, data submitted in the Biologics License Application, the FDA reviews and determines whether the prescribing information adequately and accurately reflects the approved indications, usage, dosing and administration. Prescribing information is updated as needed in order to include the most current information about the vaccine that is available and reviewed by the FDA.

**Vaccine safety Surveillance:** The FDA, in collaboration with other federal agencies, academic and large non-government health care systems, uses both passive and active surveillance systems to monitor the safety of vaccines after approval. These systems include the Vaccine Adverse Event Reporting Systems (VAERS), the FDA Sentinel BEST (Biologics Effectiveness and safety) program, a partnership with the Centres for Medicare and Medicaid Services to assess Medicare claims, and the CDC’s Vaccine Safety Datalink.

**Lot Release:** Manufacturers are not permitted to distribute a specific lot (batch) of vaccine until the FDA releases it. To release a vaccine lot, the FDA reviews the manufacturer’s test results that typically include vaccine sterility, purity, potency, and consistency, and may perform confirmatory testing.

**FDA Regulatory Research:** Ongoing research is fundamental to the FDA’s ability to provide effective vaccine regulation. FDA scientists conduct a variety of research that contributes to policy, risks assessments, new methods and standards, and changes to product labelling, including promoting new techniques for assessing vaccine safety, potency, and effectiveness in addition to strategies for new vaccine development.

**COVID-19 Vaccine Development Process:** Bringing a new vaccine to the public involves many steps including vaccine development, clinical trials, U.S. Food and Drug Administration (FDA) authorization or approval, manufacturing, and distribution. Many different public organizations and private companies have worked together to make COVID-19 vaccines which is to be available to the public. While COVID-19 vaccines were developed rapidly, all steps have been taken to ensure their safety and effec-

tiveness.

### The Vaccine Process:

**FROM LAB: INITIAL DEVELOPMENT-** New vaccines are first developed in laboratories. Scientists have been working for many years to develop vaccines against coronavirus, such as those that cause severe acute respiratory syndrome (SARS) and Middle East respiratory syndrome (MERS). SARS-CoV-2, the virus that causes COVID-19, is related to these other coronaviruses. The knowledge that was gained through past research on coronavirus vaccines helped speed up the initial development of the current COVID-19 vaccines.

**CLINICAL TRIALS-** After initial development, vaccines go through 3 phases of clinical trials to make sure they are safe and effective. But, during the development of COVID-19 Vaccines, these phases overlapped to speed up the process so the vaccines could be used as quickly as possible to control the pandemic. No trial phases have been skipped.

**AUTHORIZATION AND APPROVAL-** before vaccines are made available to people in real-world settings, FDA assesses the findings from clinical trials. Initially, they determined that three COVID-19 Vaccines met FDA’s safety and effectiveness standards and granted those vaccines. Then, Emergency Use Authorizations (EUA’s) allowed the vaccines to be quickly distributed for use while maintaining the same high safety standards required for all vaccines. FDA has now granted full approval for Pfizer-BioNTech (COMIRNATY) COVID-19 Vaccine for people ages 16 years and older and for Moderna (Spikevax) COVID-19 Vaccine for people ages 18 years and older. Before, granting approval, FDA reviewed evidence that built on the data and information submitted to support the EUA. This included pre-clinical and clinical trial data and information, as well as details of the manufacturing process, vaccine testing results to ensure vaccine quality and inspections of the sites where the vaccine is made. These vaccines were found to meet the high standards for safety, effectiveness, and manufacturing quality FDA requires of an approved product.

**Manufacturing and Distribution-** The U.S. government has invested substantial resources for both manufacturing and distribution of COVID-19 Vaccines. This allowed manufacturing to begin when the vaccines were still in the third phase of clinical trials so that distribution could begin as soon as FDA authorized each vaccine.

**Tracking Safety using Vaccine Monitoring Systems-** As vaccines are distributed outside of clinical trials, several monitoring systems continue to track them to ensure their

safety. Hundreds of millions of people in the United States have received COVID-19 vaccines under the most intense safety monitoring in U.S. history. Some people have no side effects. Many people have reported common side effects after COVID-19 vaccination, like pain or swelling at the injection site, a headache, chills, or fever. These reactions are common and are normal signs that your body is building protection.

**NOTE:** Reports of serious adverse events after vaccination are rare. CDC and FDA continue to closely monitor several reporting systems, like the Vaccine Adverse Event Reporting System (VAERS), Vaccine Safety Datalink (VSD), and v-safe, which help look for safety issues now that the vaccines are being given to patients in real-world settings across the country.

This means that COVID-19 vaccines have been rapidly developed and distributed to help fight the pandemic. During this process, all steps have been taken by the CDC to ensure their safety and effectiveness.

## Monitoring and Reporting of Covid-19 Vaccine Side Effects:

Further the monitoring of safety of COVID-19 Vaccines are done by U.S. Food and Drug Administration (FDA) where they have fully approved the use of the Pfizer-BioNTech COVID-19 vaccine in people ages 16 years and older and has authorized its emergency use for children ages 5 years and older. All COVID-19 Vaccines currently authorized or recommended for use in the United States are safe and effective. However, CDC recommends that people who are starting their vaccine series or getting a booster dose get either Pfizer-BioNTech or Moderna (mRNA covid-19 Vaccines). The mRNA vaccines are preferred over Johnson and Johnson's Janssen COVID-19 Vaccine in most circumstances. After FDA approves a vaccine or authorizes a vaccine for emergency use, CDC and other federal partners continue to assess the vaccine to determine how well it works under the conditions. Such evaluations are necessary to made as it will help us to understand if the vaccines are performing as expected outside the more controlled setting of a clinical trial. As vaccines uptake increases naturally, we try to monitor that how well the vaccines will work:

- Performs in specific subpopulations.
- Reduce the risk of infection
- Protect against the milder COVID-19 illness.
- Prevent more serious outcomes, including hospitalization.
- Prevent spread of illness.
- Provide long term protection
- Protection against changes in the virus.
- Protect against COVID-19 after the first dose of a 2-dose vaccine because somehow the second dose is delayed.

## Factors Affecting Vaccine Effectiveness:

- Population host factors (people not included in clinical trials who may respond differently to the vaccine).
- Virus factors (Variants).
- Programmatic factors (adherence to dosing schedules or storage/handling of vaccines).

## Existing Safety Monitoring Systems:

As people get vaccinated, CDC, FDA and other federal partners will use the following existing system and the data sources to conduct ongoing safety monitoring. The general public includes:

- CDC and FDA Vaccine Adverse Event Reporting System (VAERS).
- CDC Vaccine Safety Datalink (VSD).
- CDC Clinical Immunization Safety Assessment (CISA) Project.
- FDA and the Centres for Medicare and Medicaid Services.
- FDA Biologics Effectiveness and Safety Systems (BEST).

## Ensuring the continued safety of COVID-19 Vaccine:

It has become a major responsibility for the health workers to ensure the continued safety of vaccine even once it's done to maintain a proper balance in the lifestyle and so as to know that vaccine is not harming anyone. There are COVID-19 vaccine side effects also that needs to be monitored.

This includes majorly the six steps:

- Step1: Ask
- Step2: Assess
- Step3: Communicate
- Step4: Vaccinate
- Step5: Observe
- Step6: Inform

These are the six steps that needs to be followed in proper order to ensure the maximum safety. The foremost three steps need to be done before vaccination and the latter two followed afterwards vaccination.

## CDC and FDA Vaccine Adverse Event Reporting System (VAERS)

VAERS is the nation's early warning system that monitors the safety of vaccines after they are authorized or licensed for use by the U.S. Food and Drug Administration (FDA). VAERS is part of the larger vaccine safety system in the United States that helps make sure vaccines are safe. The system is co-managed by CDC and FDA. VAERS accepts and analyses reports of possible health problems—also called “adverse events”—after vaccination.

Some related facts about VAERS- a passive surveillance system:

- VAERS is a national vaccine safety surveillance program that helps to detect unusual or unexpected reporting patterns of adverse events for vaccines.
- VAERS is a passive surveillance system, meaning it relies on people sending in reports of their experiences after vaccination.
- VAERS accepts reports from anyone, including patients, family members, healthcare providers and vaccine manufacturers.
- Healthcare providers and vaccine manufacturers are required by law to report certain events after vaccination.
- VAERS is not designed to determine if a vaccine caused or contributed to an adverse event. A report to VAERS does not mean the vaccine caused the event.
- If VAERS detects a pattern of adverse events following vaccination, other vaccine safety monitoring systems conduct follow up studies.

### Working of VAERS:

VAERS is part of the larger post-licensure vaccine safety monitoring system in the United States. After vaccines are licensed or authorized for use by FDA, they are continually monitored for safety by multiple, complementary systems. These systems also conduct safety studies in populations that are larger and more diverse than those typically included in vaccine clinical trials.

As a passive reporting system, VAERS relies on individuals to send in reports of adverse health events following vaccination. From these reports, VAERS scientists can:

- Assess the safety of newly licensed vaccines
- Detect new, unusual, or rare adverse events that happen after vaccination
- Monitor increases in known side effects, like arm soreness where a shot was given
- Identify potential patient risk factors for particular types of health problems related to vaccines
- Identify and address possible reporting clusters
- Recognize persistent safe-use problems and administration errors
- Watch for unexpected or unusual patterns in adverse event reports
- Serve as a monitoring system in public health emergencies.

The information collected by VAERS can quickly provide an early warning of a potential safety problem with a vaccine. Patterns of adverse events, or an unusually high number of adverse events reported after a particular vaccine, are called “signals.” If a signal is identified through VAERS, scientist may conduct further studies to find out if the signal

represents an actual risk.

### Advantages of VAERS:

- VAERS accepts reports from anyone. This also allows VAERS to act as an early warning system to detect rare adverse events.
- VAERS collects information about the vaccine, the person vaccinated, and the adverse event. Scientist obtain follow-up information on serious reports.
- All data (without identifying patient information) are publicly available.

### Limitations of VAERS:

- VAERS is a passive reporting system, meaning that reports about adverse events are not automatically collected. Instead, someone who had or is aware of an adverse event following vaccination must file a report.
- VAERS reports are submitted by anyone and sometimes lack details or contain errors.
- VAERS data alone cannot determine if the vaccine caused the reported adverse event.

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## Alwar Local Chapter Report



These online activities were conducted by IPGA Alwar Local Chapter during the first quarter of the calendar year 2022.

Date	Name / Topic of the event	Speaker/ Guest	Mode
22-02-2022	Indo-UK Higher Education & Career Summit 201-2022. Great Careers and courses in the United Kingdom - M.Sc., Stem Cells and Regenerative Medicines	Ms. Claire Merriman & Dr. Eric Hill, with GECF	Online
19-02-2022	Challenges to Healthcare team on Long COVID – Post COVID Complications	Dr. Dheeraj Kaul, MD, USA Dr. Bharti Malhotra, SMS, Jaipur Dr. D. Muralikrishnan, USA Prof. Vikas Sharma, M.Sc., Nursing	Online
05-02-2022	New Designer Drugs and its impact on healthcare.	Dr. D. Muralikrishnan, USA Dr. Indu Pal Kaur, President, Punjab University	Online
29-01-2022	Opportunities and challenges to Indian Pharmacy Graduates in Post COVID Scenario	Dr. Dheeraj Kaul, MD, USA Dr. Lokendra Sharma, SMS, Jaipur Dr. Monica Jain, SMS, Jaipur	Online
23-01-2022	Artificial Intelligence: Application in Pharma Industry	Sh. Ranjit Barshikar	Online

### Pharmacy News

Diploma in Pharmacy Exit Examination(DPEE)Regulations, 2022

**PCI mandate Pharmacy Exit Examination (DPEE) for diploma students to become registered pharmacist in India from 2021-22**

**Gazette of India**

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## Gujarat Branch Report

### Virtual Industrial Visit

PharmaSynth Formulations Ltd. (Haridwar Unit)  
By IPGA Gujarat State Branch & K.B. Institute of  
Pharmaceutical Education and Research, Gandhinagar  
Date: 21st February 2022

K.B. Institute of Pharmaceutical Education and Research, A Constituent college of Kadi Sarva Vishwavidyalaya, Gandhinagar, Gujarat in association with Indian Pharmacy Graduates' Association Gujarat State Branch organized the Virtual Industrial Visit at Pharma Synth Formulations Ltd. on 21st February 2022 at 2 PM. At the event, Dr. Divyesh H Shastri (Gen Secretary, IPGA-Gujarat) welcome the delegates and all the participants and open the events by sharing activities done in past year. Dr. Shrikalp Deshpande, Principal KBIPER, Vice President-IPGA Gujarat welcome the chief guests and all the panelists and participants. The chief guests of the event Dr. Vijay Bhalla (Treasurer, IPGA New Delhi) addressed the participants on the IPGA-organization, management, and activities so far. Dr. Bhagirath Patel (President IPGA Gujarat) followed by speech of Dr. Arvind Kumar Gupta, Director, PharmaSynth Formulations Ltd., and Mr. Arjun

Gupta, CEO PharmaSynth Formulations Ltd. They briefed about Pharmasynth Formulations ltd. to all the participants followed by virtual industrial visit.

More than 500 Participants from all over India were registered and joined in this virtual event through Zoom and few at YouTube live. Around 150 participants at Alwar Pharmacy College joined the live-streaming through projector in one seminar hall. The event was bedecked by eloquent and eminent speaker, Dr. Arvind Gupta. The Virtual tour was divided into several parts in a single video with different sections enlisted as Raw-material or Warehouse unit, Oral powder & Tablet Section, Semisolid Section, Capsule Section, Syrup Section and Packaging Section, QA/QC, Finished Goods Store etc. The video presentation and journey was lucid in flow with sufficient exploratory coverage of each section of pharmaceutical industry. Technical aspects make this journey easy in present time, very insightful under the one umbrella video covered all the industry section. Dignitaries of the event Dr. Jeyabalan Govindasamy, Dean-Alwar Pharmacy College joined as a panelist and facilitated the technical support during the event.



**K.B. INSTITUTE OF PHARMACEUTICAL EDUCATION AND RESEARCH**  
(A Constituent College of Kadi Sarva Vishwavidyalaya, Gandhinagar)

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**INDIAN PHARMACY GRADUATES' ASSOCIATION**  
(GUJARAT STATE BRANCH)

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**Virtual Industrial Visit**  
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Indian Pharmacy Graduates' Association (IPGA)  
(Gujarat State Branch)

**DATE: 21st Feb. 2022**

Click the QR code or given Link below for registration:  
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5 pm to 12 pm  
Zoom

Every industrial revolution brings along a learning revolution

**Virtual Industrial Visit**  
of  
**Pharma Synth Formulations Ltd.**  
Haridwar Unit

of Thanks and final remarks and concluded the webinar a successful event. E-Certificates of participation were awarded to all participants.





## Haryana Branch Report




DST (SERB) & IPGA funded conference hosted by SMAS entitled **“Drug Repurposing - A New Ray to Overcome Covid- 19 Disaster”** held on 29<sup>th</sup> April 2022 at K.R. Mangalam World School, Gurugram.

The School of Medical and Allied Sciences, K. R. Mangalam University, Sohna Road, Gurugram, Haryana organised first national conference on clinical pharmacology. The DST (SERB) & IPGA funded conference hosted by SMAS entitled **“Drug Repurposing-A New Ray to Overcome Covid- 19 Disaster”** was held on 29<sup>th</sup> April 2022 at K.R. Mangalam World School, South City-1, Gurugram and acclaimed the presence of world renowned scientist from all over the country. The Chief guest Dr. S. Eswara Reddy, Joint Drugs Controller, India lit the lamp and inaugurated the ceremony with Prof. C. S. Dubey, Vice Chancellor, KRMU, Prof. Pushplata Tripathi, Pro-vice chancellor, KRMU, Dr. Arun Garg, Convenor and Dr. Manish pal Singh, organizing secretary.

The Guests of Honours Dr. Atul Kumar Nasa President IPGA, Head Drug Control Department, Government of NCT, Delhi and Mr. B.R. Sikri, Director of ABS Mercantiles (P) Ltd spoke about the intricacies involved in the


treatment of COVID-19 and elaborated the phenomenon of Drug repurposing for the treatment of COVID-19. The event was sessioned by several speakers from industry and academia including Dr. Ashok Rattan, Advisory Director Pathkind lab, Dr. Rakesh Sharma Ex-Director, DRDO, Mysore Dr. Dheeraj Kaul, Geriatric Medicine, New York, USA and Dr. Sandeep Sharma Executive QA, Torrent Pharmaceuticals Ltd. The speakers spoke about the latest trending aspects of repurposed drugs such as 2-Deoxy-D-Glucose for COVID-19, their benefits and efficacy in treating the disease. Dr. Ashok Rattan discussed in detail about clinical information of oral anti Covid-19 antiviral drugs.

The event was a grand success with participation of more than 500 delegates including eminent scientists, successful entrepreneurs, senior academicians as well as pharmacists in regulatory authorities, thereby enriching the knowledge and skills of the students, pharmacy graduates, post-graduates and pharmacy professionals. The conference exhibited around 200 scientific poster presentations from the acclaimed researchers from premier organisations of India.



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## Haryana Branch Report

School of Medical Allied Sciences, KR Mangalam University, Gurugram, Haryana, organized “1st National Conference on Clinical Pharmacy on the theme Drug Repurposing- A New Ray to overcome Covid 19 Disaster” on Friday 29<sup>th</sup> April, 2022, for the Pharmacy students as well as Professionals from Industry, Research and Academics from all over the world. The conference was sponsored by Science and Engineering Research Board (SERB), Department of Science and Technology, Government of (India).

The concept behind organizing the “1st National Conference on Clinical Pharmacology” was to bring together the professionals from Hospital Pharmacy, Community Pharmacy, Clinical Pharmacy, Industry, Research, Academics, Regulatory and other sectors of Pharmacy profession on a common platform to accomplish the objectives of drug repurposing of old medicines in treatment of common and rare disorders while addressing future challenges like COVID-19 or POST COVID-19 experiences in the past.

The focus of the event was to give attention and spread awareness regarding repurposing/retesting/repositioning of drugs that offers an alternative to new drug discovery and which had given us a new hope for solving the pandemic COVID problem. Drugs including antiviral, antimalarials, statins and monoclonal antibodies (remdesivir, favipiravir, ribavirin, lopinavir-ritonavir combination) that were prescribed for patients of COVID-19 on compassionate grounds were seen to have promising changes and this experience heralds a new direction towards drug repurposing.

### REPRESENTATION

#### **Chief Guest:**

- Dr. S. Eswara Reddy, Joint Drug Controller (India)

#### **Guest of Honour:**

- Mr. B. R. Sikri, Director at ABS Mercantiles (P) Ltd, Chairman, CII Committee of Life Sciences and Biotech
- Dr. Atul Kr. Nasa, Head Drug Control Department, Government of NCT, Delhi





### Keynote Speaker:

- Prof. Ashok Rattan, MD, MAMS, Common Wealth Fellow, INSA DFG Fellow, Ex- WHO Temporary Advisor (SEARO), Ex- WHO Lab Director (CAREC/PAHO)
- Dr. Pooja Sharma, Director and Head of Medanta Institute of Education and Research
- Dr. Rakesh Sharma, Ex- Director, DRDO, Mysore
- Dr. Sandeep Sharma, Quality Assurance Executive, Torrent Pharma, Baddi, Himachal Pradesh, India
- Dr. Dheeraj Kaul, USA Board certified in Internal medicine and Geriatric Medicine



### Chairman of Scientific Session:

- Dr. Manoj P. Jadhav, Founder and CEO, ISHA Therapeutics, Translational Clinical Pharmacologist
- Prof. (Dr.) Vijay Bhalla, Director, College of Pharmacy, SGT University, Gurgaon
- Prof. Roop Krishen Khar, Director, B. S. Anangpuria Group of Institutions, Faridabad (Delhi NCR)
- Prof. Devender Pathak, Dean and Director, Rajiv Academy for Pharmacy, Mathura, Uttar Pradesh

**Dr. S. Eswara Reddy**, Joint Drug Controller (India), in his address stressed on drug repurposing as a viable treatment option which has emerged as an effective and economical solution in limited time and resources. Also, he explained

his experience with Covid regarding use of older drugs which further augments the importance of this conference.

**Mr. B. R. Sikri**, Director ABS Mercantiles (P) LTD, Chairman, CII committee of Life Sciences and Biotech motivated and gave the message to delegates and volunteers for startups industries, explaining the importance of entrepreneurship in India at personal or national level and to promote health in India and in doing so, contribute towards the fame of India in the world.



**Mr. Atul Nasa**, Deputy Drug Controller, Head of Office cum Licensing Authority, Drugs Control Office, President, IPGA, Vice President –AIDCOC, Executive Member-PCI from Delhi State Drugs Control Department, NCT Delhi graced the occasion as Guest of Honour the event. Mr. Atul Nasa, complemented and elaborated the message of Dr. Eshwara Reddy and Mr. B. R. Sikri and also shared his own experience regarding reuse of drugs since past years.

**Prof. Ashok Rattan**, MD, MAMS, Common Wealth Fellow, INSA DFG Fellow, Ex- WHO Temporary Advisor (SEARO), Ex- WHO Lab Director (CAREC/PAHO)



delivered the keynote address on the theme “Discovery & development of specific, Oral anti Covid-19 drugs”. In his talk, he recalled the pattern of Covid-19 spread since 2019 to the world. He applauded the efforts of the health workers (Doctors and Pharmacist) who tested and repurposed oral drugs to combat the pandemic while simultaneously working on production and testing of vaccine by using serology. He also stressed on some drugs which were initially used for different purpose and underwent repurposing during covid era.

**Dr. Pooja Sharma**, Director and Head of Medanta Institute of Education and Research, delivered the keynote address on the theme “Re-appropriation of drugs- Experience from the Covid pandemic”. She talked about how they (health workers) categorized the Covid patients and treated them with the drugs which are already approved by the FDA for different diseases. She focused on how the repurposing of drug occurs on covid patient on the basis of clinical trial and shared her experience. She also named some drugs as examples which are given to patient.

**Dr. Rakesh Sharma**, Ex- Director, DRDO, Mysore, in his presentation explained about repurposing of 2-Deoxy-D-Glucose (2-DG) during treatment of COVID-19. He elaborated on the life cycle of virus and the steps where we attach our drug combination to destroy the virus. Also, he

explained rationale, clinical/preclinical, pharmacokinetics, pharmacodynamic and scientific basis of repurposing of 2-DG.

**Dr. Sandeep Sharma**, Quality Assurance Executive, Torrent Pharma, Baddi, Himachal Pradesh, India shared his experience of repurposing of Methylene Blue to treat and manage Covid-19. Also, he discussed the challenges encountered during repurposing of Methylene blue in covid era and what is the rationale behind choosing it, problems with conventional therapy and outcomes which give future direction for randomized clinical trials highlighting its multifarious uses.

## PARTICIPATION INFORMATION:

#	Participation in the event	Nos.
1.	Key-note speakers	4
2.	Senior Scientist	3
3.	Young Scientist	2
4.	Postgraduate Students	100
5.	Undergraduate Students	250
6.	Industry persons	50
7.	Other category (Please specify each category) (PhD Scholar)	30





## Karnataka Branch Report



The following activities are conducted by State Branch Karnataka

1. On 20.12.2021 IPGA Secretary Sri Raghuram, Asst Drugs Controller and Joint Secretary Sri Sunil hiplunkar of Groups Pharmaceuticals participated as guests speakers at Continued Pharmacy Education Programa organised by Dawangere Dist Chemists Association at Davangere More then 500 Chemists and pharmacists participated
2. IPGA state Secretary Sri Raghuram Trained the Govt Pharmacy Officers at belagavi on 17.01 under capacity

- building traini program organised by State ( Trained such four batche 35 Pharmacy Officers at Dist Training Center, Belgavi Institute of Medical Sciences, Belgavi.
3. Several NGO's including IP state branch conducted mega blood donation camp at belagavi in association with Drug Control Department on 26.01.22 at Belagavi 432 units of blood collected during the camp and are donated to BIMS, KLE hospitals belagavi.





## Madhya Pradesh Branch Report



IPGA MP State Branch Activities from Dec 2021 to March 2022.

IPGA MP State Branch Jan Ayushadhi Awareness Programme.

IPGA MP State Branch MSME Awareness Programme.

IPGA MP State Head Dr Karunakar Shuukla met MSME officials to plan Campus Recruitment Drive

IPGA MP State Head Dr Karunakar Shukla done MOU for Campus Recruitment of UG Students.

IPGA MP State EC Meeting held at MP State Headquarter Indore.

IPGA MP State Branch have given the Financial Assistance to Indore Institute of Pharmacy for E Conference.

IPGA MP State Branch Organized Industrial Educational Trip with UG Students of Dr. APJ Abdul Kalam University.





IPGA MP State Branch celebrated World Pharmacist Day with students of Dr APJ Abdul Kalam University Indore.

IPGA MP State Branch organised Indoor Sports Activity.







## Rajasthan Branch Report



The following activities of IPGA Rajasthan including all activities of local chapters, Women's forum, Student forum of IPGA in Rajasthan State, during the past three months.

1. National Webinar on "Optimization Techniques for in-process Quality Control of Ayurvedic Formulations" organized by IPGA Women Forum & B.N. University, Udaipur Rajasthan. Dr. Pallavi Manish Lavhale, Professor & Principal, Ram-Eesh Institute of Vocational & Technical Education, Greater Noida, U.P. on Feb 26, 2022 05:00 PM India.
2. IPGA sponsored Panel Discussion on the topic "Challenges to Healthcare Team on Long COVID - Post COVID Complications" organized by IPGA Alwar Local Chapter with expert Physicians, Professors and regulator and academia leaders on Feb 19, 2022 09:00 AM India.
3. A webinar on "New Designer Drugs and its impact on healthcare" organized by IPGA Alwar Local Chapter

with Dr. Muralikrishnan Dhanasekaran, Professor at Harrison School of Pharmacy, Auburn University, USA and the session is Chaired by Dr. Indu Pal Kaur, Professor of Pharmaceutics, Ex-Dean Faculty of Pharmaceutical Sciences, Chairperson, University Institute of Pharmaceutical Sciences, Panjab University, Chandigarh, India on Feb 5, 2022 09:00 AM India.

4. A Zoom meeting organized by IPGA Alwar Local Chapter on the topic "Opportunities and challenges to Indian Pharmacy Graduates in Post COVID Scenario" on Jan 29, 2022 09:00 AM India.
5. A Zoom meeting organized by IPGA Alwar Local Chapter with Sh. Ranjit Barshikar delivered his 50th online lecture on "Artificial Intelligence: Applications in Pharma Industry" on Jan 23, 2022 10:30 AM India.





## Tamilnadu Branch Report



List of activities of IPGA Tamilnadu Branch from April 2021 to March 2022

**Number of Executive Meetings held: 12** (On every second Saturday 5.00 PM virtually) (10.04.21, 08.05.21, 12.06.21, 10.07.21, 14.08.21, 11.09.21, 09.10.21, 13.11.21, 11.12.21, 08.01.21, 12.02.21, 12.03.22)

**New Members enrolled during 2021- 22: 69 nos**

Details of conferences/seminar/work-shops held:

1. On 25th September 2021, an webinar was conducted. 3 successful Alumnus of Madras medical College who are presently working in big organizations in USA came in as speakers. Our sincere thanks to Dr. Thanikaivelan B. Pharm, MS, PhD, Dr.Sujatha Menon B.Pharm,MS, MS, PhD & Dr. Jyothi Kesan B. Pharm, MS, PhD who spoke very enthusiastically to encourage our student participants. Prof. Guru Prasad Mohanta, Annamalai University delivered the Key note address on this occasion.
2. International Pharmacist day celebrated at Madras Medical College under the chairmanship of Dr. Radhakrishnan, Health Secretary, Tamilnadu Government
3. National Pharmacy week celebrations ,Seminar and Quiz competition at Coimbatore

### Representation to Governments:

1. Representation to add B. Pharm as eligibility for Drug Inspector (Medical Devices)
2. Objection letter for starting online Pharmacy
3. Request for a separate section officer for Pharmacy in Ministry of Health Government of India.
4. Request letter to Tn Govt to add one registered pharmacist in the 2000 Mini clinic program of the Govt.
5. Letter to cyber crime, Police & Govt about Fake Job offers being floated in digital media to get recruitment as Govt pharmacist. 2 such fake advertisements were stopped with immediate & swift action taken by our association.
6. Representation to the Chair person of FSSAI to include B.Pharmacy as eligibility for appointment as Food Safety Officer.
7. Meetings with Tamilnadu Health minister, Health Secretary & Director, Medical Services Recruitment Board in connection with the pending court case &

amendment of Recruitment rule.

8. Representation to Chairman UPSC to add Pharmacy as one of the subject for Civil service Examinations.
9. Press conferences during Pharmacist Day celebrations.

### Other Activities:

#### 1. GPAT Free coaching classes:

We believe that this program is the most unique & well appreciated activity of our IPGA Tn branch. When our EC decided to go for this Free GPAT coaching none of us believed that we will be able to succeed because (1) no such event happening any-where in India (2) The amount of labor involved viz deciding the syllabus, time schedule, faculties who can come forward to teach Free (we cannot afford to Pay), getting the students registered, arranging hassle free E class IT facility etc etc was really daunting.

But the trio of Prof. Gopal, Prof.Jayakumari & Ms.Meenatchi with the help of our office secretary Mr.Kannan did it exceedingly well & surpassed all our expectations.

Our 21-22 Second batch was conducted from Nov 21 to March 22 again on weekends. This time we were fortunate to collaborate with the PAA-MMC (Pharmacy Alumni Association- Madurai Medical College). Both these teams together conducted & completed the syllabus well in time for the students to appear for their GPAT exams. This batch benefitted about 120 students from across Tamilnadu.

Our sincere appreciation to PAA-MMC team Dr. Seenipandian, Mr. Saravanan & Mr.Malarkannan for their great co-operation & support

#### 2. Blood donation camp at Chennai:

In 2021 event was conducted at Madras Medical College premises with the help of Madras Pharmacy college staffs & students led by Prof. Deattu. Dr. Radhakrishnan our Health Secretary inaugurated the event & blood Donation camp. 98 units of blood were collected.

#### 3. Blood Donation camp at Madurai:

On the same day our Madurai branch also conducted a blood donation through the leadership initiative of our senior pharmacist Shri. Ponrajan of Pharmafabikon. 72

units of blood were collected.

#### 4. Quiz competition:

In 2021 Prof. Elango & Prof. Mohan had jointly organized & conducted this Quiz completion at the campus of Karpagam College of Pharmacy Coimbatore. Students from 24 colleges participated & the winners were selected on the same day. Thanks to the management of Karpagam College of Pharmacy for their expellant hospitality & for arranging Lunch for all the participants

#### 5. Legal case to add B.Pharmacy as Eligibility to apply for Govt Pharmacist In Tamilnadu:

We have support the legal case initiated by some of our members both technically & financially. We have followed all the hearings, brief the advocates with valid points & finally won the case in our favor. Further followed with Health Department & Medical Recruitment to for the amendment of Recruitment rules (as per the court directive) & got the amendment Gazetted as well.

### PROCEDURE FOR ONLINE NEW REGISTRATION

Go to Council website [www.tnpc.ac.in](http://www.tnpc.ac.in)

Enter SIGN UP

Click NEW APPLICANT

Provide Mail Id, Password and confirm password

Enter SIGN UP

An activation link will be sent to your mail id

Open your mail id and click the link to activate your user id

Now login to council website [www.tnpc.ac.in](http://www.tnpc.ac.in) with your user id and password

Go to Registration and fill up the form. All details such as Name, Father's Name, Date of Birth, etc. should be as per the originals.

Select Native for Registration and Transfer for Transfer of Registration from Other State Pharmacy Councils to Tamil Nadu.

Scan all original documents [List of documents required furnished below] in pdf format and upload as attachments. The attachment may be made in multiple documents and a single consolidated document. If uploading in consolidated scan, see that all documents are placed in one direction readable.

Photo and signature [good pixel quality images] in .jpg format should be uploaded. Signature should be in black ink on white background. These will be printed in the Registration certificate.

**DO NOT UPLOAD MOBILE SCANS OF PHOTOS AND SIGNATURE IMAGES.**



## Telangana Branch Report

IPGA Telangana Activities from January - March 2022.

### Webinar on 22 January 2022

IPGA New Delhi in Co-Ordination with IPGA TS conducted a webinar on 22 January 2022 (Sunday) between 11.00 am and 12.30 pm on Artificial Intelligence-Application in Pharma Industry by Mr.Ranjit Barshikar, CEO, QbD International, United Nations Adviser, Geneva. Around 1000 people attended the webinar.

### Contribution of Covid related drugs to RTC Central Hospital, Hyderabad.

About 25 Lakhs worth of covid related drugs (Favipiravir) were donated to Sri V.C. Sajjanar, IPS, Vice Chairman/MD, TSRTC, Hyderabad on 22 January 2022 by Sri G.Koteshwar Rao, Sri J.Rajamouli and Sri Guru Mohan. The medicines were contributed by Sri J.Rajamouli, MD, Euro Medicare International, Hyderabad.


### Medical Devices Regulations (MDR) Meeting on 5 February 2022

IPGA Telangana State branch conducted a Physical meeting with Medical Devices Association in SIPRA Labs Corporate Office, Sanath Nagar, Hyderabad on 5th February 2022. Around 50 members were attended the event. Experts discussed about MDR Guidelines and implementation in India. Dr.V.Satyanarayana, MD of Sipra Labs shown the company and hosted the event.

### Webinar on Pharma Career: Opportunities and Challenges on 12 Feb 2022







IPGA Central and South were conducted a webinar on Pharma Career: Opportunities and Challenges on 12 Feb 2022 by Mr.Ranjit Barshikar, CEO, QbD



**INDIAN PHARMACY GRADUATES' ASSOCIATION (South Zone)**  
In Co-ordination with IPGA - Telangana

**NATIONAL LEVEL WEBINAR**  
**PHARMA CAREER OPPORTUNITIES & CHALLENGES**  
DATE: 12th February 2022, Saturday 11.00 A.M. TO 1.00 P.M.

Meeting ID : Pass Code :

<p><b>CHIEF GUEST</b> <b>Pro. Dr. Pramode Yeole</b> President (i/c), Pharmacy Council of India, New Delhi.</p>			
<p><b>KEYNOTE SPEAKER</b> <b>Mr. Ranjit Barshikar</b> CEO - QbD International, United Nations Advisor, Geneva Member of Editorial Board of Journal of Generic Medicine UK</p>			
<p><b>Moderator</b>  <b>Vijay R Annapareddy</b> M: 7352446000</p>	<p><b>Co-ordinator</b>  <b>Dr. Nishit MC</b> M: 8086635651</p>	<p><b>Co-ordinator</b>  <b>Dr. P. Rajashekar</b> M: 9849611238</p>	<p><b>Organiser</b>  <b>G. Koteshwar Rao</b> Co-ordinator South M: 9721279828</p>

Request to forward to Students, Professionals from Industry, Regulators & fellow Pharmacists. All the Participants will get E-Certificate.  
Live Webinar will be available on YouTube and Facebook.  
For details contact : [inspectordrugs@gmail.com](mailto:inspectordrugs@gmail.com)



**INDIAN PHARMACY GRADUATES' ASSOCIATION TELANGANA**

In Coordination with SkillYari, a SAS Education Partner organizes  
National Level Webinar

**Career Opportunities for Pharmacists**  
Clinical SAS Programming

February 26th, 2022 7:00 PM - 8:30 PM Zoho Online Webinar

**Guaranteed Scholarship to learn from SAS India directly!**

Clinical SAS Programming is just analysing healthcare data using worlds Top analytics software called SAS. Clinical SAS Programming is a combination of Clinical Data Analysis, Reporting to Regulatory bodies like US FDA, Clinical Research and SAS Programming. This is a guidance session that provides information of SAS training, Job opportunities, Salary, overseas opportunities, and guaranteed scholarships offered to pharmacists.

Hardship Guaranteed Scholarship is provided by SkillYari that is an Official SAS Education Partner that facilitates students training by SAS company - SAS India (Indian headquarters). Guaranteed scholarship of a minimum amount of 5,000 INR is offered so, don't miss the session and scholarship opportunities.

**Request you to forward the webinar registration link to all Pharma Students, Professionals from Industry, Regulators, Faculty and Fellow Pharmacists.**

  
Srikanth K.  
Indian Pharmacists  
Clinical Clinical SAS  
Programmer  
MSc Clinical Pharmacology

  
G. Koteswar Rao  
G. Koteswar Rao  
President Telangana  
Indian Pharmacy Graduate  
Association Telangana

Website: <https://ipgaan.com> More Info: +91 7681502677 Social Media: [support@ipgaan.com](https://support@ipgaan.com)

International, United Nations Adviser, Geneva. Around 1000 people attended the webinar. Prof. PG Yeole, VC, BAM University, Aurangabad acted as Chief Guest and grace the

## Webinar on 12 March 2022



**INDIAN PHARMACY GRADUATES' ASSOCIATION**  
**WOMEN FORUM SOUTH ZONE**  
**INTERNATIONAL WOMEN'S DAY 2022 CELEBRATION**  
Campaign Theme: Gender Equality Today for a Sustainable Tomorrow #BreakTheBias

DATE: 12th MARCH 2022 DAY: SATURDAY TIME: 10 AM to 1 PM

Registration at Hyderabad for 10th Workshop - 12th March 2022 (10 AM to 1 PM) - Free of charge (Lunch and Refreshments will be provided).  
Registration at Hyderabad for 10th Workshop - 12th March 2022 (10 AM to 1 PM) - Free of charge (Lunch and Refreshments will be provided).  
Registration at Hyderabad for 10th Workshop - 12th March 2022 (10 AM to 1 PM) - Free of charge (Lunch and Refreshments will be provided).

**Guests of Honour**  
Dr. T. Chandrasekhar (President, Indian Pharmacists Association, Hyderabad)  
Dr. M. V. S. Rao (President, Indian Pharmacists Association, Hyderabad)  
Dr. V. S. Rao (President, Indian Pharmacists Association, Hyderabad)

**Panel of Experts**  
Dr. M. V. S. Rao (President, Indian Pharmacists Association, Hyderabad)  
Dr. M. V. S. Rao (President, Indian Pharmacists Association, Hyderabad)  
Dr. M. V. S. Rao (President, Indian Pharmacists Association, Hyderabad)

**Panel of Experts**  
Dr. M. V. S. Rao (President, Indian Pharmacists Association, Hyderabad)  
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Dr. M. V. S. Rao (President, Indian Pharmacists Association, Hyderabad)

**Panel of Experts**  
Dr. M. V. S. Rao (President, Indian Pharmacists Association, Hyderabad)  
Dr. M. V. S. Rao (President, Indian Pharmacists Association, Hyderabad)  
Dr. M. V. S. Rao (President, Indian Pharmacists Association, Hyderabad)

webinar.

## Webinar on 26 February 2022

IPGA TS conducted a webinar in Coordination with SkillYari (a SAS Education Partner) on Pharma Career opportunities for Pharmacists on 22 Feb 2022 by K. Srikanth. Around 500 students attended the webinar.

IPGA TS President Sri GK Rao Visited JNTU, Antapur  
IPGA TS President Sri GK Rao attended a conference in Kolkata

IPGA TS President Sri GK Rao Visited SK University, Antapur

IPGA TS President Sri GK Rao Visited Kakatiya University, Warangal

## Workshop on 25 & 26 March 2022





## Workshop on 25 & 26 March 2022

CMR College of Pharmacy, Hyderabad conducted a workshop with IPGA, TS on Advanced Techniques in Experimental Pharmacology on 25&26 March 2022. Dr.V.Prabhakar Reddy, Secretary delivered a talk on Role of Animal/Human Models in Drug Discovery and Research Development. Around 1000 students attended the event. Upcoming year, we are planning to organize the following activities

2 - 4 work shops in association with industry.

4- 6 seminars In association with educational institutions.

2 -4 online quizzes.

## Membership drive to strengthen the organization.

Upcoming year, we are planning to organize the following activities

Job Mela in association with Drug Control Department and Pharma Industries.

Training of analytical instruments in association with DTL TS.

Improvement of analytical skills and procedures to the students and the working professionals with the help of local Analytical Labs.



**CMR COLLEGE OF PHARMACY**  
(Approved by AICTE & PCI, New Delhi & Affiliated to JNTU Hyderabad)  
B Pharmacy: NBA accredited, Recognized under section 2(f) & 12(B) of the UGC Act, 1956  
Kandlakota (V), Medchal, Hyderabad - 501 401

**TWO DAYS NATIONAL WORKSHOP ON  
"ADVANCED TECHNIQUES IN  
EXPERIMENTAL PHARMACOLOGY"**  
March 25<sup>th</sup> & 26<sup>th</sup>, 2022  
IN ASSOCIATION WITH  
INDIAN PHARMACY GRADUATES' ASSOCIATION, TELANGANA STATE BRANCH

**Resource Persons:**  
**Dr. N. Harishankar** (Retd)  
Scientist E, NIN, Hyderabad.  
**Dr. V. Prabhakar Reddy**  
Hod, UCPS, Pabumma University, Mohadnagar,  
Central Council Member - PCI, New Delhi.  
Secretary - IPGA, Telangana State.  
**Dr. M. J. Mahesh Kumar**  
Principal Scientist, CCMB, Hyderabad.

**Patron**  
**Dr. Ch. Gopal Reddy**  
Secretary & Correspondent,  
CMR Group of Institutions

**Last date for Registration  
March 21<sup>st</sup>, 2022**  
Registration Link: <https://forms.gle/A7dD90X84QVmpJE7>

**Venue:**  
Auditorium  
CMR College of Pharmacy

**Registration Fee:**  
Rs. 400/-

**Convenor**  
**Dr. T. Rama Rao**  
Principal,  
CMR College of Pharmacy

**Co-ordinators**  
**Dr. V. V. Rajesham**  
Associate Professor  
(Contact- 9908124092)  
**Dr. Suwendu Saha**  
Associate Professor  
(Contact- 9533400909)

Online Transfer A/c No: 15403640000014  
Account Holder Name: CMR College of Pharmacy  
IFSC Code: HDPC0001640  
Bank's Branch: HDPC (Bank), Medchal (branch)

Website: [www.cmrcp.ac.in](http://www.cmrcp.ac.in)  
Social Media: [cmrcpofficial](https://www.instagram.com/cmrcpofficial)



IPGA Central, IPGA Telangana Branch in association with DCO India Drugs Control Forum organized an International Webinar entitled **“Designer Drugs”** A modern day threat of future therapeutic agent, on 17th April, 2022.

The National President Dr. Atul Nasa in his welcome address appreciated such events and expressed. That such events should be continued.

Dr.S. Eswara Reddy, Jt. Drugs Cotroller of India (CDSCO, New Delhi), made his gracious presence available as Chief Guest to bless the young Pharmacy Sauls. The scientific session was presented by the Key Note Speaker Prof. Muralikrishnan Dhanasekeran, Auburn University (USA).

While addressing a gathering of delegates close to 1000 including Youtube viewers, Prof. Muralikrishnan emphasized on the Designer Drugs and their applicability in Prophylactic, diagnostic and Therapeutic Scales. He also explained the in silico, invitro and invivo stages in the process of drug design followed by drug synthesis and

evaluation.

The event was graced by Mr. Lalit Kr Goel, Mr. Rakesh Dahiya, Mr. S.K. Tiwari under the leader ship of Mr. G. Koteswar Rao, Group Head, DCO India, Drugs Control Forum, Co-ordinator IPGA South Zone and President IPGA Telangana.

Feed back from the delegates was taken and also the session was made open to Questions to make scientific embellishments possible.

The webinar was indeed a nourishment to young brains of pharma proffessionals present during the session.

Session ended with National Anthem and Dr. M.C. Nishit, Kerala has Coordinated entire event.





## Uttar Pradesh Branch Report



MESCO Institute of Pharmacy (MIP), Amroha organized **IPGA sponsored One Day National Conference-2022** on the theme: **QSAR antiviral agents Vs SAR CoV-2: An Overview** on Saturday, 14<sup>th</sup> May, 2022.

In the inaugural session, Dr. Mujeeb Ur Rahman, Principal MIP, presented welcome address & briefed about the event. The dais was graced by Chairman MIP Mr. Kamal Faruqui, chief guest Dr. Arun Garg, General Secretary IPGA, Prof. & Dean School of Medical & Allied Sciences, K R Mangalam University, Gurgaon. In his keynote address, he focused on the post pandemic scenario & discussed about simpler & more accessible antiviral treatment options, Guest of Honour Dr. G. Jeyabalan, Professor & Principal, Alwar Pharmacy College, Alwar, Dr. Satyender Kumar Rajput Joint Secretary IPGA Central & Head – Department of Pharmaceutical Sciences, Professor - Pharmacology & Toxicology Gurukula Kangri (Deemed to be University).

The Souvniar was released and made open to students by the eminent personalities.

The presidential address given by MIP Chairman Mr. Kamal Faruqui.

Dr. Arun Garg General Secretary of IPGA has inaugurated & declared IPGA Amroha- Local Chapter and distributed the IPGA life membership certificates for new members.

The deliberation of three scientific session spread across wherein the speakers were introduce to the audience by Dr. Gazala Parveen, HOD MIP.

Scientific Session-I had Dr. Murali Dhanasekaran, Professor Department of Pharmacology, Harrison School of Pharmacy, Auburn University, Auburn, AL (USA) as Keynote speaker, he has elaborated on the topic QSAR antiviral agents Vs SAR CoV-2: An overview".



Scientific Session-II had Prof. Devendra Pathak, Dean & Director Rajiv Academy for Pharmacy Mathura., he has discussed on the topic "Therapeutic importance of Antiviral drugs and Repurposing of some drugs for Covid- 19".

Scientific Session-III had Dr. Tanveer Naved, Principal, Amity Institute of Pharmacy, Amity University, Uttar Pradesh. He has delivered interesting & interactive talk on "Herbal and Traditional drugs: Hope against covid 19".

The scientific sessions were followed by panel discussion wherein professional queries by the delegates were address by expert panel. Poster presentation and evaluation by subject experts by carried out in a meticulous manner in a spacious and dedicated area over 31 selected abstract out of 50 from different pharmacy college had participated in poster presentation.

During the valedictory function Prize distribution for scientific posters in which awards & certificates were distributed to the winners followed by Honoring to different colleges, LOC members by Momentos.

Finally, the conference was concluded with vote of thanks by Mr. Kamal Faruqui, Chairman MIP. He expressed his thanks to all the guests for accepting the invitations, and encouragement. The conference can be declared as a grand success with total number 300+ of delegates from different colleges.







WOMEN FORUM

## Central Executive Report

IPGA Women Forum Central Executive Committee in collaboration with IPGA Students Forum, I&E Cell, Amity Institute of Pharmacy, Amity University and K.R. Manglam University organized a webinar on "Career Choices in Pharmacy Field" to celebrate International Women's Day on 5th March, 2022.

More than 200 students attended the event and one on one questions of the students were discussed by the panelist.





**IPGA Women Forum**

*Central Executive Committee*

**Celebrating International Women's Day**

IN COLLABORATION WITH

**IPGA Student's Forum**

**I&E Cell, Amity Institute of Pharmacy, Amity University  
and S.M.A.S., K.R.Mangalam University**

**Topic: *Career Choices in Pharmacy Field***

**PANELIST**



**Dr. Kanchan Kohli**  
Convener - IPGA-WF



**Dr. Sanju Dhawan**  
Coordinator - South Zone - IPGA-WF



**Dr. Arti R. Thakkar**  
Co-Convener - IPGA-WF



**Dr. Rikta Saha**  
ADC - CDSCO, New Delhi

SAT  
DAY

MAR  
**05**

TIME  
**02pm**

**FACULTY COORDINATOR**



**Dr. Neerupma Dhillon**  
EC Member - IPGA-WF

**STUDENT COORDINATORS**



**Hazel Aggarwal**  
B.Pharm, 8 Year, Amity University  
Shalimar Bagh, Delhi-110029, IPGA-SP



**Aarushi Gupta**  
B.Pharm, 8 Year, Amity University  
Preeti, I&E Cell



**Apoorvi Suri**  
B.Pharm, 8 Year, Amity University  
Jawahar Bagh, Delhi-110029, IPGA-SP



**Rohan Nagpal**  
B.Pharm, 8 Year, Amity University  
The Preeti, I&E Cell

**Moderator** - Hazel Aggarwal (+91 89681 10995) and Aarushi Gupta (+91 87918 50770)  
**For Student Outreach** - Apoorvi Suri (+91 98738 60024) and Rohan Nagpal (+91 95994 41919)

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WOMEN FORUM

## Kerala Branch Report

As a part of National Pharmacist Day celebration 2022 IPGA-WF Kerala Branch organised a virtual national webinar on the topic "Role and Responsibility of Pharmacist in Antibiotic Stewardship Program" on 6th February 2022 under the leadership of Dr. Sanju Dhwan, IPGA-WF South Zone Coordinator along with programme Co-ordinators Dr Mahalakshmy.R, IPGA-WF Kerala Co-ordinator, Dr. Moniveena M.G, Dr. Kala D, Dr. Gini.E.J, MimoonKhan and Dr.Limce Thampi

The Chief Guest Mr.Jayan PM, Drugs Controlle, Kerala, Renjish. C, Vice President IPGA Kerala State, Dileep G, Secretarey IPGA Kerala State along with guest speakers –Dr. Atul Nasa, President of IPGA shared their views about significance of Antimicrobial Resistance in the contemporary situation.

The Speaker of the day Dr.Ann Vazhayil Kuruvilla had completed his PhD thesis work on Antimicrobial Stewardship Program. The speaker is Clinical Pharmacist/ Resident and preceptor in General Surgery Department, JSS Hospital. She was quite knowledgeable about the subject and passionately explained the details to the audience. More than 150 participants joined the webinar through Zoom and the event was streamed on youtube. (895 views).

In addition IPGA WF Kerala had organized a poster making competition on the topic "Impact of Antimicrobial Resistance on Future Generation", among various pharmacy colleges all over Kerala and top 3 winners were announced in the webinar as an appreciation tp the student community. Participants who had submitted the feedback form were given E-certificates. According to feedback, the event was need of the hour and all the people were satisfied with the event.

### INDIAN PHARMACY GRADUATES' ASSOCIATION WOMEN'S FORUM KERALA

6 FEBRUARY 2022  
11:30 am to 1:30 pm

MEETING ID: 89947626678  
PASS CODE : 947676

CLICK HERE

## NATIONAL WEBINAR

#### Program Schedule

<p>11:30 am Introduction: <b>Dr. Mahalakshmy.R</b> IPGAWF Kerala state Co-ordinator</p>	<p>11:35 am Welcome Speech <b>Dr. Sanju Dhwan</b> IPGAWF South Zone Co-ordinator</p>
<p>Chief Guest <b>Mr. Jayan P.M</b> Drugs controller Kerala state</p>	<p>11:40 am Felicitation <b>Dr. Satheesh Kumar C.S</b> President, IPGA Kerala state branch</p>
<p>11:45 am Felicitation <b>Mr. Dileep G.</b> Secretary, IPGA Kerala state branch</p>	<p>11:50am Introduction of Speaker <b>Dr. Kala D</b></p>

12-12:30 pm

### ROLE & RESPONSIBILITY OF PHARMACIST IN ANTIMICROBIAL STEWARDSHIP PROGRAM

Speaker  
**Dr. Ann Vazhayil Kuruvilla**, Pharm D  
Clinical Pharmacist At JSS Hospital

12.30-12.45 pm Question Answer Session

<p>12.45-1.15 pm Announcement of result of Poster Presentation and best posters <b>Dr. Gini E.J</b></p>	<p>Moderator <b>Mimoon Khan</b></p>
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1.15pm  
Vote of Thanks  
**Dr. Moniveena M.G**

Request to forward to Students, Regulators and fellow Pharmacists

All the participants will get E - Certificate

YouTube Live webinar will be available on youtube



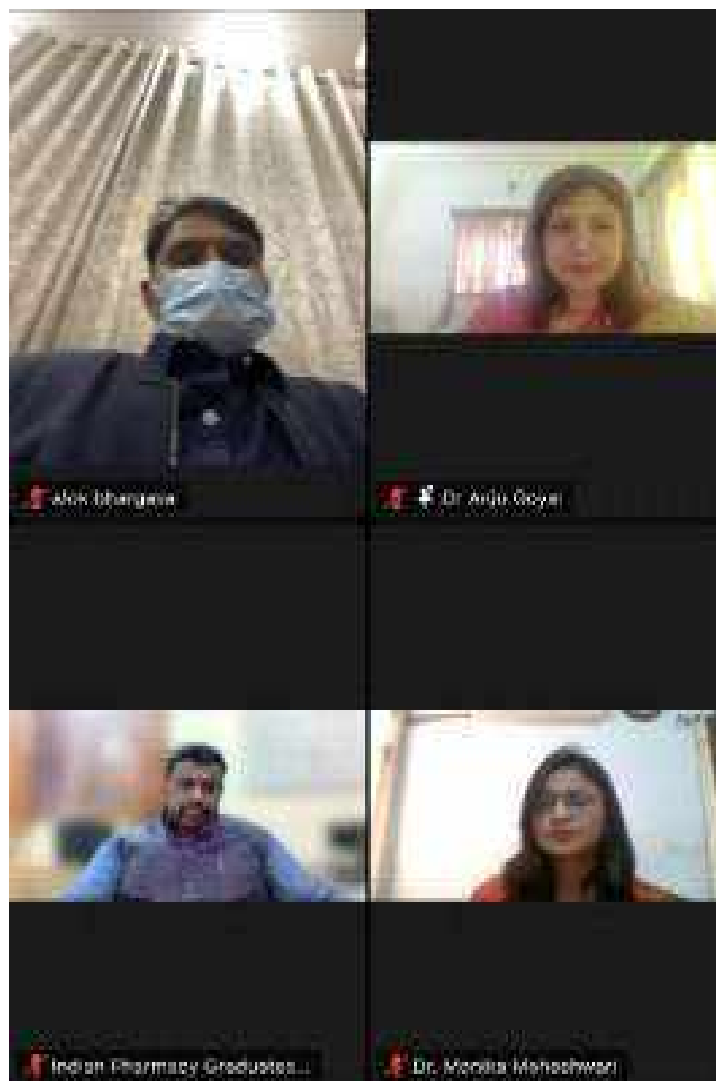
## Rajasthan Branch Report

A National Webinar on the theme Optimization techniques for In-process quality control of Ayurvedic formulations was organised by IPGA-Women forum Rajasthan in collaboration with B N University, Udaipur (Rajasthan) on 26 February 2022 (Saturday) at 5 PM on zoom platform and telecasted live on YouTube. The Lecture was delivered by Dr. Pallavi Manish Lavhale, Professor and Principal of Ram-Eesh Institute of vocational and technical education, Greater Noida.



### Dr. Pallavi presenting Webinar

The Programme was inaugurated by Dr. N. B. Singh, President of B N University, Udaipur. Dr. Kanchan Kohli, convener of IPGA women forum explained the purpose of the forum and the need of Ayurvedic formulations. The Keynote speaker Dr. Pallavi spoke about the formulation of ayurvedic medicines and their quality control. Various quality control techniques have been described in detail to ensure that high quality medicines are manufactured in Ayurveda. Dr. Pallavi said that some ayurvedic medicine have the presence of toxic metals. Therefore, they have to be prepared properly so that they do not harm any patient.



### Dr. Anju Goyal organising the webinar

West zone coordinator IPGA-women forum, Dr Anju Goyal while thanking the participants underlined the need for manufacturing high quality medicines in underlined the need for manufacturing high quality medicines in the field of Ayurvedic medicines. The webinar started at 5:00 pm with Vande mataram and ended with National Anthem. The webinar was moderated by Dr. Monika Maheshwari, Associate Professor, Geetanjali Institute of Pharmacy and EC member IPGA-WF. In this webinar Dr. Udichi Kataria, State coordinator IPGA-WF, Dr. Y S Sarangdevot, Dean, B N University, Dr. M. S. Ranawat, Pricipal, BNIPS, Dr. SS Sisodia, Principal, BN college of Pharmacy, Dr. Kamal singh rothore, Dr. G. Jayabalan, Mr. Alok Bhargav were present. Total 500 participants have registered from all across the country in this national webinar.



WOMEN FORUM

## Tamilnadu Branch Report

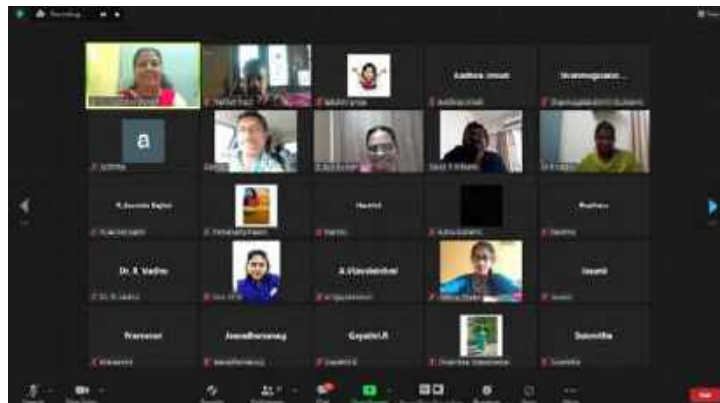
The Indian Pharmacy Graduate Association Women Forum Tamilnadu Branch celebrated 60 National Pharmacy Week Celebration 2021 virtually through Join Zoom Meeting on the theme, Theme : Pharmacist: An integral part of healthcare on 08 January 2022 from 10 am - 5 pm.

The event was started at 10 am with the conduct of various competitions by respective coordinators in the presence of Dr Sanju Dhawan Coordinator, IPGAWF South Zone and Dr. S. Jayakumari, Coordinator, IPGA WF TN. The theme for each contests such as Women Safety and Protection (Short film), Women entrepreneurs in Pharmacy profession (Drawing and Painting), Women Empowerment based songs (Singing) and Women entrepreneurs in the field of Pharmacy (English & Tamil Essay) were well executed by more than 70 women participants from 10 pharmacy colleges, by showcasing their talents towards the empowerment of Women.

Judges from various disciplines such as Mr. David P. Williams, Director, Exim advertisers, Chennai, Mr N Elangovan, Associate Centralized monitoring lead, IQVIA, Bangalore, Clinical researcher & Short film maker, Ms. Sneha Sivasdas, Pondicherry University, Puducherry. Dr. N. Srinivasan, Assistant Professor, Department of Pharmacognosy, Faculty of Engineering, Annamalai University, Chidambaram, Dr. A. Geethalakshmi, Professor & HOD Department of Pharmaceutics, RR College of Pharmacy, Bangalore, Karnataka, Mr. K. Hariharan, Head Constable, Tamil Nadu Police Department, Organized Crime Intelligence Unit Coimbatore City, Dr. P. Azhagarasi M.D (Siddha) Professor and Vice Principal in Gunapadam (Marunthakaviyal) RVS Siddha Medical College & Hospital, Coimbatore., Dr. C. Surya Head, Department of Biochemistry, Dhanalakshmi Srinivasan College of Arts and Science for Women, Dr. M. Prabhakaran, Dept. of Tamil, VISTAS, Pallavaram, Dr. A. Porselvi., Dept. of Pharmacy Practice, Sathyabama Institute of Science and Technology, Chennai, have generously accepted our request and evaluated as per the evaluation sheets provided.

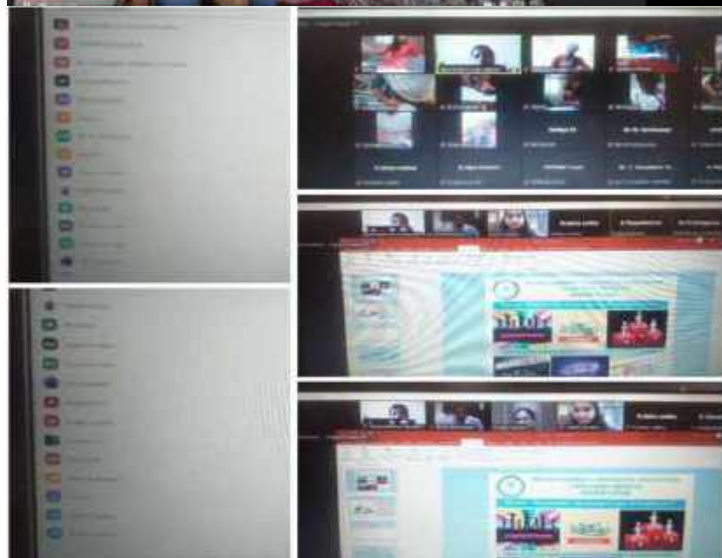
The various Pharmacy colleges across the state have participated and has won cash awards and e certificates to their credits. The results were declared on the same day at 3-5 pm program graced and specially addressed by Shri. R. Narayanaswamy, President IPGA TN and Shri. M. Rajarathinam, Hon. Gen. Secretary IPGA TN. The Coordinators, Dr. C. Vinodhini, Dr. M. Vadivu, Dr. S. Sarumathy, Dr. A. Vijayalakshmi, Dr. N. Selvasudha, Dr. S. Dhanalakshmi, Mrs. Jasmin Sajini. R, Mrs. Kaaviya Gadi made the presentation of summary of the contest to the august virtual gathering. The winners of the competitions with first, second & third in different events respectively were Sri Ramachandra Faculty of Pharmacy, SRIHER, Chennai, School of Pharmacy, Chettinad Academy of Research and Education, Chennai, C L Baid Metha College of Pharmacy, Chennai, Jaya College of Pharmacy, Chennai, Sri Balaji Vidyapeeth Deemed to be University, Puducherry, Periyar College of Pharmaceutical Sciences, Trichy, PSG College of Pharmacy, Coimbatore, SRM College of Pharmacy, Kattankulathur.

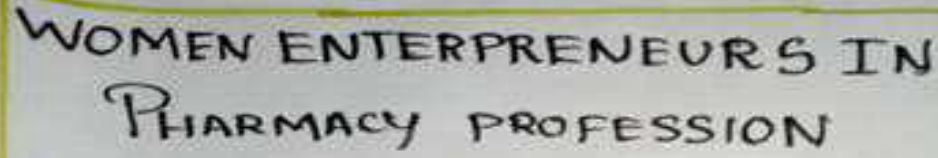
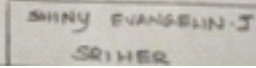
Finally the most interesting and inspiring (Q&A) session moderated by Dr. K. Lakshmi & Dr. V. Sowmyalakshmi on Gynecological Counseling for Women: A general awareness by a Gynecologist Dr S Bhuvaneshwari MBBS., MD. Consultant Obstetrics and Gynecology. Deepam Med First Hospital. The questions related to Gynecological problems were collected through Google form by online mode from various community people – students, women faculties about general public. All questions were discussed. The questions related to problems starting from puberty phase till menopause stage of women were discussed with the



doctor during the session. Nearly about more than 100 participants attended and benefited by this program. Really it created an Awareness among girls to improve their gynecological issues by food and nutritional

supplements. Then the session was ended with vote of thanks proposed by Dr. S. Jayakumari, Coordinator, IPGA WFTN.





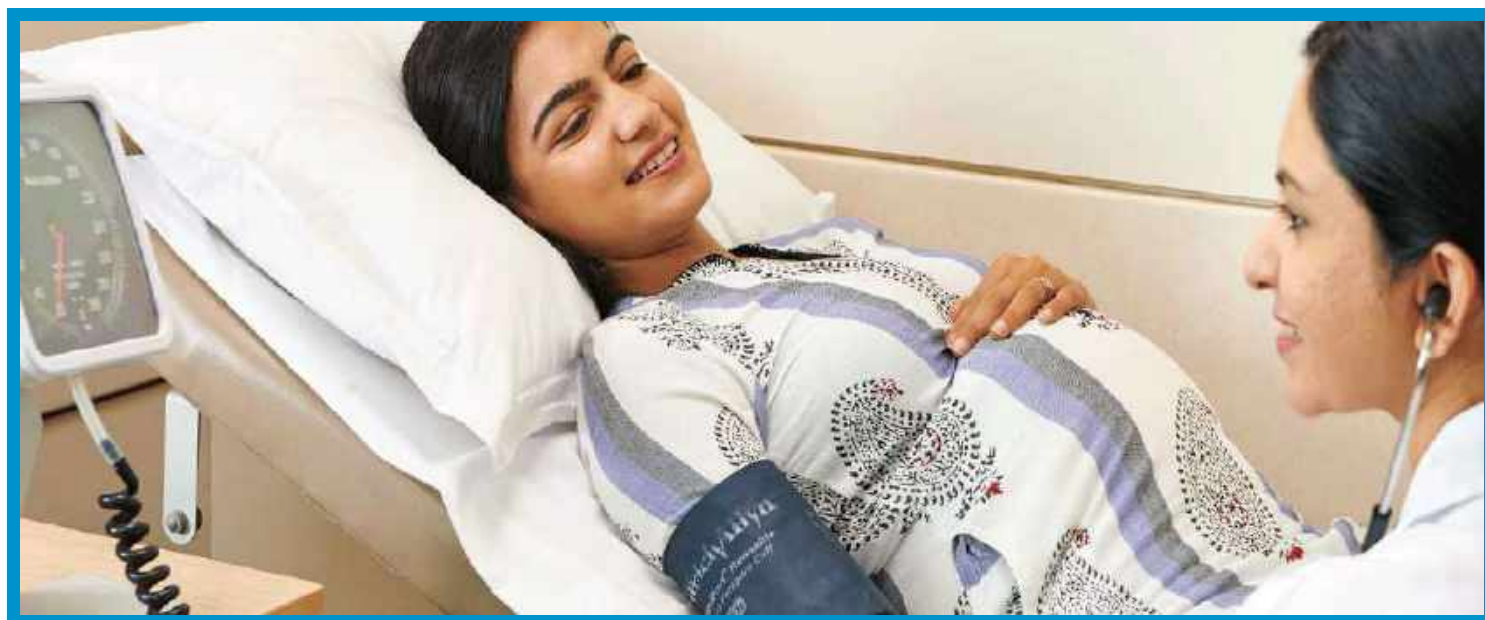
## GYNEOLOGY SESSION

The Gynecological Counseling for Women: A general awareness session by a Gynecologist (Q&A) Session was organized at 4pm by the respective coordinators in the presence of Chairperson Dr Sanju Dhawan and Coordinator Dr S Jayakumari. Ms Kaviya Gaddi moderated the session. The speaker of the session Dr S Bhuvaneshwari MBBS., MD. Consultant Obstetrics and Gynecology. Deepam Med First Hospital.

The questions related to Gynecological problems were collected through Google form by online mode from various

community people – students, women faculties about general public. All questions were discussed. The questions related to problems starting from puberty phase till menopause stage of women were discussed with the doctor during the session. Nearly about more than 100 participants attended and benefited by this webinar. Really it created an Awareness among girls to improve their gynecological issues by food and nutritional supplements.

Then the session was ended with vote of thanks





## Students Forum Activities

**ENVISAGE** : Envisage is an initiative by IPGA-SF (in collaboration with IPSF-APRO) to spread awareness about Antimicrobial Resistance (AMR).



Main Goal of this initiative is:-

1. To present and understand AMR on a global perspective
2. Publicize the work in progress and actions taken to combat AMR.

**Antimicrobial Resistance Campaign:** Antimicrobial resistance (AMR) is one of the biggest global health threats we face. AMR infections are estimated to cause 700,000 deaths each year globally.

The misuse of antibiotics during COVID-19 pandemic has led to accelerated emergence and spread of antimicrobial resistance. COVID-19 is caused by a virus, not by a bacteria and therefore antibiotics should not be used to prevent or treat viral infections, unless bacterial infections are also present.

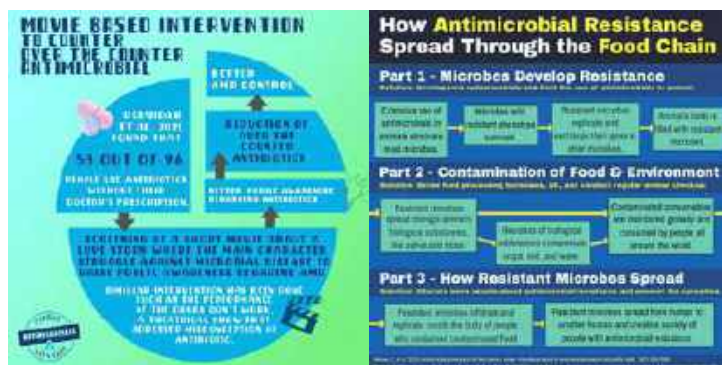
IPGA-SF initiated a global awareness campaign to spread awareness about AMR.

**The Vision to Fruition:** For the very first time IPGA-SF



launched its first international event (in collaboration with IPSF-APRO) 'The Vision to Fruition' - A Flow Diagram Making Competition.

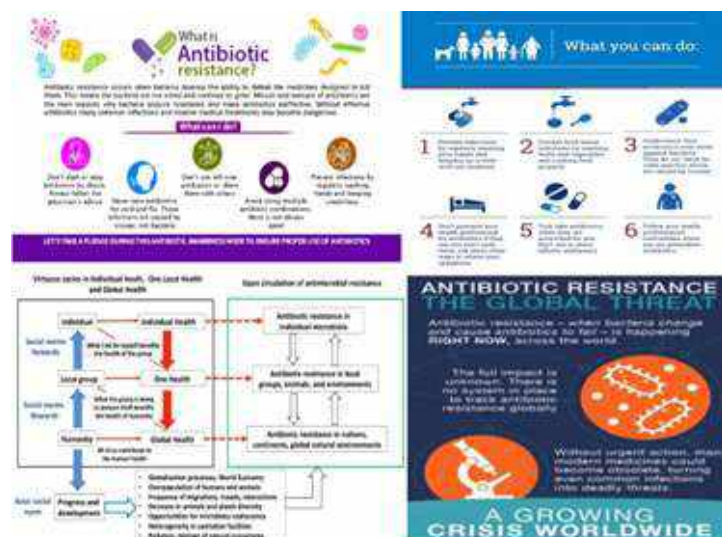
**PRELIMINARY ROUND** : The participants all around



the globe were asked to submit digital Flow Diagrams on any topic related to AMR. We received innovative and informative submissions from different countries like Jordan, Indonesia, Nigeria and India. Out of all the submissions, top 10 submissions were selected (by Judges) and all the works were published on IPGA-SF instagram handle.

**Judges for the First Round:**

1. Dr Gaurav Kumar Jain (Associate Professor Deptt. Pharmaceutics, DPSRU, New Delhi)
2. Mr. Sanjeev Kumar (Assistant Professor, K.R. Mangalam University)
1. Hosea Imanuel (BEM FF UI, Indonesia),
2. Andrew Jonathan Brahms (IPSF APRO, Indonesia)



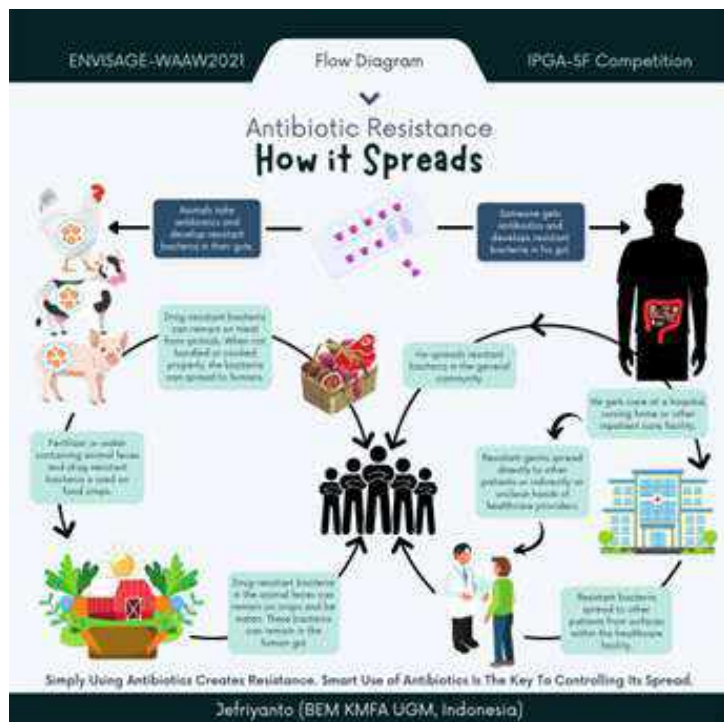
## FINAL ROUND

For the final round, we asked our student forum members to rate the work of participants according to their creativity and uniqueness of the concept of the flow diagram.

**Winner** - Niharika Singh (Jamia Hamdard, India)

**First Runner Up** - Jefriyanto (BEM KMFA UGM, Indonesia)

**Second Runner Up** - Dhruv Malik (IPGA-SF, India)



## INFINITO - Research Proposal Event

World Cancer Day is an international day marked on 4 February to raise awareness of cancer and to encourage its prevention, detection, and treatment. This year's theme of World Cancer Day is CLOSE THE CARE GAP.



'Close the Care Gap' campaign is all about understanding and recognising the inequities in cancer care around the globe.

Keeping this in mind, IPGA-SF launched an Event INFINITO on the occasion of World Cancer Day.

The main goal of the event is to:-

- To understand about cancer care facilities in different countries around the world.
- To find practical solutions to 'Close the Care Gap' in Cancer Care.

The event was divided into three rounds:-

- Preliminary Round
  - Participants were given approximately 4 weeks to complete a proposal as a team.
  - The students were asked to make summary drafts of their research proposal for evaluation of this



necessary changes

in the final proposal.

- The Proposals were evaluated by a panel of two judges - Dr. Gaurav Jain, Associate in the Department of Pharmaceutics, School of Pharmaceutical Sciences, DPSRU and Dr. Bharti, DPSRU.
- Top 6 Teams were selected for the final presentation round.

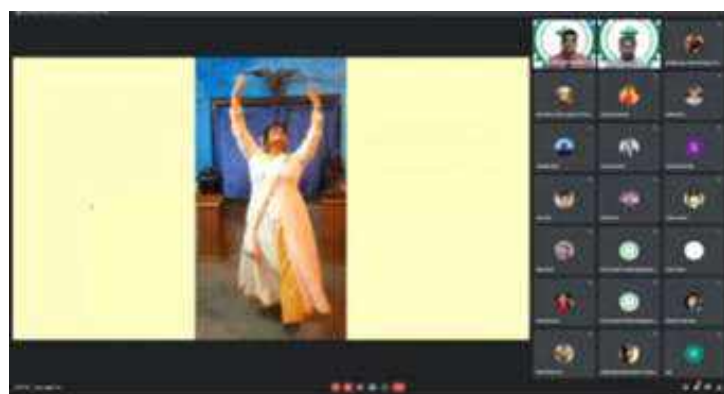
## IPGA-SF Bengal Branch Report

**Interactive Webinar conducted by IPGA-SF Bengal Branch based on the theme- Pharmacist: An Integral**



**Part of Healthcare on the occasion of National Pharmacy Week, 2021.**

On the occasion of National Pharmacy Week 2021, IPGA-SF Bengal Branch also organized a webinar on 27th November,



based on the theme- Pharmacist: An Integral Part of Healthcare. It was an interaction event which was held solely between the IPGA-SF Bengal Branch's core



committee members: Executive Committee, Council, College Representatives and the active members of IPGASF

Based on the theme, each of the core committee members presented something on that special day to pay a tribute to all the pharmacist out there: the frontline healthcare warriors who work hard day and night to save human lives. The event was hosted by the President Rupam Mahish. The Vice President started by giving a speech on National Pharmacy Week, followed by Sukannya Saha who



presented a patriotic dance to pay tribute to all the pharmacists. College Representatives Kuntal Ghosh Roy and Sandip Paul presented powerpoint presentations on Role of Pharmacist in Hospital Management and Growth of Pharmacy Profession after Covid Pandemic respectively. Then The Director of Professional Relations, Oishee Bhowmik's song was presented. After that, a power point presentation was contributed by the Joint Secretary, Saudipa Nag on Nanotechnology in Pharmacy and Formulation Development on Nanoparticles. After her presentation, Director of Media and Publicity, Anita Kumbhakar presented a short video on antibiotic resistance, since antibiotic resistance week also fell on the

same week as National Pharmacy Week. After her speech, Director of Content and Research, Shayani Das' poem was presented, followed by College Representatives Pallabi Saha and Manas Pratim Roy's presentations on 3D Printing in Pharmaceutical Industry and Artificial Intelligence in Pharmaceutical Industry. Director of Planning and Strategy, Sayantan Goswami's story on choosing his Pharmacy career was presented, followed by College Representatives Soham Dutta's video on Role of Community Pharmacist and Kasturi Maity's drawing to pay immense respect to the pharmacy profession. Vote of thanks was given by President, Rupam Mahish. The entire event was streamed live on facebook on the official page of IPGA Student Chapter West Bengal by the Treasurer, Rahul Bhattacharya.

## TREE PLANTATION EVENT

**Theme:** World Wetland Day

**Date:** 2<sup>nd</sup> August 2022 | **Venue:** Ghogli Village

This event was held in Ghogli village in Koradi, Nagpur in collaboration with Taywade College of Pharmacy to spread a word of Go green in the village on the occasion of world wetland day 'wetland and biodiversity'. The panchayat of the respective village was also involved in the event and was looking forward toward the event. Many students participated to support the cause along with the locals.



### 1-Alymsys Injection by Amneal Pharmaceuticals LLC

The U.S. Food and Drug Administration on April 13, 2022 approved Alymsys injection. Alymsys (bevacizumab-maly) is a vascular endothelial growth factor inhibitor biosimilar to Avastin (bevacizumab) for the treatment of multiple types of cancer including metastatic colorectal cancer; non-small cell lung cancer; glioblastoma; metastatic renal cell carcinoma; cervical cancer; and epithelial ovarian, fallopian tube, or primary peritoneal cancer.



### 2-Vioice (alpelisib) Tablets by Novartis Pharmaceuticals Corporation

The U.S. Food and Drug Administration on 5 April 2022 approved Vioice Tablets. Vioice (alpelisib) is a kinase inhibitor indicated for the treatment of adult and pediatric patients 2 years of age and older with severe manifestations of PIK3CA-Related Overgrowth Spectrum (PROS) who require systemic therapy.



### 3-Igalmi (dexmedetomidine) Sublingual Film by BioXcel Therapeutics, Inc.

The U.S. Food and Drug Administration on 5 April 2022 approved Igalmi sublingual film. Igalmi (dexmedetomidine) is a sublingual film formulation of the approved alpha2-adrenergic receptor agonist dexmedetomidine indicated for the acute treatment of agitation associated with schizophrenia or bipolar I or II disorder in adults.



### 4-Pluvicto Injection by Novartis Pharmaceuticals Corporation

The U.S. Food and Drug Administration on 23 March 2022 approved Pluvicto injection. Pluvicto injection used to treat prostate cancer. Pluvicto (lutetium lu 177 vipivotide tetraxetan) is a radioligand therapeutic agent indicated for the treatment of prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer (mCRPC).



### 5-Hyftor topical gel by Nobel pharma America, LLC

The U.S. Food and Drug Administration on 22 March 2022 approved Hyftor topical gel. Hyftor topical gel is used to treat Facial Angiofibroma



Associated with Tuberous Sclerosis. Hyftor (sirolimus topical gel) is an mTOR inhibitor immunosuppressant indicated for the treatment of facial angiofibroma associated with tuberous sclerosis in adults and pediatric patients 6 years of age and older.

### 6-Ztalmy (ganaxolone) Oral Suspension by Marinus Pharmaceuticals, Inc.

The U.S. Food and Drug Administration on 18 March 2022 approved Ztalmy oral suspension. Ztalmy oral suspension is used to treat CDKL5 Deficiency Disorder. Ztalmy (ganaxolone) is neuroactive steroid gamma-aminobutyric acid (GABA) A receptor positive modulator indicated for the treatment of seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD).



### 7-Fleqsuvy (baclofen) Oral Suspension by Azurity Pharmaceuticals

The U.S. Food and Drug Administration on 4 February 2022 approved Fleqsuvy oral suspension. Fleqsuvy oral suspension is used to treat Spasticity. Fleqsuvy (baclofen) is an oral suspension formulation of baclofen for the treatment of spasticity resulting from multiple sclerosis, particularly for the relief of flexor spasms and concomitant pain, clonus, and muscular rigidity.



### 8-Xelstrym (dextroamphetamine) Transdermal System by Noven Pharmaceuticals, Inc.

The U.S. Food and Drug Administration on 22 March 2022 approved Xelstrym transdermal system. Xelstrym transdermal system is used to treat ADHD. Xelstrym (dextroamphetamine) transdermal system is a central nervous system (CNS) stimulant indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in adults and children 6 years and older.



### 9- Nasonex 24HR Allergy Nasal Spray by Perrigo company

The U.S. Food and Drug Administration on 17 March 2022 approved Nasonex 24HR allergy nasal spray. Nasonex 24HR Allergy Nasal Spray is used to treat Allergic Rhinitis. Nasonex 24HR Allergy (mometasone furoate monohydrate) is a corticosteroid nasal spray available over-the-counter for the temporary relief of the symptoms of hay fever or other upper respiratory allergies.



- **NPPA hikes prices of 800 essential drugs by 11%:** In a major development, the National Pharmaceutical Pricing Authority (NPPA) has announced a hike in prices of around 800 essential drugs from 1 April. The rise in drug prices works out at around 10.76% based on the Wholesale Price Index (WPI) data. The clause 16 of Drugs Price Control Order 2013, allows NPPA to revise the ceiling price of scheduled formulations as per the annual wholesale price index (WPI) for the preceding calendar year on or before 1 April of every year and notify the same on the first day of April every year. The pharmaceutical industry welcomed the government's decision stating that this 10% hike in scheduled drugs is after many years.
- **Local manufacturing of 35 APIs started after PLI scheme:** As per Mandaviya, the Minister of Health & Family Welfare and Chemical and Fertilisers, 35 APIs are being manufactured from 32 different manufacturing plants and will help in giving a boost to AatmaNirbhar Bharat. These 35 active pharmaceutical ingredients (APIs) are among the 53 APIs, for which India has 90 percent import dependence. Last year, the government announced the Rs 15,000 crore PLI scheme for the pharmaceutical sector. He said there has been a good response from the pharma industry to the PLI scheme and manufacturing of the other APIs is also expected to start in India in due course of time.
- **Serum Institute seeks emergency use authorisation for its rBCG tuberculosis vaccine:** The Serum Institute of India has applied to the Drugs Controller General of India seeking emergency use authorisation for its recombinant BCG (rBCG) vaccine for the prevention of tuberculosis. The EUA application was submitted on March 22 by Prakash Kumar Singh, Director of Government and Regulatory Affairs at the SII. India's TB immunisation programme currently offers BCG vaccination at birth or as early as possible till one year of age. The number of tuberculosis cases in India has seen a 19% rise in 2021 over the previous year, and there has been an increase in the mortality rate due to all forms of TB between 2019 and 2020 by 11%, according to the annual TB report released by Union Health Minister Mansukh Mandaviya. Under leadership of CEO Adar C Poonawalla, the firm is committed to make available a safe, efficacious and high-quality world class TUBERVAC-rBCG vaccine for newborns, children, adolescents and adults at

affordable price.

- **19 Indian companies get licence to make generic form of Pfizer's oral antiviral Covid-19 pill:** The Medicines Patent Pool (MPP) has granted licences to 19 Indian pharmaceutical firms to manufacture and commercialise the generic version of Paxlovid, Pfizer's oral antiviral Covid-19 pill. These include Cipla, Sun Pharma, Laurus Labs, Divi's Laboratories, Glenmark, Emcure, Macleods, SMS Pharmaceuticals, Strides, Torrent, Cadila, Biocon, Aurobindo Pharma, Hetero, Granules, Amneal, and Viatris, among others. Pfizer's Paxlovid comprises nirmatrelvir, which inhibits a SARS-CoV-2 protein to stop the virus from replicating, and ritonavir, which slows down nirmatrelvir's breakdown to help it remain in the body for a longer period at higher concentrations. Paxlovid is administered as three tablets (two tablets of nirmatrelvir and one tablet of ritonavir) taken together orally twice daily for five days. The partnership with MPP to make a generic version of Paxlovid for the global community will contribute towards reducing the health burden due to the pandemic.
- **FDI in pharma sees 'sudden spurt' in 2020-21: Survey:** Foreign direct investment in India's pharmaceutical sector saw a "sudden spurt" in 2020-21 mainly on account of investments to meet COVID-19-related demands for therapeutics and vaccines, according to the Economic Survey. In the April-September 2021 period, the FDI inflows continued to be buoyant at Rs 4,413 crore, growing at the rate of 53 per cent over the same period in 2020-21, according to the Survey tabled in Parliament by Finance Minister Nirmala Sitharaman. Stating that the Indian pharmaceutical industry ranks third in the world in production by volume, the Survey said that during 2020-21, the total pharma export stood at USD 24.4 billion as against the total pharma import of USD 7.0 billion, thereby generating a trade surplus of USD 17.5 billion. Also, the Indian pharmaceutical sector witnessed a 200% increase in FDI in 2020-21, noted the Economic Survey 2021-22.
- **USFDA revokes emergency use status to two Covid antibody therapies:** The USFDA has revised the authorizations for two monoclonal antibody treatments bamlanivimab and etesevimab sold by Eli Lilly and Regeneron's casirivimab and imdevimab – to limit their use to only when the patient is likely to have

been infected with or exposed to a variant that is susceptible to these treatments. According to USFDA the data showed that these treatments were highly unlikely to be active against the omicron variant, which is circulating at a very high frequency throughout the United States, also these treatments were not authorized for use in any U.S. states, territories, and jurisdictions during that time. USFDA said several other therapies such as Paxlovid, sotrovimab, Veklury (remdesivir), and molnupiravir – are expected to work against the omicron variant.

- Glenmark receives DCGI nod to conduct clinical trials of its molecule on cancer patients:** Glenmark Pharmaceuticals has received approval from the Drug Controller General of India (DCGI) to conduct phase 1 clinical trials of its novel molecule on patients with advanced solid tumors. Glenmark Specialty SA has received approval from the DCGI to conduct a Phase 1 clinical trial of its novel small molecule, GRC 54276, a hematopoietic progenitor kinase 1 (HPK1) inhibitor. The Mumbai-based drug major said, GRC 54276 has shown tumor cell killing ability in preclinical studies as a single agent and as well in combination with checkpoint inhibitors, making it a high-priority target in immuno-oncology.
- Themis Medicare's anti-viral COVID drug gets DCGI nod:** Mumbai-based pharmaceutical company Themis Medicare's anti-viral drug Viralex has received Drugs Controller General of India's (DCGI) approval. The drug helps in early relief of clinical symptoms in mild-to-moderate COVID-19 patients. According to the company, as per the results of Phase 3 Randomized, Double-blind, Placebo-controlled Trial, 80.17% of patients treated with Viralex showed clinical improvement on day 6, which is significantly higher ( $p < 0.001$ ) from that in the controlled group & (52.38%) among the mild to moderate non-hospitalized COVID-19 patients.
- GE Healthcare to open all-women manufacturing plant in Bengaluru:** Wipro GE Healthcare on Monday said its upcoming greenfield manufacturing facility in Bengaluru will be managed entirely by women. The company will initially employ 33 women and the number will be increased to 100 when production expands. The around Rs 100-crore unit is being built under the government's production-linked incentive (PLI) scheme. It will manufacture machines

for CT-scans, cath labs and ultrasonography, besides ventilators and patient monitors. The factory was built in a record time of eight months.

- Molnupiravir reduced Covid-linked hospitalisation by over 65%: Study:** A study by pharma company Hetero has found that its anti-Covid drug Molnupiravir reduced hospitalisation by 65% in patients with mild cases of Covid-19. The Phase III trial results of Hetero's Movfor (Molnupiravir), presented at the Conference on Retroviruses and Opportunistic Infections (CROI) demonstrated that Molnupiravir along with Standard of Care (SOC) reduced the risk of hospitalisation by over 65% compared to SOC alone. Hetero entered into a non-exclusive voluntary licensing agreement with MSD in April 2021 for the manufacturing and distribution of investigational oral therapeutic antiviral drug Molnupiravir for the treatment of Covid-19. The drug was granted emergency use authorisation (EUA) in India by the drug controller General of India last year. Under the licensing deal, Hetero was allowed to expand access of Molnupiravir in India and in other low-and middle-income countries (LMICs), following the approvals for emergency use authorisation by local regulatory agencies.



## Felicitation of Dr. Montu Kumar Patel as elected President, Pharmacy Council of India.





रजिस्ट्री सं. सी.एल.-33004/99

REGD. No. D. L.-33004/99

  
**भारत का राजपत्र**  
**The Gazette of India**

सी.जी.-डी.एल.-अ.-18052022-235838  
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असाधारण  
EXTRAORDINARY

भाग II—खण्ड 3—उप-खण्ड (i)  
PART II—Section 3—Sub-section (i)

प्राधिकार से प्रकाशित  
PUBLISHED BY AUTHORITY

सं. 341]  
No. 341]

नई दिल्ली, बुधवार, मई 18, 2022/वैशाख 28, 1944  
NEW DELHI, WEDNESDAY, MAY 18, 2022/VAISAKHA 28, 1944

**MINISTRY OF HEALTH AND FAMILY WELFARE**  
(Department of Health and Family Welfare)

**NOTIFICATION**

New Delhi, the 18th May, 2022

**G.S.R. 357(E).**—Whereas a draft of certain rules further to amend the Drugs Rules, 1945, was published as required under sub-section (1) of section 12 and sub-section (1) of section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940) vide notification of the Government of India in the Ministry of Health and Family Welfare (Department of Health and Family Welfare) number G.S.R. 75(E), dated the 1<sup>st</sup> February, 2022, in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), inviting objections and suggestions from persons likely to be affected thereby, before the expiry of a period of thirty days from the date on which the copies of the Official Gazette containing the said notification were made available to the public;

And whereas, copies of the said Official Gazette were made available to the public on the 2<sup>nd</sup> February, 2022;

And whereas, objections and suggestions received from the public on the said draft rules have been considered by the Central Government;

Now, therefore, in exercise of the powers conferred by sections 12 and 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, after consultation with the Drugs Technical Advisory Board, hereby makes the following rules further to amend the Drugs Rules, 1945, namely:—

1. (1) These rules may be called the Drugs (Fourth Amendment) Rules, 2022.  
(2) They shall come into force with effect from the 1<sup>st</sup> day of November, 2022.
2. In the Drugs Rules, 1945, in Schedule H, after serial number 551 and the entries relating thereto, the following serial number and entry shall be inserted, namely:—  
“552. Acitretin”.

[F. No. X.11014/11/2021-DR]

Dr. MANDEEP K BHANDARI, Jt. Secy.

**Note :** The principal rules were published in the Gazette of India vide notification number F.28-10/45-H (1), dated the 21st December, 1945 and last amended vide notification number G.S.R. 158(E), dated the 24th February, 2022.

रजिस्ट्री सं. बी.एन.- 33004/89

REGD. No. D.L.-33004/89



# भारत का राजपत्र The Gazette of India

सी.जी.-डी.एन.-अ.-18052022-235837  
CG-DL-E-18052022-235837

असाधारण  
EXTRAORDINARY

भाग II—खण्ड 3—उप-खण्ड (i)  
PART II—Section 3—Sub-section (i)

प्राधिकार से प्रकाशित  
PUBLISHED BY AUTHORITY

सं. 340]  
No. 340]

नई दिल्ली, बुधवार, मई 18, 2022/वैशाख 28, 1944  
NEW DELHI, WEDNESDAY, MAY 18, 2022/VAISAKHA 28, 1944

## MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

### NOTIFICATION

New Delhi, the 18th May, 2022

**G.S.R. 356(E).**—Whereas a draft of certain rules further to amend the Medical Devices Rules, 2017, was published as required under sub-section (1) of section 12 and sub-section (1) of section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940) vide notification of the Government of India in the Ministry of Health and Family Welfare (Department of Health and Family Welfare) number G.S.R. 23(E), dated the 18th January, 2022, in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), inviting objections and suggestions from persons likely to be affected thereby, before the expiry of a period of forty-five days from the date on which the copies of the Official Gazette containing the said notification were made available to the public;

And whereas, copies of the said Official Gazette were made available to the public on the 19th January, 2022;

And whereas, objections and suggestions received from the public on the said draft rules have been considered by the Central Government;

Now, therefore, in exercise of the powers conferred by sections 12 and 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, after consultation with the Drugs Technical Advisory Board, hereby makes the following rules further to amend the Medical Devices Rules, 2017, namely:—

1. (1) These rules may be called the Medical Devices (Third Amendment) Rules, 2022.
- (2) They shall come into force on the date of their publication in the Official Gazette.

2. In the Medical Devices Rules, 2017, after rule 43, the following rule shall be inserted, namely:—
- “43A. Suspension and cancellation of licence.— (1) If the manufacturer or licensee fails to comply with any of the conditions of an import license, or any provisions of the Act and these rules, the Central Licensing Authority may after giving the manufacturer or licensee an opportunity to show cause why such an order should not be passed, by an order in writing stating the reasons therefor, cancel a license issued under rules, or suspend it for such period as it may think fit either wholly or in respect of any of the part of medical device to which it relates or direct the licensee to stop import, sale or distribution of the said medical device and, thereupon, order the destruction of medical device and the stock thereof in the presence of an officer authorised by the Central Licensing Authority, if in its opinion, the licensee has failed to comply with any of the conditions of the licence or with any provisions of the Act or the rules made thereunder:

Provided that a person who is aggrieved by the order passed by the Central Licensing Authority under this rule may, within thirty days of the serving of the order, file an appeal to the Central Government, and the Central Government may, after such enquiry into the matter, as it considers necessary and after giving the said appellant an opportunity of being heard, pass such order as it thinks fit.”.

[F. No. X.11014/4/2019-DR]

Dr. MANDEEP K. BHANDARI, Jt. Secy.

**Note :** The Medical Devices Rules, 2017 was published in the Official Gazette vide notification number G.S.R. 78(E), dated the 31st January, 2017 and last amended vide notification number G.S.R. 174(E), dated the 4th March, 2022.

रजिस्ट्री सं. सी.एल.-33004/99

REGD. No. D. L.-33004/99



# भारत का राजपत्र The Gazette of India

सी.जी.-डी.एल.-अ.-30032022-234674  
CG-DL-E-30032022-234674

असाधारण  
EXTRAORDINARY

भाग II—खण्ड 3—उप-खण्ड (i)  
PART II—Section 3—Sub-section (i)

प्राधिकार से प्रकाशित  
PUBLISHED BY AUTHORITY

सं. 224]  
No. 224]

नई दिल्ली, मंगलवार, मार्च 29, 2022/चैत्र 8, 1944  
NEW DELHI, TUESDAY, MARCH 29, 2022/CHAITRA 8, 1944

## MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

### NOTIFICATION

New Delhi, the 29th March, 2022

**G.S.R. 227(E).**—The following draft of certain rules further to amend the Drugs Rules, 1945, which the Central Government proposes to make, in exercise of the powers conferred by sub-section (1) of section 12 and sub-section (1) of section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), is hereby published after consultation with the Drugs Technical Advisory Board for information of all persons likely to be affected thereby and notice is

hereby given that the said draft rules shall be taken into consideration on or after the expiry of a period of thirty days from the date on which copies of the Gazette of India containing these draft rules are made available to public;

Objections and suggestions which may be received from any person within the period specified above will be considered by the Central Government;

Objections and suggestions, if any, may be addressed to the Under Secretary (Drugs), Ministry of Health and Family Welfare, Government of India, Room No. 434, C Wing, Nirman Bhavan, New Delhi - 110011 or emailed at [drugsdiv-mohfw@gov.in](mailto:drugsdiv-mohfw@gov.in).

## DRAFT RULES

1. (1) These rules may be called the Drugs (.....Amendment) Rules, 2022.  
(2) These rules shall come into force on the date of their final publication in the Official Gazette.
2. In the Drugs Rules, 1945, in rule 127, in sub-rule (1), for the existing Proviso, the following Proviso shall be substituted, namely:—  
“Provided that in case of disinfectants, in addition to the above said colours, the colours referred in IS 4707 (Part I) as amended by Bureau of Indian Standards from time to time and any of the colours which is non-staining specified below shall be permissible to use.

Common name of the colour	Colour Index Number	Chemical name of the colour
1	2	3
Guinea Green B	42085	Monosodium salt of 4-(N-ethyl-p-sulfobenzylamino)-diphenylmethylen-1-(N-ethyl-N-p-sulfoniumbenzyl)Δ 2,5-cyclohexadienimine).
Light Green SF Yellowish	42095	Disodium salt of 4-[4-(N-ethyl-p-sulfobenzylamine)-phenyl]-4-sulphoniumphenyl methylene]-2-(N-ethyl-N-sulfobenzyl) Δ 2,5-Cyclohexadienimine.
Tartrazine	19140	Trisodium salt of 3-carboxy-5-hydroxy-1-p-sulphophenyl-4-p-sulphophenylazo-pyrazole.
Sunset yellow FCF	15985	Disodium salt of 1-p-sulphophenylazo-2-naphthol-6-sulfonic acid.
Ponceau 3R	16155	Disodium salts of a mixture of 1-alkyl-phenylazo-2-naphthol 3, 6-disulfonic acids.
Amarnath	16185	Trisodium salt of 1-(4-sulfo-1-naphthylazo) 2-naphthol 3, 6-disulfonic acid.
Erythrosine	45430	Disodium salt of 9-0-carboxyphenyl-6-hydroxy 2,4,5, 7-tetraiodo-3-isoxanthone.
Ponceau SX	14700	Disodium salt of 2-(5 sulfo-2, 4-xylyl-azo)-1-naphthol-4-sulfonic acid.
Brilliant Blue FCF	42090	Disodium salt of 4-(9-4-(N-ethyl-p-sulfobenzylamino)-phenyl)-2-sulfonium phenyl- methylene)-(1-(N-ethyl-N-p-sulfobenzyl)-Δ 2, 5-cyclohexadienimine).
Indigocarmine	73015	Disodium salt of 5,5'-indigotindisulfonic acid.
Wool Violet 5 BN (Acid- violet 6B)	42640	Monosodium salt of 4-(N-ethyl-p-sulfobenzylamino)-phenyl)-(4-(N-ethyl-p-(sulfonium-benzylamine)-phenyl) methylene)-(N, N- dimethyl-Δ 2,5-cyclohexadienimine)
Light Green SF Yellowish	42095	Calcium salt of 4-(4-(N-ethyl-p-sulfobenzyl) (minophenyl) (4-sulfonium-phenyl)methylene), (1-(N-ethyl-N-p-sulfobenzyl)-Δ 2,5-cyclohexadienimine).
Alizarin Cyanine Green F	61570	Disodium salt of 1,4-bis (O-sulfo-p-toluino) anthraquinone
Quinazarine Green SS	61565	1,4-bis-(p-Toluino)-anthraquinone
Fast Green FCF	42053	Disodium salt of 4-(4-(ethyl-p-sulfobenzylamino)-phenyl) (4-hydroxy-2 sulphoniumphenyl) methylene)-(1-(N-ethyl-N-p-sulfobenzyl) Δ 2, 5, cyclohexadienimine).

[भाग II—खण्ड 3(i)]

भारत का राजपत्र : असाधारण

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Acid Fast Green	42100	Monosodium salt of 4-(4-N-ethyl-p-sulfobenzylomino) phenyl)- (o-chlorophenyl)-methylene)- 1-(N-ethyl-N-p-sulfonium benzyl- $\Delta$ 2,5, cyclohexadienimine).
Pyranine Concentrated	59040	Trisodium salt of 10-hydroxy-3,5,8-pyrene-trisulfonic Acid
Quinoline Yellow WS	47005	Disodium indandione.
Quinoline Yellow SS	47000	2-(2-quinolyl)-1, 3 indandiene.
Ponceau 2 R	16150	Disodium salt of 1-xylylazo-2-naphthol-3, 6-disulfonic acid.
Lithol Rubin B	15850	Monosodium salt of 4-(o-sulfo-p-tolylazo)3 hydroxy-2-naphthoic acid.
Lithol Rubin BCA	15850	Calcium salt of 4-(o-sulfo-p-tolylazo)-3-hydroxy-2-naphthoic acid
Lake Red D	15500	Monosodium salt of 1-0-carboxyphenylazo-2-naphthol.
Lake Red DBA	15500	Barium salt of 1-o-carboxyphenylazo-2-naphthol.
Lake Red DCA	15500	Calcium salt of 1-o-carboxyphenylazo-2-naphthol.
Toney Red	26100	I-p-phenylazophenylazo-2-naphthol.
Oil Red OS	26125	I-Xylylazoxylazo-2-naphthol
Tetrabromofluorescein	45380	2,4,5,7-Tetrabromo-3, 6-fluorandiol.
Eosin TS	45380	Disodium salt of 2,4,5,7-tetrabromo-9-0 carboxyphenyl-6-hydroxy-3-isoxanthone.
Eosin YSK.	45380	Dipotassium salt of 2,4,5,7-tetrabromo-9-0 carboxyphenyl-6-hydroxy-3-isoxanthone
Tetrachlorofluorescein NA	45366	2,4,5,7- tetrachloro-S, 6-Fluorandiol
Tetrachlorofluorescein K	45366	Disodium salt of 9-0-carboxyphenyl-2,4,5,7-tetrachloro-6-hydroxy-3-isoxanthone.
Tetrachloro Tetrabromo fluorescein	45410	2,4,5,7-Tetrabromo-12,13,14,15-tetrachloro-3, 6-fluorandiol.
Phloxine B	45410	Disodium salt of 2,4,5,7-tetrabromo-9 (3,4,5,6-tetra chloro- o-carboxyphenyl)-6-hydroxy-3-isoxanthone
Bluish Orange T.R.	45457	1,4,5,8, 15-Pentabromo-2, 7-dicarboxy-3, 6-fluorandiol.
Helindone Pink CN	73360	5, 5-Dichloro-3, 3' dimethyl-thioindigo
Deep Maroon (Fanchon Maroon)	15880	Calcium salt of 4-(I-sulfo-2-naphthylazo 3- hydroxy-2-naphthoic acid.
Toluidine Red	12120	1-(o-Nitro-p-tolylazo)-2-naphthol.
Flaming Red	12085	I- (o-Chloro-p-nitrophenylazo)-2-naphthol
Deep Red (Maroon)	12350	3-Hydroxy-N- (m-nitrophenyl)-4-(o-nitro-p-tolylazo)-2-naphthamide.
Alba Red	13058	o-(p, $\beta$ , $\beta$ -Dihydroxy-diethylamino)- phenylazo)-benzoic acid.
Orange G	16230	Disodium salt of 1-phenylazo-2-naphthol-6-8-disulfonic acid
Orange II	15510	Monosodium salt of 1-p-sulfophenylazo-2-naphthol.
Dichlorofluorescein	45365	4,5-Dichloro-3, 6-fluorandiol.
Dichlorofluorescein NA	45365	Disodium salt of 9-o-carboxyphenyl-1-4,5- dichloro-6-hydroxy-3-isoxanthone
Diiodofluorescein	45425	4,5 -Diiodo-3, 6-fluorandiol
Erythrosine Yellowish NA	45425	Disodium salt of 9-o-carboxyphenyl-6- hydroxy-4, 5- diiodo-3-isoxanthone.
Erythrosine Yellowish K	45425	Dipotassium salt of 9-o-carboxyphenyl-6-hydroxy-4, 5-diiodo-3-isoxanthone.
Erythrosine Yellowish NH	45425	Dipotassium salt of 9-o-carboxyphenyl-6-hydroxy-4, 5-diiodo-3-isoxanthone
Orange TR	45456	4,5, 15-Tribromo 2, 7-dicarboxy-3, 6- fluorandiol.
Alizarin	58000	1,2- Anthraquinonediol.
Dibromodiiodofluorescein	45371	4,5- Dibromo-2, 7-diiodo-3, 6-fluorandiol.
Alphazurine FG	42090	Diammonium salt of 4-(N-ethyl-p- sulfobenzyl amino)-phenyl)-(2-sulfoniumphenyl)-Methylene)-(1 (N-ethyl-N- p-sulfobenzyl) $\Delta$ 2,5-cyclohexadienimine).
Allarin Astrol B	61530	Monosodium salt of 1-methylamino-4-(o-sulfo-p-toluiino)-anthroquinone.

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THE GAZETTE OF INDIA : EXTRAORDINARY

[PART II—SEC. 3(i)]

Indigo	73000	Indigotin.
Patent Blue NA	42052	Monosodium salt of 4-(4- (N-ethyl- benzyl-amino)-phenyl – (5-hydroxy-4-sulfo-2-sulfoniumphenyl-methylene)(N-ethyl- Benzyl- $\Delta$ 2, 5-cyclohexadienimine).
Patent Blue CA	42052	Calcium salt of 4-(4- (N-ethyl- benzyl-amino)-phenyl)-(5 hydroxy-4-sulfo-2-sulfoniumphenyl, methylene)- (N-ethyl- N-benzyl- $\Delta$ 2- 5-cyclohexadienimine).
Carbranthrene Blue	69825	3, 3- Dichloroindanthrene.
Naphthol Blue Black	20470	Disodium salt of 8-amino-7-p- nitrophenylazo 3- phenylazo-1- naphthol-3, 6-disulfonic acid
Alizarol purple SS	60725	1-hydroxy-4-p-toluno-anthraquinone.
Acid Red 89	23910	----
Acid Red 97	22890	----
Acid Blue 1	42045	----
Food Blue 3	42045	----
Natural Orange	75480	----
Solvent Blues 4	44045	----
Solvent Yellow 18	12740	----
Food Yellow 12	12740	----
Solvent Yellow 32	48045	----
Fanchon Yellow (Hansa Yellow G)	11680	( $\alpha$ ) -(O-Nitro-p-tolylazo) accetoacetanilide

[F. No. X.11014/14/2021-DR]

Dr. MANDEEP K BHANDARI, Jt. Secy.

**Note:** The principal rules were published in the Official Gazette *vide* notification No. F.28-10/45-H(1), dated 21<sup>st</sup> the December, 1945 and last amended *vide* notification number G.S.R.....(E), dated the .....

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REGD. No. D. L-33004/99



# भारत का राजपत्र The Gazette of India

सी.जी.-डी.एल.-अ-25022022-233731  
CG-DL-E-25022022-233731

असाधारण  
EXTRAORDINARY

भाग II—खण्ड 3—उप-खण्ड (i)  
PART II—Section 3—Sub-section (i)

प्राधिकार से प्रकाशित  
PUBLISHED BY AUTHORITY

सं. 155]

नई दिल्ली, बृहस्पतिवार, फरवरी 24, 2022/फाल्गुन 5, 1943

No. 155]

NEW DELHI, THURSDAY, FEBRUARY 24, 2022/PHALGUNA 5, 1943

**MINISTRY OF HEALTH AND FAMILY WELFARE****(Department of Health and Family Welfare)****NOTIFICATION**

New Delhi, the 24th February, 2022

**G.S.R. 158(E).**—Whereas a draft of certain rules further to amend the Drugs Rules, 1945, was published as required under sub-section (1) of section 12 and sub-section (1) of section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940) *vide* notification of the Government of India in the Ministry of Health and Family Welfare (Department of Health and Family Welfare) number G.S.R. 840(E), dated the 29<sup>th</sup> November, 2021, in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), inviting objections and suggestions from persons likely to be affected thereby, before the expiry of a period of thirty days from the date on which the copies of the Official Gazette containing the said notification were made available to the public;

And whereas, copies of the said Official Gazette were made available to the public on the 29<sup>th</sup> November, 2021;

And whereas, objections and suggestions received from the public on the said draft rules have been considered by the Central Government;

Now, therefore, in exercise of the powers conferred by sections 12 and 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, after consultation with the Drugs Technical Advisory Board, hereby makes the following rules further to amend the Drugs Rules, 1945, namely:—

1. (1) These rules may be called the Drugs (3<sup>rd</sup> Amendment) Rules, 2022.
- (2) They shall come into force on the date of their publication in the Official Gazette.

[भाग II—खण्ड 3(i)]

भारत का राजपत्र : असाधारण

3

2. In the Drugs Rules, 1945, in rule 127, in sub-rule (1), under the heading (3) relating to 'Coal Tar Colours', after the entry 'Carmoisine' and before the entry 'BLUE Indigo Carmine', the following entry shall be inserted, namely:—

Common Name of the Colour	Colour Index Number	Chemical Name
1	2	3
"Allura Red	16035	Disodium 6-hydroxy-5-[(2-methoxy-5-methyl-4-sulphophenyl)azo]-2-Naphthalenesulfonic acid"

[F.No. X.11014/22/2021-DR]

DR. MANDEEP K BHANDARI, Jt. Secy.

**Note:** The principal rules were published in the Gazette of India *vide* notification number F.28-10/45-H (1), dated the 21<sup>st</sup> December, 1945 and last amended *vide* notification number G.S.R. 30(E), dated the 20.01.2022.

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रजिस्ट्री सं. डी.एल.- 33004/99

REGD. No. D. L.-33004/99



# भारत का राजपत्र The Gazette of India

सी.जी.-डी.एल.-अ.-10022022-233278  
CG-DL-E-10022022-233278

असाधारण  
EXTRAORDINARY

भाग II—खण्ड 3—उप-खण्ड (ii)  
PART II—Section 3—Sub-section (ii)

प्राधिकार से प्रकाशित  
PUBLISHED BY AUTHORITY

सं. 534]  
No. 534]

नई दिल्ली, बुधवार, फरवरी 9, 2022/माघ 20, 1943  
NEW DELHI, WEDNESDAY, FEBRUARY 9, 2022/MAGHA 20, 1943

## MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

### NOTIFICATION

New Delhi, the 9th February, 2022

**S.O. 553(E).**—Whereas, there is an outbreak of COVID-19 pandemic throughout India, resulting into dangerous and opportunist infections, disease like Mucormycosis, etc., due to which emergency has arisen to make available new drugs for treatment or management of COVID-19 and related diseases;

Whereas, the Central Government is satisfied that making available suitable new drugs is essential to meet the requirements of emergency arising due to pandemic COVID-19, and in public interest it is necessary and expedient to regulate the manufacture and stock for sale or distribution of such new drugs for prevention and treatment of COVID-19 and associated infection;

Now, therefore, notwithstanding anything contained in the Drugs Rules, 1945 and New Drugs and Clinical Trials Rules, 2019, for the purposes of making available suitable drugs to meet the requirements of emergency arising due to COVID-19, in exercise of the powers conferred by section 26B of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, hereby notifies the following, namely:—

- (a) In case a person intends to manufacture and stock a new drug for COVID-19, which is under clinical trial for marketing authorisation for sale or distribution, then, such person shall have to obtain permission in Form CT-06 to conduct clinical trial of such drug and on successful completion of the clinical trial and after obtaining permission in Form CT-23 from the Central Licensing Authority under the New Drugs and Clinical Trials Rules, 2019, he shall make an application under rule 69 or rule 70A

or rule 75 or rule 75A of the Drugs Rules, 1945, as the case may be, to the concerned Licensing Authority appointed by the State Government along with the permission obtained for conducting clinical trial in Form CT-06 under the New Drugs and Clinical Trials Rules, 2019, for grant of license to manufacture and stock the drug for sale or distribution under the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) (hereinafter referred to as the said Act) and the rules made thereunder:

Provided that the requirement of prior permission from the Central Licensing Authority under rule 81 of the New Drugs and Clinical Trials Rules, 2019 to manufacture the new drug as required under rule 83 of the said rules shall be deferred in public interest to meet the emergent situation arisen out of COVID-19 and such person shall obtain the said permission after successful completion of the clinical trial and submission of application along with fees, data and particulars in accordance with the provisions of the New Drugs and Clinical Trials Rules, 2019.

- (b) The Central License Approving Authority or the State Licensing Authority, as the case may be, if satisfied that requirements under the provisions of the said Act and the Drugs Rules, 1945 and the New Drugs and Clinical Trials Rules, 2019 have been complied with, grant License in accordance with the provisions of the Drugs Rules, 1945 to manufacture and stock the new drug subject to the condition that the licensee shall sell or distribute the new drug only after obtaining permission for such new drug in Form CT-23 from the Central Licensing Authority under the New Drugs and Clinical Trials Rules, 2019.

2. In case of any inconsistency between this notification and any rule made under the said Act, the provisions of this notification shall prevail over such rule in public interest so as to meet the emergency which has arisen due to COVID-19 pandemic.

3. This order shall come into force on the date of its publication in the Official Gazette.

[F. No. X.11014/02/2020-DRS]

Dr. MANDEEP K BHANDARI, Jt. Secy.

रजिस्ट्री सं. डी.एल.- 33004/99

REGD. No. D. L.-33004/99



# भारत का राजपत्र The Gazette of India

सी.जी.-डी.एल.-अ.-10022022-233279  
CG DL E-10022022 233279

असाधारण  
EXTRAORDINARY

भाग II—खण्ड 3—उप-खण्ड (i)  
PART II—Section 3—Sub section (i)

प्राधिकार से प्रकाशित  
PUBLISHED BY AUTHORITY

सं. 102]  
No. 102]

नई दिल्ली, बुधवार, फरवरी 9, 2022/माघ 20, 1943  
NEW DELHI, WEDNESDAY, FEBRUARY 9, 2022/MAGHA 20, 1943

## MINISTRY OF HEALTH AND FAMILY WELFARE (Department Of Health And Family Welfare)

### NOTIFICATION

New Delhi, the 9th February, 2022

**G.S.R. 104(E).**—The following draft of certain rules further to amend Medical Device Rules, 2017, which the Central Government proposes to make, in exercise of the powers conferred by sub-section (1) of section 12 and sub-section (1) of section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), is hereby published after consultation with the Drugs Technical Advisory Board for information of all persons likely to be affected thereby and notice is hereby given that the said draft rules shall be taken into consideration on or after the expiry of a period of forty-five days from the date on which copies of the Gazette of India containing these draft rules are made available to public;

Objections and suggestions which may be received from any person within the period specified above will be considered by the Central Government;

Objections and suggestions, if any, may be addressed to the Under Secretary (Drugs), Ministry of Health and Family Welfare, Government of India, Room No. 434, C Wing, Nirman Bhavan, New Delhi - 110011 or emailed at [drugsdiv-mohfw@gov.in](mailto:drugsdiv-mohfw@gov.in).

### DRAFT RULES

- (i) These rules may be called the Medical Devices (.....Amendment) Rules, 2022.  
(ii) These rules shall, unless specified otherwise, come into force on the date of their final publication in the Official Gazette.
- In the Medical Devices Rules, 2017(hereinafter to be referred as said rules), in rule 34, in sub-rule (1), after the words “wholesale licence for sale or distribution” and before the words “under these rules”, the following words and figure shall be inserted namely:—  
“or registration certificate in Form-42”
- In the said rules, in rule 87, at the end of sub-rule(1), the following sub-rule shall be inserted, namely: —  
“(1)(A) Notwithstanding anything contained in sub-rule(1), any person intends to sale medical devices exclusively as referred in clause (zb) of rule 3 shall obtain registration certificate as provided hereinafter in these rules.”

4. In the said rules, after rule 87, the following rules shall be inserted, namely:—

**“87(A) Registration Certificate to sell, stock, exhibit or offer for sale or distribute a medical device including *in vitro* diagnostic medical device.—**

- (1) The State Licencing Authority shall appoint Licensing Authorities for the purpose of issuing Registration Certificate in this Part for such areas as may be specified.
- (2) Any person who intends to sell, stock, exhibit or offer for sale or distribute a medical device including *in vitro* diagnostic medical device shall make an application in Form MD-41 for grant of Registration Certificate to sell, stock, exhibit or offer for sale or distribution to the State Licensing Authority.
- (3) The application made under sub-rule (2), shall be accompanied with
  - i. a fees prescribed in Second Schedule of the said rules;
  - ii. Self certificate of compliance with respect to Good Distribution Compliance;
  - iii. Details of the applicant/firm including its constitution, along with ID proof *viz*: Aadhar card, PAN card;
  - iv. Documentary evidence in respect of ownership or occupancy on rental of the premises;
  - v. Details of competent technical staff under whose direction and supervision the sales activity of medical device shall be undertaken and such staff shall possess the following educational qualification and experience,—
    - (a) holds a degree of a recognized University; or
    - (b) is a registered Pharmacist; or
    - (c) has passed intermediate examination or its equivalent examination from a recognized Board with the one-year experience in dealing with sale of Medical Devices.
  - vi. Brief description on other activities carried out by applicant, *viz*: storage of drugs, medical items, food products, stationeries etc or any other activities carried out by applicant in the said premises.
  - vii. The application made under sub-rule (2), shall be accompanied with an undertaking to the effect that the storage requirements to sell, stock, exhibit or offer for sale or distribute a medical device will be complied with.
- (4) The State Licensing Authority shall, after scrutiny of documents and on being satisfied that the requirements of these rules have been complied with, grant a Registration Certificate in Form MD-42, or if not satisfied, reject the application for reasons to be recorded in writing, within ten days from the date, the application is made under sub-rule (2).
- (5) If the application for grant of Registration Certificate to sell, stock, exhibit or offer for sale or distribute a medical device is rejected under sub-rule (4), the aggrieved person may prefer an appeal before the State Government within forty-five days from the date of receipt of such rejection, which may, after such enquiry and after giving an opportunity of being heard to the appellant, dispose it within a period of sixty days from the date of receipt of such appeal.

**87(B) Conditions of registration certificate to sell, stock, exhibit or offer for sale or distribute a medical device including *in vitro* diagnostic medical device.—**

- i. The Registration Certificate shall be displayed at a prominent place in the premises visible to the public.
- ii. The Registration Certificate holder shall provide adequate space, proper storage condition for storage of the Medical Devices.
- iii. The Registration Certificate holder shall maintain required temperature and lighting as per requirements of such Medical Devices.
- iv. The Medical Devices shall be purchased only from Importer or licensed manufacturer or registered/licenced entity under said rules.
- v. Separate records, in form of invoice or register or electronic details including software of purchases and sales of Medical Devices showing the names and quantities of such Medical Devices, names and addresses of the manufacturers/importers, Batch Number/Lot Number, Expiry Date shall be

maintained. Such records shall be open to inspection by a Medical Device Officer appointed under the sub-rule (2) of rule 18 of the said rules, who may, if necessary, make enquiries about purchases and sale of the Medical devices and may also take samples for testing.

- vi. All registers and records mentioned under these rules, shall be preserved for a period of not less than two years from the last entry, therein.
- vii. The Registration Certificate holder shall maintain an inspection book in Form MD-43 to enable the Medical Devices Officer to record his/her observations and defects noticed.

**87(C) Validity of registration certificate.—**

- (1) A Registration Certificate issued in Form MD-42, shall remain valid in perpetuity, subject to payment of Registration Certificate retention fee as specified in the Second Schedule before completion of the period of five years from the date of its issue, unless, it is suspended or cancelled by State Licensing Authority.

Provided that, If the Registration certificate holder fails to pay the required Registration Certificate retention fee on or before due date as referred to in sub-rule(1), the Registration Certificate holder shall, in addition to the Registration Certificate retention fee, be liable to pay a late fee calculated at the rate of two percent. of the Registration Certificate retention fee for every month or part thereof within six months.

Provided further that, in the event of non-payment of such fee during that period, the Registration Certificate shall be deemed to have been cancelled.

**87(D) Suspension and cancellation of Registration Certificate.—**

- (1) Where the Registration Certificate holder, contravenes any provision of the Act and the said rules, the State Licensing Authority, shall, after giving the Registration Certificate holder an opportunity to show cause as to why such an order should not be passed, shall by an order and for reasons to be recorded in writing, suspend it for such period as it considers necessary either wholly or in respect of any of the medical device or cancel the Registration Certificate.
- (2) A Registration Certificate holder whose Registration Certificate has been suspended or cancelled by the State Licensing Authority under sub-rule (1), may within forty-five days of the receipt of a copy of the order by such authority, prefer an appeal to the State Government or Authority designated by the State Government, and the State Government or Authority designated by the State Government, shall after giving the Registration holder an opportunity of being heard, confirm, reverse or modify such order, with reasons to be recorded in writing."

- 5. In the said rules, in Appendix, after Form MD-40, the following Forms shall be inserted, namely:—

**“Form MD-41**

[See sub-rule (2) of rule 87(A)]

**APPLICATION FOR GRANT OF REGISTRATION CERTIFICATE TO SELL, STOCK, EXHIBIT OR OFFER FOR SALE OR DISTRIBUTE A MEDICAL DEVICE INCLUDING *IN VITRO* DIAGNOSTIC MEDICAL DEVICE**

- 1. Name of Applicant:
- 2. Address of the premises to be registered:
- 3. Contact details of applicant including telephone number, mobile number, fax number and email id:
- 4. Nature and constitution of applicant: (i.e. proprietorship, partnership including Limited Liability Partnership, private or public company, society, trust, other to be specified)
- 5. Name, Qualification and experience of competent person appointed:
- 6. Fee paid on \_\_\_\_\_ Rs \_\_\_\_\_ receipt/challan/transaction Id \_\_\_\_\_.

7. I have enclosed the documents as specified in the rule 87(A)(3) of Medical Devices Rules, 2017.

Place: \_\_\_\_\_

Date: \_\_\_\_\_

Name, Designation & Signature of Director/Proprietor/Partner

### Form MD-42

[See sub-rule (4) of rule 87(A) and rule 87(C)]

### REGISTRATION CERTIFICATE TO SELL, STOCK, EXHIBIT OR OFFER FOR SALE OR DISTRIBUTE A MEDICAL DEVICE INCLUDING *IN VITRO* DIAGNOSTIC MEDICAL DEVICE

Registration No.: .....

1. M/s, .....(Name of the firm) situated at  
.....(full address with telephone and e-mail) has been registered to sell, stock, exhibit or offer for sale or distribute a medical device including in vitro diagnostic medical device under the Medical Devices Rules, 2017.

2. Name and Qualification of competent person:

3. This Registration is subject to the conditions as specified in the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Medical Devices Rules, 2017.

Place: \_\_\_\_\_

Date: \_\_\_\_\_

State Licensing Authority

### Form MD-43

[See clause (vii) of rule 87(B)]

### Form in which the Inspection Book shall be maintained

(A) The cover of the inspection book shall contain the following particulars, namely:—

1. The name and address of the Registration Certificate holder \_\_\_\_\_.
2. Registration Certificate Number \_\_\_\_\_.

(B) (i) The pages of the inspection book shall be serially numbered and duly stamped by the State Licensing Authority\*. The pages, other than the first and the last pages, shall have the following particulars:—

[भाग II—खण्ड 3(i)]

भारत का राजपत्र : असाधारण

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Name and designation of the medical device officer who inspected the premises:

Date of inspection \_\_\_\_\_

Observations of the medical device officer \_\_\_\_\_

Signature of the medical device officer

(ii) The first and last pages of the inspection book shall be endorsed by the State Licensing Authority with the following words, namely:—

Inspection book maintained by M/s \_\_\_\_\_ situated at \_\_\_\_\_ for Registration number \_\_\_\_\_ in Form MD-43 \_\_\_\_\_ under the Medical Devices Rules, 2017.

State Licensing Authority

**Notes:**

(i) Printed copy of the Inspection Book may be obtained by the licensee from the Licensing Authority on payment of fee as may be specified by the concerned Licensing Authority from time to time.

(ii) The inspection book shall be maintained at the premises of the licensee.

(iii) The original copy of observations made by the medical device officer shall be maintained in the premises of the licensee and duplicate copy shall be sent to the State Licensing Authority. The triplicate copy shall be taken as record by the medical device officer.

## 6. In the said rules,—

- (i) in rule 88, in sub-rule (1), after the words “or wholesale” and before the words “may, supply”, the following words and figure shall be inserted, namely:—

“or registration certificate in Form-42”.

- (ii) In Second Schedule, after the figures “64(1), 81(1), 84,” and before the figure “91”, the following figures and letters shall be inserted, namely:—

“87(A)(3) and 87(C)(1)”.

- (iii) In Second Schedule, in the table, after serial number 51 and the entries relating thereto, the following serial number and entries shall be inserted, namely:—

Sr.No.	Rule	Subject	In rupees (INR) except where specified in dollars (\$)
(1)	(2)	(3)	(4)
52.	87(A)(3)	Registration Certificate for sale of Medical Devices	3000
53.	87(C)(1)	Retention fee for Registration certificate for sale of Medical Devices	3000

- (iv) In Fourth Schedule, in Part I, after the words “manufacturing licence” and before the words “with telephone”, the words “or registration certificate” shall be inserted.

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THE GAZETTE OF INDIA : EXTRAORDINARY

[PART II—SEC. 3(i)]

- (v) Under Appendix, in Form MD-14, in para 3, sub-para (ii), after the words "manufacturing licence" the words "or registration certificate" shall be inserted.
- (vi) Under Appendix, in Form MD-15, in para 1, after the words "manufacturing licence" and before the words "of authorised agent" the words "or registration certificate" shall be inserted.
- (vii) Under Appendix, in Form MD-26, in para 3, sub-para (ii), after the words "manufacturing licence" the words "or registration certificate" shall be inserted.
- (viii) Under Appendix, in Form MD-28, in para 3, sub-para (ii), after the words "manufacturing licence" the words "or registration certificate" shall be inserted."

[F.No. X.11014/15/2021-DR]

Dr. MANDEEP K BHANDARI, Jr. Secy.

**Note:** The principal rules were published in the Official Gazette *vide* notification number G.S.R. 78(E), dated the 31<sup>st</sup> January, 2017 and last amended *vide* notification number G.S.R. .... (E), dated.....

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रजिस्ट्री सं. डी.एल.- 33004/99

REGD. No. D. L.-33004/99



# भारत का राजपत्र The Gazette of India

सी.जी.-डी.एल.-अ.-02022022-233070  
CG-DL-E-02022022-233070

असाधारण  
EXTRAORDINARY

भाग II—खण्ड 3—उप-खण्ड (i)  
PART II—Section 3—Sub-section (i)

प्राधिकार से प्रकाशित  
PUBLISHED BY AUTHORITY

सं. 75]  
No. 75]

नई दिल्ली, मंगलवार, फरवरी 1, 2022/माघ 12, 1943  
NEW DELHI, TUESDAY, FEBRUARY 1, 2022/MAGHA 12, 1943

## MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

### NOTIFICATION

New Delhi, the 1st February, 2022

**G.S.R. 75(E).**—The following draft of certain rules further to amend the Drugs Rules, 1945, which the Central Government proposes to make, in exercise of the powers conferred by sub-section (1) of section 12 and sub-section (1) of section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940) and in consultation with the Drugs Technical Advisory Board is hereby published for information of all persons likely to be affected thereby and notice is hereby given that the said draft rules shall be taken into consideration on or after the expiry of a period of thirty days from the date on which the copies of the Gazette of India containing these draft rules are made available to public;

Objections and suggestions which may be received from any person within the period specified above will be considered by the Central Government;

Objections and suggestions, if any, may be addressed to the Under Secretary (Drugs), Ministry of Health and Family Welfare, Government of India, Room No. 434, C Wing, Nirman Bhavan, New Delhi - 110011 or emailed at [drugsdiv-mohfw@gov.in](mailto:drugsdiv-mohfw@gov.in).

### DRAFT RULES

- (1) These rules may be called the Drugs (.....Amendment) Rules, 2022.  
(2) These rules shall come into force on the date of their final publication in the Official Gazette.
- In the Drugs Rules, 1945, in Schedule H, after serial number 551 and the entries relating thereto, the following shall be inserted, namely:—

“552. Acitretin”.

[F. No. X.11014/11/2021-DR]

Dr. MANDEEP K. BHANDARI, Jt. Secy.

**Note:** The principal rules were published in the Gazette of India *vide* notification number F.28-10/45-H(1), dated the 21<sup>st</sup> December, 1945 and last amended *vide* notification number G.S.R. ....(E), dated the.....

रजिस्ट्री सं. डी.एल.- 33004/99

REGD. No. D. L.-33004/99

  
**भारत का राजपत्र**  
**The Gazette of India**

सी.जी.-डी.एल.-अ.-20012022-232790  
CG-DL-E-20012022-232790

असाधारण  
EXTRAORDINARY

भाग II—खण्ड 3—उप-खण्ड (i)  
PART II—Section 3—Sub-section (i)

प्राधिकार से प्रकाशित  
PUBLISHED BY AUTHORITY

सं. 30]  
No. 30]

नई दिल्ली, बृहस्पतिवार, जनवरी 20, 2022/पौष 30, 1943  
NEW DELHI, THURSDAY, JANUARY 20, 2022/PAUSHA 30, 1943

**MINISTRY OF HEALTH AND FAMILY WELFARE**

(Department of Health and Family Welfare)

**NOTIFICATION**

New Delhi, the 20th January, 2022

**G.S.R. 30(E).**—Whereas a draft of certain rules further to amend the Drugs Rules, 1945, was published as required under sub-section (1) of section 12 and sub-section (1) of section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940) *vide* notification of the Government of India in the Ministry of Health and Family Welfare (Department of Health and Family Welfare) number G.S.R. 628(E), dated the 13<sup>th</sup> September, 2021, in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), inviting objections and suggestions from persons likely to be affected thereby, before the expiry of a period of thirty days from the date on which the copies of the Official Gazette containing the said notification were made available to the public;

And whereas, copies of the said Official Gazette were made available to the public on the 13<sup>th</sup> September, 2021;

And whereas, objections and suggestions received from the public on the said draft rules have been considered by the Central Government;

[भाग II—खण्ड 3(i)]

भारत का राजपत्र : असाधारण

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Now, therefore, in exercise of the powers conferred by sections 12 and 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, after consultation with the Drugs Technical Advisory Board, hereby makes the following rules further to amend the Drugs Rules, 1945, namely:—

1. (1) These rules may be called the Drugs (2<sup>nd</sup> Amendment) Rules, 2022.  
(2) They shall come into force on the date of their publication in the Official Gazette.
2. In the Drugs Rules, 1945, in Schedule K, in the table, after serial number 38 and the entries relating thereto, the following serial number and entries shall be inserted, namely:—

<i>Class of Drugs</i>	<i>Extent and Conditions of Exemption</i>
"39. Liquid Antiseptics for household use	<p>The provisions of Chapter IV of the Act and rules made thereunder, which require them to be covered with a sale license in Form 20 or Form 20A, subject to the following conditions, namely:—</p> <ol style="list-style-type: none"> <li>(a) The drugs are manufactured by licensed manufacturers;</li> <li>(b) the drugs do not contain any substance specified in Schedule G, H, H1 or X;</li> <li>(c) the drugs are sold in the original unopened containers of the licensed manufacturer;</li> <li>(d) the drugs are purchased from a licensed wholesaler or a licensed manufacturer." </li></ol>

[F.No. X.11014/10/2021-DR]

Dr. MANDEEP K BHANDARI, Jr. Secy.

**Note:** The principal rules were published in the Gazette of India *vide* notification number F.28-10/45-H (1), dated the 21<sup>st</sup> December, 1945 and last amended *vide* notification number G.S.R. 20(E), dated the 18<sup>th</sup> January, 2022.

## GUIDELINES FOR IPGA AWARDS

### CALL FOR NOMINATIONS

The Indian Pharmacy Graduates' Association established in 1973, recognizes the contribution made by a person through his/her life in the field of Pharmacy profession by conferring the prestigious IPGA AWARDS. This award will be given during the 29th Annual Conference of Indian Pharmacy Graduates' Association on 22nd November 2014 at Lovely Professional University, Phagwara, Punjab. Last date of receiving the nomination is 15th September 2014 at our IPGA Office address : F-2, A-Block, D.D.A. Shopping Complex, Meera Bagh, New Delhi-110087

#### 1. IPGA Life Time Achievement Award

##### Eligibility Criteria

Prospective candidate should

- Be graduate in pharmacy
- Be Life member of IPGA, at least, for 10 years
- Have made significant contribution in his field (pharmacy)
- Be 60 years or more of age

##### Guidelines for award

- Nominations for the award may be invited by publishing in the IPGA Today (News Letter), Pharmaceutical journals and putting the call for nomination on the website of IPGA highlighting the eligibility criteria
- In case, no nominations are received, the EC can select a person whose contributions are known in the Pharmaceutical field
- All the nominations received in the office of IPGA should be forwarded to the Screening Committee for Awards after verifying that the candidate is LM of the association for the last 10 years
- If there are more than one nominations, the Screening Committee for Awards shall have regard to:
  - Publication of contributions
  - Other awards and /or recognition of the work
  - Participation in the national / Inter- national events in the field of pharmacy
  - Authorship of book(s)
  - Contributions made to IPGA Screening Committee for Awards, after

#### Selection of the deserving candidate,

will forward the name to the President of the Association who will get it ratified by the EC. Requirement of LM for 10 years may be waived in exceptional cases where the contribution is of national or international importance or has been recognized nationally or internationally.

#### 2. IPGA Professional Excellence Award

##### Eligibility Criteria

Prospective candidate should

- Be graduate in pharmacy
- Be Life member of IPGA, at least, for 05 years
- Have made significant contribution in his field (pharmacy)
- Be 40 years or more of age

##### Guidelines for award

- Nominations for the award may be invited by publishing in the IPGA Today (News Letter), Pharmaceutical Journals and putting the call on the website of IPGA highlighting the eligibility criteria
- All the nominations received in the office of IPGA should be forwarded to the Screening Committee for Awards after verifying that the candidate is LM of the association for the last 05 years
- If there are more than one nominations, the Screening Committee for Awards shall have regard to:
  - Publication of contributions
  - Other awards and /or recognition of the work
  - Participation in the national / Inter- national events in the field of pharmacy
  - Authorship of book(s)
  - Contributions made to IPGA

This award will be given in four major fields of pharmacy i.e. (i) pharmacy education, (ii) industrial pharmacy, (iii) regulatory, and (iv) pharmacy practice. In one year, only one award will be given from any of the fields. Usually, the efforts shall be made to give award on rotation basis, so that all the four fields of pharmacy are covered during four years.

Screening Committee for Awards, after selection of deserving candidate, will forward the name to the

President of the Association who will get the name ratified by the EC of the Association.

### 3. IPGA Promising Pharmacist Award

#### Eligibility Criteria

Prospective candidate should

- Be graduate in pharmacy
- Be Life member of IPGA, at least, for 05 years
- Have excelled in his field of work
- Be less than 40 years of age

#### Guidelines for award

- Nominations the award may be invited by publishing in the IPGA Today (News Letter), pharmaceutical journals and putting the call on the website of IPGA highlighting the eligibility criteria
- All the nominations received in the office of IPGA should be forwarded to the Screening Committee for Awards after verifying that the candidate is LM of the association for the last 05 years
- If there are more than one nominations, the Screening Committee for Awards shall have regard to:
  - Publication of contributions
  - Other awards and /or recognition of the work
  - Participation in the national / Inter- national events in the field of pharmacy
  - Contributions made to IPGA

This award will also be given in four major fields of pharmacy i.e. (i) pharmacy education, (ii) industrial pharmacy, (iii) regulatory, (iv) pharmacy practice. In one year, only one award will be given from any of the fields. Usually, the efforts shall be made to give award on rotation basis, so that all the four fields of pharmacy are covered during four years.

Screening Committee for Awards, after selection of deserving candidate, will forward the name(s) to the President of the Association who will get the name(s) ratified by the EC of the Association.

### 3. IPGA Fellowship Award

#### Nomination procedure

Any person fulfilling the above criteria should be nominated by a life member of IPGA and the same should be seconded by at least two Life members of the IPGA. Nominations for IPGA Fellowship Award can be invited by publishing a notice for the award in IPGA Today and/or other pharmaceutical journals.

#### Scrutiny of Nominations

Scrutiny of nominations will be done by the IPGA fellowship award committee of the IPGA to verify the information furnished by the applicants on the basis of record available in the office of IPGA.

#### Consideration by the Committee

A five member Committee may be constituted with one member as the chairman and may be named as IPGA Fellowship Award Committee. While constituting committee, apart from chairman, one eminent member each from the following fields may be taken:

- Pharmaceutical Education
- Regulatory Affairs
- Pharmaceutical Industry
- Hospital, Community and Clinical

#### Pharmacy (Pharmacy Practice)

#### Award Committee

The nominations with correct information should be considered by the committee and the Committee should give recommendations for the award of Fellowship to the nominated persons as it may deem fit. The nominations with incorrect information should be rejected summarily. The committee should forward their recommendations to the Executive Committee of IPGA which should take final decision in the matter

#### Privileges of IPGA Awardee

Awardee will be entitled to attend the professional conferences/seminars organized by the federating associations of IPGA in India on behalf of the association and will be entitled to reimburse delegation fee and travelling expenses as per policy of the association for the one year in which the award is granted. The fellowship award will be given at the annual conference of the IPGA.

#### Scroll of Honour and Certificate

The awardee will be presented with a scroll of honour which will highlight the achievements of the recipient that

empowered him to get this award. FIPGA, will be entitled to attend the conference/ seminar organized by IPGA on behalf of the association for the whole life.

All the members unanimously approved the above guidelines and it has been decided that the same may be published in coming issue of IPGA TODAY for calling the nomination of the IPGA fellowship award.

#### General Guidelines:

- (i) The current members of Screening Committee for

Awards of the Association will not be eligible for awards during their term. Screening Committee for Awards shall have members one each from four afore said fields besides one chairman.

- (ii) The Committee shall prepare an assessment document laying down parameters for evaluation in line with above mentioned guidelines.
- (iii) The assessment/evaluation performed by the Screening Committee for Awards shall be final and shall not be challenged in any court of law.

## **Call for Nominations for K.C. Chatterjee Memorial Award 2014**

The Indian Pharmacy Graduates' Association established in 1973, recognizes the contribution made by a person through his/her life in the field of Pharmacy profession by conferring the prestigious K.C. Chatterjee memorial award. This award will be given during the inaugural session of 66th Indian Pharmaceutical Congress 2014 at Hyderabad. Last date of receiving the nomination is 30th Sept. 2014 at our IPGA Office Address or can be sent by mail at [atulnasa@gmail.com](mailto:atulnasa@gmail.com) or [agarg333@hotmail.com](mailto:agarg333@hotmail.com)

## **Guidelines for Selection of Candidate for K.C. Chatterjee Memorial Award**

The nominations received for the award of K.C. Chatterjee Memorial Award will be scrutinized by the K.C. Chatterjee Memorial Award Committee. The committee will evaluate candidates on the following considerations:

### **Qualifications**

The candidate should hold at least graduation degree in Pharmacy. Beyond graduation will be added qualification which will earn a candidate a point higher per degree/diploma held. Candidates other than holding a minimum degree in Pharmacy will be considered only in exceptional cases like international recognition in the field of pharmacy.

### **Experience**

The candidate should have an experience of not less than 20 years in any of the following field of Pharmacy:

- Pharmaceutical Industry
- Regulatory
- Pharmaceutical Education
- Pharmacy Practice

Experience beyond qualifying years i.e. 20 years will earn a candidate one point higher for every 5 years.

### **Publications**

The publications may be in the form of

- Research papers
- Articles
- Books

Publications will have more weightage in case of candidates from the field of Pharmacy education.

### **Membership of Professional Bodies**

The candidate should have membership of professional bodies like IPA, IPGA, APTI, AIDCOC, IHPA.

### **Membership of Statutory Bodies**

Membership of professional and/or statutory body (bodies) like state pharmacy council, Pharmacy Council of India will earn a candidate one additional point for each statutory body membership. The membership may be current or it may be in the past. Similarly membership of pharmaceutical professional bodies will earn a candidate one point for each association. Beyond this, if the candidate is or has been office bearer of such association, it will earn extra point subject to a limit of 3 points.

### **Membership of Other Committees**

A candidate might have been nominated to the committee(s) by professional body, statutory body or the Govt. Such each membership will earn a candidate one point per membership. The membership may be current or it may be in the past.

### **Contributions**

Contributions of the candidate to the profession will be evaluated under the following elements:

- Dedication
- Service
- Achievements

Do the achievements benefit:

- Self
- Profession
- Pharmacy Graduates
- Society

Achievements benefiting the pharmacy profession and/or pharmacy students will carry more weightage.

# WELCOME

*New Members*



7349  
Mr. Sankalp Bhola



7350  
Mrs. Razia Shaik



7351  
Dr. Kiran Sharma



7352  
Mr. Pankaj



7353  
Dr. Osman Ahmed



7354  
Dr. Gaurav Jain



7355  
Mrs. Ayesha Siddiqua Gazi



7356  
Dr. Thomas Kurian



7357  
Mr. Venkateshvaralu M



7360  
Mr. Kumar Vikram



7361  
Dr. Revathi Boyina



7362  
Prof. Sunil Shivajirao Deshmukh



7363  
Ms. Angana Naskar



7364  
Prof. Mananijgun Vishwanath M



7365  
Ms. Rakhi Bakuli



7366  
Mr. Manoj Kumar



7367  
Mr. Praveen Kumar Singh



7369  
Dr. Paul Richards Mooni



7370  
Mr. Munwar Shaik



7371  
Mr. Gaurav Ramakant Singh



7372  
Mr. Akashay Basavraj Mali



7373  
Ms. Yashika Tandon



7374  
Ms. Khushi Kumari



7376  
Mr. Gilbert Tony



7377  
Mr. Satish Vishwanath Udbale



7378  
Mr. Aditya Arun Kale



7380  
Mrs. Manisha Thakur



7382  
Mrs. Sonia Kamboj



7383  
Mr. Mayur Chandrashekhar Patil



7384  
Ms. Alpna



7385  
Mr. Sai Kiran Korlam



7386  
Prof. Sanjay Jegarkal



7387  
Mr. Yatharth Goel



7388  
Dr. Monika Kaurav



7389  
Dr. Ritesh Agrawal



7390  
Mrs. Arti Gautam



7391  
Dr. Sanjay Sharma



7392  
Mr. Suvojit Mondal



7393  
Mr. Nawaj Sarif



7394  
Mr. Suvrojyoti Ghosh Roy



7395  
Mr. Ramesh Kumar K.



7396  
Dr. Pazhani G.P.



7397  
Ms. Monika N



7398  
Mr. Arun Prasad Krishnan



7399  
Mr. R. Selva Kumar



7400  
Prof. Sekarbabu. M



7401  
Dr. Sarumathy S



7402  
Mr. Imrankhan Nizam



7403  
Ms. Lakshmi Madhavi Chitra



7404  
Ms. Mohini Diwan



7406  
Mr. Balakrishna Ale



7408  
Mr. Vishwanath J Hooli



7409  
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