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# IDMA BULLETIN

VOL. NO. 53 | ISSUE NO. 31 (PAGES: 40) | 15 TO 21 AUGUST 2022 | ISSN 0970-6054 | WEEKLY PUBLICATION

## INDIAN PHARMA - GLOBAL HEALTH CARE

INDIAN DRUG MANUFACTURERS' ASSOCIATION

## HIGHLIGHTS

- ★ **Report of IDMA-GSB, DoP and SIDBI - Awareness Program for the Scheme for Strengthening of Pharmaceuticals Industry (SPI) held on Friday 05th August 2022 at Ahmedabad, Gujarat** *(Page No. 13)*
- ★ **Report of IDMA, DoP and SIDBI in Association with HSBC Bank - Awareness Program for the Scheme for Strengthening of Pharmaceuticals Industry (SPI) held on Friday 12th August 2022 at Mumbai** *(Page No. 14)*
- ★ **Register Now for DIA-USFDA-PMDA-TGA-CDSCO: Advanced Manufacturing Workshop on 12th & 13th September 2022 from 3.00 p.m. to 7.00 p.m. (Virtual)** *(Page No. 28)*
- ★ **IDMA appeals to entrepreneurs to utilize various govt schemes to make pharma a US$ 600 billion industry by 2047** *(Page No. 36)*

# LIMITLESS FOCUS ON QUALITY. THAT'S WHAT MAKES US **SUPERIOR.**

**Dear Partner,**

Our diverse portfolio of starch-related products, covers everything from binders and fillers to sweeteners and solubilizers. In proud partnership with the undoubted 'polyols' expert, Roquette.

The company is the world's leading producer of starch, starch derivatives, polyols and a variety of other specialty products. Being one of the frontrunners of 'integrated bio-refining' of the highest standard, for a wide range of applications, demonstrates just how quality focused and innovation driven they are.

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• KLEPTOSE HPB (Hydroxypropyl Betacyclodextrin)

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• Dextrose • Dried Glucose Syrup

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• Magnesium Stearate

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# IDMA BULLETIN

**Vol. No. 53** **Issue No. 31** **15 to 21 August 2022**

## IDMA ACTIVITIES:



## USFDA MATTERS:



## PARLIAMENT NEWS:



## NATIONAL NEWS:


Dear Member,

## APPQM - EXECUTIVE PROGRAM IN PHARMACEUTICAL QUALITY MANAGEMENT

***For companies who want to grow their business in Europe & the US.***

## APPQM+ Series 3 Commences November 2022

We are looking forward towards registrations from your esteemed organization for APPQM+ Series 3.

### Why APPQM in INDIA?

We live in a world of 'Brutal Disruption'. Covid pandemic – what next? Prosperity awaits those who do the basics to PhD level.

When launching the first series of the APPQM, we at IDMA along with NSF Health Sciences, UK boldly stated that APPQM, the unique, World-Class education program will just do that and **Develop Change Agents For Quality Excellence.**

Well, Series One & Two lived up to the expectations of the industry. Over 40 delegates attended Series One & 28 delegates attended Series Two.

Both the series were a resounding success and this is what the delegates thought:

- ✓ Transformative
- ✓ World-class
- ✓ Best business investment we've ever made
- ✓ Worth every penny and more
- ✓ Has helped transform our quality culture
- ✓ Educating oneself while Educating others
- ✓ The course was really pragmatic and foundational in understanding the core Quality Systems framework

'Work Placement Projects' have been completed by APPQM delegates. These have generated $ millions in savings for their parent companies, improved their operational efficiency (profit), regulatory compliance and reduced risk.

### APPQM+ Series 3

Based on the success of Series 1 & 2, we are pleased to announce the launch of APPQM+ Series 3 that is expected to commence in November 2022 and covers special sessions on Digitization.

Please refer to the enclosed brochure and the video link for details of the Program covering: ( Enclosure 1)

- ✓ Challenges Facing the Pharmaceutical Industry
- ✓ How APPQM can help
- ✓ Benefits of the Program
- ✓ Course Format
- ✓ Details of Key Topics of the 5 Course Modules and the List of Tutors

**Additional Benefits:**

This virtual education program offers the following additional benefits.

- Safety of Individuals during this COVID-19 pandemic.
- Reduction in Course Fees (from £8000 for Physical Class to £3300 for Virtual Class)
- Saving of time especially travel time to venue in Bangalore and travel & hotel stay expenses

Please don't get left behind and register for the third series of APPQM to have a competitive edge in the global market and to be future ready.

Tentative Dates for APPQM+ Series 3 - November 2022 to June 2023

**MODULE 1:** Monday, November 7th, 2022 to Thursday 10th, 2022

**MODULE 2:** Monday, December 12th, 2022 to Thursday, December 15th, 2022

**MODULE 3:** Monday, January 30th, 2023 to Thursday, February 2nd, 2023

**MODULE 4:** Monday, March 13th, 2023 Thursday March 16th, 2023

**MODULE 5:** Monday, April 24th, 2023 to Thursday, April 27th, 2023

**WORK PLACEMENT PROJECTS SUBMISSION:** Two Months from the Last Module.

**VALEDICTORY PROGRAM:** Friday, 9th June 2023 (Tentatively)

Registration Fee for APPQM+ Series 3

The Registration Fee for APPQM+ Series 3 is Rs.4,00,000/- (Rupees Four Lakh Only) Plus 18% GST Per Participant.

You can initially block the seats by paying an advance amount of Rs.1,00,000/- (Rupees One Lakh Only) and balance 15 days before commencement of the program.

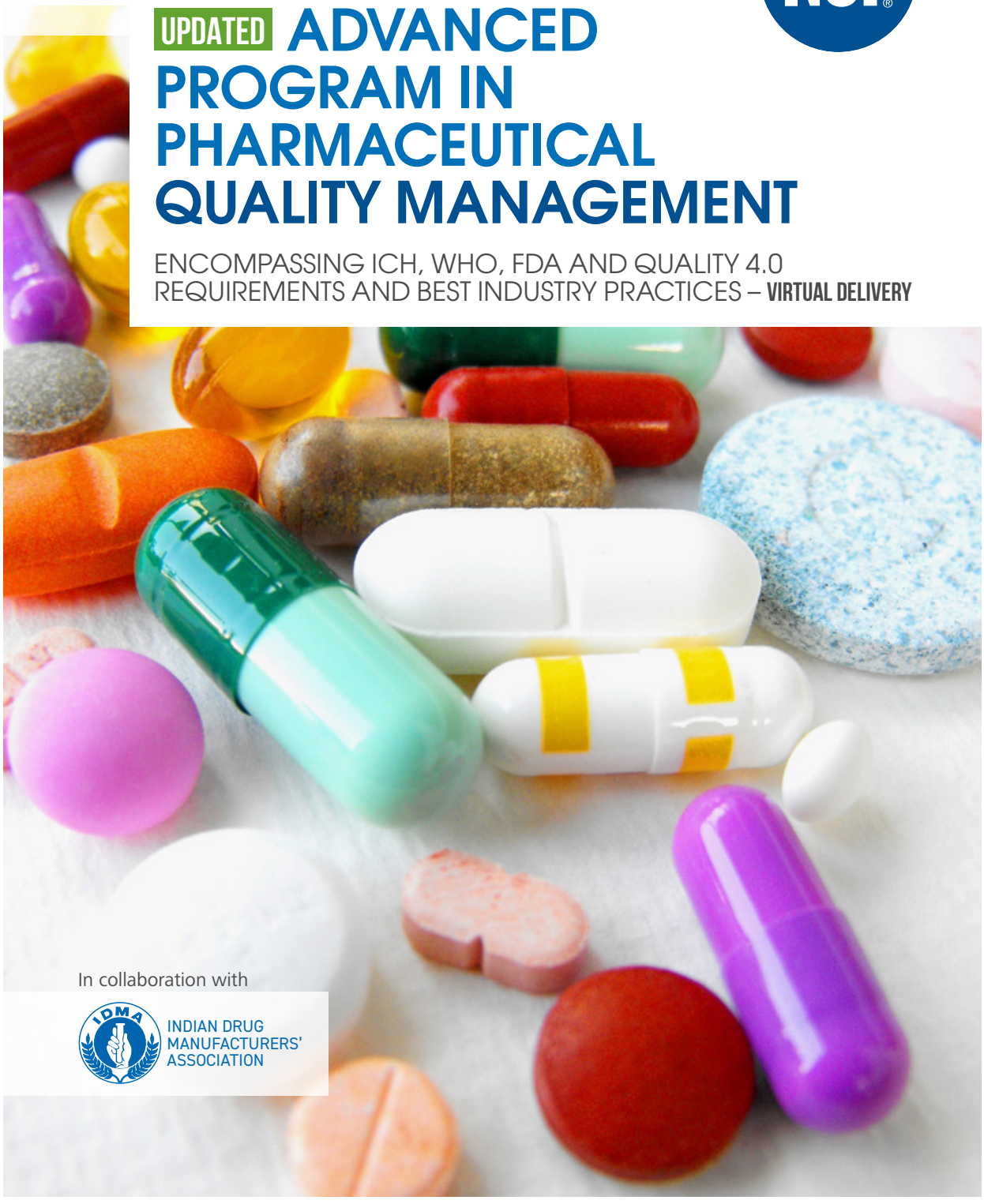
**Registration Procedure :** Please fill the enclosed **Registration Form** and send it to

| **Melvin** | **Batul** |
|---|---|
| actadm@idmaindia.com | technical@idmaindia.com |
| 9821868758 | 9920045226 |

For further information / queries : You may also contact Mr. S. M. Mudda
@ mudda.someshwar@gmail.com / 9972029070

We sincerely hope that you see the benefit of attending this World-Class, MBA style, education program in order that you may reap the same benefits.

| | | | |
|---|---|---|---|
|  |  |  |  |
| **S M Mudda**<br>Chairman, Regulatory Affairs Committee, IDMA & Program Director, APPQM | **Dr. Viranchi Shah**<br>National President, IDMA | **Mehul Shah**<br>Hon. General Secretary IDMA | **Daara B Patel**<br>Secretary – General, IDMA |


UPDATED ADVANCED PROGRAM IN PHARMACEUTICAL QUALITY MANAGEMENT
ENCOMPASSING ICH, WHO, FDA AND QUALITY 4.0 REQUIREMENTS AND BEST INDUSTRY PRACTICES – VIRTUAL DELIVERY
In collaboration with
INDIAN DRUG MANUFACTURERS' ASSOCIATION

# FOR COMPANIES WHO WANT TO GROW THEIR BUSINESS IN EUROPE AND THE U.S.

**For companies who want to grow their business in Europe and the U.S.**

## CHALLENGES FACING THE PHARMACEUTICAL INDUSTRY

India is the world's third largest pharmaceutical generics producer with the highest number of FDA and MHRA GMP-approved manufacturing plants outside the U.S. and Europe. The challenge of remaining in GMP compliance continues to be the main concern. India has seen a resurgence of breach of data integrity and quality issues. Regulatory requirements continue to become more stringent and rigorous.

Technical and QA professionals in India are trained in GMP compliance mainly through experience and need a formal education in pharmaceutical quality management of international standards.

- Sixty-four percent of companies say a shortage of skilled staff is curtailing their growth (Deloitte).
- 'There is an urgent need for more effective training, coaching and mentoring to remove fear and empower.' (Dr. Azaj Hussain, former U.S. FDA Deputy Director of the Office of Pharmaceutical Science)
- We live in a world of 'brutal disruption'. The pandemic – what next? The regulatory landscape will continue to change, and prosperity awaits those who can do the basics to Ph.D. level.

## HOW THIS TRAINING CAN HELP

This unique, world-class program will provide the training needed to comply with GMP regulations. Course modules are very interactive and led by world-class, international experts. You will learn best-in-class practices and apply them in practical problem-solving and real-life case studies. You will learn by doing.

In addition to module-specific content, you will be provided with a deep understanding of simplification, risk-based decision making and advanced problem-solving skills. You will receive practical instruction on the leadership and communication skills required to add value to your organisation and to successfully interact with regulatory agencies in the U.S. and EU and other key stakeholders.

## WHY CHOOSE NSF?

NSF's Advanced Program in Pharmaceutical Quality Management is taught by world leaders in PQM. Based in the UK, NSF have a global reputation for excellence in PQM. Our course tutors have a minimum of 30 years' global, hands-on industry experience. Many are former MHRA inspectors. All have profound knowledge of PQM and some have authored ICH and WHO guidance documents.

NSF has trained regulators from eight regulatory agencies including those in the EU and USA. Respected by regulatory agency and industry associations, NSF has excellent relationships with IDMA, ISPE, PDA organisations and U.S. FDA, WHO and EU regulatory authorities.

With offices in Delhi, NSF has an excellent understanding of Indian culture and the Indian pharma industry, gained over the last 30 years.

## BENEFITS OF THIS TRAINING

From attending this program, you will gain the skills and knowledge to help your company improve business performance and regulatory compliance. Clients who have attended NSF programs have generated $ millions in savings.

For example by:

- Reducing repeat deviations by 78 percent
- Reducing 'human error' deviations by 67 percent
- Achieving 99 percent 'right first time' at product release
- Using risk-based decision making to simplify processes and systems, and to focus resources
- Achieving zero regulatory observations following an audit

Attendees will also:

- Change how they think. NSF courses are designed to change behaviours, not just provide knowledge. Participants will be able to transfer the learning into their workplace
- Learn best industry practices in PQM so that their companies can compete with the best
- Gain an in-depth understanding of the critical aspects of PQM (see Course Modules)
- Leave with the knowledge required to help protect their company's legacy, reputation and future

## COURSE FORMAT

The program is presented in five modules, each comprising four days, over a 10-month period. Training takes place using virtual instructor led training via Zoom. Attendees at the second series which was delivered virtually were impressed with how easy it was to interact with other participants and how the course was specifically developed with virtual breakout rooms and information using the NSF Learning Management System. You will receive:

- A minimum of two tutors per module, to ensure a good tutor-to-delegate ratio
- An intensive, distraction-free and highly interactive learning environment using real-life case studies and problem solving exercises
- A work-based project to complete

## COURSE MODULES

**Some of the key topics covered in each module are provided below.**

### MODULE ONE: Pharmaceutical Quality Management Systems – Best Industry Practices

Tutors: **Mr Rob Hughes and Mr S. Mudda**

- How to ensure your PQS is regulatory compliant, improves your competitive edge and drives business improvements
- Integration of quality systems across the product lifecycle (quality systems approach for cGMP implementation, from philosophy to practice)
- Making use of risk information to drive improvements (risk-based decision making)
- Senior management roles and responsibilities for the PQS – who must do what
- The essentials of data integrity
- Best practices in designing an electronic PQS
- Integration of Industry 4.0 into the design of the PQS
- The art and science of simplification
- Batch release system: How to achieve 100 percent 'right first time'
- How to become stronger and better following complaints and recalls
- Product quality reviews: How to use data and knowledge to drive improvement
- Management review of quality systems and the use of quality metrics (measuring only what matters)
- Continuous quality improvement and the cost of poor quality

### MODULE TWO: Managing Change; Change Control and Deviations

Tutors: **Mr Rob Hughes, Mr S. Mudda and Ms R. Carmichael**

- Change control: How to use your system to:
  - Stop unnecessary change to ensure resources are focused on changes that only add value
  - Approve changes in minutes, not hours or days
  - Improve successful implementation of approved changes
  - Make change control fast and efficient
- CAPA management
- Investigation and report writing skills
- Deviation management: How to ensure your system:
  - Prevents repeat deviation incidents
  - Is simple, fast and effective
- Data Integrity:
  - Data Integrity principles and how to implement them effectively
  - Understanding data lifecycle

### MODULE THREE: Human Factors – Getting People to Follow the Rules

Tutors: **Mr Rob Hughes and Mr S. Mudda**

- Human error: Causes and prevention
- Behavioural GMP: How to improve behaviours in the workplace
- How to get the best from your people and keep them
- Train vs. educate: How to build second-level leadership for quality management
- Making your quality organisation fit for purpose, whether centralised, decentralised or site managed
- How to overcome pitfalls in remediation programs and integrate them within the PQS
- Fostering a culture of quality (how to identify the relationship between company quality performance and prevailing quality culture and make quality normal, easy and rewarding)

▶▶

### MODULE FOUR: Data Analysis for Business Improvement

Tutors: **Dr P. Gough and Dr D. Young**

- Summarising and visualising data (histograms, probability curves and box plots)
- Confidence in your means and proportions
- Statistical process control
  - Control charts
  - Fishbone diagrams and Pareto charts
  - Process capability
  - Six Sigma
  - Statistical testing
  - T-test
  - ANOVA
  - Outliers
- Regression analysis
- Design of experiments
- Multivariate analysis

### MODULE FIVE: Quality by Design, Process Validation and Technology Transfer

Tutors: **Mrs Emma Ewins and Mr Richard Kettlewell**

- Quality by Design (QbD): ICH Q 8, 9, 10 and 11
- Modern approach to process validation
- Process design
- Application of quality risk management to process validation
- Tools for process validation implementation
- Equipment and utilities qualification
- Applying statistics for process validation
- Process performance qualification (PPQ) – How many batches?
- Process validation strategy and planning
- Ongoing/continued process verification
- Packaging validation
- Technology transfer
- Laboratory electronic data management
- Computer systems validation

## NEXT STEPS YOUR CALL TO ACTION

If you would like more information on this unique opportunity, please:

- View a video of past participants on this course, click **here**
- Contact IDMA at: **actadm@idmaindia.com** or **technical@idmaindia.com**
- Contact NSF at: **pharmamail@nsf.org**

- **S. M. Mudda**
  Chairman, Regulatory Affairs Committee, IDMA & Program Director, APPQM
- **Dr Viranchi Shah**
  National President, IDMA
- **LynneByers**
  Global Managing Director, Pharmaceutical Consulting, NSF Health Sciences

## NSF INTERNATIONAL

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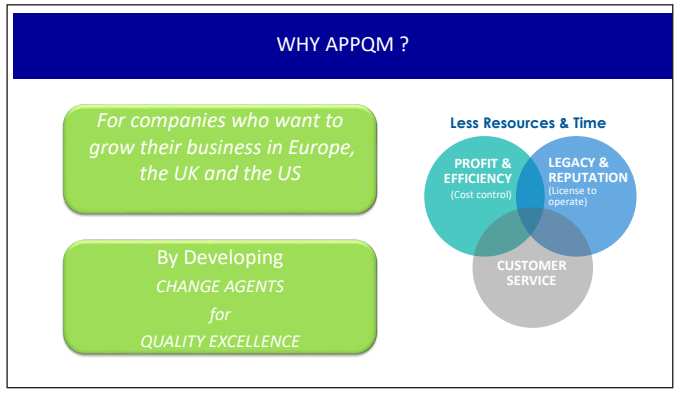
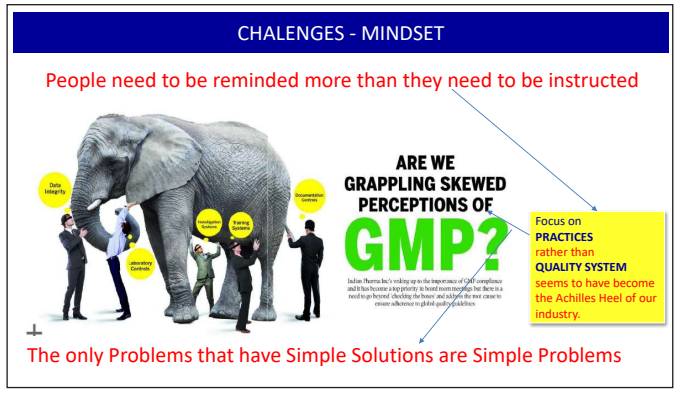
PRESENTATION

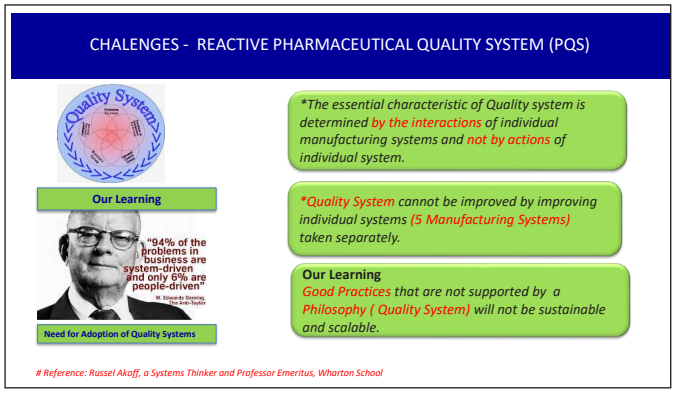
# Launch of APPQM Series 3

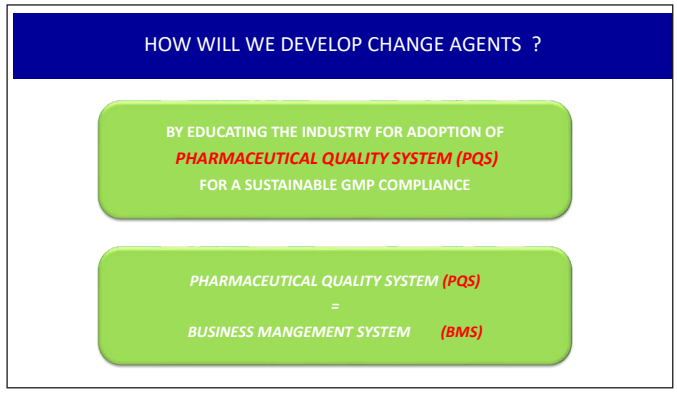
***Mr S M Mudda, Program Director & Chairman Regulatory Affairs Committee, IDMA***





## APPQM IS DESIGNED FOR INDIAN COMPANIES

*APPQM is adopted from highly successful Quality Management Program of NSF UK.*

*The contents are selected by experts* keeping in mind challenges faced by India Pharma*

- *NSF is the global leader in providing 'Qualified Person'(QP) training across the EU.The expert faculty include ex-regulators (MHRA) and*
- *Seasoned professionals with 35 years plus hands on experience .*

**Mr. S.M.Mudda*
*Chairman, Regulatory Affairs, IDMA and a strong Proponent of Quality Systems*

**Mr. Martin Lush*
*Ex- Global VP, NSF International, UK and a leading consultant & tutor*

**Dr. Ajaz Hussain*
*Ex-Deputy Director US FDA , Educationist, Advisor and Mentor*

## HOW APPQM IS DIFFERENT FROM OTHER TRAINING PROGRAMS ?

APPQM is
Not a TRAINING PROGRAM
but
An EDUCATION PROGRAM in PQS
Focussed on 21st century Leadership Development of QA , QC, Manufacturing and R&D professionals

## APPQM- Program Modules

- Pharmaceutical Quality Management Systems – Best Industry Practices *(How to ensure your QMS drives business improvements)*
- Managing Change; Change Control and Deviations *(Advanced problem solving, deviation management, report writing and change management)*
- Human Factors–Getting people to follow the rules *(How to improve performance, reduce human error, embed a quality mind-set & keep your people)*
- Transforming Data into Information – the Practical Application of Statistics to Transform your Business *(The practical application of statistics to transform your business)*
- Quality by Design, Process Validation and Technology Transfer *(Building a foundation for Product Quality and Knowledge Management)*

## APPQM SERIES 1 & 2 DELEGATES SURVEY FEEDBACK

### APPQM SERIES 1 & 2 DELEGATES SURVEY FEEDBACK

OUR DAY AT THE PLACE OF WORK WILL NEVER BE THE SAME

*This is what they thought after a year of implmenatation of APPQM Learnings:*

*Transformative and Life Changing.*

*It is highly recommended for anyone who wants to challenge the status quo (at work) but doesn't know how.*

*Decision making has become more efficient and so the inter-personal relationship.*

*Educating Oneself while Educating Others*

*Has helped transform our quality culture.*

*Best business investment we've ever made.*

*Worth every penny and more.*

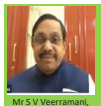
## APPQM SERIES 2 VALEDICTORY – APPRECIATION FROM DIGNITARIES

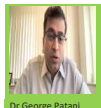

APPQM will help build the quality culture in Indian Pharma Industry
Dr V G Somani, DCGI


APPQM will help develop future quality leaders
Dr. B Suresh, Pro-Chancellor, JSS University

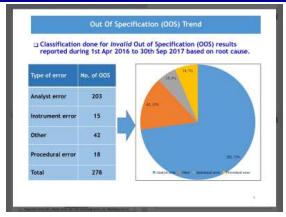

Virtual APPQM Program will be a boon for saving Time, Travel & Cost and yet deliver the same quality education
Dr. Viranchi Shah- National President -IDMA


Inclusion of Digitization topics will enhance the next series of APPQM
Mr Mehul Shah MD, Encube Ethicals &Hon. General Secretary, IDMA


IDMA should aim at developing 1000 Change Agents for quality excellence in coming years
Mr S V Veerramani, MD, Fourrts India


APPQM will help to remain competitive even while complying with the regulations
Dr George Patani ,VP ( Western Region), IDMA

## Benefits of APPQM –ROI

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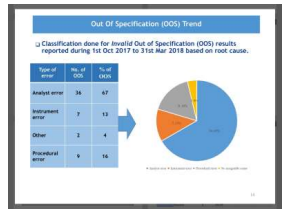
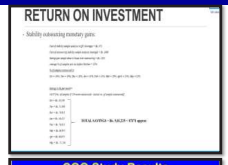
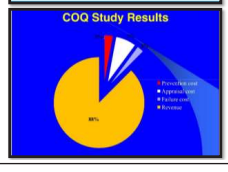



AFTER

TOTAL SAVING OF Rs. 5 Cr.

## Benefits of APPQM -ROI






## Acknowledgments

**S.V. Veerramani** — Past National President, IDMA for mentoring this program & providing his unstinted support.

**Mahesh Doshi** — Immediate Past National President, IDMA for his continued support

**Sudhanshu Pandey,** — Joint Secretary, Department of Commerce, Ministry of Commerce & Industry, Govt. of India, for his support

**S. M. Mudda** — Chairman, Regulatory Affairs, IDMA and Program Director, APPQM for his Vision & Innovation and for his unstinted support & active participation in conducting this World Class program

**Dsara B Patel** — Secretory General IDMA for his continual support, active participation and coordination success of APPQM

**R.S.Iyer** — Renowned Quality Guru and our Inspiration "Quality of Work Determines The Quality Of Products"

THANK YOU FOR YOUR ATTENTION

# Report of IDMA-GSB, DoP and SIDBI - Awareness Program for the Scheme for Strengthening of Pharmaceuticals Industry (SPI) held on Friday 05th August 2022 at Ahmedabad, Gujarat

The Indian Drug Manufacturers' Association (IDMA) - Gujarat State Board (GSB) organised an event to create awareness about the scheme for Strengthening of Pharmaceutical Industry (SPI) at Ahmedabad on Friday, 5th August 2022. The event was organised in association with the DoP, Ministry of Chemicals and Fertilizers, and SIDBI.

The programme began with Mr Sumit Agrawal, Honorary Secretary of IDMA GSB, giving a brief introduction about it. He said the event has been organised as an outreach initiative by the Department of Pharmaceuticals. He expressed confidence that the scheme for Strengthening of Pharmaceutical Industry will help the pharma industry to upgrade and achieve higher standards.

In his welcome address, Dr. Shrenik Shah, Chairman, IDMA GSB, announced that they are planning to set up a help desk at IDMA GSB to ensure MSMEs can easily access information about SPI and various other government schemes.

In his address, Dr. Viranchi Shah, National President, IDMA, spoke about the SPI and how it would go a long way in enhancing the capabilities of the Indian pharma industry. He also said that the scheme would help the manufacturing units at the lower end of the pyramid add value to their operations and grow. He also said that the Indian pharma market size is projected to increase from $45 billion at present to $600 billion by 2047, an increase of 12 to 13 times. He said that few industries globally can boast of such growth possibilities and said it is important that MSME units get adequate handholding so that the growth story is not just about large industries but also the smaller manufacturers.

The event was graced by

- Mr Abhishek Kumar Singh, Deputy Secretary, DoP
- Mr. HL Rawat, Joint Commissioner, FDCA Gujarat
- Mr Jayant Kumar, Deputy Drugs Controller (DDC), Gujarat

These dignitaries addressed at the event and explained in brief about the scheme.

The event was also attended by SIDBI representatives Mr Vinay Kumar, DGM and Mr Amulya Mishra, AGM.

They made a detailed presentation about the scheme. They further said the scheme addresses the demands and requirements for support to already existing pharma

clusters and MSMEs to improve productivity, quality and sustainability. Since making the investments is beyond the ability of MSMEs, the government is supporting them in implementing and creating infrastructure. They also shared details about the various benefits of the scheme.

They also said that a dedicated portal SPI.udyamimitra.in has been established to process applications made under the scheme.

Among the other dignitaries, the event was also attended by many bankers.

Mr. Parag Thakkar, Market Head of IndusInd Bank, Mr. Dharmendrasinh Jadeja, Deputy Commissioner in the MSME Commissioner in Gandhinagar and Mr. Amit Saluja, Senior Director and Centre Head of NASSCOM Centre of Excellence (CoE), Gandhinagar addressed at the event. Later there was a very interactive Question & Answer Session.

Vote of thanks was presented by Mr Sumit Agrawal, Honorary Secretary, IDMA GSB. He appreciated the scheme and also showed confidence that in Gujarat the number of WHO GMP compliant companies will increase from 800 to 1,500 in coming 3 years with the help of the scheme.

● ● ●

# Report of IDMA, DoP and SIDBI in Association with HSBC Bank - Awareness Program for the Scheme for Strengthening of Pharmaceuticals Industry (SPI) held on Friday 12th August 2022 at Mumbai

IDMA had organized an Awareness program for the Scheme for Strengthening of Pharmaceuticals Industry (SPI) for its members to explain in detail the various schemes and its benefits. The Department of Pharmaceuticals, Govt. of India has been actively involved in these schemes and along with SIDBI are ensuring that every MSME get an opportunity to upgrade their facilities and develop their manufacturing units to meet the necessary standards for exports. IDMA was pleased to be associated with The Hongkong and Shanghai Banking Corporation Limited (HSBC) for this awareness program.

The event was graced by the following Government Officials :

- Dr. N Yuvaraj, IAS, Jt. Secretary, DoP was the Chief Guest.
- Shri D R Gahane, Jt. Commissioner, FDA Maharashtra
- Shri A Senkathir, Deputy Drugs Controller (West Zone), CDSCO
- Mr. L R Narayana, AGM &
- Mr. Pratyush Mishra, DGM, SIDBI

IDMA was duly represented by the Senior Members from the Pharma Industry along with representatives from Pharma MSMEs, State Government officials, representatives from IPA, SLBC and Bankers. In total there were approx. 120+ participants for this awareness program.

The Program began with brief introduction of the event by Mr. Daara B Patel, Secretary General of IDMA wherein he said that IDMA congratulate and appreciate the efforts of the Government specially our Dr. Mansukh Bhai Mandaviya, our Honourable Minister who launched this New Scheme to Strengthen the Indian Pharmaceutical Industry on 21st July 2022. He said that the new scheme will help the industry to enhance its quality, technology & infrastructure upgradation & capacity building and encourage collaboration between various stakeholders for the overall development of the pharma sector. He further added that IDMA applauds this excellent initiative of the Government which is an excellent opportunity for our Pharma Industry.

Mr. Mehul Shah Hon. General Secretary delivered his welcome address. (Welcome address reproduced below).

Dr. N Yuvaraj, IAS, Jt. Secretary, DoP who was the Chief Guest at the event delivered an inspiring and motivating address which proved this enthusiasm and proactive involvement in this schemes. It also showcased the whole hearted involvement of the Govt in making these schemes successful. He explained about the Articles of Association and the Beneficiary. He then said that the MSMEs plays a big role in India's economy i.e. nearly 76% . The objective of the scheme is to strengthen the existing infrastructure facilities, assistance to pharma clusters for creation of Common Facilities, to improve the quality and ensure substantial growth of the clusters and upgrade the production facilities of SMEs and MSMEs to meet national and international regulatory standards by providing interest subvention or capital subsidy on their capital loans which will facilitate the growth in volumes as well as in quality.

Shri D R Gahane, Jt. Commissioner, FDA Maharashtra and Shri A Senkathir, Deputy Drugs Controller (West Zone), CDSCO also addressed the event and requested the IDMA members to take benefit of this schemes.

Mr. S R Vaidya, Chairman, MSME Committee, IDMA began the technical session with an address which talked about IDMA initiatives and representations made to the Government over a decade requesting the Government to support the MSMEs. The address is reproduced below.

Mr. L R Narayana AGM, SIDBI made a detailed presentation of the schemes.(Presentation is reproduced below)

Mr. R D Deshmukh, Dy. General Manager, Financial Inclusion & Member Secretary, State Level Bankers Committee (SLBC), Maharashtra expressed his views with regards to the scheme.

The Hongkong & Shanghai Banking Corporation who were associated with us for this event displayed their forte in the banking sector and Mr. Anurag Tripathi, Head- Assets, Business Banking Commercial Banking, India Management Office, HSBC India made an excellent presentation to the august gathering (presentation reproduced below). Later, Mr. Raghav Handa, Director-Strategic Business Development and Govt. Affairs Central Management Services - CEO Office, HSBC and Mr. Anurag suitably responded to the queries raised by the participants. Thus making the banking session very interactive. IDMA thanks HSBC for their excellent support and co-operation.

The Question and Answer Session was amicably moderated by Mr. B G Barve Chairman, Excise & Taxation Committee, IDMA and the panellist responded to every query raised by the participants.

Dr. George Patani, Vice President, Western region, IDMA aptly concluded the awareness program with truly captivating points with regards to these schemes. He thanked Dr Yuvaraj for his vibrant participation which showed how much he is involved and wants these schemes to succeed. He thanked all the dignitaries from the Govt. as well as the pharma industry. Lastly, he sincerely urged the MSMEs to take advantage of these schemes from the Government of India.

# Glimpses


In association with
DRUG MANUFACTURERS' ASSOCIATION
(IDMA)
INDIAN DRUG MANUFACTURERS' ASSOCIATION
(IDMA)
DSC_9072


sidbi
INDIAN DRUG MANUFACTURERS' ASSOCIATION
DSC_9081


INDIAN DRUG MANUFACTURERS' ASSOCIATION
(IDMA)


DEPARTMENT OF PHARMACEUTICALS
MINISTRY OF CHEMICALS AND FERTILIZERS,
GOVERNMENT OF INDIA
idbi
(IDMA)
DSC_9133


HSBC
August 2022
DSC_9107


INDIAN DRUG MANUFACTURERS' ASSOCIATION
DSC_9111





# Welcome Address by Mr Mehul Shah, Hon. General Secretary, IDMA

Good Afternoon, Ladies and Gentlemen:

Namaste.

I am Mehul Shah, Honorary General Secretary, IDMA and Managing Director, Encube Ethicals. It is an honour for me to welcome all dignitaries and guests today.

Respected -

1. Dr. N Yuvaraj IAS, *Joint Secretary - Department of Pharmaceuticals, Government of India*
2. Shri D R Gahane, *Joint Commissioner - FDA, Government of Maharashtra*
3. Shri A Senkathir, *Deputy Drugs Controller - CDSCO*
4. Shri Pratyush Mishra, *DGM - SIDBI*
5. Shri L Narayan, *AGM - SIDBI*
6. Shri Anurag Tripathi, *Head (SME Banking) - HSBC*, and
7. Shri R D Deshmukh, D*GM (Financial Inclusion) - Bank of Maharashtra and Member Secretary, SLBC*

and my dear friends and stakeholders from the Indian pharmaceutical industry.

It is a privilege for me to be present here and on behalf of our National President, Dr. Viranchi Shah. I extend heartfelt gratitude to Department of Pharmaceuticals, HSBC, and IDMA for organising today's State-level

Outreach Program in Maharashtra for the "Strengthening of Pharmaceutical Industry" Scheme.

The Indian pharmaceutical industry hails astute leadership of Honourable Prime Minister Shri Narendra Modi and Dr. Mansukh Mandaviya for providing a conducive policy framework for growth and development of the industry. The government officers and staff have played an instrumental role in providing policy direction, support, and encouragement to the industry. Thank you, Sirs and Mesdames.

The industry is valued at $44 Billion and is expected to grow to $600 Billion by 2047 at 11% CAGR. It is an opportune time that SMEs pursue a greater share in the growth story of the industry. This can most likely happen when we invest ahead of time in growth, quality, risk, and compliance management.

The Government of India launched a series of policy measures in recent past - Atmanirbhar Bharat, Pradhan Mantri Jan Aushadhi Pariyojna, Ayushman Bharat, and Production Linked Incentives. More encouragement and impetus are expected in near future through OTC policy, Research Linked Incentives, pricing, and decriminalisation reforms. In this direction, we are fortunate to get a dedicated SME sector - - "Strengthening of Pharmaceutical Industry (SPI)".

The Indian pharmaceutical industry is fragmented, with SMEs accounting for about 40% production in value terms. The SME companies have braced through uncertainty with robust demand in domestic and export markets amidst ever-increasing inflation and supply chain challenges.

IDMA, an association of largely pharmaceutical SMEs, welcomes the noble and timely policy of "Strengthening of Pharmaceutical Industry (SPI)" by the Government of India. Dear pharmaceutical company promoters and professionals, I urge you to make the best of this policy and deliver to exceed on stakeholder expectations. The government has reposed trust and respect in your capability to grow and offer innovative cost-effective medicines.

SPI subsumes 3 schemes viz. Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS), Assistance to Pharmaceutical Industries for Common Facilities (APICF), and Pharmaceutical and Medical Devices Promotion and Development Scheme (PMPDS). PTUAS intends to facilitate MSMEs on upgrading their P&M to WHO-GMP standards. APICF intends to support creation of common facilities–training centres, testing centres, R&D centres, logistics centres, and ETP– in pharmaceutical clusters. PMPDS intends to bring industry leaders, academia, and policy makers together to share their knowledge and experience for overall development of the industry. Also, the scheme intends to conduct studies, organize awareness programs, create databases, and promote the industry.

With such a holistic and comprehensive policy support, pharmaceutical SMEs can upgrade themselves to latest technology, pool together in clusters to own and operate common facilities at efficient cost of operations, and exchange best practices or insights to advance every stakeholder with a collaborative approach.

I am hopeful that Indian pharmaceutical industries will reciprocate trust of the government with high-level of participation in SPI and translate "resources into results".

IDMA is committed in our "Seva for Sampoorna Swasthya" to the entire world with supply of safe, efficacious, and reliable medicines. IDMA is always there to help Indian pharmaceutical SMEs – their success is the country's success.

The Indian pharmaceutical industry continues to put its best foot forward to Innovate-in-India and Make-in-India. We will work with the union and state governments apart from banks to marshall all resources for your growth.

I wish everyone best for today's session and look forward to interacting with many people.

Best wishes. Thank you.

# Technical session address by Mr. S R Vaidya, Chairman, MSME Committee, IDMA

Good Afternoon Respected Dignitaries and my dear friends,

Greetings from Indian Drug Manufacturers' Association (IDMA).

IDMA has been in the forefront for over a decade in requesting DoP and the Government to come up with various schemes for the upgradation of the MSMEs and their facilities and thus ensuring growth and competitiveness of the MSMEs in the Indian Pharma Industry.

IDMA has conducted various seminars and workshops in collaboration with Department of Pharmaceuticals such as the successfully organized series of Workshops titled 'GMP Workshop for SMEs – Schedule M and Beyond' for upgradation of GMP standards and Seminar series on 'Meeting Quality Challenges and Achieving Global Compliance' all over India. Just before the pandemic, as requested by Drugs Controller General of India Dr V G Somani, IDMA had organized a 'Workshop on E-Governance Initiatives of CDSCO' at Mumbai jointly with CDSCO and CDAC.

IDMA is pleased to be associated with DoP & SIDBI for this awareness program.

As you are aware, MSMEs are considered to be the key driver of any Economy and their contribution is extremely important and critical to meet the goal to be a $5 trillion economy.

For your information, Micro, Small and Medium Enterprises (MSMEs) contribute towards 17% of the country's GDP, 45% of the manufactured output and 40% of our exports. **MSMEs in Pharma Industry contribute more than 70% of Medicine supply to Central and State Government requirements.**

MSMEs provide employment to about 12 Crores people through 5 Crores enterprises. Thus forming the largest generator of employment in the Indian economy. Also, MSMEs are the major portion of the industrial activity and produce 8000 different products.

**I would like you all to deliberate on the challenges of Classification of Pharma Industry faced by the MSMEs such as :**

1. There are various dynamic changes like increased regulatory requirements and the stipulations along with the mandatory changes expected from the industry for becoming a WHO qualified enterprise progressing from the Schedule M stages.
2. Existing and New Units require minimum Investment of Rs.15 crores to accomplish Schedule M and WHO GMP compliance. In order to upgrade from Schedule M to WHO GMP: An Existing unit will require minimum Rs.10 crores Investment and handholding for technology upgradation.
3. Capital in terms of Land & Building along with Plant & Machinery and Formulation & Development Cost is very high in case of Pharma Manufacturing. Hence, Government is required to give special benefits for the MSME segment.

**You all would be pleased to know that IDMA has represented its MSME members with a representation citing the above challenges as well as the Major challenges which are as follows :-**

- **Ease of doing business**
- **Financial Expertise**
- **Access to Financing Solutions**
- **Security and collateral for loans**
- **Remission of Duties and Taxes on Exported Products (RoDTEP) scheme.**
- **Interest subvention scheme with enhanced coverage.**
- **Withdrawal of Weighted Tax deduction under 35(2AB) of Income tax Act for R & D.**
- **Payments against the Government Supplies**
- **Access to Technology**

**IDMA would be pleased to put forth some of the Key Suggestions from Pharma Industry:**

1. **Cash flow under PTUAS of Rs.10 crores** from any Nationalized bank.
2. Sanction should be with **One Window Clearance.**
3. Loan has to be sanctioned in a short time frame. It may be distributed in 5 instalments of 2 crore each

based on the progressive reports available from the entrepreneur.

4. There should **not be any demand for collateral from the SMEs**.
5. Request to the Department of Pharmaceuticals (DoP) to facilitate **SME payments against the Government supplies within 45 days.**
6. **Pharma sector should be accorded the Infrastructure Industry status whereby interest Moratorium of 5 years and 20 years for Loan repayment under 5:20 scheme should be applicable to them.**
7. Interest Equalization scheme to be restored to provide pre-shipment and post-shipment export credit to exporters in rupees.
8. Redemption of accumulated GST within 90 days from filing returns.

We at IDMA feel that it is always a unique experience working together with Government Officials & Industry Associations for the benefit of the patients not only in India but the entire world.

We are sure that with the necessary support from the Government and SIDBI and also the other banks to our IDMA Members and the Indian Pharma Industry, we can proudly say that most of the new drugs which will hit the world and make a difference to the world will be coming from India and that will make a huge difference to our INDIAN PHARMA INDUSTRY.

Thank you very much.

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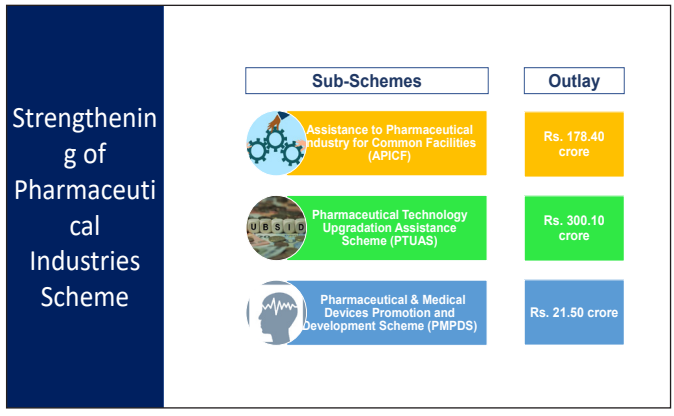
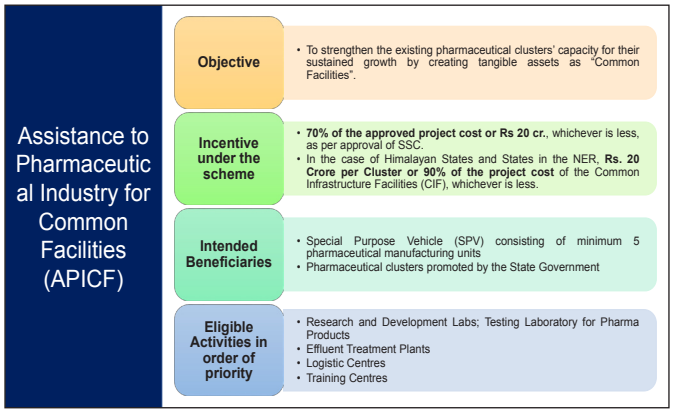
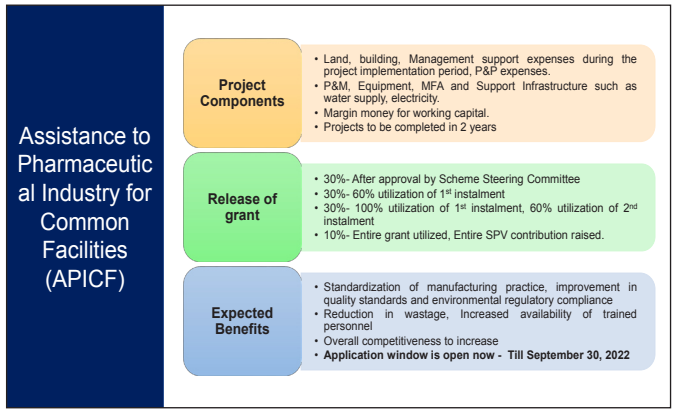
PRESENTATION

# Strengthening of Pharmaceutical Industry (SPI) by Mr. L R Narayana, AGM, SIDBI

## Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS)

| | |
|---|---|
| **Objective** | • To facilitate MSME Pharma units of proven track record to upgrade their technology to meet **WHO-GMP** or **Schedule M** standards. |
| **Incentive under the scheme** | • **Capital Subsidy -** 10% on loan component eligible under the scheme. **(or)**<br>• **Interest Subvention** - Max 5% P.A. (6% in case of units owned and managed by SC/ STs) for loan component eligible under the scheme |
| **Intended beneficiaries** | • Existing MSMEs in pharmaceutical sector.<br>• P&M, Equipment, Electronic MIS required for technological up gradation (only new machinery shall be considered)<br>• GST, Import Duty, Custom Charges to be included in the cost |
| **Eligible Activities** | • Indicative list of such equipment categories provided in detailed guidelines<br>• Technical Committee to decide on the eligibility of the P&M, equipment under the scheme |

## Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS)

| | |
|---|---|
| **Loan parameters** | • Maximum limit of loan will be Rs. 10.00 crore<br>• At least 50% of the sanctioned loan has to be on eligible components under the scheme.<br>• Minimum repayment period : 3 years<br>• Application on the portal to be filled withing 90 days from the date of sanction |
| **Timelines** | • **Application window is open now (From August 01, 2022)**<br>• Window open till 29th February 2024 (First Come First Serve)<br>• Tech. upgradation to be completed in 30 months from 1st disbursement<br>• Necessary Documents for tech. upgradation to be submitted by 31st December 2025. |
| **Expected Benefits** | • Improvement in quality of manufactured pharma products.<br>• Improvement in adherence to global quality standards. |

## Newspaper Advertisement Dated 01/08/2022

Government of India
Ministry of Chemicals & Fertilizers
Department of Pharmaceuticals

**Advt. No. G-30012/09/2022-Scheme**
**Online Applications Under the Scheme for Strengthening Pharmaceuticals Industry**

Online applications are invited from eligible pharma clusters and pharma MSMEs to avail assistance under the two sub-schemes of the Scheme for Strengthening of Pharmaceuticals Industry (SPI).

**i. Assistance to Pharmaceutical Industry for Common Facilities (APICF)**

Pharma clusters may apply for availing support under the component of the Scheme -Assistance to Pharmaceutical Industry for Common Facilities (APICF) in clusters.

Applications for APICF would be ranked as per scheme guidelines.

Applications submission commencing date : 01/08/2022

Last date for submission of applications : 30/09/2022

**ii. Pharmaceutical Technology Upgradation assistance Scheme (PTUAS)**

Individual Pharma MSME Units may apply to avail capital subsidy or interest subvention under Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS) for upgrading their units. Applications for PTUAS would be considered on First Come First Served basis.

Applications submission commencing date : 01/08/2022

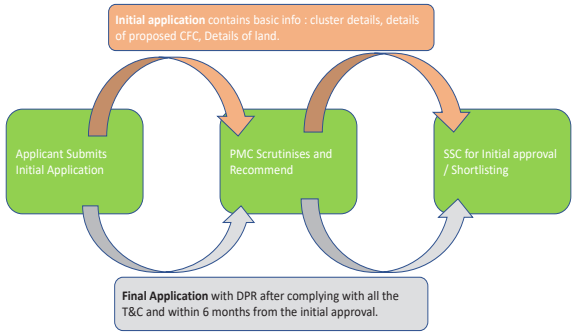
The details of the scheme including objectives, eligibility criteria, parameters and incentive available with validity are available at **https://spi.udyamimitra.in** and the applications have to be submitted online through the said portal.

Under Secretary to Government of India,
Scheme Division,
Department of Pharmaceuticals

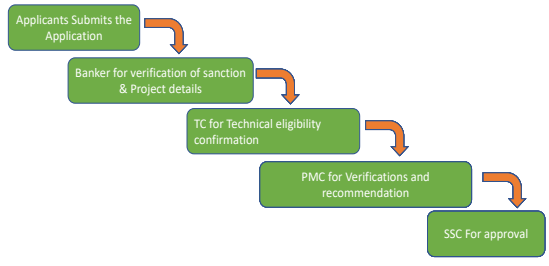
## Pharmaceutical & Medical Devices Promotion and Development Scheme (PMPDS)

| | |
|---|---|
| **Objective** | • Promote Pharmaceutical and Medical Device Industry by bringing stakeholders together for sharing of knowledge and experience for overall development of the sectors.<br>• For conducting studies, organizing awareness programs, creation of databases for promotion of industry. |
| **Organizations eligible** | • Government agencies - Academic institutions and autonomous bodies / PSUs under the Department.<br>• National/ State level Industries Associations in related sector.<br>• A specialized organization with proven expertise in the related field |
| **Eligible Activities** | • Preparation of study reports on topics of importance.<br>• organizing seminars, conferences, conventions, workshop etc.<br>• Creation of Database of pharmaceutical and medical device sector.<br>• Organizing Mega events and participating in other events. |
| **Expected Benefits** | • Create awareness about the policies of the Government and identifying problems/ issues faced by the industry.<br>• Provide support/ facilities for promotion of investment & growth of pharma sector for the benefit of the pharma industry |

## Application Process Flow - APICF



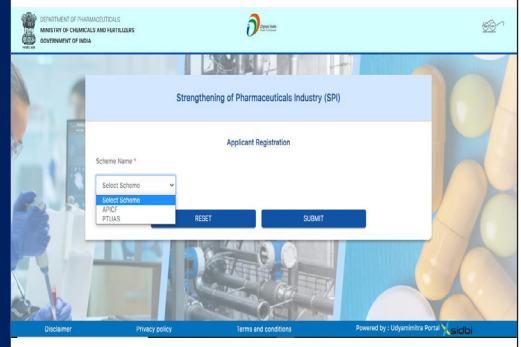

## Application Process Flow - PTUAS



- Udyamimitra platform
- Scheme Guidelines and Amendments
- Downloadable Scheme Brochures
- Ticker Message for Important dates and Announcements
- Online Registration
- Online Application
- Contact details (Dedicated Email & Mobile No.)


SPI Portal : https://spi.udyamimitra.in/

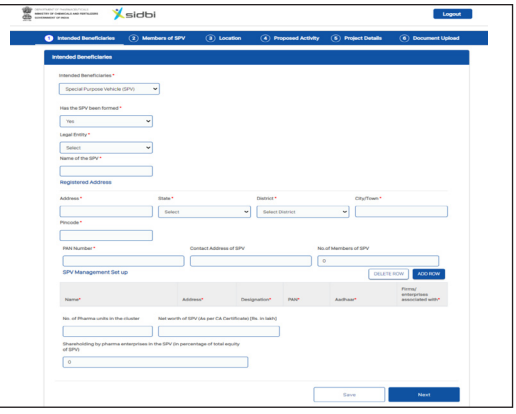
Registration : APICF & PTUAS



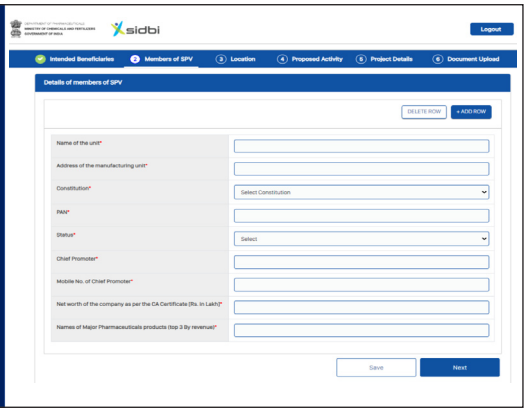

## APICF Initial Application

| | |
|---|---|
| Intended Beneficiary | • Name of SPV & Cluster, Address, PAN, No. of Pharma Units, etc. |
| Members of SPV | • Details of Member units, Multiple units can be added |
| Location | • Proposed land details, Area, Date of acquisition, Owner |
| Proposed Activity | • Proposed technology, How it will address the cluster issues |
| Project Details | • Components of Project, Tentative Cost of project, Means of finance |
| Document Upload | • CA Certificates and other related documents |

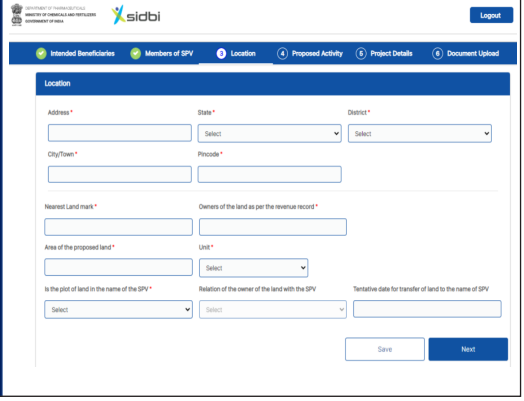
APICF Initial Application : Tab 1



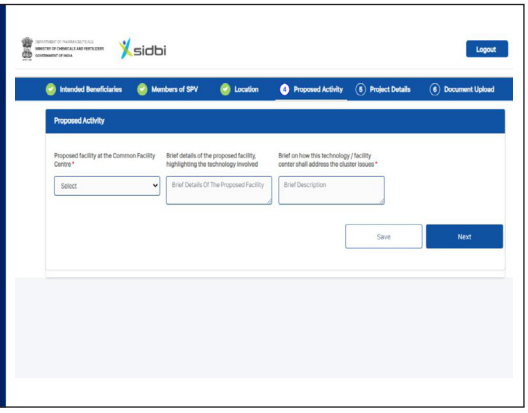

APICF Initial Application : Tab 2



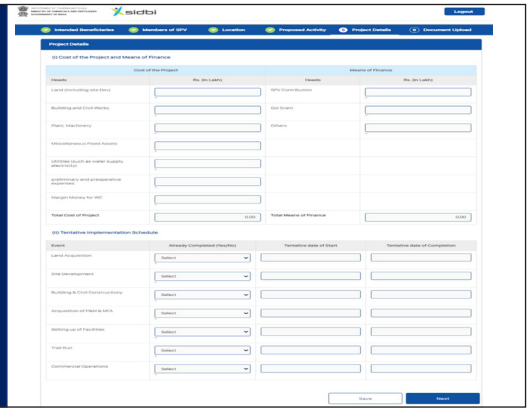

APICF Initial Application : Tab 3



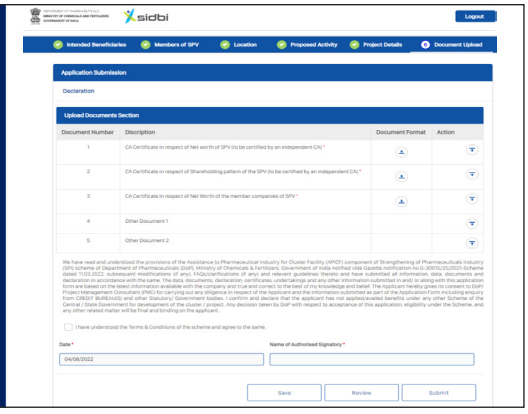
APICF Initial Application : Tab 4




APICF Initial Application : Tab 5



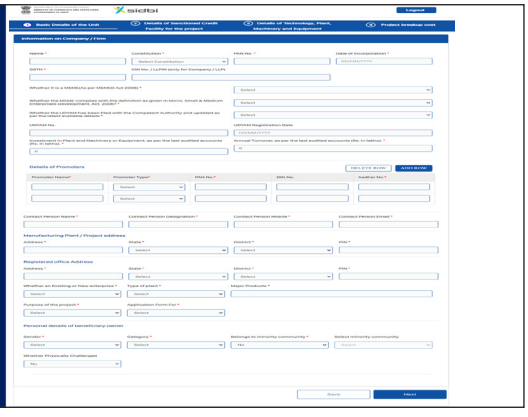

APICF Initial Application : Tab 6



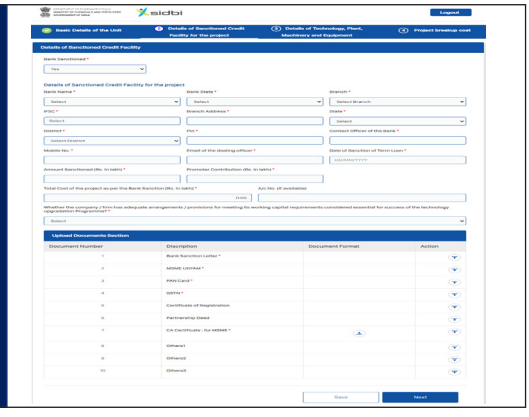

## PTUAS Application

| | |
|---|---|
| Basic Details of the Unit | • KYC, MSME Status, UDYAM, Investment in P&M, Operations, Management Details |
| Details of the credit Facility | • Status of credit sanction, Bank, Branch, Relationship manager etc.<br>• Document upload - PAN, GSTN, UDYAM, Sanction Letter etc. |
| Details of Technology | • Machinery, Cost, Eligible activity as per the guidelines.<br>• Upload Proforma / Tax Invoice |
| Project Cost Break up | • Project cost as per the sanction, tentative implementation schedule. |

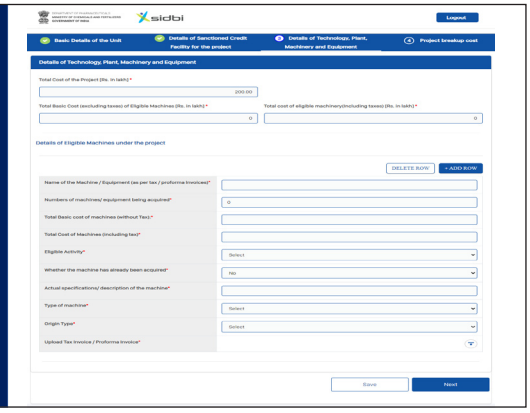
PTUAS Application : Tab 1



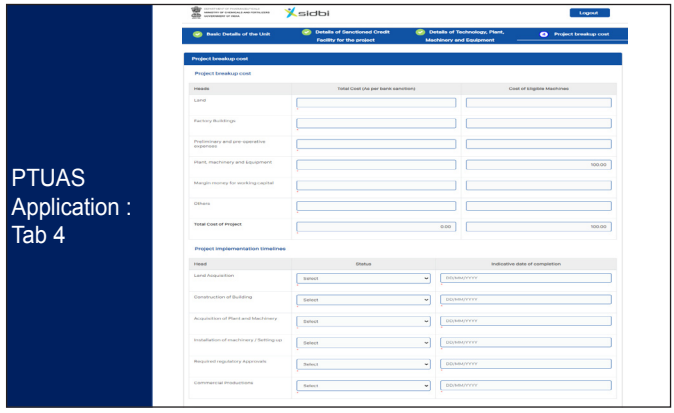

PTUAS Application : Tab 2



PTUAS Application : Tab 3




PTUAS Application : Tab 4





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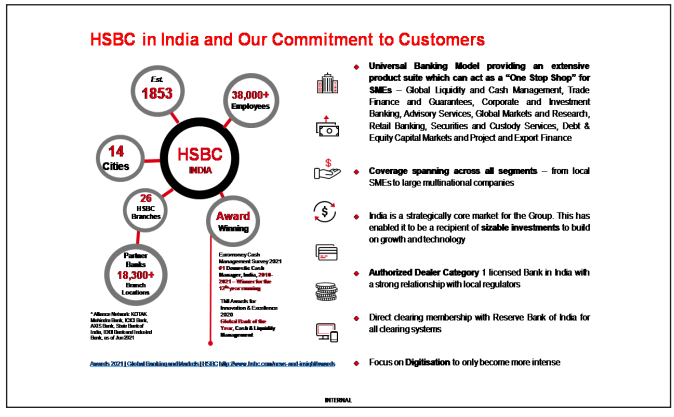
PRESENTATION

# HSBC India Healthcare Segment Focus by Mr. Anurag Tripathi, Head-Assets, Business Banking Commercial Banking, India Management office, HSBC India

## Indian Pharma Industry & HSBC

- India's Pharmaceutical Industry **accounts for 33% of world's** volume. Accounts for **20% of World's Generic** Drugs.
- Current Market size of **USD 40 Bn** (Equally split between Domestic and Exports). Expected to grow to **USD 50 Bn by 2025.**
- **Covid vaccine exports** provided an addition **growth of 5-8%** in FY22. **Chronic therapies** will bring future growth.
- **2nd Largest USA FDA** site outside USA. Focus for growth is **supplies to Europe, Canada, Australia and semi regulated markets** as margins are shrinking for US supplies due to Price Pressure along with slow growth.
- **HSBC India** is supporting domestic clients to expand business **across borders** by way of facilitating subsidiaries/group companies at 70+ network geographies.
- **HSBC** supports importers by arranging **buyers credit/loan against Imports** and to Exporters by arranging **export financing** in both **FCY/INR**
- **HSBC** has a **digitized platform** for the clients to support paperless regularization for Imports/Export transactions .
- **HSBC India** currently has 78 MSME clients **with sanction limits of USD 200M** in Healthcare. Aim to **double by 2023**.

INTERNAL

## Business Banking(MSME) Overview

**Provides comprehensive banking offerings to SMEs (Small & Medium Sized Enterprises) by offering a wide range of tailor made solutions to meet the banking needs of the customers, both domestic and international**

- 200+ business banking staff covering 11 Indian cities.
- India: One of the fastest growing business banking site within HSBC Group.

| Lending | Transaction Banking | Startups/New Age |
|---|---|---|
| ▪ Working capital financing.<br>▪ Capex & term loan financing.<br>▪ Export–Import Financing.<br>▪ Bank guarantees.<br>▪ Secured lending program.<br>▪ Trade finance & forex hedging.<br>▪ Supply chain solutions.<br>▪ Controls & risk management.<br>▪ Portfolio management. | ▪ Domestics & international payments and receivables.<br>▪ Trade services - (import & export payments, letters of credit).<br>▪ Foreign exchange services – (currency hedges: forwards & options).<br>▪ Issuer services - Escrow Services, Foreign direct investment, Overseas direct investment. | ▪ Simple and agile banking.<br>▪ Digital onboarding – capital, current & EEFC accounts.<br>▪ Transaction processing at scale.<br>▪ API Banking supporting instant pull and push payments (mobile app).<br>▪ Omni Channel- One stop solution for merchants. |

INTERNAL

## Global Trade & Receivable Finance in India

- #1 Trade bank in India through leadership in Structured Trade, Digitization and Service Excellence


1. DGFT India data on India cross border flows and HSBC India internal information ; India cross border flows pertaining to Gems &Jewellery and Nuclear sectors are excluded. With available data as of Jun'21

INTERNAL

# Beyond Banking

Building a deeper engagement with ecosystem…

#BeBa

INTERNAL

## #Beyond Banking

*Catering to all lifecycle needs of the customer*

- Integrated Banking

  Zoho– Financial Management on the go

- Partner Alliances

Developing Landscape of **#HSBCBeyondBanking**

Theme 1: Digital business enablers

aws activate  Google Workspace

Theme 2: Financial management and compliance

Zoho Books  cleartax  idos

Theme 3: Enablers of Online commerce, Supply chain, & Logistics

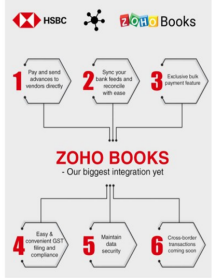
EUNIMART  Shiprocket  Zoho Inventory

Theme 4: HR and Expense Management solutions

greytHR  Zoho Payroll  Zoho Expense

*& many more are Work in Progress…*

***End to end flow for domestic and cross-border payments, real time account balance fetch and smart reconciliation***




# Q & A

INTERNAL

# Glimpses of Healthcopeia South Asia Summit 2022 on 23rd July 2022 at Goa




# IDMA Congratulates Dr V G Somani, DCGI on his Extension

***IDMA have congratulated Dr V G Somani, DCGI on his extension dated 17th August 2022 communication as reproduced below:***

On behalf of our National President, Dr. Viranchi Shah and the entire IDMA membership, we wish to congratulate you on getting an Extension as Drug Controller General of India for a period of three months.

IDMA has always been closely associated with the DCG(I)'s office and during the pandemic the bond has increased manifold.

We assure you of our whole hearted support and co-operation in all your future endeavors.

We once again congratulate you and look forward towards working closely with you.

With best regards,

Sincerely,

Daara B Patel
Secretary – General

No. A.12025/1/2022-DRS-Part(3)
Government of India
Ministry of Health and Family Welfare
Department of Health and Family Welfare
(Drugs Regulation Section)

Nirman Bhawan, New Delhi-110011
Dated 16th August , 2022

**OFFICE ORDER**

It has been decided with the approval of the competent authority, that Dr. V. G. Somani, shall continue to hold the charge of the post of Drug Controller of (India) under FR 49(v) for a period of three months w.e.f 16.08.2022 or until further orders, whichever is earlier.

16/8/22

(Dr. Kiran Kumar Karlapu)
Deputy Secretary to the Government of India
Tel:-011-23061141

Copy to:

1. Dr. V. G. Somani, CDSCO, FDA Bhawan, Kotla Road, New Delhi.
2. Director (Admn.), CDSCO, FDA Bhawan, Kotla Road, New Delhi.
3. Establishment Officer, Department of Personnel & Training, North Block, New Delhi.
4. Vigilance Section, Ministry of Health and Family Welfare, New Delhi.
5. Director (A &V) / Director (Admn.) (HQ)/A&V Unit/Admn.I Section, Dte.GHS.

Copy for information to:

PS to HFM/PS to MoS(BPP)/Sr. PPS to Secretary (HFW)/PPS to DGHS/PS to JS(R)

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

Dear Member,

As you are aware, IDMA is continuously working closely with the US FDA India Office and we are indeed pleased to inform you that the U.S. Food and Drug Administration (USFDA) India Office and the Drug Information Association's (DIA) India Office would be hosting a **2 -day workshop (VIRTUAL)** on regulatory policies, guidance and support for the adoption of advanced manufacturing technologies featuring USFDA, Pharmaceuticals and Medical Devices Agency (PMDA), Therapeutic Goods Administration (TGA), Central Drugs Standard Control Organization (CDSCO) and Industry representatives. **The Registration Form, Registration Fees and Agenda of the said workshop is given below for your kind perusal and information.**

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

**Featured topics:**

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

The US FDA India Office has requested IDMA Members to kindly register for this workshop and reap benefits from the same.

**How do I register?: Online**

**Agenda: Refer the link**

Request members to kindly register for this workshop at the earliest.

Thanks & regards,

**Daara B Patel**

Secretary – General

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# In Rajya Sabha & In Lok Sabha

## In Rajya Sabha

## Sale of generic medicines through PM Jan Aushadhi Kendra

### Rajya Sabha Unstarred Question No. 979

### Dr. Ashok Bajpai:

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

(a) the number of Pradhan Mantri Jan Aushadhi Kendras and total sales by them during the last three years;

(b) the details of the policy initiatives to promote the production and sale of generic medicines;

(c) whether every physician should prescribe drugs with generic names legibly to ensure their rational prescription and use;

(d) if so, whether physicians do so and to what extent; and

(e) whether the Medical Council of India took any action against physicians and Government hospitals for not complying with the above requirement?

### Answered on 26th July, 2022

**A.** (a): The details about number of *Pradhan Mantri Bhariya Janaushadhi Kendras* (PMBJKs) opened and sales made by them during the last three years are as under:-

| Sr. No. | Year | Number of PMBJKs opened | | Sales at MRP Value (In Rs. Crore) |
|---|---|---|---|---|
| | | Yearly Net Addition | Cumula-tive | |
| 1. | 2019-20 | 1166 | 6306 | 433.61 |
| 2. | 2020-21 | 1251 | 7557 | 665.83 |
| 3. | 2021-22 | 1053 | 8610 | 893.56 |

(b): With an objective of making quality generic medicines available at affordable prices to all citizens *Pradhan Mantri Bhartiya Janaushadhi Pariyojana* (PMBJP) was launched by the Department of Pharmaceuticals. Under the Scheme, more than 8,700 dedicated outlets known as *Pradhan Mantri Bhartiya Janaushadhi Kendras* (PMBJKs) have been opened all across the country to provide quality generic medicines at affordable prices.

Further, Ministry of Health & Family Welfare had on 01.10.2012 directed Health Secretaries of all States/UTs to instruct their respective Drug Licensing Authorities to grant/renew licenses to manufacture for sale or for distribution of drugs in proper/generic names only as the grant of drugs manufacturing licenses under a Trade name is not in accordance to the spirit of the legislation.

(c) to (e): Medical Council of India vide their circular dated 21-04-2017 has prescribed that "*all registered medical practitioners should prescribe drugs with generic names legibly and preferably in capital letters and he/she shall ensure that there is a rational prescription and use of drugs".*

Further, Department of Pharmaceuticals periodically write to States/UTs Administrations to ensure that Government doctors prescribe only generic medicines.

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

## Pharmaceuticals industry under Atmanirbhar Bharat programme

### Rajya Sabha Unstarred Question No. 980

### Shri K.R. Suresh Reddy:

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

(a) whether Government agrees with the view that the pharmaceuticals industry is a key sector for the Atmanirbhar Bharat programme; and

(b) if so, the steps taken/proposed to be taken by Government to reduce import dependence on Active Pharmaceutical Ingredients (APIs), Drug Intermediates (DIs) and Key Starting Materials (KSMs)?

### Answered on 26th July, 2022

**A.** (a) whether Government agrees with the view that the pharmaceuticals industry is a key sector for the Atmanirbhar Bharat programme, and

(b) if so, the steps taken/proposed to be taken by Government to reduce import dependence on Active Pharmaceutical Ingredients (APIs), Drug Intermediates (DIs) and Key Starting Materials (KSMs)?

### Answered on 26th July, 2022

**A.** (a) & (b): Yes, Sir. The Indian Pharmaceutical industry is the 3rd largest in the world by volume. India exported pharmaceuticals worth Rs. 1,75,040 crore in the financial year 2021-22, including Bulk Drugs/ Drug Intermediates. India exported about Rs 33,321 crore and imported Rs 35,249 crore worth APIs and Bulk drugs in 2021-22. In order to make the country Atmanirbhar in APIs and drug intermediates, the Department of Pharmaceuticals is implementing the following three schemes by attracting large investments in the sector to ensure their sustainable domestic supply and thereby reduce India's import dependence on other countries -:

i. The Production Linked Incentive (PLI) Scheme for promotion of domestic manufacturing of critical Key Starting Materials (KSMs)/ Drug Intermediates (DIs) and Active Pharmaceutical Ingredients (APIs) in India, with a financial outlay of Rs. 6,940 crores and the tenure from FY 2020-2021 to FY 2029-30, provides for financial incentive for 41 identified products. A total of 51 applicants have been selected under the scheme.

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

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

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

## "Evasion of Custom and Excise Duties at SEZs"

### Rajya Sabha Unstarred Question No. 998

### Shri Shaktisinh Gohil:

**Q.** Will the **MINISTER OF FINANCE** be pleased to state:

(a) The number of cases pertaining to evasion of customs and excise duties coming to light at the SEZs in Gujarat and Maharashtra respectively

(b) The steps taken by Government to prevent the cases of Customs and Excise Duties evasion on Large Scale in the said SEZs.

### Answered on 26th July, 2022

**A.** Part (a) & (b):

Reply **(a):** 1) Number of Cases pertaining to evasion of Customs and Excise Duties coming to light at the SEZs in Gujarat: **20(details in the table below)**

2) Number of Cases pertaining to evasion of Custom and Excise duties coming to light at the SEZs in Maharashtra: **13(details in the table below)**

Reply **(b):** On detection of such cases of evasion of Customs Duty(or Central Excise), action including seizure, confiscation, and invoking penal provisions is taken in accordance with the Customs Act, 1962 or Central excise Act, 1944, as applicable.

| Year | Number of cases pertaining to evasion of Customs duty | | Number of cases pertaining to evasion of Excise duty | |
|---|---|---|---|---|
| | SEZ Gujarat | SEZ Maharashtra | SEZ Gujarat | SEZ Maharashtra |
| 2019-2020 | 7 | 1 | 0 | 0 |
| 2020-2021 | 3 | 2 | 0 | 0 |
| 2021-2022 | 7 | 10 | 0 | 0 |
| 2022-2023 (Till date) | 3 | 0 | 0 | 0 |
| **Total** | **20** | **13** | **0** | **0** |

**Minister of State for Finance**

## In Lok Sabha

# Jan Aushadhi Kendras

### Lok Sabha Unstarred Question No. 2123

### Shri Vishnu Dayal Ram:

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

(a) whether the fund(s) for the promotion of Jan Aushadi Kendra has been enhanced from Rs. 2.5 lakh to Rs. 5 lakh by the Government;

(b) if so, the details thereof;

(c) whether Jan Aushadhi Scheme has become a means to both service and employment in the country; and

(d) if so, the details thereof?

### Answered on 29th July, 2022

**A.** (a) & (b): The incentive provided to the Pradhan Mantri Bhartiya Janaushadhi Kendra (PMBJK) owners has been enhanced from Rs. 2.50 lakh to up to Rs. 5.00 lakh which is given @ 15% of monthly purchases made by them, subject to a ceiling of Rs. 15,000/- per month. Further, a one-time additional incentive of Rs. 2 lakh is reimbursed to Kendras opened by women, divyang, SC & ST entrepreneurs and the Kendras opened in aspirational districts, Himalayan, Island territories and North-Eastern States, for procurement of furniture, fixtures, computer and peripherals.

(c) & (d): As on 30.06.2022, about 8,742 Pradhan Mantri Bhartiya Janaushadhi Kendras (PMBJKs) have been opened across the country providing quality generic medicines available at affordable prices to all the citizens of the country. On an average about 4 to 5 lakh people visit theses Kendras every day. In addition, the scheme has provided direct source of sustainable employment for about 18,000 educated unemployed youths of the country. As such, the Scheme has become a means to both service and employment in the country.

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

# Unethical Marketing Practices

### Lok Sabha Starred Question No. 191

### Shri Hemant Sriram Patil

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

(a) whether the Government has taken note of any unethical marketing practices adopted by the pharmaceutical companies to increase their sale of medicines and their unethical collusion with doctors;

(b) if so, the details thereof;

(c) the details of the steps taken by the Government to prevent such unethical practices and collusion;

(d) whether the Government proposes to formulate a law in this regard; and

(e) if so, the details thereof and the time by which such law is likely to be implemented?

### Answered on 29th July, 2022

**A.** (a) to (e): A statement is laid on the Table of the House.

**Statement Referred to in reply to Parts (a) To (e) of Starred Question No. 191 for Reply on 29.07.2022**

(a) to (c): Yes, Sir. The Government has put in place a Uniform Code for Pharmaceutical Marketing Practices (UCPMP) for Pharmaceutical companies, which is in operation since 01.01.2015, to prevent unethical practices by the pharmaceutical companies.

This is a voluntary code which governs the conduct of pharmaceutical companies in their marketing practices, duly covering the various aspects such as medical representatives, textual and audio-visual promotional materials, samples, gifts, etc. Further, the code establishes relationship with healthcare professionals, wherein the provisions related to travel facilities, hospitality and cash or monetary grants to physicians or their families have been elaborated. The code also details the mode of operation of the code, responsibilities of the Pharmaceutical Associations in constituting the Ethics Committee for Pharmaceutical Marketing Practices (ECPMP) for handling the complaints and Apex Ethics Committee for Pharmaceutical Marketing Practices (AECPMP) for review, procedure of lodging a complaint, procedure of handling of complaints by the Pharmaceutical Associations and various penalty provisions. The code is adopted by the all the major associations of pharmaceutical companies.

The Department on various instances has reviewed implementation of the voluntary code.

Besides UCPMP, there exists sufficient and enforceable legal regime to counter, control and dis-incentivize the unethical marketing practices such as "Indian Medical Council Professional Conduct, Etiquette and Ethics) Regulations, 2002" under the Indian Medical Council Act, 1956, provisions available under Income Tax Act, Drugs and Cosmetics Act, Prevention of Corruption Act, etc.

(d) & (e): There is no proposal to formulate a law in this regard.

**Minister in the Ministry of Chemicals & Fertilizers (Dr. Mansukh Mandaviya)**

## Bulk Drug Park in Telangana

### Lok Sabha Starred Question No. 194

### Dr. G. Ranjith Reddy:

### Shri Venkatesh Netha Borlakunta:

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

(a) whether the Union Government has received any proposal from the Government of Telangana for setting up of bulk drug park in the State;

(b) if so, the details of the proposal received, estimated cost, the number of people who are going to benefit in terms of employment opportunities; and

(c) the status of the project and the time by which it is likely to be operational?

### Answered on 29th July, 2022

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

**Statement Referred to in Reply to Parts (a) to (c) of Starred Question No. 194 For Reply On 29.07.2022**

(a) to (c): Department of Pharmaceuticals implements the Scheme for Promotion of Bulk Drug Parks to facilitate setting up of Three (3) Bulk Drug Parks in the country with the objective to bring down the cost of manufacturing of bulk drugs by creation of world class common infrastructure facilities.

The financial assistance by the centre is subject to a maximum limit of Rs.1000 Crore per park or 70% of the project cost of CIF (90% in case of North Eastern States and Hilly States i.e. Himachal Pradesh, Uttarakhand, UT of Jammu & Kashmir and UT of Ladakh), whichever is less. The total financial outlay of the scheme is Rs. 3000 crore and the tenure of the Scheme is from 2020-21 to 2024-25.

Under the scheme, the Department has received a proposal from the Government of Telangana along with proposals from 12 other States.

All the 13 proposals including the proposal of the Government of Telangana are under evaluation.

**Minister In The Ministry of Chemicals & Fertilizers (Dr. Mansukh Mandaviya)**

## Increase in Prices of Drugs

### Lok Sabha Starred Question No. 182

### Shri Sadashiv Kisan Lokhande:

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

(a) the percentage increase in prices of drugs during the last five years;

(b) whether permission has been sought from the Government to increase the prices of any drugs;

(c) if so, the details of permission granted to increase the prices of drugs including the names thereof; and

(d) the details of the drugs whose prices have come down or have been reduced?

### Answered on 29th July, 2022

**A.** (a) to (d): A statement is laid on the Table of the House.

**Statement referred to in reply to Lok Sabha Starred Question No. †*182 for answer on 29.07.2022 regarding Increase in Prices of Drugs.**

(a) : As per extant provisions of Drugs (Prices Control) Order, 2013 (DPCO, 2013), the ceiling prices of scheduled formulations as per Schedule-I of DPCO, 2013 based on the National List of Essential Medicines (NLEM) issued by the Ministry of Health & Family Welfare (MoH&FW) are fixed by the National Pharmaceutical Pricing Authority (NPPA) under the Department of Pharmaceuticals. All manufacturers of scheduled medicines are required to sell their products within the ceiling price (plus applicable Goods and Service Tax) fixed by the NPPA. Annual revision of ceiling prices of scheduled medicines is permissible based on Wholesale Price Index (WPI) for

all commodities for the preceding calendar year. The Compounded Annual Growth Rate (CAGR) of WPI for the last 5 years is 4.12%. In respect of non-scheduled formulations, while a manufacturer can fix its Maximum Retail Price (MRP) but cannot increase the same by more than 10% of what was prevalent during the preceding 12 months. Further, WPI increase in case of scheduled drugs and 10% increase in case of non- scheduled drugs is the maximum increase permissible, which may or may not be availed. The manufacturers normally decide the market price of their drugs based on market dynamics, within the ceiling, wherever prescribed, by NPPA.

(b) & (c): NPPA had received applications for upward price revision of 74 formulations claiming increase in price of Active Pharmaceutical Ingredients (APIs), increase in cost of production, exchange rate variations, repeated price control, etc. which had resulted in unviability in sustainable production and marketing of various drugs. Considering these applications, NPPA allowed one-time price increase of up to 50% on the then applicable ceiling price in public interest as an exceptional measure by invoking para 19 of the DPCO, 2013 as under:

- Heparin Injection 5000 IU/ml and 1000IU/ml in June, 2020.
- 21 scheduled formulations of 12 medicines in December, 2019;
- 9 scheduled formulations of 3 drugs in July 2021.

The details of price revision as notified by NPPA vide S.O. No. 4461 (E) dated 13.12.2019 and S.O. 2654(E) dated 01.07.2021 respectively are attached as **Annexure**.

(d) : NPPA has fixed ceiling prices of 890 scheduled formulations across various therapeutic categories including scheduled medical devices, viz., Intra Uterine Devices (IUD), condoms and coronary stents and retail price of approx. 2,023 new drugs. Further, it has capped the price of Liquid Medical Oxygen (LMO) and Oxygen Inhalation (Medicinal gas) in cylinders.

Further, the details of drugs, including medical devices, for which prices have been reduced under Para 19 of DPCO, 2013 in public interest are as under:

a. Fixed ceiling price of Orthopaedic Knee Implants.
b. Capped MRP of 106 non-scheduled drug formulations, including 22 diabetic and 84 cardiovascular drugs.
c. Capped Trade Margin of non-scheduled formulations of 42 select Anti-cancer medicines as a pilot for proof of concept.
d. Regulated price of Oxygen Concentrators, Pulse Oximeter, Blood Pressure Monitoring Machine, Nebulizer, Digital Thermometer and Glucometer under 'Trade Margin Rationalisation' Approach during COVID period.

**The details of ceiling prices and retail prices of various formulations fixed by NPPA are available at its website at nppaindia.nic.in.**

**Annexure**

**Details of Price revision of drugs notified by NPPA vide S. O. No. 4461 (E) dated 13.12.2019**

| Sr. No. | Name of the Scheduled Formulation | Dosage form & Strength | Unit | Ceiling Price (Rs.) | Existing S.O. No. & Date | |
|---|---|---|---|---|---|---|
| (1) | (2) | (3) | (4) | (5) | 6(a) | 6(b) |
| 1 | BCG vaccine | | Each Dose | 8.75 | 1485(E) Sl. No. 95 | 29.03.2019 |
| 2 | Benzathine benzylpenicillin | Powder for Injection 12 lac units | Each Pack | 17.84 | 1485(E) Sl. No. 96 | 29.03.2019 |
| 3 | Benzathine benzylpenicillin | Powder for Injection 6 lac units | Each Pack | 11.81 | 1485(E) Sl. No. 97 | 29.03.2019 |
| 4 | Benzyl penicillin | Powder for Injection 10 Lac Units | Each Pack | 7.64 | 1485(E) Sl. No. 100 | 29.03.2019 |

| | | | | | | |
|---|---|---|---|---|---|---|
| 5 | Chloroquine | Tablet 150mg | 1 Tablet | 1.16 | 1485(E) Sl. No. 176 | 29.03.2019 |
| 6 | Dapsone | Tablet 100 mg | 1 Tablet | 0.35 | 1485(E) Sl. No. 243 | 29.03.2019 |
| 7 | Furosemide | Tablet 40 mg | 1 Tablet | 0.74 | 1485(E) Sl. No. 344 | 29.03.2019 |
| 8 | Furosemide | Injection 10mg/ml | 1 ml | 2.43 | 1485(E) Sl. No. 345 | 29.03.2019 |
| 9 | Metronidazole | Oral Liquid 200 mg/5ml | 1 ml | 0.44 | 1485(E) Sl. No. 555 | 29.03.2019 |
| 10 | Metronidazole | Tablet 200 mg | 1 Tablet | 0.68 | 1485(E) Sl. No. 556 | 29.03.2019 |
| 11 | Metronidazole | Tablet 400 mg | 1 Tablet | 1.25 | 1485(E) Sl. No. 557 | 29.03.2019 |
| 12 | Metronidazole | Injection 500mg/100ml | 1 ml | 0.20 | 1485(E) Sl. No. 554 | 29.03.2019 |
| 13 | Ascorbic Acid (Vitamin C) | Tablet 500 mg | 1 Tablet | 1.34 | 1485(E) Sl. No. 74 | 29.03.2019 |
| 14 | Co-trimoxazole (Sulphamethoxazole (A)+ Trimethoprim (B)] | Tablet 400 mg(A)+80 mg(B) | 1 Tablet | 0.77 | 1485(E) Sl. No. 227 | 29.03.2019 |
| 15 | Co-trimoxazole (Sulphamethoxazole (A)+ Trimethoprim (B)] | Tablet 800 mg(A)+160 mg(B) | 1 Tablet | 1.98 | 1485(E) Sl. No. 228 | 29.03.2019 |
| 16 | Co-trimoxazole (Sulphamethoxazole (A)+ Trimethoprim (B)] | Oral Liquid 200mg(A)+40mg (B)/5ml | 1 ml | 0.32 | 1485(E) Sl. No. 226 | 29.03.2019 |
| 17 | Pheniramine | Injection 22.75 mg/ml (10ml pack) | 1 ml | 1.67 | 1485(E) Sl. No. 639 | 29.03.2019 |
| 18 | Pheniramine | Injection 22.75 mg/ml (2ml pack) | 1 ml | 2.24 | 1485(E) Sl. No. 638 | 29.03.2019 |
| 19 | Prednisolone | Drops 1% | 1 ml | 4.92 | 1485(E) Sl. No. 672 | 29.03.2019 |
| 20 | Clofazimine | Capsule 50 mg | 1 Capsule | 2.13 | 1485(E) Sl. No. 199 | 29.03.2019 |
| 21 | Clofazimine | Capsule 100 mg | 1 Capsule | 3.63 | 1485(E) Sl. No. 198 | 29.03.2019 |

**Details of Price revision of drugs notified by NPPA vide S.O. 2654(E) dated 01.07.2021**

| Sl. No. | Name of the Scheduled Formulation | Dosage form & Strength | Unit | Ceiling Price (Rs.) | Existing S.O. No. & Date | |
|---|---|---|---|---|---|---|
| (1) | (2) | (3) | (4) | (5) | 6(a) | 6(b) |
| 1. | Carbamazepine | Oral Liquid 100 mg/5ml | 1 ml | 0.29 | 1330(E) Sl. No. 139 | 25.03.2021 |
| 2. | Carbamazepine | CR Tablet 200 mg | 1 tablet | 2.34 | 1330(E) Sl. No. 140 | 25.03.2021 |

| | | | | | | |
|---|---|---|---|---|---|---|
| 3. | Carbamazepine | CR Tablet 400 mg | 1 tablet | 4.61 | 1330(E) Sl. No. 141 | 25.03.2021 |
| 4. | Carbamazepine | Tablet 100 mg | 1 tablet | 1.02 | 1330(E) Sl. No. 142 | 25.03.2021 |
| 5. | Ranitidine | Oral Liquid 75 mg/5ml | 1 ml | 1.08 | 1330(E) Sl. No. 722 | 25.03.2021 |
| 6. | Ranitidine | Tablet 150 mg | 1 tablet | 1.10 | 1330(E) Sl. No. 723 | 25.03.2021 |
| 7. | Ranitidine | Injection 25mg/ml | 1 ml | 2.43 | 1330(E) Sl. No. 724 | 25.03.2021 |
| 8. | Ibuprofen | Tablet 200 mg | 1 tablet | 0.59 | 1330(E) Sl. No. 431 | 25.03.2021 |
| 9. | Ibuprofen | Tablet 400 mg | 1 tablet | 1.04 | 1330(E) Sl. No. 432 | 25.03.2021 |

**Minister in the Ministry of Chemicals & Fertilizers (Dr. Mansukh Mandaviya)**

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## IDMA appeals to entrepreneurs to utilize various govt schemes to make pharma a US$ 600 billion industry by 2047

The Indian Drug Manufacturers' Association (IDMA) has appealed to the large, medium and small entrepreneurs to utilize the opportunities unveiled by the Union ministry of health and family welfare during the platinum jubilee year of India's Independence to support the vision of the government to achieve 600 billion USD in 2047, when the country will hit a century of independence.

During the platinum jubilee celebration of India's independence, the government has launched multiple schemes to strengthen the Indian pharmaceutical industry which is now recognized by the government as the 'sunrise sector' for the country's economy and is expected to reach US$ 600 billion in next 25 years.

Hailing the proactive role being taken by the Union ministry of health, the honorary secretary of the IDMA, Mehul Shah said this is a time of very good opportunity for the pharma manufacturers irrespective of big or small to benefit out of the schemes. New entrepreneurs should come forward to become part of this growth.

In an online chat with Pharmabiz on the eve of the Independence Day, Mehul Shah expressed the hope that along with the growth of the formulation industry India will become self-sufficient in the production of APIs in another five to ten years time. The present schemes are beneficial for the existing business and for the new entrepreneurs. Currently, the size of the Indian pharma industry is US$ 44 billion which will become US$ 600 billion in 2047 as per the plan of the government. To achieve this target, the government has launched several schemes such as Atmanirbhar Bharat, Make in India, PLI 1, PLI 2 etc and also simplified the regulatory norms and introduced special schemes for the MSMEs. Only thing is that the existing and the new entrepreneurs should utilize all these schemes for the industry's growth, he said.

"It is a long journey, it will take time to prosper as the pharma sector is a knowledge driven one, not merely vested in investment. Secondly, the growth of the industry depends on support from central and state governments. If the industry has to grow both the governments have to join their hands and all sections of the industry should come together," he opined.

As regards support by state governments for the growth of API industry, Mehul Shah said the pricing of APIs imported from China at present is lower than the cost of production here. The government is aware of this, so it introduces several schemes to support the industry. Along with, a lot of policies are announced by state governments like Andhra Pradesh, Telangana, and recently by Madhya Pradesh to support the API industry. These states are working hard to establish strong API industries. They are giving land, water and power at cheaper rates to attract more entrepreneurs. So, in the distant future India will become self-sufficient in APIs also. "It will happen, but it will take time", he concluded with a hope.

*Source: Peethaambaran Kunnathoor, Pharmabiz, 16.08.2022*

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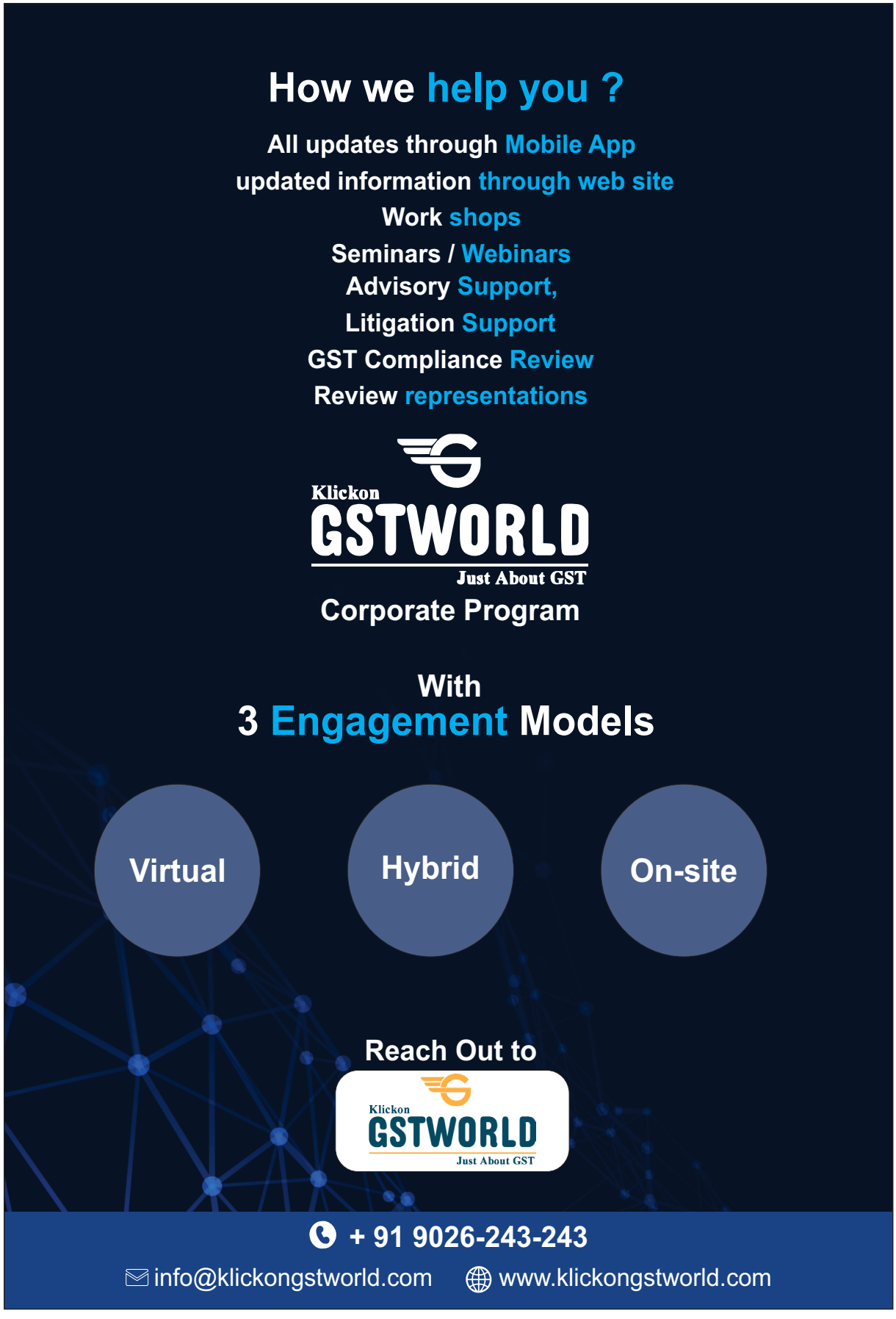
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