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IDMA BULLETIN

VOL. NO. 53 | ISSUE NO. 29 (PAGES: 48) | 01 TO 07 AUGUST 2022 | ISSN 0970-6054 | WEEKLY PUBLICATION

INDIAN PHARMA - GLOBAL HEALTH CARE

INDIAN DRUG MANUFACTURERS' ASSOCIATION

Invitation for the Awareness Program for the
"Scheme for Strengthening of Pharmaceuticals Industry (SPI)"
on Friday 12th August 2022 at Royal Hall,
3rd Floor, Sunville Banquet Worli, Mumbai at 3.00 p.m. to 6.00 p.m

(Details on Page No. 13)

HIGHLIGHTS

QUALITY

BEYOND QUESTION. THAT'S OUR PROMISE.

Dear Partner,

It has been one of the founding fundamentals of Signet to provide our clients with products only of the highest quality, in every capacity. That's why we team up with the likes of Shin-Etsu and Japan Vam & Poval Co.

The Shin-Etsu group and its company, Japan Vam & Poval Co., are paving the way forward with their 'Six Sigma' activities and principles of 'Total Quality Control'. They possess the perfect blend of high technology, business intent and level of innovation, needed to meet the ever-changing and growing consumer needs.

Through them, we are able to access cellulose ethers and derivates across a wide variety of applications such as film coatings, enteric coatings, quick disintegration and binding. As well as a unique range of Polyvinyl Alcohol (PVA) products, so that our customers get exactly what they need, in the highest possible standard.

Shin-Etsu

PHARMACOAT
- HPMC (Low Viscosity Grades)

METOLOSE SH
- HPMC (High Viscosity Grades)

METOLOSE SR
- HPMC (Sustained Release Grades)

METOLOSE SM
- Methyl Cellulose

L-HPC AND L-HPC NBD
- Low Substituted Hydroxypropyl Cellulose

HPMCP
- Hypromellose Phthalate

SHIN-ETSU AQOAT
- HPMC Acetate Succinate

SMARTEX
- Compound of Mannitol, L-HPC & PVA

JVP
JAPAN VAM & POVAL CO.LTD.

POVAL PE-05-JPS
- Polyvinyl Alcohol

Signet-ure Quality

Signet
The Complete Excipients Company

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IDMA BULLETIN

Vol. No. 53 **Issue No. 29** **01 to 07 August 2022**

IDMA ACTIVITIES:

DGFT MATTERS:

GOVERNMENT COMMUNICATIONS:

PARLIAMENT NEWS:

IPR MATTERS:

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 September 2022

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 September 2022 and covers special sessions on Digitization.

Please refer to the brochure and the video link for details of the Program covering:

- ✓ 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.

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 Registration Form and send it to

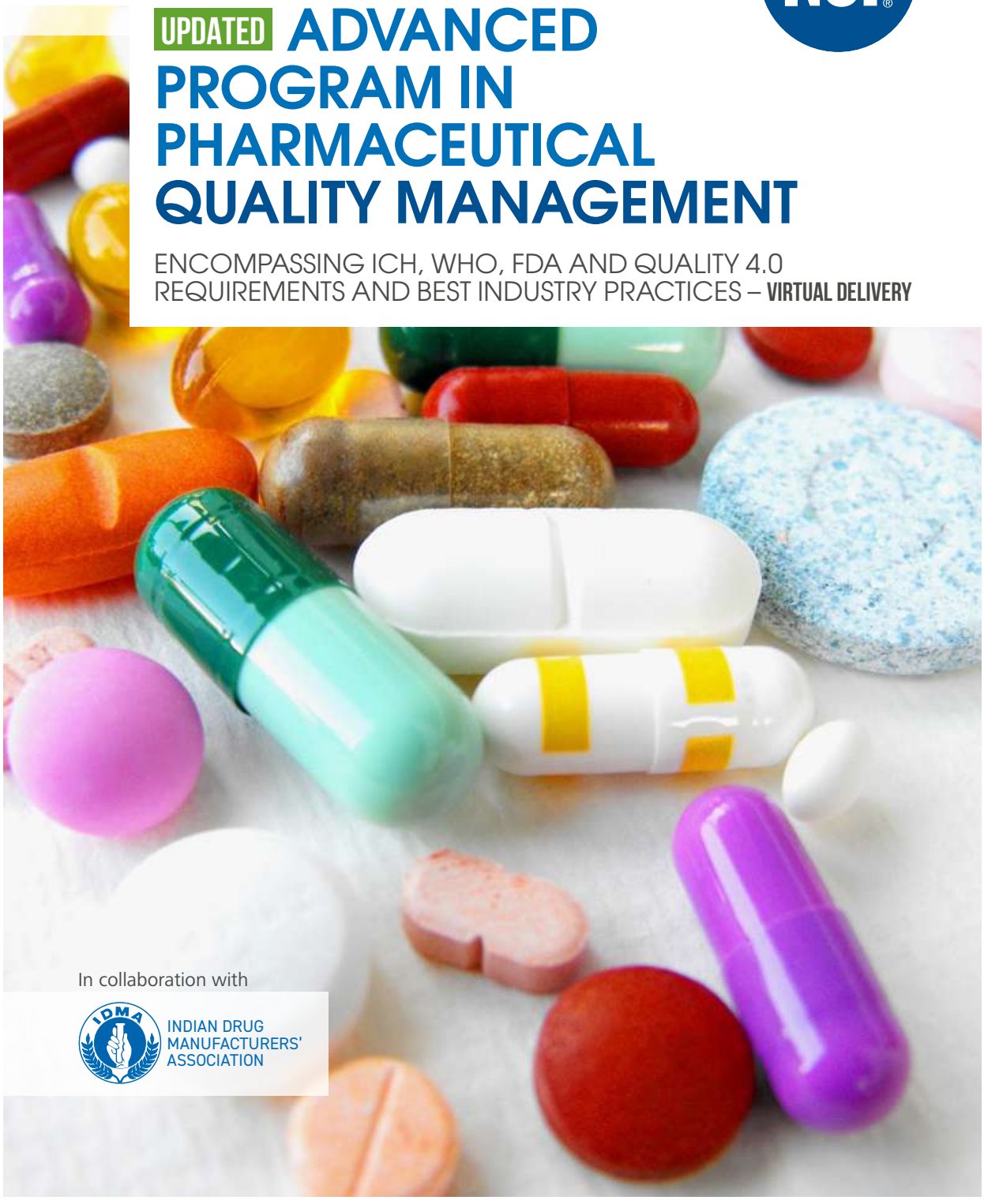
Melvin	**Batul**
actadm@idmaindia.com	technical@idmaindia.com
9821868758	9920045226

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.

Sincerely Yours,

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


NSF
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
IDMA
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

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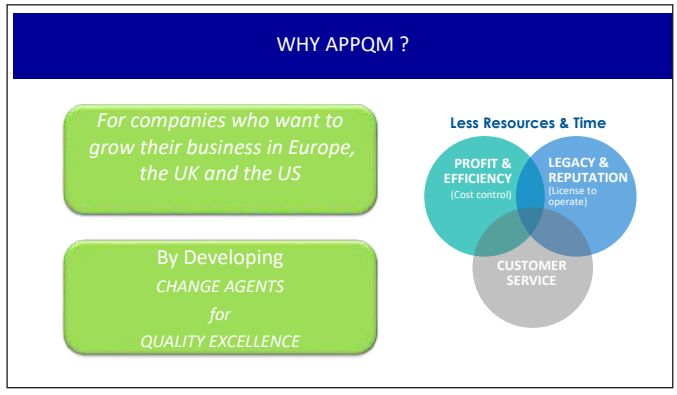
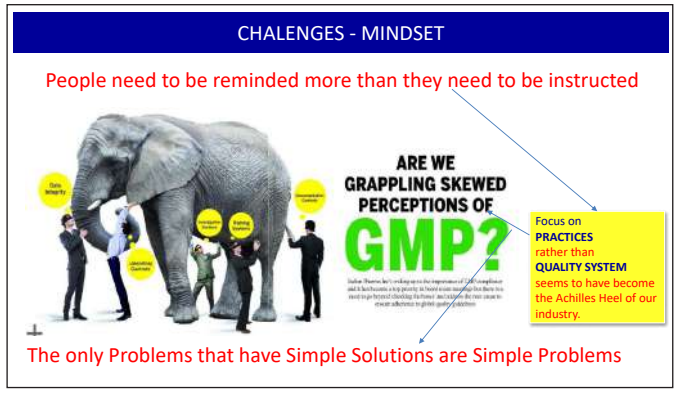
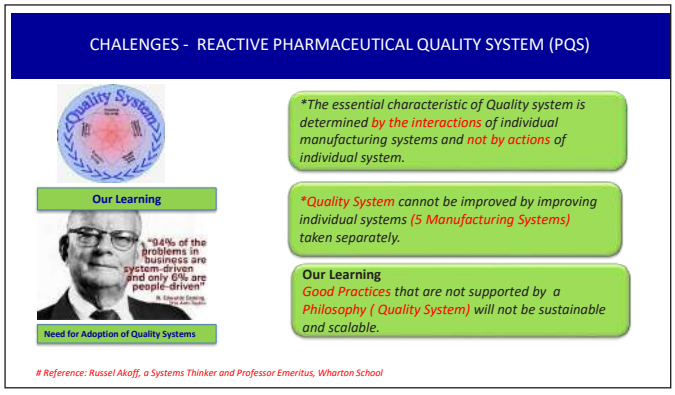
PRESENTATION

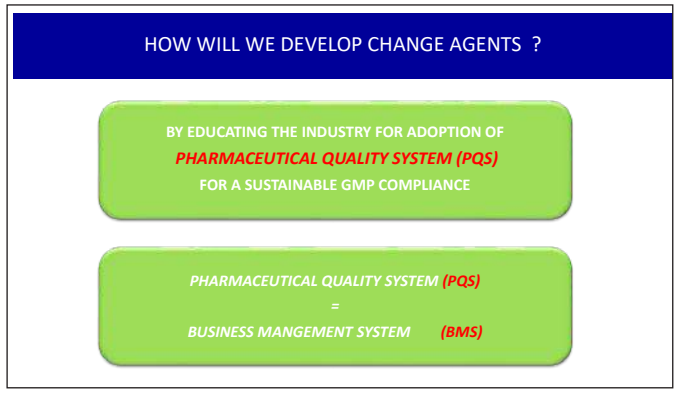
Launch of APPQM Series 3

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 2 VALEDICTORY – APPRECIATION FROM DIGNITARIES

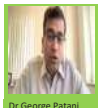

APPQM will help build the quality culture in Indian Pharma Industry
Dr V G Somani, DCGI


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

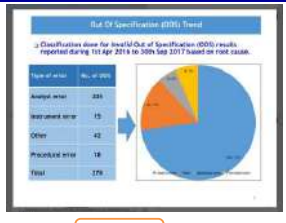

Virtual APPQM Program will be a boon for saving Time, Travel & Cost and yet deliver the same quality education
Dr. Viranchi Shah- National President -IDMA


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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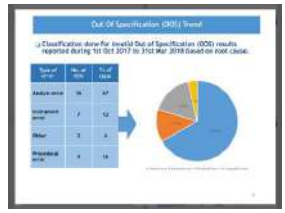
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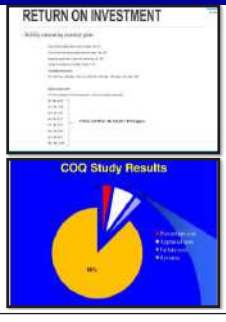
TOTAL SAVING OF Rs. 5 Cr.

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

INDIAN DRUG MANUFACTURERS' ASSOCIATION (IDMA)

102, Poonam Chambers, A Wing, 1st Floor, Dr. Annie Besant Road, Worli, Mumbai - 400 018. Maharashtra, India. Tel: +91-22-24974308 / 24944624 Email: actadm@idmaindia.com Website: www.idma-assn.org

Dear Members,

Subject : **Invitation for the Awareness Program for the Scheme for Strengthening of Pharmaceuticals Industry (SPI) on Friday 12th August 2022 at Royal Hall, 3rd Floor, Sunville Banquet Worli, Mumbai at 3.00 p.m. to 6.00 p.m.**

IDMA along with Department of Pharmaceuticals, Govt. of India and SIDBI is organizing an awareness program for our members to explain in detail the benefits of the various **Schemes for Strengthening of Pharmaceuticals Industry (SPI)**. The meeting would be held at **Royal Hall, 3rd Floor, Sunville Banquet Hall, Next to Worli Flyover, Dr. Annie Besant Road, Worli, Mumbai 400018** from 3.00 p.m. to 6.00 p.m. which would wind-up with Hi-Tea.

As you are aware, Dr. Mansukh Bhai Mandaviya, our Honourable Minister launched this New Scheme to Strengthen the Indian Pharmaceutical Industry on 21st July 2022 and in his address 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 sector. IDMA applauds this excellent initiative of the Government which is an excellent opportunity for our Pharma Industry.

The objective of this meeting is to bring awareness about the policies of the Government and identifying problem / issues faced by the industry. The impact of this awareness program will help in providing financial assistance to our pharma companies and provide support / facilities for promotion of investment and growth of pharma sector which would benefit the pharma industry.

Please find below the agenda for the event:

AGENDA

Time	Particulars	Speaker
3.00 pm to 3.10 pm	Welcome address by IDMA	IDMA
3.10 pm to 3.40 pm	Opening Remarks and Brief Information regarding the schemes	DoP
3.40 pm to 4.10 pm	Details of the Schemes	SIDBI
4.10 pm to 4.40 pm	Bankers View on the Schemes	HSBC Bank
4.40 pm to 4.55 pm	Address by **Dr. Harshadeep Kamble, I.A.S.**Secretary (Small & Medium Industries) & Development Commissioner (Industries) Government of Maharashtra.	
4.55 pm 5.25 pm	Question & Answer Session	IDMA
5.25 pm to 5.30 pm	Vote of Thanks	
5.30 pm onwards	Hi-Tea	

REGISTRATIONS

The Registration for this awareness program is complimentary but prior confirmation is necessary.

We give below the registration link for this awareness program :

https://docs.google.com/forms/d/e/1FAIpQLSe5c6FgYQ6StkbhJ_GF4ZHa_ZaKOY_s72uFxeLFP0m1At19Ew/viewform?vc=0&c=0&w=1&flr=0&usp=mail_form_link

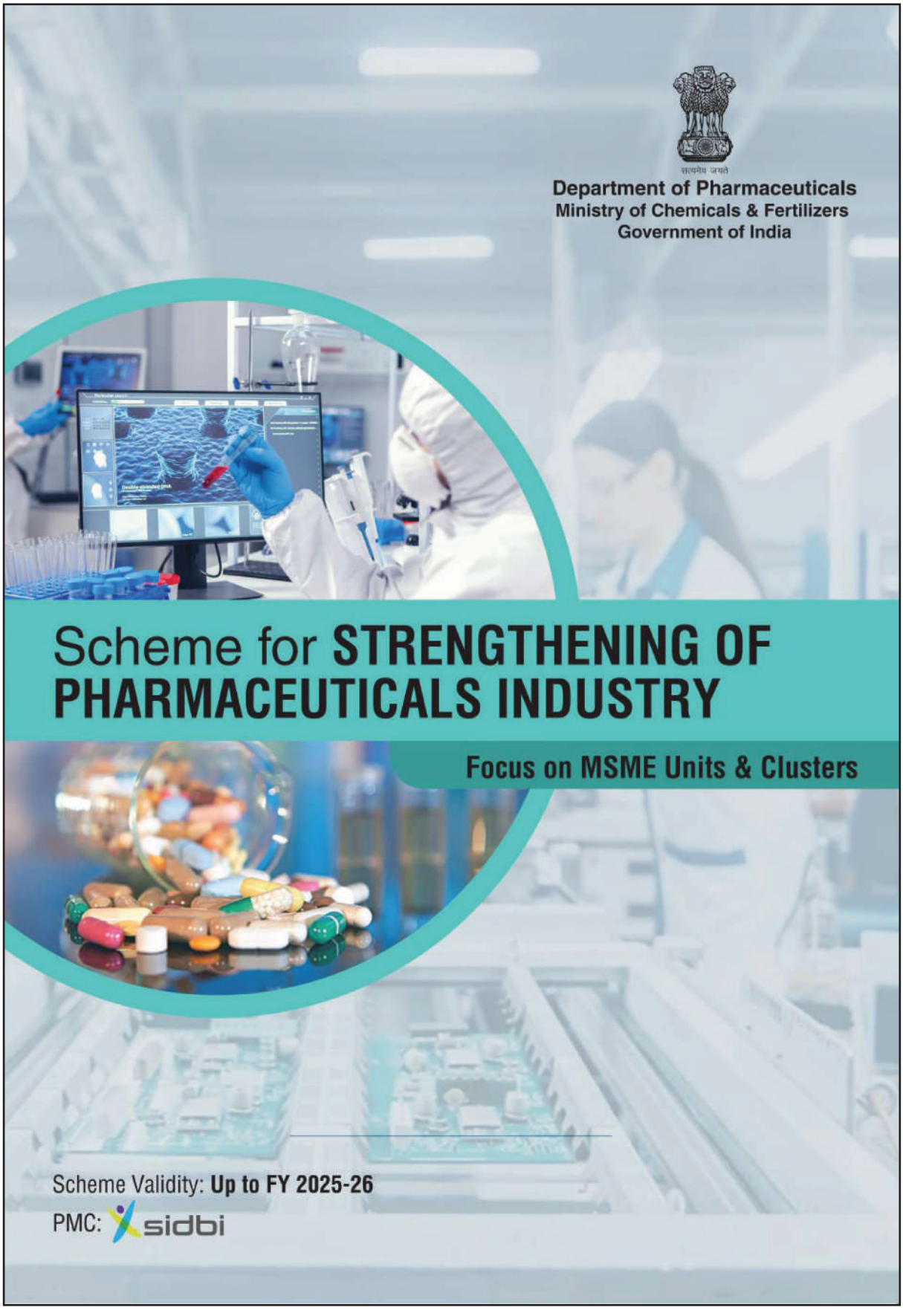
For any further clarifications / assistance, please feel free to call :
Ms. Sapna Patil - (9619802299 / admin@idmaindia.com) & Ms. Batul (9920045226 / technical@idmaindia.com)

Request our members to kindly register for this event and participate actively so as to understand the benefits from the Schemes for Strengthening of Pharmaceuticals Industry (SPI).

Looking forward to welcoming you at this awareness program.

Thanks & regards,

Daara B Patel
Secretary – General


सत्यमेव जयते
Department of Pharmaceuticals
Ministry of Chemicals & Fertilizers
Government of India
Scheme for STRENGTHENING OF PHARMACEUTICALS INDUSTRY
Focus on MSME Units & Clusters
Scheme Validity: Up to FY 2025-26
PMC: sidbi

SCHEME FOR STRENGTHENING OF PHARMACEUTICALS INDUSTRY

Scheme Objective:

- To strengthen existing pharmaceutical clusters' capacity for sustained growth by creating common facilities
- To facilitate Existing MSME Pharma manufacturing units to meet national / international regulatory standards by upgrading their facilities to Schedule M or WHO GMP Standard.
- To facilitate growth and development of Pharmaceutical and Medical Devices Sectors through study/survey reports, awareness programs, creation of database, and promotion of industry.

THREE COMPONENTS OF THE SCHEME:

- Assistance to Pharmaceutical Industry for Common Facilities (APICF)
- Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS)
- Pharmaceutical & Medical Devices Promotion and Development Scheme (PMPDS)

ASSISTANCE TO PHARMACEUTICAL INDUSTRY FOR COMMON FACILITIES (APICF)

Objective : Creation of common infrastructure facilities for strengthing of MSME pharma clusters

Eligible Activity in order of Priority:

- Research and Development Labs, Testing Laboratory for Pharma Products, Effluent Treatment Plants, Logistic Centres, Training Centres etc.
- Other allied activity can be taken up based on recommendation of Scheme Steering Committee

Project Component:

Land, Building, Internal Infra, Plant and Machinery, Misc. Fixed Assets, Preliminary and Pre-operative Expenses, Utility infra, Margin Money for Working Capital etc.

GoI Grant per Common Facility Project:

- Up to 70% of the project cost subject to Max. ₹ 20 Crore
- Up to 90% of the project cost subject to Max. ₹ 20 Crore - For Himalayan and NER States

Eligibility parameters:

- SPV to be formed by the cluster members with minimum of 5 members
- Cluster promoted by State Governments with a distinct project implementing agency would also be eligible
- Pharma enterprises shall hold at least 51% equity of the SPV
- Minimum Net worth criteria for SPV as a whole and also for members as stipulated

Expected benefits:

Standardization of manufacturing process, Improvement in quality standards and environmental regulatory compliance, Reduction in wastage, Increased availability of trained Personnel

PHARMACEUTICAL TECHNOLOGY UPGRADATION ASSISTANCE SCHEME (PTUAS)

Objective : To incentivise MSME Pharma units for undertaking capital expenditure necessary towards obtaining of WHO-GMP or Schedule M certifications. The scheme is a credit linked subsidy scheme with a loan cap of ₹10 crore sanctioned by any scheduled commercial bank

- Applicant can choose from either Capital Subsidy or interest subvention

Capital Subsidy	Interest Subvention
10% of loan component eligible under the scheme	• maximum of 5% per annum on eligible component
	• maximum 6% in case of units owned and managed by SC/ STs

Eligible Activities (indicative) :

- Up gradation of HVAC system to WHO Norms
- Stability testing chambers
- State-of- art lab equipment
- All lab scale and pilot scale manufacturing equipment for R&D
- Water management and purification systems
- Automatic particle counters for sterile areas
- Laboratory information management system
- Only New machinery acquired after sanction of the credit facility

Eligibility Parameters:

- Only new Machinery and equipments acquired after sanction of credit facility with at least 50% of the sanctioned loan being towards eligible component
- Minimum Loan Repayment period: 3 Yrs.
- Applications to be received till 29th February 2024
- Necessary certifications for Technological upgradation to be submitted as stipulated

PHARMACEUTICAL & MEDICAL DEVICES PROMOTION AND DEVELOPMENT SCHEME (PMPDS)

Eligible Activities:

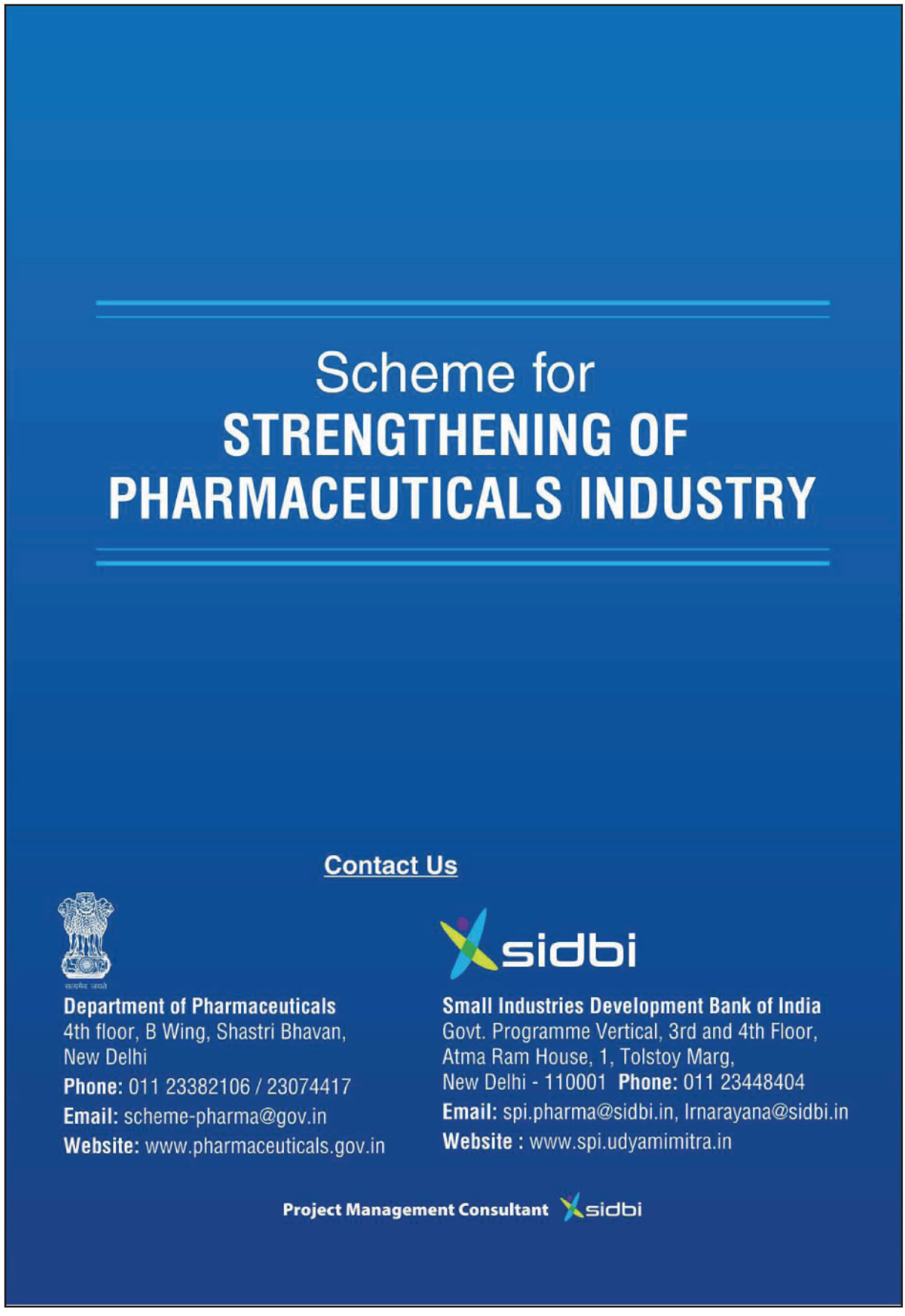
- Preparation of study reports on topics of importance.
- Support to organize seminars, conferences, conventions, workshop & exhibitions.
- Non-financial Logo support for Pharma and Medical Devices events.
- Creation of Database of pharmaceutical and medical device sector.
- Organizing Mega events and participating in other events.

Eligible Organization:

- Government agencies like Academic institutions, autonomous bodies, PSUs under DoP
- Prominent Industries Associations in Pharmaceuticals, Medical Device and related sector.
- Specialized organization with expertise in the field in which proposed event is to be organized.

Expected benefits:

- Creation of awareness about the policies of the Government
- Identification of problems/ issues faced by the industry.
- Support/ facilitate investment promotion & growth


Scheme for
STRENGTHENING OF
PHARMACEUTICALS INDUSTRY
Contact Us
Department of Pharmaceuticals
4th floor, B Wing, Shastri Bhavan,
New Delhi
Phone: 011 23382106 / 23074417
Email: scheme-pharma@gov.in
Website: www.pharmaceuticals.gov.in
sidbi
Small Industries Development Bank of India
Govt. Programme Vertical, 3rd and 4th Floor,
Atma Ram House, 1, Tolstoy Marg,
New Delhi - 110001 Phone: 011 23448404
Email: spi.pharma@sidbi.in, lrnarayana@sidbi.in
Website : www.spi.udyamimitra.in
Project Management Consultant sidbi

IDMA-GSB, IPA-GSB & LMCP organized Technical Talk by Dr Saranjit Singh

IDMA - Gujarat State Board, IPA- Gujarat State Branch and L. M. College of Pharmacy jointly organized technical talk cum felicitation of Dr. Saranjit Singh, Ex-Professor & Ex Dean, NIPER, Mohali on 21 July 2022 at Ahmedabad University Auditorium. Dr. Shrenik Shah, Chairman of IDMA GSB gave a warm welcome address and touched upon the importance of QbD in the present industry scenario. Dr. Mahesh Chhabria, Principal of L. M. College of Pharmacy talked about 75 years of glorious journey of the college and Atal Incubation Centre for encouraging budding entrepreneurs in the healthcare segment. Dr. Jayant Dave, President of IPA Gujarat State Branch recalled the contribution of Prof. Singh to Academia, Industry and briefly explained the scope of the technical talk.

Prof Saranjit Singh paid laurels to LMCP and the pharma industry of Gujarat and then delivered a lucid talk on 'Exciting Transition from QbD to Continuous Manufacturing. He touched upon recent advances in terms of 'Quality by Design' starting from Q8 and evolving further into Q9 and Q10 that extends to the product life cycle which takes into consideration risk-based and science-based decisions. He held that the MSE sector is very important for us but it has to become global in its outlook. The pharmaceutical Quality System is aimed at cultural and operational excellence. ICH Q8 & Q9 are imperative for its implementation. He elaborated on concepts of Quality by design, Quality Risk Management, and Regulatory flexibility. The last part of the talk referred to futuristic developments in terms of ICH Q13 Continuous Manufacturing of Drug substances and Drug products and ICH Q14 Analytical Procedure Development.

At the end of the talk, Prof. Singh was felicitated by offering a plaque containing quintessential points of his professional career, a bouquet, and a shawl by three organizing units. He lovingly accepted them saying that this was the first formal felicitation he had received after his retirement. Sri Jayantkumar, Deputy Drug Controller, Ahmedabad paid tributes to Prof. Saranjit Singh and referred to the regulator's perspective of technology upgradation and QMS. The organizing units also felicitated Mr. Gaurang Oza, EC member of IPA Gujarat State Branch for his dedicated selfless contribution to the cause of the Indian Pharmacopoeia Committee and professional bodies like IDMA & IPA. Faculty and students of LMCP played a vital role in organizing the event that was attended by the industry and regulatory officials, faculty, and students of pharmacy colleges. Dr. Praful Bharadia, Secretary IPA GSB effectively served as master of ceremony and gave concluding observations. Dr. Anuradha Gajjar, a senior IPA member and faculty at LMCP gave a spirited vote of thanks. The program concluded with a national anthem and refreshments.

Prof. Saranjit Singh interacted with all the faculty members of L. M. College of Pharmacy, AIC officials, and IDMA GSB EC members before the scheduled lecture and shared his motivational thoughts imbibed during his flourishing journey at NIPER, Mohali, and gave an account of the work pursued by the institute in association with leading industries.

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A Report on IDMA & APTAR Pharma - Webinar on "Innovation And Differentiation In Dermal Drug Delivery System"

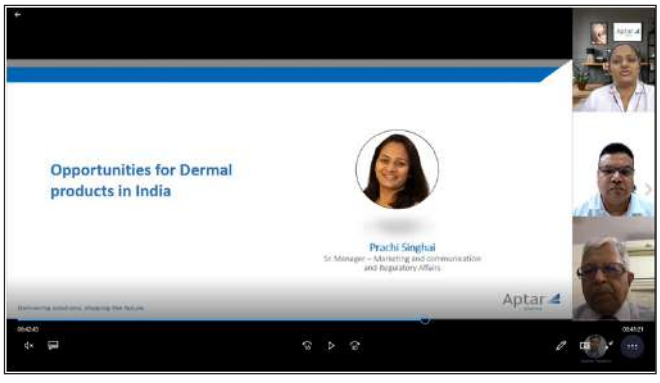
IDMA & APTAR Pharma organized a Webinar on "**Innovation and Differentiation in Dermal Drug Delivery System**"on Thursday, 28thJuly 2022. Webinar was successful with the active participation of members and excellent addresses by the speakers.

Mr. S.R Vaidya welcomed all the speakers and participants (*as reproduced below*). Speakers Dr. Stefan Hellbardt - Vice President, Business Development and Scientific Affairs CHC, Mr. Marcus Bates - Vice President, Global Business Development, Aptar Digital Health and Ms. Katja Bertsche - Product Manager CHC, Aptar Villingen, Germany made an informative and excellent presentation.

Ms Prachi Singhai, Manager – Marketing & Communications, India & S. E. Asia, Aptar Pharma made a presentation on the Opportunities in India and How to Contact Aptar Pharma for Project support.

The Moderator of the webinar was Mr. Kamal S. Mehta, Head R&D, Encube Ethicals Pvt. Ltd. Ms Sapna Patil, Deputy Secretary – General, IDMA proposed Vote of thanks (*as reproduced below*).

Glimpses of Webinar



Welcome address by Mr. S R Vaidya, Chairman, MSME Committee, IDMA

Good evening Ladies and Gentlemen!

Greetings from Indian Drug Manufacturers' Association (IDMA) and Aptar Pharma.

It gives me great pleasure to be with you and address you all at this Innovative Webinar. On behalf of our National President, Dr. Viranchi Shah, Mr. Daara B Patel, Secretary General of IDMA &Team Aptar Pharma, I welcome you all to this interesting & informative webinar aptly titled **'Innovation and Differentiation in Preservative Free and Dermal Drug Delivery System'**

Aptar Pharma has been enhancing its reputation as a go-to drug delivery expert and can proudly state that when Pharmaceutical companies around the world want to develop safe, efficient and compliant medicines, they turn to Aptar Pharma. Because Aptar Pharma has proven and complete drug delivery solutions and services.

Aptar Pharma is a global leader in drug delivery, consumer product dispensing and active material science solutions, they use insights, design, engineering and science to create dosing, dispensing and protective packaging technologies for the world's leading brands. Aptar Pharma Airless Dispensing in Topical Dermal Drug Delivery.

Indian Drug Manufacturers' Association (IDMA) has successfully completed 60 glorious years of its existence, providing support to its members for supplying affordable quality medicines, not only to the people of India, but also to people all over the world. The IDMA Membership consists of over 1000 plus wholly-owned Indian large, medium and small companies manufacturing Formulations & APIs. At present, we have 8 State Boards located pan India.

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

This is something that we can be proud of. We can look back with a sense of satisfaction.

IDMA also organizes other Webinars, Conference, Seminars & Training Programs regularly.IDMA has organized two (2) Series of "Advanced Program in Pharmaceutical Quality Management" (APPQM) in collaboration with NSF Health Sciences, UK. Developed 68 Change Agents for the Pharma Industry. The Third (3) Series is an updated APPQM Plus which begins in mid-September 2022. The Registrations are open for this series 3, you can contact the IDMA Office for more information.

We have excellent speakers for today's webinar –

- **Dr. Stefan Hellbardt** - Vice President, Business Development and Scientific Affairs CHC.
- **Mr. Marcus Bates** - Vice President, Global Business Development, Aptar Digital Health.
- **Ms. Katja Bertsche** - Product Manager CHC, Aptar Villingen, Germany.

Season's Greetings from IDMA and Aptar and a warm welcome to you all for this webinar.

I wish you all fruitful deliberations and I am sure at the conclusion of this webinar we will be more enlightened about the Innovation and Differentiation in Preservative Free and Dermal Drug Delivery System.

I am thankful to Mr. Kamal Mehta of Encube Ethicals for joining us in spite of his busy schedule and he will be setting up the tone for this webinar.

With pleasure I introduce Mr. Kamal Mehta to you … ……

Mr. Kamal S. Mehta's Profile

Kamal S. Mehta is associated with Encube Ethicals as Head R&D

Mr. Kamal is an alumni of Prestigious BITS Pilani and has completed Bachelor and Post graduate degree in Pharmacy

Mr. Kamal has 27+ years' of experience and having Broad knowledge of the pharmaceutical industry, including in-depth operation knowledge of various functions involved in Product development and commercialization.

Mr. Kamal is having key expertise for development of generics with high barrier, complex IP, complex manufacturing process and technologies, specialized equipment demand, regulatory challenges, packaging challenges etc.

Mr. Kamal has extensive experience in development of Generics, OTC and 505 (b)2 of various Dosage forms like Oral Solids (IR, NDDS), Solution, (Suspension, Solution), Topical (ointment, Cream, Gel, Emulsion), Sterile (Injectable Solution, Lyophilized, complex injectable, ophthalmic solution), cold kit for radiopharmaceuticals for various marketing like US, EU, CA, Japan, Australia and ROW.

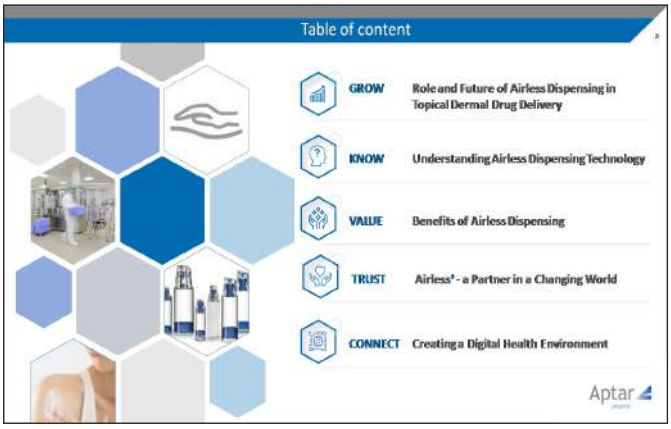
Mr. Kamal has granted patents/publications covering various technologies filed across the globe.

I am very pleased to handover the webinar in the safe and talented hands of Mr. Kamal who will set the tone as well as moderate the webinar.

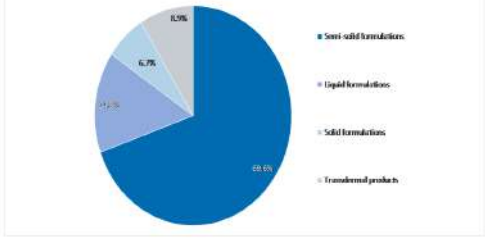
Over to you Mr. Kamal

PRESENTATION

Innovation and Differentiation in Dermal Drug Delivery



The topical drug delivery market



Source: Visiongain 2020

Delivering solutions, shaping the future.

Aptar

Dispensing semi-solid formulations

Delivering solutions, shaping the future.

Aptar

Airless dispensing market

Source: Market Research Future 2019

Delivering solutions, shaping the future.

Aptar

Existing Airless technology at the healthcare market

Delivering solutions, shaping the future.

Aptar

How does Airless technology work?

Video of top fill airless dispenser originally played here

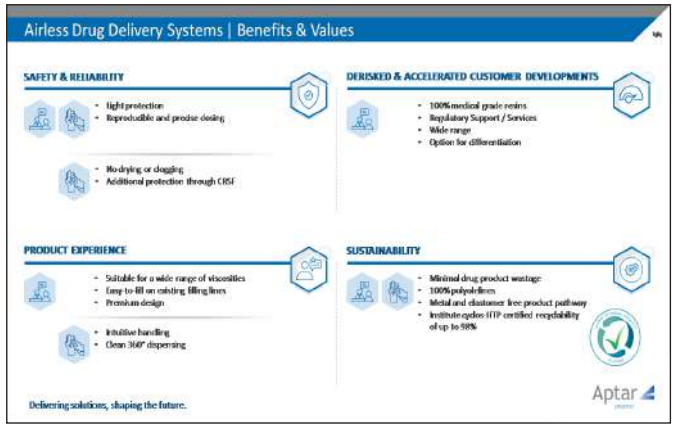
Delivering solutions, shaping the future.

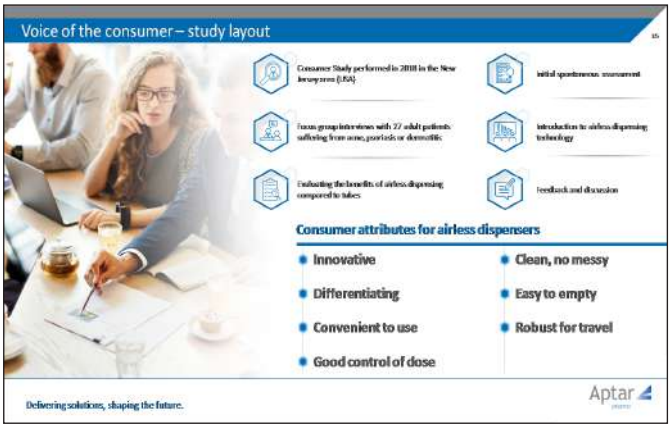
Aptar

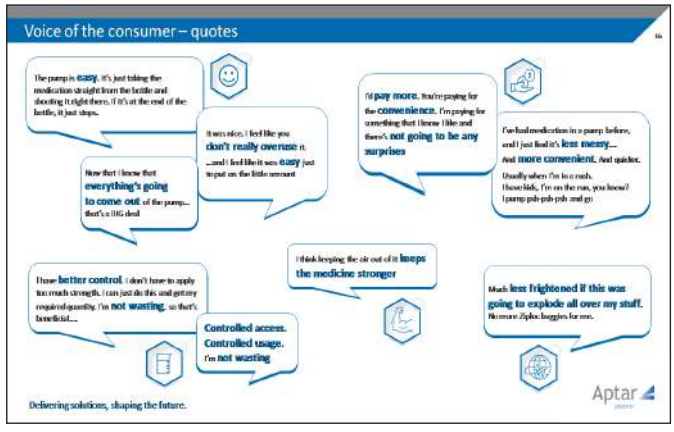

Aptar Airless systems dedicated for the healthcare market
Wide range of options available
Suitable for a wide range of viscosities
Customizable fill volumes
Filling and snapping is done under atmospheric conditions
Matching common filling processes
Tube-based system
Top Fill models
Bottom Fill models
Delivering solutions, shaping the future.
Aptar


Aptar Airless systems dedicated for the healthcare market
Diverse range of applicators for targeted application
Self-closing actuator for increased protection of formulations against environmental exposure
Child-Resistant Senior-Friendly (CRSF) feature for prevention of accidental access
→ ISO 8317 & US 16 CFR 1700.20 certified
Delivering solutions, shaping the future.
Aptar


Aptar Pharma
Airless+ - Benefits & Values
VALUE

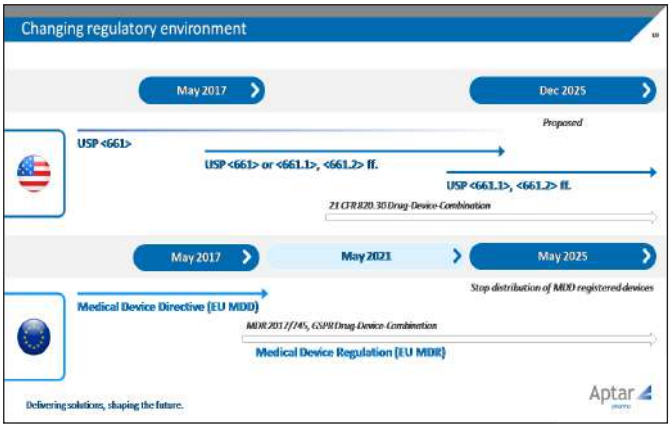

Airless Drug Delivery Systems | Benefits & Values
SAFETY & RELIABILITY
Light protection
Reproducible and precise dosing
No drying or clogging
Additional protection through CRSF
DERISKED & ACCELERATED CUSTOMER DEVELOPMENTS
100% medical grade resins
Regulatory Support / Services
Wide range
Option for differentiation
PRODUCT EXPERIENCE
Suitable for a wide range of viscosities
Easy-to-fill on existing filling lines
Premium design
Intuitive handling
Clean 360° dispensing
SUSTAINABILITY
Minimal drug product wastage
100% polyolefines
Metal and elastomer free product pathway
Delivering solutions, shaping the future.
Aptar


Voice of the consumer – study layout
Consumer attributes for airless dispensers
Innovative
Differentiating
Convenient to use
Good control of dose
Clean, no messy
Easy to empty
Robust for travel
Delivering solutions, shaping the future.
Aptar


Voice of the consumer – quotes
Delivering solutions, shaping the future.
Aptar


Airless drug delivery systems | Sustainability
High evacuation rate
Recycling supported by 100% plastic dispensers
No green house gases
Sprue shredded & reused
Metal/Elastomer free product pathway
Plastic waste is recycled externally and e.g. used for flowerpots
Recyclability certified by cyclos-HTP
96-98%
Aptar

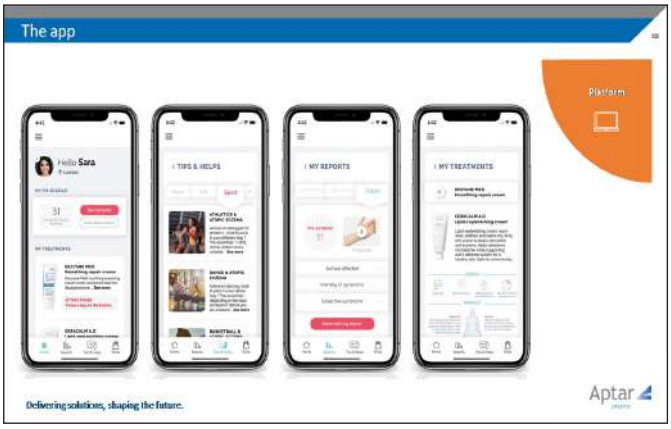

Aptar Pharma
Airless+ - Partner in a Changing World
TRUST

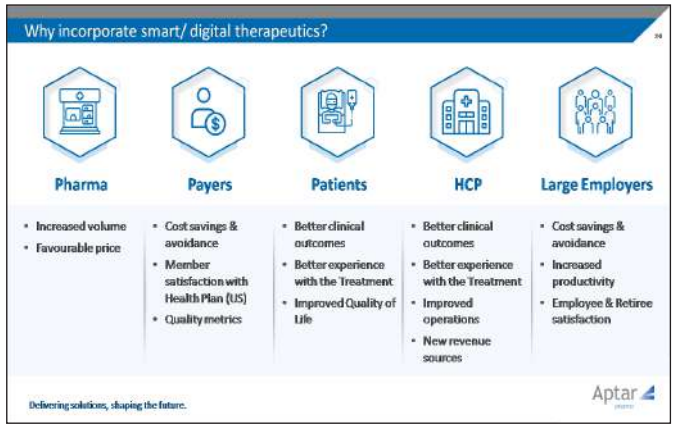

Changing regulatory environment
May 2017
Dec 2025
Proposed
USP <661>
USP <661> or <661.1>, <661.2> ff.
USP <661.1>, <661.2> ff.
21 CFR 820.30 Drug-Device-Combination
May 2017
May 2021
May 2025
Stop distribution of MDD registered devices
Medical Device Directive (EU MDD)
MDR 2017/745, GSPR Drug-Device-Combination
Medical Device Regulation (EU MDR)
Delivering solutions, shaping the future.
Aptar

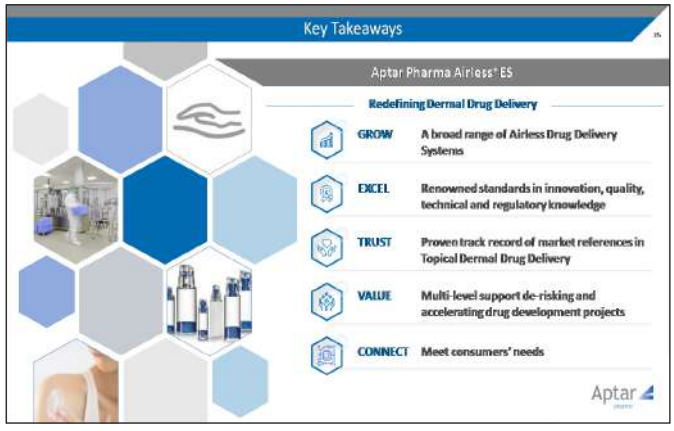

Airless+ ES – extended support for the Airless+ range
Aptar Airless+ Range
Aptar Airless+ ES
Extended Support for the Airless+ Range
Product Information
Material
Regulatory Information
Change Control
Quality
Services & Support
Extractables Study Report
Biological Reactivity Testing
Physico-chemical Testing*
Delivering solutions, shaping the future.
*excluding DSC
Aptar


Aptar Pharma
Creating a Digital Health Environment
CONNECT


What do we mean by smart device...
Product Portfolio
Delivering solutions, shaping the future.
Aptar







Vote of Thanks by Ms Sapna Patil, Deputy Secretary-General, IDMA

Good Evening everyone, I thank Aptar Pharma for a very innovative Webinar on "Innovation and Differentiation in Dermal Drug Delivery system''

The subject of Webinar was very well handled for Airless Drug Delivery System, its benefits, integrating Healthcare and more.

On behalf of our National President Dr.Viranchi shah and our Secretary General Daara Patel, I thank

Dr. Stefan Hellbardt

Mr. Marcus Bates

Ms. Katja Bertsche

for enlightening us and updating us on the complicated concept of Dermal Drug delivery system. I thank Ms Prachi for her presentation on the Opportunities in India and how to contact Aptar Pharma for Project support.

I sincerely thank Mr. Kamal Mehta for moderating this webinar. I sincerely thank Mr. Vaidya, Chairman of the MSME Committee of IDMA for always supporting us for all the Webinars with Aptar Pharma.

Vaidya Sir a big thank you for your usual excellent guidance and advice.

I thank all the participants for their time and for their active participation. This enables the webinar to be more lively and vibrant. I thank the TEAM - Aptar Pharma for their unstinted consistent support, and last but not the least, I thank Ms.Prachi and Vignesh and their team at Aptar Pharma for their diligence, creativity and for having such innovative webinars with IDMA. I also thank my colleagues for the support and co-operation.

Thank you everyone and enjoy your evening.

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IDMA Congratulates Cachet Pharmaceuticals Pvt. Ltd. on being awarded with the Prestigious Title of "Best Company to Work For - 2022" by SiliconIndia for the second time

DGFT MATTERS

Amendment in import policy condition of HS Code 29335200 under Chapter 29 of ITC (HS) 2022, Schedule - I (Import Policy)

Notification No. 23/2015-2020, dated 01st August 2022

1. In exercise of powers conferred by Section 3 and Section 5 of FT (D&R) Act, 1992, read with paragraph 1.02 and 2.01 of the Foreign Trade Policy (FTP), 2015-2020, as amended from time to time, the Central Government hereby amends the policy condition of HS Code 29335200 under Chapter 29 of ITC (HS) 2022, Schedule — I (Import Policy), with immediate effect, as under:

HS code	Item description	Import Policy	Existing Policy Condition	Revised Policy Condition
29335200	Compounds containing a pyrimidine ring (whether or not hydrogenated) or piperazine ring in the structure : -- Malonylurea (Barbituric Acid) and its salts	Free	Subject to Policy Condition No. 3 of Chapter 29 i.e. "No Objection Certificate (NOC) is required from Narcotics Commissioner, Gwalior, before import of the item"	Deleted

2. Effect of this Notification:

Import of Malonylurea (Barbituric Acid) and its salts shall be allowed without NOC from Narcotics Commissioner, Gwalior.

This issues with the approval of Minister of Commerce & Industry.

F.No.01/89/180/Misc-3/AM-04/PC-2[A]/E-1877)

Santosh Kumar Sarangi, Director General of Foreign Trade & Ex-officio Addl. Secretary to the GoI, Ministry of Commerce & Industry, Department of Commerce, Directorate General of Foreign Trade, Vanijya Bhawan, New Delhi.

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Relaxation in provision of submission of 'Bill of Export' as an evidence of export obligation discharge for supplies made to SEZ units in case of EPCG Authorisation

Policy Circular No. 43/2015-20, dated 27th, July 2022

To
All Regional Authorities of DGFT,
All Exporters/Members of Trade,
All Custom Authorities.

1. The requirement of submitting 'Bill of Export' for supplies made to SEZ is prescribed under the Foreign Trade Policy. Recently, the requirement of submission of Bill of Export for supplies made to SEZ in case of Advance Authorisation has been relaxed vide Policy Circular No. 39 dated 07.06.2022.

2. The issue has been examined and in terms of Para 2.58 of the FTP 2015-2020 (extended up to 30.09.2022), it has been decided to relax the condition of requirement of submission of `Bill of Export' in case of exports made to SEZ units under EPCG Authorization, for all such supplies made prior to 01.04.2015.

3. Accordingly, for the purpose of discharge of export obligation under EPCG Authorizations, in case of supplies made to SEZ units prior to 01.04.2015, the exporters can submit corroborative evidence in lieu of 'Bill of Exports' such as:

a. ARE-I form duly attested by jurisdictional Central Excise authorities of EPCG authorization holder.

b. Evidence of receipt of the supplies by the recipient in the SEZ.

c. Evidence of payment made by the SEZ unit to the EPCG authorization holder.

4. This Policy Circular is issued with the approval of DGFT.

File No.18/19/AM-23/P-5

Randheep Thakur, Joint. Director General of Foreign Trade, Ministry of Commerce and Industry, Department of Commerce Directorate General of Foreign Trade

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Seeking the details of domestic manufacturers of the inputs required for manufacture of Vaccines and Biopharmaceuticals - reg.

Public Notice dated 26th July, 2022

1. It is inform that the Department of Pharmaceuticals is in the process of collating the details of domestic manufacturers of the various input materials required for manufacture of Vaccines and Biopharmaceuticals. In this regard, the major vaccine manufacturers have provided a list critical raw / input materials for the manufacture of vaccines, that can be grouped as (i) Micro-reactor bags of various kinds, (ii) Cell Culture Media and (iii) Filters, Cassettes, Cartridges, Chromatography resins etc. for filtration process.

2. To explore further. the requests received from the industry for possible government support for manufacturing of these raw materials, and recognizing the fact that manufacturers of the critical raw materials of vaccines may be spread across the country, following information is sought from the existing /interested domestic manufacturers of the various input materials required for manufacture of the vaccines and bio-pharmaceuticals in the following format:

Name and other details of the domestic manufacture viz, Address of Registered office. CIN Number and contact number and Mail id.	Name of the Inputs materials and Description of the items*	Indicate the category as (i) Micro-reacor bags of varrious kinds, (ii) Cell Culture Media and (iii) Filters, Cassettes, Cartridges, Chromatography resins etc. for filtration process or (iv) as others (pl give details)	Existing domestic manufacture or interested domestic manufacturer	HSN code	Whether any licensing approval is required and if so, the details of approvals obtained / to be obtained	Whether the rnanufacturer possess the required technology to manufacture or yet to obtain?	Remarks

***- requested to give the details, input materials wise. (one row for one material). Specifications may be shared as annexure.**

3. Hence, all the existing / interested domestic manufacturers are requested to send **the requisite information to sumit.ks @nic.in latest by 10.08.2022, with a copy to js.pharma@nic.in.**

F.No.31026/57/2021-Policy

Venkat Hariharan Asha, Deputy Director, Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Government of India

Request - Response to FICCI Pharma sector Skills Survey

Dear Esteemed Industry Members,

Greetings from FICCI !

On behalf of FICCI and NIPER- Hyderabad, we would like to request for your support in reaching out to industry for their valuable time and inputs for this research survey. The survey aims to get insights from Leaders and Senior Management about their opinions ,plans and initiatives taken to embrace and assess the impact of technological and workforce disruptions on the pharma sector (with a lens of skilling/upskilling and reskilling solutions for existing employees and fresh entrants of the sector)

Their feedback is extremely valuable, and it will take a few minutes of your time to complete this survey -https://tinyurl.com/FICCI-PharmasectorSurvey

We will be happy to acknowledge and endorse efforts of your Organisation in supporting us for this survey. We look forward to your response and support in getting responses to the survey. And truly appreciate your inputs in enabling young learners & supporting India in becoming the PHARMACY OF THE WORLD.

Deepti Singh, Deputy Director, Skill Development, Federation of Indian Chambers of Commerce and Industry

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Request for inputs in the National Scientific Niche Areas of Focus - reg.

Dear All,

Greetings from the office of the Principal Scientific Adviser to the Government of India.

We are in the process of identifying niche scientific areas that the Nation should focus on to meet global challenges.

In this regard, we are crowdsourcing ideas from different stakeholders in our ecosystem. Please find attached a data capturing sheet that you may kindly fill for the short-term and long-term areas where the nation should focus on.

Please share your inputs by 7th August 2022 in the following links:

1. National Scientific Niche Areas of Focus (short term)
   https://forms.office.com/r/tRZExuNgZh
2. National Scientific Niche Areas of Focus (Long term)
   https://forms.office.com/r/mkNTUiBtRp

We look forward for your valuable inputs.

Thanks, and regards,

Strategic Alliance Division, Office of the Principal Scientific Adviser, Government of India

www.psa.gov.in

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As part of celebration of AKAM, Programme viz. Har Ghar Tiranga

Dear Member,

We have received a letter from DOP(attached) regarding Azadi Ka Amrit Mahotav (AKAM) an initiative of Government of India to celebrate and commemorate 75 years of independence. As a part of celebrations of AKAM, a programme, viz., 'Har Ghar Triganga' has been approved.

Members are requested to peruse the same, and participate in the AKAM celebrations.

Thanks & regards,

Daara B Patel
Secretary – General

रजनीश तिंगल
संयुक्त सचिव
Rajneesh Tingal
Joint Secretary
Tel. : 23074010
Fax : 23387222
Email : r.tingal@nic.in

सत्यमेव जयते

भारत सरकार
रसायन और उर्वरक मंत्रालय
औषध विभाग
शास्त्री भवन, डॉ राजेन्द्र प्रसाद रोड़
नई दिल्ली - 110001
Government of India
Ministry of Chemicals & Fertilizers
Department of Pharmaceuticals
Shastri Bhavan, Dr. Rajendra Prasad Road,
New Delhi - 110 001

DO No.50014/40/2021 (E 18822)

Dated: 02 June, 2022

Dear Sir/Madam,

As you are aware, Azadi Ka Amrit Mahotsav (AKAM) is an initiative of the Government of India to celebrate and commemorate 75 years of independence and the glorious history of it's people, culture and achievements. As part of the celebrations of AKAM, a programme, viz., `**Har Ghar Tiranga'**, has been approved which envisage inspiring Indians everywhere to hoist the national flag at their home.

2. As you know, our relationship with the flag has been more formal and institutional than personal. Bringing the flag home collectively as a nation in the 75th year of independence thus becomes symbolic of not only an act of personal connection to the Tiranga but also an embodiment of our commitment to nation-building. The idea behind the initiative is to invoke the feeling of patriotism in the hearts of the people and promote awareness about our national flag.

3. In order to achieve maximum participation, I urge you to take up appropriately with your member companies, for giving the programme wide propagation. The Companies under your umbrella body may be asked to encourage active participation of their employees, other daily workforce engaged in for ancillary jobs, etc. They may also utilize a portion of their Corporate Social Responsibility (CSR) funds, if required, to meet the resources required for making such an event of national pride a huge success.

4. A report in this regard may also be made available to this department so that the extent of support received in this regard could be documented and kept for record.

With kind regards.

Yours sincerely,

(Rajneesh Tingal)

DoP invites application for the eligible product Vitamin B1, through chemical synthesis route - reg.

Corrigendum dated 26th July, 2022

1. As per the guidelines dated 29.10.2020 for the Production Linked Incentive (PLI) Scheme for Promotion of Domestic Manufacturing of critical Key Starting Materials (KSMs)/Drug Intermediates and Active Pharmaceuticals Ingredients (APIs) in the Country, applications were invited under the Scheme under three rounds.

2. Subsequent to the decision in Empowered Committee (EC) meeting on 03.06.2022, actions are to be taken to invite application for the eligible product Vitamin B 1, through chemical synthesis route. As per the decision taken, the 10% incentive rate shall be applicable as applicable for APIs produced through Chemical Synthesis and the Incentive ceiling for vitamin B1 will remain the same as per original guidelines.

3. In this regard, the necessary modifications in the Appendix B and Appendix E in the existing guidelines **for the product Vitamin-B1 are** as follows:

S. No.	Appendix	Existing Guidelines	Revised Amendment in Guidelines
1	**Appendix-B**	Vitamin-B 1 **at Sl. No. 11 in *Fermentation based niche KSMs / Drug Intermediates*** /are ***APIs*** and Minimum annual production Capacity (Metric Tonnes) **—** 200 MT Maximum number of applicants to be selected — 2.	**Existing Sl.No.11 is deleted** Serial Numbers from 12 to 41 re-organized as Serial Numbers 11 to 40 **and following entry is made at Sl. No. 41 —** Vitamin B1 in ***Other Chemical based KSMs / Drug ntermediates /APIs*** and Minimum annual production Capacity (Metric Tonnes) — 200 MT Maximum number of applicants to be selected - 2
2	**Appendix-E (Table-2)**	Sl. No. 11 — Vitamin B1 ***in Fermentation based niche KSMs / Drug Intermediates/APIs*** and Maximum number of applicants to be selected — 2	**Existing Sl.No.11 is deleted** Serial Numbers from 12 to 41 are re-organized as Serial Numbers 11 to 40 **and following entry is made at Sl. No. 41** — Sl. No. 41 — Vitamin B1 ***in Other Chemical Synthesis based KSMs / Drug Intermediates / APIs*** and Maximum number of applicants to be selected — 2
		Rate of Incentive (in %) — FY 2023-24 to FY 2026-27: ***20 %,*** FY 2027-28: ***15 %,*** FY 2028-29: ***5 %***	**Rate of Incentive (in %)** — FY 2023-24 to FY 2027-28 — ***10 %***
		Maximum incentive per annum (Rs. Crore) — FY 2023-24 to FY 2026-27: ***20,*** FY 2027-28: ***15,*** FY 2028-29: ***5***	**Maximum incentive per annum (Rs. Crore)** FY 2022-23 — ***0**** FY 2023-24 to FY 2027-28: ***20***

		Maximum incentive for **each selected applicant per annum** (Rs. Crore)* FY 2023-24 to FY 2026-27: ***10,*** FY 2027-28: ***7.5,*** FY 2028-29: ***2.5***	Maximum incentive for **each selected applicant per annum** (Rs. Crore)* FY 2022-23 — ***0**** FY 2023-24 to FY 2027-28: ***10***

**-FY 22-23 is the installation year, as applications are being invited*

4. Due to the above, the resultant changes in other annexures are as below;

S. No.	Existing Guidelines	Revised Amendment in Guidelines
1	**Appendix E (Table - 1)** Number of Product ***10 Fermentation based niche KSMs / Drug Intermediates /APIs*** FY 23-24 Rs. 200 cr FY 24-25 Rs. 200 cr FY 25-26 Rs. 200 cr FY 26-27 Rs. 200 cr FY 27-28 Rs. 150 cr FY 28-29 Rs. 50 cr Total :- Rs. 1000 cr	**Appendix E (Table - 1)** Number of Product ***9 Fermentation based niche KSMs / Drug Intermediates /APIs*** FY 23-24 Rs. 180 cr FY 24-25 Rs. 180 cr FY 25-26 Rs. 180 cr FY 26-27 Rs. 180 cr FY 27-28 Rs. 135 cr FY 28-29 Rs. 45 cr Total :- Rs. 900 cr
2	**Appendix E (Table - 1)** Number of Product ***23 Chemical* Synthesis *based KSMs/ Drug Intermediates /APIs*** FY 22-23 Rs. 230 cr, FY 23-24 Rs. 230 cr, FY 24-25 Rs. 230 cr, FY 25-26 Rs. 230 cr, FY 26-27 Rs. 230 cr, FY 27-28 Rs. 230 cr, FY 28-29 Rs. Nil Total :- Rs. 1380 cr	**Appendix E (Table - 1)** Number of Product ***24 Chemical Synthesis based KSMs / Drug Intermediates /APIs*** FY 22-23 Rs. 230 cr, FY 23-24 Rs. 250 cr, FY 24-25 Rs. 250 cr, FY 25-26 Rs. 250 cr, FY 26-27 Rs. 250 cr, FY 27-28 Rs. 250 cr, FY 28-29 Rs. Nil Total :- Rs. 1480 cr

5. All other clauses of the guidelines dated 29.10.2010 remains the same.

Detailed guidelines of the Scheme are available at https://pharmaceuticals.gov.in/schemes. The eligible applicants may apply through online only (https://plibulkdrugs.ifciltd.com) and it is requested to make necessary changes in the IT system of the PLI scheme in this regard.

6. This issues with the approval of the competent authority.

F.No.31026/39/2020-Scheme(Pt.2)

Uma Magesh, Under Secretary to the Govt. of India, Ministry of Chemicals and Fertilizers, Department of Pharmaceuticals, Shastri Bhawan, New Delhi.

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Oman's 10th Edition of International Exhibition for Healthcare and Medical Tourism during 26 –28 September 2022

PXL/HO/Cir-038/2022-23, date 27th July 2022

We are pleased to inform our members that we have received a communication from our Embassy of India in Muscat, Oman informing about the 10th Edition of International Exhibition for Healthcare and Medical Tourism which will be held during 26 – 28 September 2022 at the Oman Convention & Exhibition Centre, Muscat. The event is supported by the Ministry of Health, Sultanate of Oman and organized by Oman Expo Group of Companies.

We understand that this Healthcare Exhibition is a showcase of the latest healthcare and medical products, services, equipment and technology, top-of-the-line hospital and medical infrastructure, as well as pharmaceutical products and services. The Oman government is encouraging foreign investment in the country's healthcare sector to support the growing demand for these services. This will also pave the way for new investment opportunities resulting from the several multi-million-dollar healthcare projects currently being constructed all over the Sultanate and in the pipeline.

Oman ranks high in terms of attractiveness as a medical tourism destination as measured by overall country image, environment, healthcare and tourism attractiveness and infrastructure, and availability and quality of medical facilities and services. The Government of Oman is keen to improve the quality of its hospitals and international accreditations, rehabilitating and developing the infrastructure, and upgrading the quality of its medical facilities and services. International players in the medical and healthcare industry are increasingly focusing efforts to leverage the lucrative Oman market.

For more details on this event members can go through the website www.omanhealthexpo.com also Exhibition sales brochure is enclosed for the ready reference. Interested members can directly contact the organizer Mr. Liji at +968-95 38 31 99 / liji@lynxads.com.

Uday Bhaskar, Director General, Pharmexcil

In Rajya Sabha & In Lok Sabha

In Rajya Sabha

Functioning of MSMEs

Rajya Sabha Unstarred Question No. 127

Shri Akhilesh Prasad Singh:

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

(a) the number of Micro, Small and Medium Enterprises (MSMEs) currently functioning across the country;

(b) their contribution, in terms of percentage, in the Gross Domestic Product (GDP) growth and service sector of the country;

(c) whether it is a fact that this industry is not able to get the benefits of schemes of Government and they are being ignored and are not even consulted during formulation of any policy; and

(d) if so, whether Government is considering to constitute any committee to address their problems?

Answered on 18th July, 2022

A. (a): As per Udyam Registration Portal, the total number of micro, small and medium enterprises registered across the country as on 12.07.2022 was 95,44,885.

(b): As per information received from Ministry of Statistics & Programme Implementation, the Share of Gross Value Added (GVA) of MSME sector in All India GDP during 2019-20 and 2020-21 were 30.50% and 26.83% respectively.

The Share of Service Sector Gross Value Added (GVA) of MSME in All India Service GVA during 2019-20 and 2020-21 were 59.98% and 54.46% respectively.

(c) & (d): The Ministry of Micro, Small and Medium Enterprises (MSME) implements various schemes and programmes aimed at growth and development of Micro, Small and Medium Enterprises (MSMEs). These schemes/programmes include MSME Champions Scheme (Erstwhile CLCS-TUS), Credit Guarantee Fund Trust for Micro and Small Enterprises (CGTMSE), Prime Minister's Employment Generation Programme (PMEGP), Micro and Small Enterprises - Cluster Development Programme (MSE-CDP) and Emergency Credit Line Guarantee Scheme (ECLGS). Benefits under these schemes are available to all eligible MSMEs throughout the country.

M/o MSME has assigned the Job for preparation of a Comprehensive Policy Document for MSMEs to Indian Institute of Public Administration (IIPA). In order to formulate MSME Policy, a series of consultation have been held with MSME Industry Associations as detailed below:-

i. A meeting with MSME Industry Associations was held in Vigyan Bhavan on 27.04.2022 wherein, about 50 MSME Industry Associations from all over the country particpated.

Participants from Central Ministries/ Departments were also present in above meeting.

ii. The five consultations with MSME industry associations were also held from 08-14 June 2022 through field offices of this Ministry across the country for getting inputs on draft MSME policy.

iii. The IIPA draft Policy document was uploaded on MyGov platform wherein, suggestions have been received from individuals.

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

MSMEs Export to Russia and Ukraine

Rajya Sabha Unstarred Question No. 128

Shri Prabhakar Reddy Vemireddy:

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

(a) the details of exports from Micro, Small and Medium Enterprises (MSMEs) to Russia, Ukraine, Belarus and other bordering countries of Russia and Ukraine during the last four years and the current year, year-wise and country-wise;

(b) whether any assessment has been made about the impact of Russia-Ukraine war on exports of MSMEs to the above countries;

(c) if so, details thereof; and

(d) implications of India's MSMEs exports to Russia in the light of sanctions imposed by United States of America and steps taken/proposed to be taken by Government in this regard?

Answered on 18th July, 2022

A. (a): The details of exports from Micro, Small and Medium Enterprises (MSMEs) to Russia, Ukraine and Belarus during the last four years, year-wise and country-wise are as follows:

Country Description	Export value in Million USD			
	2018-19	2019-20	2020-21	2021-22*
BELARUS	24.83	24.00	27.94	32.91
RUSSIA	1432.53	1819.41	1548.27	1871.58
UKRAINE	207.91	300.97	294.82	283.36
Total export from MSME Sectors for above mentioned countries	1665.27	2144.39	1871.04	2187.85
Total Export of MSME Sectors	158761.03	155909.55	143993.81	190015.14
% Share of Russia, Ukraine and Belarus w.r.t . to total export of MSME Sectors	1.05	1.38	1.30	1.15

Data source: DGCIS, Kolkata

**Figures for 2021-22 are provisional and subject to change.*

(b) to (d): India's exports to Ukraine and Russia have been led by MSMEs which include pharmaceuticals, machinery, and apparels etc. The Ukraine conflict has created supply chain disruptions affecting energy, food, and materials used in production of key technologies.

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

Nation Manufacturing Policy

Rajya Sabha Unstarred Question No. 130

Shri S. Selvaganabathy:

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

(a) whether the Micro, Small and Medium Enterprises (MSMEs) sector is a backbone of the Indian economy for its contribution to the growth of the Indian economy;

(b) if so, the details thereof; and

(c) whether this sector can help in achieving the target of the Nation Manufacturing Policy (NMP) that manufacturing should contribute 25 per cent in country's Gross Domestic Product (GDP) by 2022, and if so, the details thereof?

Answered on 18th July, 2022

A. (a) & (b): Yes, the Micro, Small and Medium Enterprises (MSMEs) sector is a backbone of the Indian economy for its contribution to the growth of the Indian economy. As per information received from Ministry of Statistics & Programme Implementation, the Share of Gross Value Added (GVA) of MSME in All India GDP during 2019-20 and 2020-21 were 30.50% and 26.83% respectively.

(c): The Ministry of Micro, Small and Medium Enterprises (MSME) implements various schemes and programmes aimed at promotion and development of Micro, Small and Medium Enterprises (MSMEs) which would help in achieving the target of the National Manufacturing Policy (NMP). These schemes/programmes include MSME Champions Scheme (Erstwhile CLCS-TUS), Credit Guarantee Fund Trust for Micro and Small Enterprises (CGTMSE), Prime Minister's Employment Generation Programme (PMEGP), Micro and Small Enterprises - Cluster Development Programme (MSE-CDP) and Emergency Credit Line Guarantee Scheme (ECLGS). The Ministry has also established Technology Centres (TCs) which provides technological support to industries through design & manufacture of tools, precision components, moulds, dies etc.

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

Domestic manufacturing of medical devices

Rajya Sabha Unstarred Question No. 174

Shri Parimal Nathwani:

Q. Will the Minister of **Chemicals and Fertilizers** be pleased to state:

(a) the steps undertaken by Government to reduce dependence on imports for meeting the medical devices requirements; and

(b) the current status of implementation of Production Linked Incentive (PLI) Scheme for promoting domestic manufacturing of medical devices?

Answered on 19th July, 2022

A. (a) The Government of India has recognized medical devices as a sunrise sector and has taken several measures to encourage domestic manufacturing to reduce import dependence for meeting medical devices requirements. The Programmatic interventions are as follows;

i. Under the scheme "Promotion of Medical Devices Parks", final approval for financial assistance of Rs. 100 crore each, has been given to the States of Uttar Pradesh, Tamil Nadu, Madhya Pradesh and Himachal Pradesh for establishment of common facilities in their Medical Device Parks.

ii. Further, under the sub-scheme "Assistance to Medical Device Industry for Common Facility Centre", grant-in-aid of ` 25 crore was provided to Andhra Pradesh Medtech Zone Ltd. (AMTZ), Andhra Pradesh for establishment of Common Facility for Super conducting magnetic coil testing and research facility

iii. Under the Production Linked Incentive (PLI) Scheme for Promoting Domestic Manufacturing of Medical Devices, with a financial outlay of Rs.3,420 Cr and with the tenure from FY 2020-21 to FY 2027-28, financial incentives will be given to selected companies at the rate of 5% of incremental sales of medical devices manufactured in India and covered under the four Target segments of the scheme, for a period of five (5) years.

iv. Under the Production Linked Incentive (PLI) scheme for Pharmaceuticals, with the tenure from FY 2020-2021 to 2028-29, Five (5) industry applicants have been selected under the scheme for In-vitro diagnostic medical devices and the scheme provides for incentives based on their incremental sales for 6 years.

v. Department has also notified the list of IVDs & medical devices, where there is sufficient local capacity and local competition available in the country, for giving preference to domestic manufacturers in public procurement as per the provisions of Public Procurement (Preference to Make in India) Order of DPIIT.

vi. Making available 240 types of surgical supplies in over 8700 stores or Jan Aushadhi Kendras at highly affordable prices under the Pradhan Mantri Bharatiya Jan Aushadhi Pariyojana.

The non-schematic interventions are as follows

i. In order to attract investments in this sector, the Government has allowed 100% foreign direct investments (FDI) in medical devices sector.

ii. To redress the specific challenges of the Industry, in view of the diversity and multi-disciplinary nature of the sector, the institutional mechanism of Standing Forum of Medical Devices Associations, has been set up to deliberate on various issues with all the stakeholders including regulators.

(b): The Production Linked Incentive (PLI) Scheme for promoting domestic manufacturing of medical devices is under implementation. Under the scheme, total 42 applications were received in Round I and Round II. 21 applicants have been approved with committed investment of Rs. 1058.97 cr and expected employment generation of around 6411 persons. Total 13 manufacturing plants have been commissioned till date.

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

Guidelines for pricing of essential medicines

Rajya Sabha Unstarred Question No. 175

Shri Harnath Singh Yadav:

Q. Will the Minister of **Chemicals and Fertilizers** be pleased to state:

(a) the details about the criteria/guidelines fixed by Government for pricing of essential medicines

including the medicines used for the treatment of cancer, diabetes, HIV, heart and kidney diseases;

(b) whether the prices of essential and other medicines have decreased, and if so, the details thereof; and

(c) the details of total Jan Aushadhi Kendras set up so far to provide inexpensive generic medicines through Pradhan Mantri Bharatiya Janaushadhi Pariyojana, State-wise?

Answered on 19th July, 2022

A. (a): The key principles for regulation of prices as per the extant National Pharmaceuticals Pricing Policy, 2012 (NPPP, 2012) are essentiality of drugs, control of formulations prices and Market Based Pricing. Based on NPPP, 2012 and powers derived from the Essential Commodities Act, 1955, the Drugs (Prices Control) Order, 2013 (DPCO, 2013) has been issued by the Department of Pharmaceuticals (DoP). National Pharmaceutical Pricing Authority (NPPA) under DoP implements the provisions of the DPCO, 2013. The medicines included in the National List of Essential Medicines (NLEM) issued by the Ministry of Health & Family Welfare are included as Schedule-I of DPCO, 2013 and their ceiling prices fixed by NPPA. These include 12 anti-diabetics, 39 anti HIV, 74 cardiovascular, 1 hemodialysis solution and 9 diuretics scheduled formulations.

(b): The ceiling prices of essential medicines included as Schedule to DPCO, 2013 are fixed by NPPA based on average price of all scheduled formulations of the medicine having at least one per cent share in market. As the manufacturers of scheduled medicines may decide the market price based on market dynamics, within the ceiling prescribed by NPPA, this generally results in decrease of their prices. Annual revision of ceiling prices of scheduled medicines is permissible based on Wholesale Price Index (WPI) for the preceding calendar year.

(c): Till 30.06.2022, about 8,742 *Pradhan Mantri Bhartiya Janaushadhi Kendras (PMBJKs)* have been opened across the country under the *Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP).* State/UT- wise list of PMBJKs is enclosed as **Annexure**.

Annexure

Statement referred to in part (c) of the Rajya Sabha Unstarred Q. No. 175 for answer on 19.07.2022 raised by Shri Harnath Singh Yadav regarding Guidelines for pricing of essential medicines

State/UT- wise list of PMBJKs opened across the country till 30.06.2022

Sl. No.	Name of the State/UT	Number of PMBJK opened
1	Andaman & Nicobar	9
2	Andhra Pradesh	170
3	Arunachal Pradesh	28
4	Assam	96
5	Bihar	300
6	Chandigarh	7
7	Chhattisgarh	208
8	Delhi	382
9	Goa	10
10	Gujarat	511
11	Haryana	237
12	Himachal Pradesh	62
13	Jammu and Kashmir	212
14	Jharkhand	78
15	Karnataka	982
16	Kerala	990
17	Ladakh	2
18	Lakshadeep *	0
19	Madhya Pradesh	253
20	Maharashtra	635
21	Manipur	32
22	Meghalaya	15
23	Mizoram	12
24	Nagaland	19
25	Odisha	356
26	Puducherry	20
27	Punjab	307
28	Rajasthan	137
29	Sikkim	3
30	Tamil Nadu	845
31	Telangana	170
32	DNH & D&D	35
33	Tripura	24

34	Uttar Pradesh	1175
35	Uttarakhand	218
36	West Bengal	202
Grand Total		**8,742**

** Medicines are directly supplied to the administration of UT of Lakshwadeep*

In Lok Sabha

Promotion of Foreign Investment

Lok Sabha Unstarred Question No. 467

Shrimati Mala Rajya Laxmi Shah:

Shri Kunwar Pushpendra Singh Chandel:

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

(a) whether the Government is making special efforts to promote foreign investment;

(b) if so, the details thereof;

(c) whether the Government also proposes to make fresh institutional reforms to attract foreign investment;

(d) if so, the details thereof; and

(e) the details of foreign investment made during the last two years?

Answered on 20th July, 2022

A. (a) to (d): To promote Foreign Direct Investment (FDI), the Government has put in place an investor-friendly policy, wherein most sectors, except certain strategically important sectors, are open for 100% FDI under the automatic route. Further, the policy on FDI is reviewed on an ongoing basis, to ensure that India remains attractive & investor friendly destination. Changes are made in the policy after having consultations with stakeholders including apex industry chambers, associations, representatives of industries/groups and other organizations. In the recent past, reforms in the FDI policy have been undertaken in sectors such as Insurance, Petroleum & Natural Gas, Telecom etc.

Government has launched 'Make in India' initiative to facilitate investment, foster innovation, build best in class infrastructure and make India a hub for manufacturing, design and innovation. Further, investment outreach activities are done through Ministries, State Governments and Indian Missions abroad for enhancing international cooperation and promoting foreign investment in the country.

(e): The foreign investment reported through Foreign Direct Investment inflow is as under:

S. No.	Financial Year	Total FDI Inflow (in USD million)	Total FDI Inflow (in INR crore)*
1.	2020-21 (P)	81,973	6,08,340
2.	2021-22 (P)	83,676	6,22,428

Source: Reserve Bank of India. (P) – Figures are provisional.

** As per yearly conversion rate as calculated from the monthly average exchange rate provided by RBI.*

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

Merchandise Trade Deficit

Lok Sabha Unstarred Question No. 497

Shri Manickam Tagore B.:

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

(a) whether India's merchandise trade deficit widened to a record $ 23.53 billion in May, 2022 and if so, the details thereof;

(b) whether the previous highest monthly trade deficit was $ 22.91 billion in November, 2021 and if so, the details thereof;

(c) whether the merchandise imports have crossed $ 60 billion and the growth continuously rose three months in a row recently; and

(d) whether the imports are likely to stay high in absolute terms as commodity prices see a renewed uptick; and

(e) if so, the details thereof?

Answered on 20th July, 2022

A. (a): India's merchandise trade deficit was US$ 24.2 billion in May 2022.

(b): The previous highest monthly trade deficit was US$ 22.4 billion in September 2021.

(c): Merchandise imports were US$ 60.1 billion in

April 2022, US$ 63.2 billion in May 2022 and US$ 66.3 billion in June 2022.

(d) & (e): Imports take place to meet the gap between domestic production and supply, consumer demand and preferences for various products. Many imports are inputs for further manufacturing in India. The Government keeps a watch on the overall deficit and takes measures periodically to address it.

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

E-Commerce Platforms

Lok Sabha Unstarred Question No. 507

Shri Kotha Prabhakar Reddy:

Q. Will the Minister of **CONSUMER AFFAIRS, FOOD AND PUBLIC DISTRIBUTION** be pleased to state:

(a) whether the Government proposes to evolve a proper mechanism for conducting regular checks of ecommerce platforms to ensure compliance with rules relating to display of Maximum Retail Price (MRP), seller details, name of manufacturer and country of origin on products offered for sale on the websites;

(b) if so, the details thereof and the present status in this regard; and

(c) if not, the reasons for delay, if any, therein and the corrective steps taken in this regard?

Answered on 20th July, 2022

A. (a) to (c): The Legal metrology (Packaged Commodities) Rules 2011 under the Legal Metrology Act, 2009 provides that an E-Commerce entity shall ensure that name and address of the manufacturer or packer or importer, maximum Retail Price (MRP), Country of Origin, Common or Generic name of the commodity, Net Quantity, Month and Year of manufacture, Customer Care details etc shall be displayed on the digital and electronic network used for e-commerce transactions. This is to ensure that the consumer is taking an informed and conscious decision based on the declaration of the product on the E-Commerce platform.

For violations of declaration by e-commerce companies, 38 notices during the period of 16th October, 2022 to 31st December, 2020, 232 notices during the period 1st January 2021 to 31st December, 2021 and 178 notices during the period 1st January, 2022 to 11th July, 2022 have been issued by the Legal Metrology Division, Department of Consumer Affairs and an amount of approximately Rs. 77, 90,500/- in the form of compounding fees has been realized from e-commerce companies. State Governments are also empowered to take actions in cases of violation of the Legal Metrology (Packaged Commodities), Rules 2011.

The Minister of State Consumer Affairs, Food and Public Distribution
(Shri Ashwini Kumar Choubey)

RTAs

Lok Sabha Unstarred Question No. 521

Dr. Manoj Rajoria:

Shri Sumedhanand Saraswati:

Shrimati Ranjeeta Koli:

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

(a) the names of the Regional Trade Agreements (RTAs) which have proved beneficial for India;

(b) whether there are any RTAs which have not been beneficial for the country;

(c) if so, the names thereof and the manner in which they have not been beneficial for India;

(d) whether the RTAs signed by India contain exit clause;

(e) if so, the names of the RTAs containing exit clause and those not having it; and

(f) whether the Asia Pacific Trade Agreement contains exit clause and if so, the details thereof?

Answered on 20th July, 2022

A. (a) to (c): India has signed 13 Regional Trade Agreements (RTAs)/Free Trade Agreements (FTAs) with various countries/regions namely, Japan, South Korea, countries of ASEAN region and countries of South Asian Association for Regional Cooperation (SAARC)Mauritius, United Arab Emirates, Australia. India's merchandise exports to all these countries/ regions have registered a growth in last ten years.

The following table gives country/region wise merchandise export details:

India's exports - RTA Partner Countries/Region wise Values in US$ billion			
India's RTA partner Countries/region	**Names of RTAs**	**Export in 2011**	**Export in 2021**
ASEAN	India-ASEAN FTA India-Singapore CECA India-Malaysia CECA India-Thailand FTA - Early Harvest Scheme (EHS)	34.5	40.6
Japan	India-Japan CEPA	5.6	6.1
South Korea	India-South Korea CEPA	4.6	7.0
SAFTA	Agreement on SAFTA India-Sri Lanka FTA India-Nepal Treaty of Trade India-Bhutan Agreement on Trade, Commerce and Transit	13.0	31.6
Mauritius	India-Mauritius Comprehensive Economic Cooperation and Partnership Agreement (CECPA)	It is too early to calculate quantifiable benefits for this RTA, as it was implemented only w.e.f. 10.04.2021.	
United Arab Emirates	India-UAE CEPA	It is too early to calculate quantifiable benefits for this RTA, as it was implemented only w.e.f. 01.05.2022.	
Australia	India-Australia Economic Cooperation and Trade Agreement (Ind-Aus ECTA)	This RTA has been signed on 02.04.2022, but not yet implemented.	
Source: Directorate General of Commercial Intelligence and Statistics (DGCI&S)			

In addition, India has also signed 6 Preferential Trade Agreements (PTAs) including Asia Pacific Trade Agreement (APTA).

(d) & (e): All of India's RTAs, as listed in the table above, have exit clauses.

(f): Yes, Sir. Article 32 of Asia Pacific Trade Agreement (APTA) mentions that "*Any Participating State may withdraw from this Agreement, such withdrawal to take effect six months following the day on which written notice of the same is served to the Participating States through the Executive Secretary of ESCAP. The rights and obligations of a Participating State which has withdrawn from this Agreement shall cease to apply as of that date".*

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

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Explanatory Note – Trademark Dispute Settlement

The Controller General of Patents, Designs & Trademarks has come out with a proposal for resolving Trademark related disputes through settlement before the Trademarks Registry. The public notice is reproduced hereinbelow:

Office of CGPDTM, Mumbai

Govt. of India

August 01, 2022

PUBLIC NOTICE

The 75th anniversary of India's independence is just a few days away. To commemorate this monumental occasion, the Government of India has launched ***'Azadi Ka Amrit Mahotsav'***. In this context, this office is taking an initiative to run a special drive for disposal of IP disputes wherein we encourage the parties to dispose the pending opposition and rectification cases. We also encourage the parties who have already settled their cases amicably should report to the Trademarks Registry (TMR) for formal settlement of dispute before registry. In case, you have sent the communication earlier and no final orders could be issued in such cases, you may again register the matter at TMR on below given link during the 'Azadi Ka Amrit Mahotsav'.

We also encourage all concerned that in cases, wherein an opposition or rectification is pending before the TMR and the parties have not arrived at an amicable settlement, they should settle the disputes utilizing the various alternate mechanisms for dispute resolutions. Parties are invited to submit the supporting documents positively for already settled matter which is not yet resolved before TMR.

The link for settlement of opposition cases is given below:

https://ipindiaonline.gov.in/trademarkefiling/OppositionSettlementRequest.aspx

The above link shall be active from August 02, 2022 to October 02, 2022.

Upon receipt of your already settled matter along with settlement letter and withdrawal request on the above online portal, we shall dispose the matter before TMR by passing suitable orders as per provisions of the Trade Marks Act. In case of any further query you can reach out to the appropriate branch office of the Trade Marks Registry.

Let the *'Azadi Ka Amrit Mahotsav'* bring dispute free IP regime.

Signed/-

(Prof Unnat P Pandit)

Controller General of Patents, Designs & Trademarks

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What SII boss Adar Poonawalla said on Monkeypox vaccine

Adar Poonawalla, Chief Executive Officer of the Serum Institute of India **(Reuters)**

NEW DELHI: Serum Institute of India CEO Adar Poonawalla on Tuesday attended a meeting with union health minister Mansukh Mandaviya amid rising cases of Monekeypox in India. The meeting as is being reported was to discuss the vaccine that could prevent the wildfire like spread of the zoonosis virus.

India has reported eight Monkeypox cases till now. The nation has also recorded one death from the viral zoonosis disease. Kerala has reported 5 monkeypox cases, and one related death.

The latest case concerns a 30-year-old man, who came from UAE last month. Speaking about the patient, Health Minister Veena George on Tuesday said that the man is currently undergoing treatment and his conditions are stable. Another Monkeypox case has been confirmed in the national capital as a Nigerian man has tested positive for the virus. This is the third monkeypox case in Delhi.

Meanwhile, the necessity for Monkeypox vaccine has arisen in order to curb the spread of the virus. The Centre announced that it would form a taskforce to look into the monkeypox cases across the country.

Ponawalla after his meeting with Mandaviya shared an update on the production of the Monkeypox vaccine. He said, "My meeting went well like always. All preparations for the vaccine are being done; I briefed the minister on this. We are researching on the vaccine for Monkeypox and if there's a need for it." National capital Delhi has also put itself under tight scanner scanner after three cases of Monkeypox virus were confirmed. The city government directed 3 private hospitals to create at least 10 isolation rooms for the infected individuals - 5 for management of suspected cases of monkeypox and 5 isolation rooms for management of confirmed cases of monkeypox.

The World Health Organisation (WHO) had earlier noted that the world needs 5-10 million doses of the Monkeypox vaccine to protect high-risk groups from the virus outbreak.

The WHO director also asked countries with smallpox vaccine to share them during the Monkeypox outbreaks. The aims to do so would be to offer equitable access to vaccines during another pandemic.

On 27 July, drugmaker Bavarian Nordic said US and European regulators have approved the use of Jynneos vaccine doses made at the company's plant in Denmark as global efforts to tackle the monkeypox outbreak pick up pace.

Bavarian has received orders for millions of doses from across the globe, including nearly 7 million vaccine doses this year and next to the United States. The Indian government had invited expression of interest (EOI) for developing a vaccine against the monkeypox virus.

Source: HT Mint, 02.08.2022

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India, Egypt set annual bilateral trade target of $12 billion

The agreed minutes of the 5th Session of the India-Egypt Joint Trade Committee (JTC), held on 25 July, were signed between the two sides in the presence of Nevine Gamea, Minister of Trade and Industry, Arab Republic of Egypt.

Affirming mutual keenness in diversifying and expanding trade and investment linkages, India and Egypt have set an annual bilateral trade target of US$ 12 billion

to be achieved within five years, the Ministry of Commerce & Industry said here on Thursday.

A five-member delegation from India led by Srikar K Reddy, Joint Secretary, Department of Commerce, Ministry of Commerce and Industry of India, accompanied by Ajit Gupte, Ambassador of India to Egypt, called on Nevine Gamea, Minister of Trade and Industry, Arab Republic of Egypt, in Cairo on 26 July.

The agreed minutes of the 5th Session of the India-Egypt Joint Trade Committee (JTC), held on 25 July, were signed between the two sides in the presence of the Minister.

To accelerate trade, both sides agreed to expeditiously address all issues impeding bilateral trade; facilitate trade promotion between the two countries; and identify bilateral focal points to further strengthen bilateral institutional cooperation.

Both sides made progress in the discussion on resolution of non-tariff barriers with the Egyptian side agreeing to expedite scheduling of the visit of its technical delegations to India to address NTB issues related to export of some of the Indian agricultural products to Egypt. Also, with reference to cooperation in pharmaceuticals sector, Egyptian side agreed to initiate technical discussions with concerned agency in India to take forward the proposal of inclusion of India in the list of reference countries accepted by Egyptian authorities for import of pharmaceutical products.

Both sides undertook a detailed review of recent developments in trade and investment ties and noted that the relationship, while already excellent, has huge potential to be scaled up even further. To this effect, both sides identified several areas of focus for enhancing both bilateral trade as well as mutually beneficial investments. These include food, agro and marine products, energy, particularly renewable energy including green hydrogen and green ammonia, health and pharmaceuticals, chemicals and petrochemicals, MSMEs, engineering goods, manufacturing, IT and IT enabled services, tourism, and so on. Both sides also reviewed the progress of ongoing discussions for Memorandum of Understanding (MoUs) in the field of standards, IT, and transport, and agreed to conclude them expeditiously.

The JTC was co-chaired by Yahya El Wathik Bellah, First Under Secretary and Head of Egyptian Commercial Service (ECS); and the Joint Secretary, Department of Commerce, Ministry of Commerce and Industry of India. The Ambassador of India to Egypt, and officials from concerned Government agencies of India and Egypt also participated in the JTC.

The 5th India-Egypt JTC took place in the backdrop of robust growth in trade and investment ties between India and Egypt. Bilateral trade reached a historic record high of USD 7.26 billion in FY 2021-22 which is an increase of 75 per cent over FY 2020-21. Egypt is also one of the largest investment destinations for India in the region with existing Indian investment of US$3.15 billion. Indian companies continue to execute several projects in Egypt.

On 26 July, the 5th meeting of the Joint Business Council (JBC) was jointly organised by FICCI and Egyptian Commercial Services. The deliberations of the 5th Sessions of India-Egypt JTC and JBC were cordial and forward-looking, reflecting the traditionally friendly and special relations between the two countries. The meetings of the JTC and JBC were timely and productive, reflecting a common desire of the business communities of both sides to renew and strengthen trade and investment ties in the post-pandemic era and take them to new heights.

Source: Statesman, 29.07.2022

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