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IDMA BULLETIN

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INDIAN PHARMA - GLOBAL HEALTH CARE

INDIAN DRUG MANUFACTURERS' ASSOCIATION

HIGHLIGHTS

UNMATCHED RIGOUR AND DEDICATION. THAT LEADS TO INCOMPARABLE **EXPERIENCE**

Dear Partner,

For over 30 years, Signet has brought the world's best excipients to Indian shores, by partnering with global firms that boast immeasurable experience. One such company is Innophos.

Innophos began it's journey in 1902 and has spent over a century advancing their phosphate technology. Today, their management systems, quality standards and formulation versatility are unmatched. They are the leading provider of high quality calcium phosphates and other minerals, having pioneered the process of manufacturing excipients in both anhydrous and dihydrate forms, with extremely low lead content.

By choosing to associate with experience, we have been able to not just keep up with our customer needs, but race far ahead, with knowledge and time on our side.

Signet-ure Experience

Innophos

DICALCIUM PHOSPHATE ANHYDROUS
- A-TAB - Granular, Directly Compressible
- CALIPHARM A - Milled Powder

DICALCIUM PHOSPHATE DIHYDRATE
- DI-TAB - Granular, Directly Compressible
- CALIPHARM D - Milled Powder

TRICALCIUM PHOSPHATE ANHYDROUS
- TRI-TAB - Granular, Directly Compressible
- CALIPHARM T - Milled Powder
- VERSACAL MP - Micronized Powder

CO-PROCESSED CALCIUM PHOSPHATES
- NUTRA TAB - Granulated TCP with Guar Gum
- A-TAB MD - DCP Anhydrous with Maltodextrin
- TRITAB PVP - TCP Anhydrous with Povidone

MINERAL AMINO ACID CHELATES

Signet

The Complete Excipients Company

A Publication of
Indian Drug Manufacturers' Association
102-B, 'A-Wing', Poonam Chambers,
Dr. A.B. Road, Worli, Mumbai - 400 018
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Indian Drug Manufacturers' Association

IDMA BULLETIN

Vol. No. 53 **Issue No. 24** **22 to 30 June 2022**

IDMA ACTIVITIES:

GOVERNMENT COMMUNICATIONS:

INDIAN PHARMACOPOEIA COMMISSION:

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 enclosed 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 enclosed Registration Form and send it to

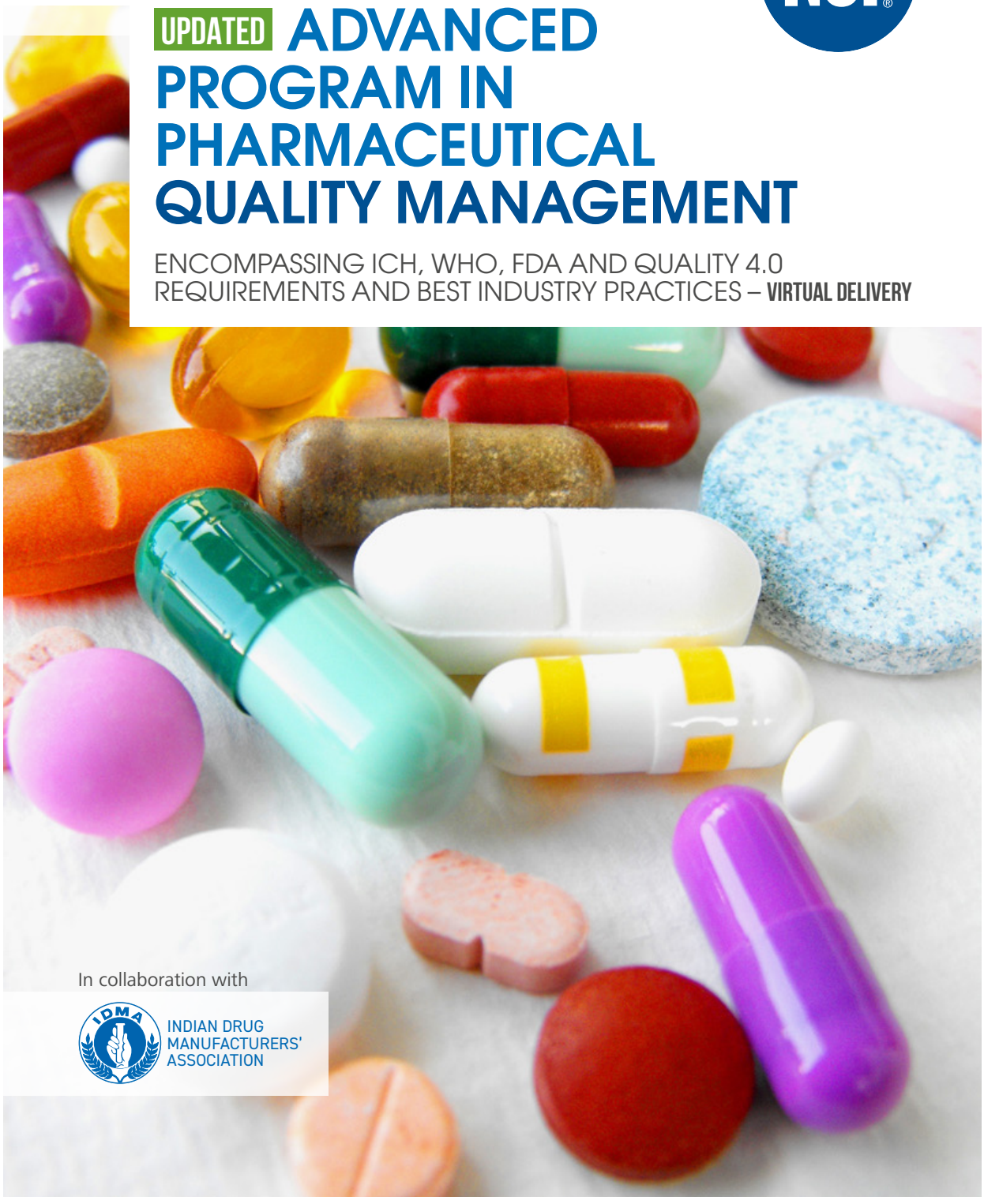
Melvin	**Batul**
actadm@idmaindia.com	technical@idmaindia.com
9821868758	9920045226

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

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

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


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

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

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

CHALLENGES FACING THE PHARMACEUTICAL INDUSTRY

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

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

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

HOW THIS TRAINING CAN HELP

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

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

WHY CHOOSE NSF?

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

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

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

BENEFITS OF THIS TRAINING

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

For example by:

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

Attendees will also:

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

COURSE FORMAT

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

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

▶▶

COURSE MODULES

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

MODULE ONE: Pharmaceutical Quality Management Systems – Best Industry Practices

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

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

MODULE TWO: Managing Change; Change Control and Deviations

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

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

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

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

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

▶▶

MODULE FOUR: Data Analysis for Business Improvement

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

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

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

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

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

NEXT STEPS YOUR CALL TO ACTION

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

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

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

NSF INTERNATIONAL

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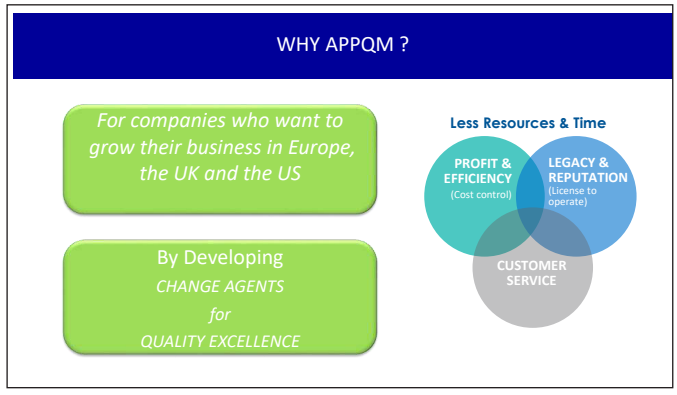
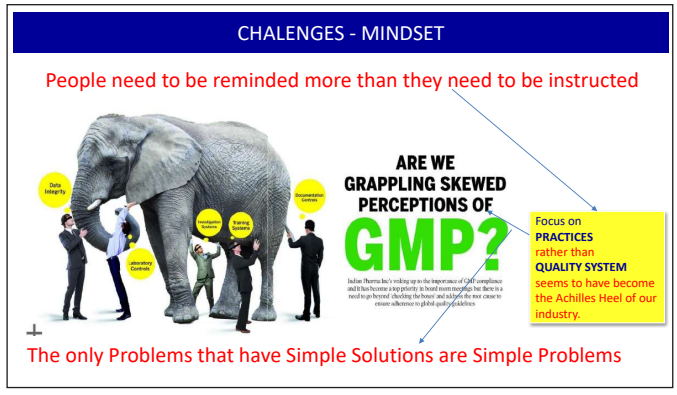
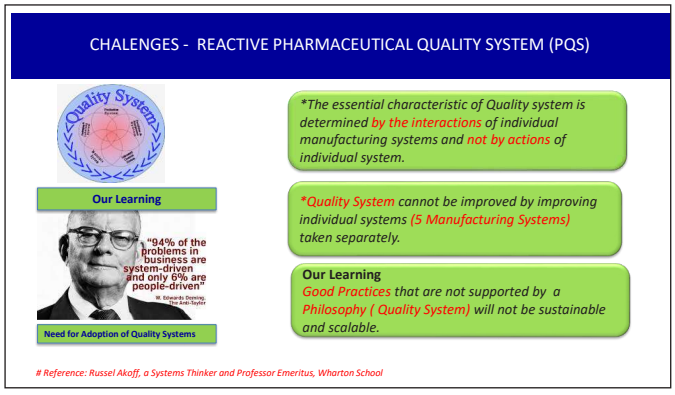
PRESENTATION

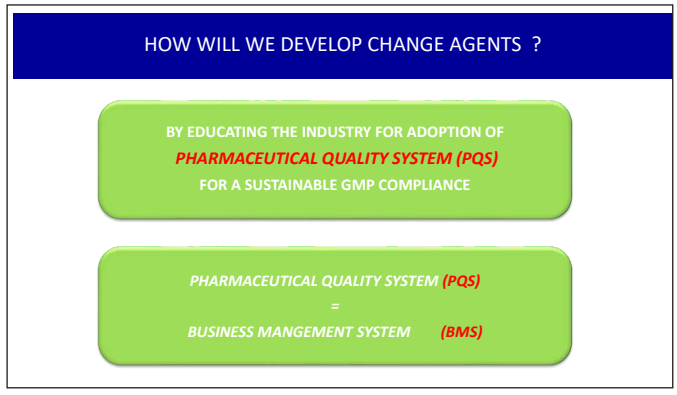
Launch of APPQM Series 3

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









APPQM IS DESIGNED FOR INDIAN COMPANIES

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

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

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

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

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

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

HOW APPQM IS DIFFERENT FROM OTHER TRAINING PROGRAMS ?

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

APPQM- Program Modules

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

APPQM SERIES 1 & 2 DELEGATES SURVEY FEEDBACK

APPQM SERIES 1 & 2 DELEGATES SURVEY FEEDBACK

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

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

Transformative and Life Changing.

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

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

Educating Oneself while Educating Others

Has helped transform our quality culture.

Best business investment we've ever made.

Worth every penny and more.

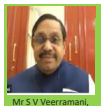
APPQM SERIES 2 VALEDICTORY – APPRECIATION FROM DIGNITARIES

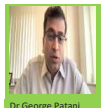

APPQM will help build the quality culture in Indian Pharma Industry
Dr V G Somani, DCGI


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

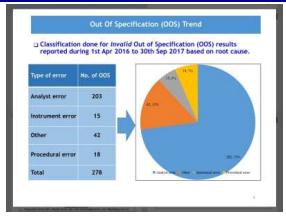

Virtual APPQM Program will be a boon for saving Time, Travel & Cost and yet deliver the same quality education
Dr. Viranchi Shah- National President -IDMA


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


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


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

Benefits of APPQM –ROI



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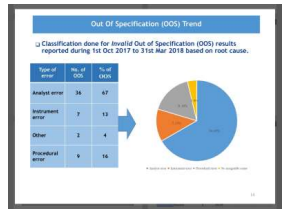

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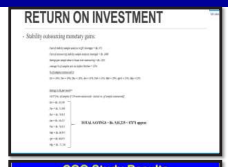
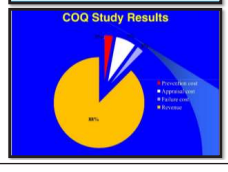
TOTAL SAVING OF Rs. 5 Cr.

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

National Medical Commission

Registered Medical Practitioner

Draft Regulations, 2022 (Professional Conduct)

PROPOSED CHANGES / ALTERATIONS BY INDIAN DRUG MANUFACTURERS' ASSOCIATION (IDMA)

SERIAL NO	PAGE NO & DETAILS	CLAUSES AS PER GUIDELINES	CHANGES SUGGESTED	REASONS
1.	Chapter 2: PROFESSIONAL CONDUCT OF RMPS **Responsibility of RMP regarding the sale of drugs :** Regulation 10 Point: A. Page No: 5	A RMP individually or as part of anorganization/ association/society shall not give to any person or to any companies or to any products or to software/platforms, whether for compensation or otherwise, any approval, recommendation, endorsement, certificate, report, or statement concerning any drug, medicine, nostrum remedy, surgical, or therapeutic article, apparatus or appliance or any commercial product or article with respect of any property, quality or use thereof or any test, demonstration or trial thereof, for use in connection with his name, signature, or photograph in any form or manner of advertising through any mode nor shall he boast of cases, operations, cures or remedies or permit the publication of report thereof through any mode. (L3)	A RMP individually or as part of an organization/ association/society shall not give to any person or to any companies or to any products or to software/platforms, whether for compensation or otherwise, any approval, recommendation, endorsement, certificate, report, or statement concerning any drug brand, or any commercial product with respect of any property, quality or use thereof or any test, demonstration or trial thereof, for use in connection with his name, signature, or photograph in any form or manner of advertising through any mode. (L3)	Barring the RMP from talking, discussing about drugs or appliances or surgical interventions or articles is contrary to the basis of dissemination of knowledge.
2.	Chapter 2: PROFESSIONAL CONDUCT OF RMPS **Prohibition of endorsement of the product or a person:**	RMP can prescribe or supply drugs, remedies, or appliances as long as there is no exploitation of the patients. Drugs prescribed by a RMP or bought from the pharmacy for a patient should explicitly state the	RMP can prescribe or supply drugs, remedies, or appliances as long as there is no exploitation of the patients. Drugs prescribed by a RMP or bought from the pharmacy for a patient should preferably also state	It seems a harsh imposition upon RMPs to remember ALWAYS the long and confusing generic names of each and every drug prescribed. Moreover, the regulation is silent about the practicality of writing

SERIAL NO	PAGE NO & DETAILS	CLAUSES AS PER GUIDELINES	CHANGES SUGGESTED	REASONS
	Regulation 12 Point: B. Page No: 6	generic name of the drug. (L2)	the generic name of the drug. (L2)	generic names of combination drugs in which there could be even 3-5 ingredients or maybe 10-15 in case of nutrients.
3.	Chapter 5:DUTIES OF RMPs TOWARDS THE PUBLIC AND ALLIED HEALTHCARE PROFESSIONALS Regulation 35 Page No: 12	RMPs and their families must not receive any gifts, travel facilities, hospitality, cash or monetary grants, consultancy fee or honorariums, or access to entertainment or recreation from pharmaceutical companies, commercial healthcare establishments, medical device companies, or corporate hospitals. However, this does not include salaries and benefits that RMPs may receive as employees of these organizations. Also, RMPs should not be involved in any third-party educational activity like CPD, seminar, workshop, symposia, conference, etc., which involves direct or indirect sponsorships from pharmaceutical companies or the allied health sector. RMP should be aware of the conflict of interest situations that may arise. The nature of these relationships should be in the public domain and should not be in contravention of any law, rule, or regulation in force. An RMP himself or as part of any society, organization, association, trust, etc. should be transparent regarding the relationship with the pharmaceutical and allied health sector industry. (L3)	RMPs and their families must not receive any gifts,or access to entertainment or recreation from pharmaceutical companies, commercial healthcare establishments, medical device companies, or corporate hospitals. However, this does not include salaries, retainerships, fees and benefits that RMPs may receive as employees or advisors of these organizations, including reimbursements for executing the assigned tasks. An RMP himself or as part of any society,organization, association, trust, etc. should be transparent regarding the relationship with the pharmaceutical and allied health sector industry. (L3)	A RMP may charge a consultancy fee or honorarium for service rendered in the form of medical camps, profession advice as an Advisor to a company. To prohibit the same may be legally unsustainable, unless it's a fraud and indirect gifting by a pharma company. There can never be a law to prohibit a citizen from earning legally via various avenues by using one's expertise and effort. Almost all educational activities involve sponsorship by pharma or corporates or hospitals.
4.	Chapter 5:DUTIES OF RMPs TOWARDS THE PUBLIC AND ALLIED	RMPs may be required to file an affidavit regarding their financial earnings and or benefits received in the past 5 past years from any	DELETE THIS CLAUSE	This regulation needs to be deleted since all payments and financial earnings are in today's times transparent and is.

SERIAL NO	PAGE NO & DETAILS	CLAUSES AS PER GUIDELINES	CHANGES SUGGESTED	REASONS
	HEALTHCARE PROFESSIONALS Regulation 36 Page No: 12	pharmaceutical companies or allied health sector. (L3)		governed by the income tax laws of the country
5.	Guidelines - 1 GENERIC MEDICINE AND PRESCRIPTION GUIDELINE Preamble: Page No: 18	1. Further, generic medicines are 30 to 80 cheaper than branded drugs. Hence, prescribing generic medicines may overtly bring down health care cost and improve access to quality care.	1. Generic medicines could be cheaper than branded drugs. Hence, prescribing especially quality generic medicines may overtly bring down health care cost.	The attempt to equate branded generic drugs with generic generic products is inappropriate as a blanket statement.
6.	Guidelines - 1 GENERIC MEDICINE AND PRESCRIPTION GUIDELINE Generic medicines vs Generic names: Branded Generic Drug: Page No: 18	A branded generic drug is one which has come off patent and is manufactured by drug companies and sold under different companies' brand names. These drugs may be less costly than the branded patent version but costlier than the bulk manufactured generic version of the drug. There is less regulatory control over the prices of these "branded" generic drugs.	A branded generic drug is one which has come off patent and is manufactured by drug companies and sold under different companies' brand names. These drugs may be less costly than the branded patent version but costlier than the bulk manufactured generic version of the drug.	The statement regarding regulatory control for branded medicines and not for generic generic versions is incorrect. The pricing controls are applicable to a particular drug or its combination and not always for specific brands. **There is also a need to educate the RMPs the difference in patented brands, out-of-patent brands, branded generics (mfg. by reputed pharmaceutical companies) and generic generics.**
7.	Guidelines - 1 GENERIC MEDICINE AND PRESCRIPTION GUIDELINE Guidance to RMPs: Page No: 18	1. Prescribe drugs with "generic"/"non-proprietary"/" pharmacological" names only	1. Prescribe drugs with "generic"/non-proprietary"/ "pharmacological" names preferably.	It seems a harsh imposition upon RMPs to remember ALWAYS the long and confusing generic names of each and every drug prescribed. Moreover, the regulation is silent about the practicality of writing generic names of combination drugs in which there could be even 3-5 ingredients or maybe 10-15 in case of nutrients.

IDMA, the largest association of Pharmaceutical Manufacturers, is forwarding the mentioned suggestions to the NMC Regulations, Code of Professional Conduct for the RMPs – 2022 which could impact drug prescribing adversely and to the detriment of patient care. It would be a win-win situation if there is symbiosis between health providers and health facilitators or else there could be spokes in the wheel with respect to patient treatment and advices, besides the RMPs' expertise.

Needless to mention, IDMA representatives could always be available to participate in any discussion or clarification required with respect to suggestions being made.

Dr R K Sanghavi
Chairman, Nutraceutical Committee

Mr Viranchi Shah
President

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Release of IDMA 60th Year Diamond Jubilee Coffee Table Book and IDMA Executive Committee Directory 2022-2023 at the 6th IDMA Executive committee meeting held on 24th June 2022, IDMA office, Mumbai

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South Africa Registration Procedure for Medicines in Public Emergency

PXL/HO/Cir-023/2022-23, date 21st June 2022

We are pleased to inform that the South African Health Products Regulatory Authority (SFHPRA) has issued an amendment effective 1st June 2022 w.r.t "Availability of Medicines for Use in a Public Health Emergency (Phe)". The guideline provides recommendations to applicants who intend to submit applications for the registration or authorization of medicines intended to be available to those affected by a public health emergency.

The guideline represents the current position of the SAHPRA on approaches to determine the quality, safety, and efficacy of the medicines required in a public health emergency. However, the guidelines are not intended as an exclusive approach. Pharmexcil members may refer to the South Africa Registration Procedure for Medicines in Public Emergency dated June 2022. Alternatively, members may also view the same at www.sahpra.org.za.

Disclaimer: It should be noted that the SAHPRA reserves the right to request any additional information to establish the safety, quality and efficacy of a medicine in keeping with the knowledge current at the time of evaluation. Member companies may also use alternative approaches, but these should be scientifically and technically justified. It is important that applicants also adhere to administrative requirements to avoid delays in the processing and evaluation of applications.

Warm Regards,

Udaya Bhaskar
Director General

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Eurasian Pharmaceutical Summit in Tashkent, Uzbekistan during 12-13 October 2022

PXL/HO/Cir-021/2022-23, date 20th June 2022

We are pleased to inform our members that we have received a communication from our Embassy of India in Tashkent, Uzbekistan informing that the world's leading event organizer, Global Pharmaceutical Leaders' Club is organizing an International Conference **"Eurasian Pharmaceutical Summit",** which will be held on October 12-13, 2022 in a hybrid format with an offline part in Tashkent.

We understand that this is the most relevant programme for the industry developed via an in-depth market research of the target audience, a unique international approach and a mix of the most engaging formats, round tables with regulators, discussion and one-to-one meetings with distributors and pharmacy chains, the chance to win an award in the competition for the Eurasian Pharma Inspiration Awards and new promotion opportunities!

Conference in numbers:

- **400+ attendees** representing regulatory authorities, leading international and local pharmaceutical manufacturing companies, distributors, pharmacy chains and service providers for the pharmaceutical sector.
- **100+ speakers** representing regulatory authorities, leading pharmaceutical production companies, distributors and pharmacy chains.

- **25 sessions** - the summit programme included 25 sessions on regulation, strategy, sales, marketing and manufacturing.

Indian companies are entitled to a **15%** discount for participating in this event by using the special code: INDIA15. For more details like Key discussion topics, registration details etc members can go through the **Announcement letter/Flyer by the organizers.**

Member companies planning to explore the business operations in Eurasian region may take advantage of this. Interested members can directly contact the organizers by email info@iventu.co.uk.

With regards

Uday Bhaskar
Director General

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India Pavilion in CPhI Worldwide at Frankfurt (1st - 3rd November 2022)

PXL/HO/Cir-020/2022-23, date 20th June 2022

We are pleased to inform you that Pharmexcil is organizing India Pavilion in CPhI Worldwide 2022 happening during 1st -3rd November 2022 at Frankfurt, Germany with support of the Ministry of Commerce, Govt. of India.

As a result of sustained effort in this regard, Indian pharma's presence in CPhI WorldWide has been very well noticed/ appreciated by all stakeholders. We are making our conscious efforts to scale up the look and feel of India Pavilion and branding of Indian Pharma at different strategic locations at the venue. Following value additions have been the Hallmark of India's participation in CPhI WorldWide since last seven years:

- Well-designed India Pavilion and specially designed stands with complete Branding images giving it a unique identity.
- Increased Digital / Show daily coverage with more coverage on exhibitors in India pavilion during the event

In our endeavor to provide the best possible opportunity to participating companies dealing Formulations & Bulk drugs, Pharmexcil is organizing India Pavilion at two separate locations in CPhI WW.

- Hall 4.0 (FDF)
- Hall 11.0 (API)
- Overall Floor Plan of CPhI WW

Stall Booking:

Members may please click on the following links to see the Overall Floor plan of India Pavilion.

India Pavilion Floor Plan

With a view to make the allotment procedure easy and transparent, we made the reservation of stalls online. To ensure that all the Members get the opportunity to reserve the stalls at the same time, the above link will open on 28th June 2022 at 2.30 PM

Interested members may please click on the following link and reserve the stall as per your choice.

ONLINE RESERVATION
(Link will open at 2.30pm on 28th June 2022)

Charges & Conditions:

- The cost of made up stall for Pharmexcil member will be Rs. 82,000/- per sq.mt (corner stand Rs.83,000 per Sq Mtr)
- Members should pay 50% advance on booking the stall and remaining 50% before 8th July 2022

- In case of non-receipt of payment by 08th July 2022, 50% cancellation charges shall be paid to the Council and the cancelled space will be allotted to members in the waiting list, without notice.
- No refund shall be made for cancellations after booking.
- The cost of stall is subsidized as the participation of Pharmexcil is under MAI scheme.
- The charges will be all inclusive i.e. Insurance, Stand cleaning, Digital product directory fee etc.
- All the Stalls are furnished with minimum furniture

MAI Support to the Participants:

Members whose export turnover during the previous financial year is less than/upto Rs. 50 Cr & have completed one year of membership will be eligible for assistance under new MAI scheme up to a maximum of Rs. 75,000/- towards air fare, subject to other conditions of MAI scheme Latest Guidelines and approval by Ministry.

For further information about the event, members may contact us at events@pharmexcil.com; events@pharmexcil.com or contact on 040 23735462/64/66

With Regards,

Uday Bhaskar
Director General

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Wide dissemination of the scheme Strengthening of Pharmaceutical Industry {SPI} - reg.

F.No.FDA/ SPI/2134-2022/11, dated 22nd June 2022

IDMA have received the below communication from Shri D. R. Gahane, Joint Commissioner HQ & Controlling Authority, Food & Drugs Administration, Maharashtra State, Mumbai dated 22nd June 2022 on the above subject:

I have great pleasure to inform you that Department of Pharmaceuticals Government of India has recently launched a scheme namely **'Strengthening of Pharmaceutical industry (SPI)** with the objective of strengthening the existing infrastructure facilities of pharmaceutical industry, in order to make India a global leader in the Pharma Sector.

This scheme has two major components.

1) Assistance to Pharmaceutical Industry for common Facilities (API-CF)
2) Pharmaceutical Technology Upgradation Assistance scheme (PTUAS)

In this regard, letter copy of Hon'ble Secretary, Government of India Ministry of Chemicals & Fertilizers Department of Pharmaceutical is attached herewith for your reference and you are hereby requested to inform all your members regarding this scheme so that maximum industries can avail the benefit of this scheme.

सुश्री एस. अपर्णा
सचिव
Ms. S. Aparna
Secretary

सत्यमेव जयते

भारत सरकार
रसायन और उर्वरक मंत्रालय
औषध विभाग
Government of India
Ministry of Chemicals & Fertilizers
Department of Pharmaceuticals

D.O No.G-30012/04/2022-Scheme
Dated 25th May, 2022

Dear Chief Secretary

I have great pleasure to inform you that Department of Pharmaceuticals has recently launched a scheme namely ***'Strengthening of Pharmaceuticals Industry (SPI)'*** with the objective of strengthening the existing infrastructure facilities of pharmaceutical industries, in order to make India a global leader in the Pharma Sector.

The scheme has two major main components viz. Assistance to Pharmaceutical Industry for Common Facilities (API-CF) and Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS).

API-CF aims at strengthening the existing pharmaceutical clusters' capacity for their sustained growth by creating common facilities. Under the scheme, financial assistance is released to Special Purpose Vehicles (SPVs) set up for the purpose. The limit of incentive will be 70% of the approved project cost or Rs 20 cr., whichever is less, as per approval of Scheme Steering Committee (SSC). In the case of Himalayan States and States in the North East Region, the grant-in-aid would be Rs. 20 Crore per Cluster or 90% of the project cost of the Common Infrastructure Facilities (CIF), whichever is less.

PTUAS aim to facilitate Micro, Small and Medium Pharma Enterprises (MSMEs) of proven track record to meet national and international regulatory standards. Under the scheme, financial assistance is provided either (i) Up to maximum of 5% per annum (6% in case of units owned and managed by SC/STs) of interest subvention for loan component eligible under the scheme taken to the upper limit of Rs. 10 Cr for a maximum period of 3 years on reducing balance for sanctioned loans by any scheduled commercial banks/financial institutions, both in the Public and the Private Sector Or (ii) Credit linked Capital subsidy of 10% on loan component eligible under the scheme. Maximum limit of loan will be Rs. 10.00 crore.

The Department has selected SIDBI, as the Project Management Agency for the Scheme. Under the sub-scheme of API-CF, it is proposed to support a total of 10 clusters. Further, under the sub-scheme of PT-UAS, it is proposed to support a total of 420 units. The detailed guidelines of the scheme ***'Strengthening of Pharmaceuticals Industry (SPI)'*** is available on the website of the Department of Pharmaceuticals (https://pharmaceuticals.gov.in/schemes). It is expected that the notification of inviting the application for the both sub-schemes of the SPI will be released in June- July 2022.

In view of the same, I request you to arrange for the wide dissemination of the scheme so that the eligible industries can avail the benefit under the major two sub-schemes of the Scheme ***'Strengthening of Pharmaceuticals Industry (SPI)'*** for the development of pharma sector in your state.

with regards,

Yours sincerely
Sparna
(S. Aparna)

Chief Secretaries
(As per list attached)

For full July 2022 month MSME Course Schedule: **https://bit.ly/3tNHfES**

What is the benefit of PMP certification?

A PMP certification can help you showcase your skills and get your work globally recognized. It gives you the opportunity to prove your experience and competencies to lead and direct projects. Gaining a PMP certification can prove to be an investment in your professional and personal development.

Is PMP certification really worth it?

PMP certification is undoubtedly beneficial. The certification offers many advantages. The PMI salary survey shows that PMP project managers earn 20% more than the average salary. There are immense PMP certification benefits, and hence, PMP certification worth is a lot more.

Is a PMP impressive?

A recent PwC survey states that certified PMP project managers handle more than three fourth of the high performing projects. Also, companies with more than one-third PMP certified managers have much better project success than companies which do not.

Will PMP get me a job?

PMP Certification Can Earn You a Higher Salary: Having PMP certification can score you a higher salary compared to those project managers who are not certified. The Project Management Professional (PMP) Certification is one of the most well known and recognizable certs within the IT industry today.

Is PMP still in demand?

Yes, PMP is highly sought after across industries. Wherever there are projects, there is a need for qualified and skilled project management professionals.

Is PMP exam hard?

The PMP exam is known for being hard, but PMI doesn't disclose specific statistics about the passing score or failure rate. Some project expert surveys estimate the failure rate at around 40-50%, meaning only about half of the first-time test takers pass the PMP exam.

Recognition and Acceptance of Indian Pharmacopoeia in Foreign Countries - reg.

F. No. T.11016/01/2020-AR&D, dated 27th June 2022

As you are aware that the Indian Pharmacopoeia Commission (IPC) has the mandate to publish Indian Pharmacopoeia (IP) editions at regular intervals. IPC has been making sincere efforts towards recognition and acceptance of IP in foreign countries. It is a matter of delight to share that in pursuant to sincere efforts and guidance provided by the Hon'ble Union Minister of Health & Family Welfare, IP has been accepted as a book of standards in following four countries and details in the matter are uploaded on IPC website:

1. **Afghanistan :** IP has been recognised formally by the National Department of Regulation of Medicines and Health Products of the Ministry of Public Health of Islamic Republic of Afghanistan and also will be used based on the requirement as reputable pharmacopoeia In the laboratory of medicines and health products quality. With this, a new beginning has been made as Afghanistan became the first country to recognize the IP.
2. **Ghana:** IP is considered as an approved reference when its monograph compares with the monographs in recognized pharmacopoeias in the Fourth Schedule of the Public Health Act.
3. **Nepal:** IP is recognised as the book of standards in Drugs Category Rules 1986 of Nepal. As per the list of pharmacopoeia or encyclopedia related to the category of drugs under Schedule 1 (related to Rule 5) of the Drugs Category Rules 1986, "Pharmacopoeia of India" published by the Ministry of Health of Government of India has been included at Sr. No. 3.
4. **Mauritius:** In order to include IP in the standards of pharmaceuticals authorized in Mauritius, Section 2 of the Pharmacy Act 1983 has been amended through Section 50 of the legal supplement published in August 2020 and in the definition of "specified standards" of the Section 2 of the Pharmacy Act, the word "or European" has been deleted and replaced with the words "European or Indian". Accordingly, the amended section reads as: "specified standards" means such standards as are specified in the British, French, United States, Europoean or India Pharmacopoeia;

Efforts are on to add more countries in the list. You are requested to share this news with concerned stakeholders so that maximum advantage is taken from these recognitions.

Thanking you,

Dr. Rajeev Singh Raghuvanshi, Secretary-cum Scientific Director, Ministry of Health & Family Welfare, Government of India, Sector 23, Raj Nagar, Ghaziabad 201002 (U.P.), India

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IDMA appeals to Sri Lankan drugs regulator to allow registered Indian drug makers to appoint multiple partners for business expansion

With an aim to increase India-Sri Lanka trade in the pharmaceutical sector, Indian Drug Manufacturers' Association (IDMA) has appealed to National Medicines Regulatory Authority (NMRA), Sri Lanka to review the policy of allowing multiple partners in the island country for registered Indian manufacturers.

Currently, an Indian manufacturer who is engaged with an existing Sri Lankan importer and wishes to engage additionally with a new agent in Sri Lanka, is required to obtain a no objection letter (NOL) from the existing Sri Lankan importer, according to NMRA policy.

This actually deters new Sri Lankan players from entering into a contract with established Indian companies. This hampers the possibilities for the Indian manufacturer to engage more actively with newer importers for differentiated ranges. If this policy is relooked, we are sure that there could be much more engagement from Indian manufacturers with more Sri Lankan counterparts, stated IDMA in a representation to NMRA chairman Dr. Rasitha Wijewantha.

The industry body having more than 1000+ members from across India stated that no other country in South East Asia has such a policy.

"This policy for insisting on an NOL from existing partners be relooked in the interest of bilateral trade. We wish to propose that a registered Indian manufacturer may please be allowed to appoint with multiple partners in Sri Lanka without the need to obtain NOL, as long as the products are different from the existing partner," it added.

"Sri Lanka is a close friend and associate of India and the Indian pharmaceutical industry. Indian drug manufacturers are keen to strengthen ties with their Sri Lanka counterparts in order to promote more Indo-Sri Lanka trade in the pharmaceutical sector, as also to help the Sri Lankan manufacturers through knowledge sharing. We have appealed to NMRA to look into the requirements of NOL from existing importers in order to enable the new Sri Lankan agent to engage and register some new products in Sri Lanka. This will help promote Indo-Sri Lanka pharma trade," said Dr Viranchi Shah, national president, IDMA.

Currently, Sri Lanka is reeling under an unprecedented economic crisis triggered by shortage in forex reserves. The economic crisis is affecting the pharmaceutical industry and the island nation is facing a shortage of essential drugs. In March 2022 India extended a USD one billion line of credit to Sri Lanka to help the country deal with the economic crisis.

Source: Laxmi Yadav, Pharmabiz, 20.06.2022

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Bulk drugs park to be allocated: Gujarat considered the strongest contender

AHMEDABAD: The central government may soon announce allocation of three bulk drug parks to states and Gujarat is considered one of the strong contenders. Fourteen states have submitted proposals to set up bulk drugs parks and the central government is scrutinizing the proposals.

Union chemicals minister Mansukh Mandaviya said, "We want to reduce dependence on imports for active pharmaceutical ingredients (APIs) and are in the process of finalizing three bulk drug parks in the country. Fourteen states have applied for these parks and a committee is scrutinizing these proposals. We will announce the allocation soon."

Apart from Gujarat, states such as Uttar Pradesh, Odisha, Tamil Nadu, Telangana, Karnataka, Maharashtra, Madhya Pradesh, Rajasthan, Punjab, Haryana, Himachal Pradesh and Andhra Pradesh have submitted proposals. The central government has introduced a special scheme, 'Promotion of Bulk Drug Parks', under which grants will be provided to set up common infrastructure facilities (CIF). API-bulk drugs account for around 65% of India's pharmaceuticals imports and the government wants to make industry self-reliant for APIs through this scheme. API production cost will be significantly lower at bulk drug parks.

According to the scheme, the financial outlay of the scheme is Rs 3,000 crore with maximum grants for a single bulk drug park limited to Rs 1,000 crore or 70% of the project cost of CIF, whichever is lower.

Indian Drug Manufacturers' Association (IDMA) president Viranchi Shah said, "The bulk drugs parks scheme aims to make India self reliant in APIs and Gujarat

is a strong contender because it has a strong pharma formulations base. Gujarat contributes 28% of India's pharma exports and 32% of production, so a bulk drugs park will make our ecosystem stronger. API demand in the state is high so a bulk drug park here will help reduce transportation costs. If a bulk drugs park is set up in Gujarat, it will see investments of at least Rs 5,000 crore and generation of 25,000 jobs."

Source: TNN, 25.06.2022

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Fin Min to release Ease of doing business rankings for states, UTs on June 30

The parameters on which the rankings are based include construction permits, labour regulation, environmental registration, access to information, land availability and single window system

The Ministry of Commerce & Industry is expected to release the *Ease of doing business* rankings of states and Union Territories (UTs) on Thursday. Finance Minister Nirmala Sitharaman will release the assessment of states/ UTs under *BRAP* (Business Reforms Action Plan), 2020, on June 30, reported PTI citing official sources.

The exercise is aimed at promoting competition among states and improving the overall business environment for domestic and international competitors.

The parameters on which the rankings are based include construction permits, labour regulation, environmental registration, access to information, land availability and single window system.

The Department for Promotion of Industry and Internal Trade (*DPIIT*) conducts the exercise under the Business Reform Action Plan (BRAP).

Andhra Pradesh followed by Uttar Pradesh, Telangana, Madhya Pradesh and Jharkhand topped the last rankings released in September 2020. So far rankings for years 2015, 2016, 2017-18 and 2019 have been released.

The larger objective of attracting investments and increasing ease of doing business in each state was sought to be achieved by introducing an element of healthy competition through a system of ranking states based on their performance in the implementation of BRAP, the report added.

In order to improve the business environment in the country, the Department for Promotion of Industry and Internal Trade DPIIT has taken up a series of measures to simplify and rationalise the regulatory processes (registration and inspection processes) and introduction 'information technology' as enabler to make governance more efficient.

Source: ET, 26.06.2022

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Exempt cheap drugs from price control, say Indian Pharmaceutical Alliance

Indian Pharmaceutical Alliance (IPA) - the industry body that represents large domestic pharmaceutical companies has sought the government to exclude low-priced scheduled products from price control citing viability issues in the wake of high raw material and logistics costs.

In an interview to ET, Samir Mehta, IPA president and chairman of Torrent Pharma said manufacturers of scheduled medicines are incurring losses because of the rising volatility of raw material prices and lack of flexibility to raise prices, and may have to cut back on supplies or have to exit products altogether.

Mehta batted for a market friendly pricing structure which will help in accessibility of medicines to the patients and increase investment in research and overall export thrust in global market.

"The COVID-19 pandemic has exposed the industry to unprecedented cost escalation across its value chain and the recent geo-political crisis in other parts of the world has further accentuated the input and logistics costs," Mehta said.

"It should be noted that the prices of medicines in India are already lowest in the world. To ensure viability in the sector, low-priced scheduled products should be considered for exclusion from price control," Mehta added.

Mehta said due lack of viability of the scheduled products - pharmaceutical manufacturers are either pushed to cut back on supplies or sell these products to other companies.

"The focus of the policy should be on ensuring quality and adequate supplies of these essential medicines. There is a need for the government to intervene which can offset these cost implications for sustaining the strategic importance of the industry," Mehta added.

At present, around 374 medicines are part of the National List of Essential Medicines (NLEM) which are subject to price controls. NLEM list is revised and the ceiling prices are fixed every five years. NLEM 2015, which was implemented from 2016 has ended in March 2021, the government is expected to revise the NLEM list anytime. The government allows annual price hikes as per the Wholesale Price Index (WPI), but industry says that this is too small to cover input raw material and logistics inflation.

The cost of logistics has risen by more than five times, while prices of raw materials such as certain critical solvents that are linked to petrochemicals and other raw materials have risen 50%-80%.

Mehta said Covid pandemic has also highlighted the need to build resilient supply chains.

"Concerted efforts are required to ensure a pandemic-proof supply chain network. The need of the hour is to reduce dependence on one single supplier, greater investment in technologies that can help in increased traceability, inventory visibility. Building a network of multiple trusted suppliers and backup supply sources from different parts of the world to ensure undisrupted supply chains," Mehta added.

"Additionally, it is really important that pharma companies do their due diligence to understand the vulnerabilities of the supply chains, set up processes for early identification, diversify production methods and chalk out a contingency plan in the event of any emergency," Mehta said.

On research and innovation - Mehta called for 'single window system' and elimination of multiple regulatory bodies, improvement in approval timelines, and creation of an enabling regulatory environment to encourage innovation and research.

"Incentivizing investment by pharmaceutical companies and exploring varied funding mechanisms or tax policies to support investments into R&D/innovation, research-linked incentives, budgetary support, venture capital, ensure improved ROI (return on investment) for innovation through reimbursement," Mehta said.

Source: Viswanath Pilla, ET, 27.06.2022

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Technology revitalising India's pharma industry

The Indian pharma industry has witnessed a complete makeover in the past few years. From online application and approval of licenses, use of robotics and automation for mass production to supplying COVID vaccines to over 150 countries across the globe. Sharing his perception of the transformation of the Indian pharma industry, ***Dr Shrenik Shah,*** *Director & Chairman, Montage Laboratories Pvt. Ltd, Indian Drug Manufacturers' Association, Gujarat State Board spoke at the* ***Pharma Leadership Summit pharma industry.***

DR SHRENIK SHAH
Director & Chairman, Montage Laboratories Pvt. Ltd, Indian Drug Manufacturers' Association, Gujarat State Board

Dr Shrenik Shah cited the example of the Hindu mythology and said, "There are three major gods - Brahma, the god of creation; Vishnu, the god of preservation and transformation; and Shiva, the god of disruption and destruction. In Ramayana, lord Hanuman, the incarnation of Shiva, disrupted Lanka's ecosystem and lord Ram, the incarnation of Vishnu, transformed the ecosystem. Perhaps, through our religious texts, we've been told that no creation is possible without disruption and no creation is valuable unless it's transformative. This is a reality today." Creating something new without disrupting the existing is humanly impossible, therefore disruption is necessary before the transformation.

Highlighting how the COVID pandemic impacted the lives of people, he said, "An officer, who didn't have to take efforts for a glass of water for himself and was served right at his table, has mopped and swept his house during the lockdown. This is a transformation."

Ahead of economic disruption, there was no thought about the open economy concept, however, the pandemic situation led to such innovative moves to continue growth. The disruption caused by the pandemic pushed the

government to take up transformative steps. Similarly, the pharma sector is going through a transformation and the industry has to match its pace to stay afloat and trail the path to growth.

Dr Shah lauded the efforts of Dr HG Koshia who made the application processes for licenses and permits online. The move not only made it easier for the retailers but also the time taken for the entire process was cut short significantly. Also, he mentioned how Dr Koshia has tried to make his authority work in a paperless fashion.

In the near future, another wave of transformation will affect the Indian pharma sector and would require us to come at par and comply with the global standards. This will further lead to significant growth and development of the Indian pharma sector. Even today, the industry is leveraging technology tools to optimise operations. Dr Shah highlighted, "The way we hold conferences, webinars and workshops on online platforms was unimaginable a few years ago. Technology has bridged the communication gap and brought the world closer. However, to match the transformation, an industry has to be agile and adaptive."

He cited various examples of how emerging technologies and digitization has transformed not only pharma but almost every economic sector. He said "change is the only constant" and the key is to constantly adapt to the changes to trail the path towards growth and development.

Source: ehealth.eletsonline.com, May-June 2022

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GST Council to take up Tightening of Systems

To discuss proposal for stricter scrutiny and verification of high-risk taxpayers; GoM led by Pawar to submit report on tax reforms

The Goods and Services Tax (GST) council is likely to take up a proposal for stricter scrutiny and verification of highrisk taxpayers ahead of the next level of reforms in the indirect tax framework that completes five years of roll-out on July One.

A group of ministers (GoM) headed by Maharashtra finance minister Ajit Pawar, which is scheduled to give its report on reforms on the GST system to the council, has recommended public disclosure of information of unregistered bogus traders and provision of information on transactions through Point of Sale (POS) by banks, among others.

The council meeting this week on June 28-29 in Chandigarh is expected to focus on ways to improve revenue collection and plug leakages as compensation to the states ends this month.

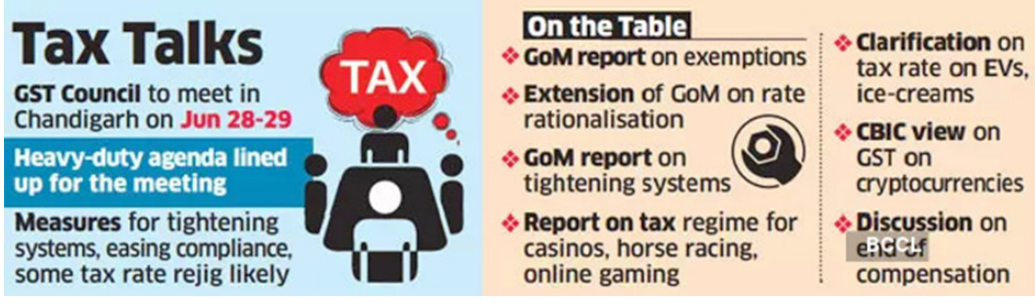
Last year the council had set up a GoM under Pawar to review IT tools and interface available to tax officers and suggest measures to make the system more effective and efficient, including changes in business processes. It was also asked to identify potential sources of evasion to plug revenue leakages.

The GoM recommended verification of physical addresses of high-risk taxpayers to prevent input tax credit fraud. It has also suggested making mention of electricity consumer registration number mandatory at the time of GSTN registration, certification of taxpayers' bank accounts by National Payments Corporation of India (NPCI) and establishment of a feedback mechanism to detect suspicious transactions.

It has also made out a case for measures to prevent harassment from tax officials and improvement in process to claim input tax credit.

MINIMAL RATE REJIG

The council is expected to refrain from undertaking any significant increase in tax rates as part of rationalisation in view of inflationary concerns. "No major rate rejig is expected apart from some tweaks and clarifications. However, there will be a detailed discussion on improving the GST system, use of technology and better cohesion between the centre



and state to plug in leakages," an official said. The fitment committee under the council has recommended status quo on tax rates for 215 goods and services.

The council is also expected to take up an interim report from the GoM on rate rationalisation, headed by Karnataka Chief Minister Basavraj Bommai, on pruning of exemptions under GST.

Exemptions such as for hotel rooms less than Rs 1,000 per night and non-branded food items could be taken up. Extension of this GoM by another six months to investigate a comprehensive rate rationalisation is also expected to be taken up by the council. The council is expected to take final call on rates on casinos, horse racing and online gaming after the ministerial panel headed by Meghalaya Chief Minister Conrad Sangma suggested imposition of 28% GST on these activities.

The council is also expected to take up the GST on cryptocurrency. The Central Board of Indirect Taxes and Customs has favoured imposition of 28% on cryptocurrency transactions.

Source: Anuradha Shukla, The Economic Times, 27.06.2022

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IDMA PUBLICATIONS RATE CARD

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3.	**IDMA APA Forum**	
	• Annual Membership	500/-
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