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RNI REGN. NO. 18921/1970
REGN NO. MCW/95/2021-23

IDMA BULLETIN

VOL. NO. 53 | ISSUE NO. 26 (PAGES: 36) | 08 TO 14 JULY 2022 | ISSN 0970-6054 | WEEKLY PUBLICATION

INDIAN PHARMA - GLOBAL HEALTH CARE

INDIAN DRUG MANUFACTURERS' ASSOCIATION

HIGHLIGHTS

EXCEPTIONAL PRODUCTS, THAT COME FROM EXCEPTIONAL LEADERSHIP

Dear Partner,

We, at Signet, haven't become industry leaders overnight. Our position at the forefront of the market comes down to always delivering only the highest level of products and services. And to the like-minded partnerships we've built, such as with IFF (Formerly Dupont Nutrition & Health).

IFF (Formerly Dupont Nutrition & Health) boasts a superior product portfolio, including its best-selling brand of microcrystalline cellulose, 'Avicel'; as well as alginates, carageenans and croscarmellose sodium harnessed from natural resources. They are the foremost producers of cellulose-based excipients, with keen emphasis on developing new technologies and applications.

But what best reflects this successful partnership, is the shared belief and commitment to providing our customers the highest standards of quality and service.

For that's what strong leadership does.

Signet-ure *leadership*

iff

FILLERS / DILUENTS
- AVICEL PH – Microcrystalline Cellulose
- AVICEL SMCC – Silicified Microcrystalline Cellulose
- AVICEL DG / CE / HFE – Co-processed Microcrystalline Cellulose

SUPERDISINTEGRANT
- AC-DI-SOL – Croscarmellose Sodium

SUSPENDING AGENT
- AVICEL RC / CL – Colloidal Microcrystalline Cellulose

HYDROCOLLOIDS
- PROTACID – Alginic Acid
- PROTANAL / MANUCOL – Alginate
- GELCARIN / VISCARIN – Carrageenan

LUBRICANT
- ALUBRA PG 100 – Sodium Stearyl Fumarate

FUNCTIONAL COATING
- AQUATERIC N100 – Ready-to-use Alginate based Enteric Coating System

Signet

The Complete Excipients Company

A Publication of
Indian Drug Manufacturers' Association
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Tel : 022-2494 4624 / 2497 4308 **Fax:** 022-2495 0723
e-mail: publications@idmaindia.com/
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Published on 7th, 14th, 21st and 30th of every month

Annual Subscription
₹ 1000/- *(for IDMA members)*
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IDMA BULLETIN

Vol. No. 53 **Issue No. 26** **08 to 14 July 2022**

IDMA ACTIVITIES:

GOVERNMENT COMMUNICATIONS:

MoEFCC MATTERS:

INDIAN PHARMACOPOEIA COMMISSION:

GST 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

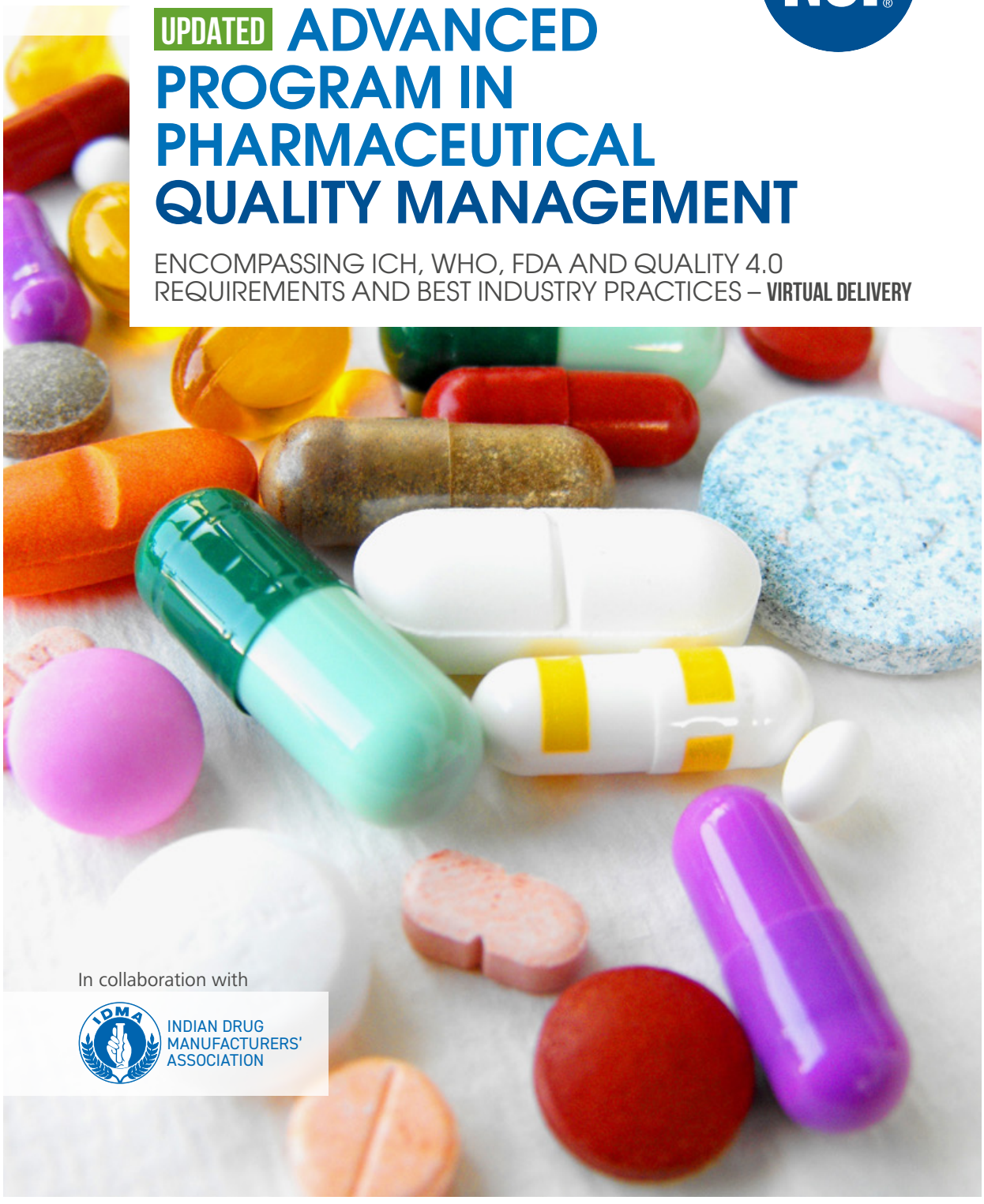
Melvin	**Batul**
actadm@idmaindia.com	technical@idmaindia.com
9821868758	9920045226

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


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

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

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

CHALLENGES FACING THE PHARMACEUTICAL INDUSTRY

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

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

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

HOW THIS TRAINING CAN HELP

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

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

WHY CHOOSE NSF?

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

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

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

BENEFITS OF THIS TRAINING

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

For example by:

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

Attendees will also:

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

COURSE FORMAT

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

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

▶▶

COURSE MODULES

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

MODULE ONE: Pharmaceutical Quality Management Systems – Best Industry Practices

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

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

MODULE TWO: Managing Change; Change Control and Deviations

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

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

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

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

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

▶▶

MODULE FOUR: Data Analysis for Business Improvement

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

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

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

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

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

NEXT STEPS YOUR CALL TO ACTION

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

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

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

NSF INTERNATIONAL

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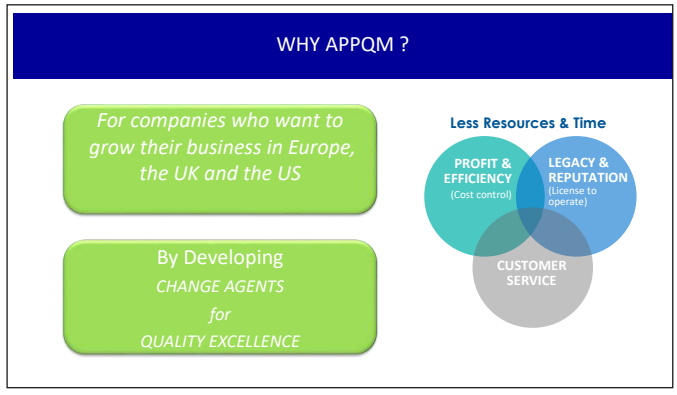
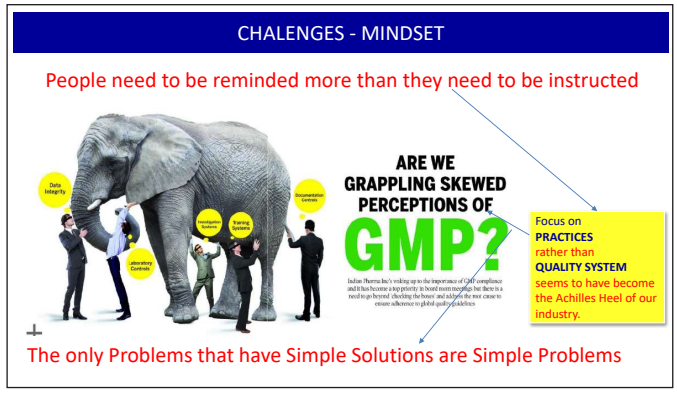
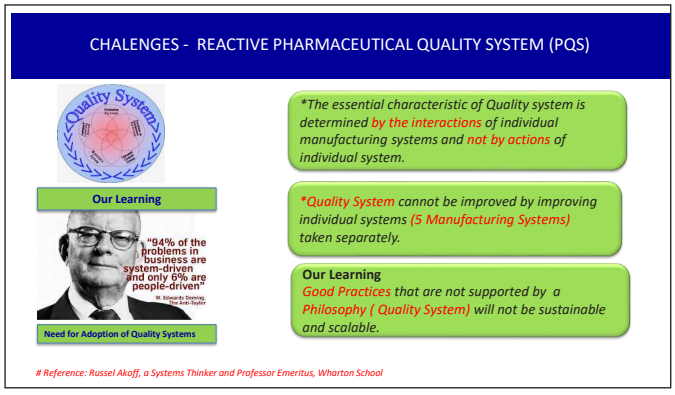
PRESENTATION

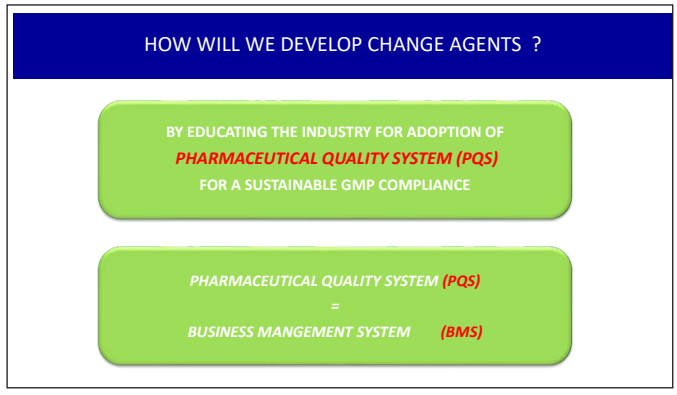
Launch of APPQM Series 3

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









APPQM IS DESIGNED FOR INDIAN COMPANIES

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

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

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

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

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

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

HOW APPQM IS DIFFERENT FROM OTHER TRAINING PROGRAMS ?

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

APPQM- Program Modules

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

APPQM SERIES 1 & 2 DELEGATES SURVEY FEEDBACK

APPQM SERIES 1 & 2 DELEGATES SURVEY FEEDBACK

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

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

Transformative and Life Changing.

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

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

Educating Oneself while Educating Others

Has helped transform our quality culture.

Best business investment we've ever made.

Worth every penny and more.

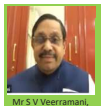
APPQM SERIES 2 VALEDICTORY – APPRECIATION FROM DIGNITARIES

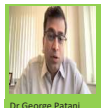

APPQM will help build the quality culture in Indian Pharma Industry
Dr V G Somani, DCGI


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

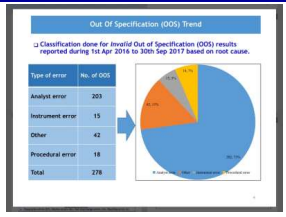

Virtual APPQM Program will be a boon for saving Time, Travel & Cost and yet deliver the same quality education
Dr. Viranchi Shah- National President -IDMA


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


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


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

Benefits of APPQM –ROI



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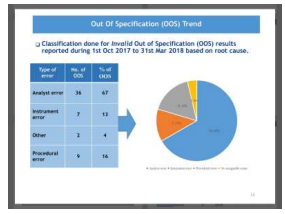
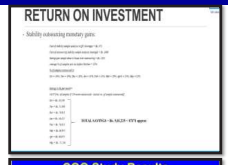
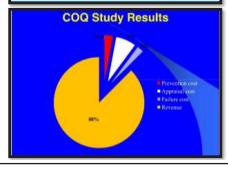


AFTER

TOTAL SAVING OF Rs. 5 Cr.

Benefits of APPQM -ROI





Acknowledgments

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

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

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

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

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

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

THANK YOU FOR YOUR ATTENTION

Pharma Research in India & Role of CSIR Laboratories and Science education in India

Dr. Gopakumar G. Nair, *Editor, Indian Drugs*

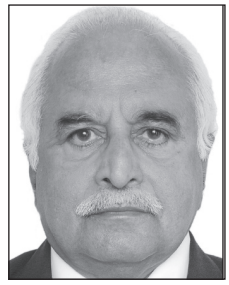
Dear Reader,

It is indeed heartening to note that Dr. D. Srinivasa Reddy, who has close research and professional connections with IDMA and other Pharma Associations and has received Awards also from Industry, has joined the Indian Institute of Chemical Technology (IICT), Hyderabad as the new Director. Dr. Srinivasa Reddy continues to hold the charge as Director, Central Drug Research Institute (CDRI) and the CSIR-IIIM (Indian Institute of Integrative Medicine), Jammu. The fact that Dr. Reddy is simultaneously holding charge of two more leading CSIR Laboratories, while being appointed as the Director of IICT, speaks volumes about his research credentials.

Dr. D. Srinivasa Reddy

Dr. Reddy is recipient of the Bhatnagar Award, J C Bose Fellowship, FASc, FNASc and many more National and International Research Awards. Dr. Srinivasa Reddy is well known for his work on Organic Synthesis applied to human well-being. He is also known for application of "silicon-switch" approach in medicinal chemistry. "Crop protection" research has been close to his heart. He has over 120 publications and around 35 patents. He was at NCL (National Chemical Laboratories, Pune) for nearly 10 years. He has industry experience in India (Dr. Reddy's, Advinus) and research experience in USA.

We from Indian Drugs and IDMA wish him a very productive and innovative research performance times at IICT.



Dr. Gopakumar G. Nair is a Ph.D in Organic Chemistry (1966) from National Chemical Laboratory, Pune (Pune University). He was a Post-Doctoral fellow at IIT Bombay, Powai (1967) before joining the Pharma Industry. He was Director of Bombay Drug House P. Ltd., later Chairman of BDH Industries Ltd. as well as CMD of Bombay Drugs & Pharma Ltd., which was merged with Strides Arcolab Ltd. in 2001. Dr. Nair served IDMA as office bearer for many years from 1972 onwards and was Chairman of various Committees for nearly 4 decades. He was the President of IDMA in 1999/2000. Currently, Dr. Nair is the Chairman of the IPR Committee in IDMA.

Having moved into the Intellectual Property field, he was the Dean of IIPS (Institute of Intellectual Property Studies) at Hyderabad in 2001/2002. Later, he set up his own boutique IP firm, Gopakumar Nair Associates, as well as Gnanlex Hermeneutics Pvt. Ltd., having done his L. L. B. from Mumbai University. He is also CEO of Patent Gurukul and President of Bharat Education Society, Kurla, Mumbai, managing many educational institutions in and around Mumbai.

While highlighting the fact that Dr. Srinivasa Reddy is currently Director of the three most well-known research laboratories under CSIR (IICT, CDRI, IIIM), it is time for us to wake up and take note that there is acute dearth of highly qualified scientists of repute in India to take charge as Director. It is no wonder that the Indian Government is compelled or attracted to appoint overseas Directors of MNCs and International Research Laboratories as Directors in CSIR Laboratories or CSIR itself. Scientists of repute such as Dr. Nitya Nand (CDRI), Dr. R. A. Mashelkar (NCL, Pune), Dr. A. V. Rama Rao and Dr. Chandrasekhar (IICT), Dr. Kapil and

Dr. Handa (IIIM, Jammu) and others such as Prof. CNR Rao, Dr. Satish Dhawan, Dr. CV Raman, Dr. Govardhan Mehta (to name a few) had made Indian innovative research proud in their time. I remember the days in the sixties when Dr. T. R. Seshadri, Dr. Asima Chatterjee and Dr.Venkataraman used to have heated exchanges in basic research topics. Dr. T. R. Govindachari and Dr. Selvavinayakam of CIBA Research Centre were their contemporaries. I will be failing if I leave out mentioning Dr. Homi Bhabha, Dr. Abdul Kalam, Dr. P.C. Ray, Dr. Khurana, Dr. S. S. Bhatnagar, Dr. Anil Kakodkar and the like. Will the new generation come up with gems and jewels of research in India? Not unless, we make the right moves now.

Of late, for whatever reason (food for thought) there is an acute dearth of high calibre scientific talent in India. With all the sloganeering over "innovation" and "Drug Discovery Research" as well as National wealth creation through IP generation and patenting, one is forced to ponder, where are all the human talents for research and innovation. The fact that most distinguished research laboratories of India are being jointly headed by a single Director (Acting Directors) should alert the Indian Leaders of technical education to self-introspect as to why the new generation (Nextgen) is not attracted to scientific research and higher education in science subjects. Is there a brain-drain in science from India to the international arena? Indian origin scientists are dominating international research in International Universities and most of the fortune 500 companies globally. The industry in India, especially in Science, Chemistry, Pharmacy and Biotechnology need to join hands to ensure that distinguished students, researchers and even faculty are produced in larger numbers in years to come to meet the supply chain demand for distinguished research scientists, professors of repute and disruptive research innovators. Let us all work together towards this common goal.

Courtesy: Indian Drugs, Editorial, 59 (05), May 2022

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Cooperation with the Russian company "Kardinal"

PXL/HO/Cir-032/2022-23, dated 08th July 2022

Members are kindly aware that Pharmexcil has been facilitating several trade enquiries in close coordination with our missions abroad and promoting Indian pharmaceuticals worldwide. Pharmexcil is further in receipt of communication from Trade Representation of Russia in India that currently the **Russian fishing company "Kardinal" is looking for the partners to increase its manufacturing capabilities by constructing capsule line production.** This company is located in the Russian Sakhalin region and manufactures Nutraceuticals (omega-3). In this regard "Kardinal" is inviting all interested Indian companies to help them organize this production line.

Companies interested in developing cooperation with Russian company Kardinal in this direction may contact the following directly:

The Ministry of Invest of the Sakhalin region
E-mail: investsakh@ya.ru
Tel.: +74242671765, +74242671771
Whatsapp/telegram: +79621097722

Uday Bhaskar, Director General, Pharmexcil

● ● ●

Procedure to be followed for Subsequent applicant in respect of FDCs declared as rational by Prof. Kokate Committee and approved by DCG(1) - reg.

File No. 4-01/2013-DC (Misc. 13-PSC) (Pt. II), dated 04 July 2022

To,
All State/UT Drugs Controllers

This is in continuation to this office letter of even number dated 12.12.2018 and 27.08.2021 thereby enclosing a list of 1687 FDCs w.r.t obtaining manufacturing licenses directly from State Licensing Authorities. Certain typographical error has been observed in the said list at sr. no. 809 and accordingly the list in supersession of earlier list has been updated on the website of CDSCO.

This is for your information and further necessary action.

Dr V G Somani,
Drugs Controller General (India),
Directorate General of Health Services,
Central Drugs Standard Control Organization,
FDC Division,
FDA Bhawan,
Kotla Road,
New Delhi.

795	Levocetirizine HCl IP 2.5mg+Ambroxol HCl IP 15mg+Guaiphenesin IP 50mg+Menthol IP 1mg per 5ml syrup	17.07.15
796	Calcitrol IP 0.25mcg+Calcium carbonate IP eq .to Elemental Calcium 200mg+Vitamin B6 IP 3mg+Methylcobalamin 1500mcg+Foilc acid IP 1.5mg soft gelatin capsules	17.07.15
797	Ferric Amonium Citrate (Eq. to Elemental Iron) 200mg+Cyanocobalamin IP 7.5mcg+Pyridoxine HCl IP 1.5mg+Folic Acid IP 1mg+Zinc Sulphate Monohydrate BP (Eq .to Elemental zinc) 7.0mg per 5ml syrup	17.07.15
798	Alpha Lipoic Acid USP 200mg+Benfotiamine 150mg+Methylcobalamin 1500mcg+Chromium Picolinate USP 200mcg+Inositol BP 100mg soft gelatin capsules	17.07.15
799	Gliclazide IP 40mg+Metformin HCl IP 500mg Uncoated tablets	17.07.15
800	Calcium citrate USP 500mg+ Soy Isoflavones 40% 100mg+ Calcitriol IP 0.25mcg tablet/soft gelatin capsules	16.07.15
801	Amlodipine 5mg+Olmesartan medoxomil 40mg+Hydrochlorothiazide IP 12.5mg film coated tablets	16.07.15
802	S(+) Etodolac 200mg+Thiocolchicoside 4mg film coated tablets	17.07.15
803	Carbonyl Iron eq. to elemental Iron 100mg+Folic Acid IP 1.5mg+Cyanocobalamin IP 15mcg+Zinc Sulphate Monohydrate IP 61.8mg per15ml syrup	17.07.15
804	Pyridoxine HCl 50mg+Nicotinamide IP 50mg+Methylcobalamin 500mcg+Benzyl Alcohol IP 2%v/v per ml Inection	17.07.15
805	Alpha Lipoic Acid 100mg+Pyridoxine Hydrochloride 3mg+Methylcobalamin 1500mcg+Folic Acid 1.5mg hard gelatin capsules	16.07.15
806	Fusidic Acid BP eq. to Anhydrous Fusidic Acid 20mg+Betamethasone Valerate BP eq. to Betamethasone 1mg per gram cream	17.07.15
807	Iron (III) Hydroxide Polymaltose Complex eq. to elemental Iron 100mg+Folic Acid IP 350mcg chewable tablets	17.07.15
808	Betamethasone Sodium Phosphate IP Eq. to Betamethasone 0.1%w/v+Ofloxacin IP 0.3%w/v+Benzalkonium Chloride IP 0.02%w/v Eye Drops	17.07.15
809	~~Calcium Carbonate eq. to elemental Calcium 1250mg~~ Calcium Carbonate IP 1250mg eq. to elemental Calcium 500mg+Vitamin D3 IP 2000IU+Methylcobalamin 1500mcg+L- Methylfolate Calcium 1mg+Pyridoxal 5 Phosphate 20mg film coated tablets	17.07.15
810	Refined borage oil providing Linolenic Acid 60mg + Alpha Lipoic Acid USP 100mg + Methylcobalamin 1.5mg + Pyridoxine Hydrochloride IP 5mg + Chromium Picolinate Eq. to Chromium 50mcg soft gelatin capsules	17.07.15
811	Betamethasone Sodium Phosphate Ip eq. to Betamethasone 0.1%w/v+Gatifloxacin IP eq. to Anhydrous Gatifloxacin 0.3%w/v+Benzalkonium Chloride Solution IP 0.02%v/v eye drops	17.07.15
812	1250mg Calcium Citrate Maleate eq. to Calcium 250mg+Calcitroil IP 0.25mcg tablets	16.07.15
813	Calcium Carbonate from an Organic Source(Oyster Shells) Eq. to Elemental Calcium 250mg+Cholecalciferol (Vitamin D3)IP 125IU+Cyanocobalamin (Vitamin B12) IP 2.5mcg/1.5mcg per 5ml suspension	16.07.15
814	Alpha Lipoic Acid USP 200mg+Vitamin D3 IP 1000IU+Pyridoxine Hydrochloride IP 3mg+Methylcobalamin 1500mcg+Folic Acid IP 1.5mg+Biotin USP 200mcg tablets	16.07.15
815	Hydroxypropyl Methylcellulose 0.3%w/v+Borax 0.19%w/v+Boric Acid 0.19%w/v+Sodium Chloride 0.45%w/v+Potassium Chloride 0.37%w/v eye drops	17.07.15
816	Docosahexaenoic acid 100mg+Methylcobalamin 750mcg+Folic acid 5mg soft gelatin capsules	17.07.15
817	Calcium Citrate USP 1000mg+Alfacalcidol BP 0.25mcg tablets	16.07.15
818	Ciprofloxacin Hydrochloride IP Eq. to Ciprofloxacin 0.3%w/v +Dexamethasone IP 0.05%w/v + Benzalkonium Chloride solution IP 0.02%v/v (As preservative) eye/ear drops	17.07.15
819	Ferrous Ascorbate Eq .to Elemental Iron 60mg+Folic Acid IP 1.5mg+Methylcobalamin 500mcg film coated tablets	17.07.15
820	Esomeprazole Magnesium Trihydrate IP Eq. to Esomeprazole 40mg+Domperidone Maleate IP Eq. to Domperidone 10mg enteric coated tablets	17.07.15
821	Chlorpheniramine maleate 4mg+Phenylephrine hydrochloride 2.5mg tablets	17.07.15
822	Gabapentine USP 300mg+Methylcobalamin IP 500mcg hard gelatin capsules	17.07.15
823	Ofloxacin IP 0.3%w/w/0.3%w/v+Dexamethasone Sodium Phosphate IP Eq. to Dexamethasone Phosphate 0.5%w/v/0.1%w/v eye drops	17.07.15
824	Pantaprazole Sodium 20mg/40mg+Domperidone 10mg/10mg tablets	17.07.15
825	Potassium Iodine IP 3.3%w/v + Sodium Chloride IP 0.83%w/v + Calcium Chloride Dihydrate IP 1.0%w/v + Sodium Methyl Hydroxy Benzoate IP eq. to Methyl Hydroxybenzoate 0.023%w/v + Sodium Propyl Hydroxy Benzoate IP eq. to Propyl Hydroxybenzoate 0.011%w/v (As preservatives) eye drops	17.07.15
826	Coal Tar USP 6%w/w+Salicylic Acid 3%w/w Ointment	17.07.15
827	Telmisartan IP 40mg+Metoprolol Succinate USP Eq. to Metoprolol Tartrate 25mg (As extended release) film coated tablets	17.07.15
828	Sodium feredetate 231mg eq. to Elemental Iron 33mg+Folic acid 1.5mg+Cyanocobalamin IP 15mg tablets	17.07.15
829	Ferrous Ascorbate eq. to elemental Iron 60mg+Folic Acid IP 1.5mg+Methylcobalamin 500mcg+Docosahexaenoic Acid 100mg capsules	17.07.15
830	Ferrous Gluconate IP 20mg+Calcium Gluconate IP 20mg+Thiamine Hydrochloride IP 1.0mg+Riboflavine IP 1.0mg+Pyridoxine Hydrochloride I.P 0.5mg+Niacinamide IP 15mg+L-Lysine Mono Hydrochloride USP 40mg per 5ml syrup	17.07.15
831	Sodium Acid Phosphate IP 10gm+Sodium Phosphate IP 8gm per 100ml enema	17.07.15
832	Clobetasol propionate BP 0.05%w/w+Neomycin sulphate IP 0.5%w/w cream	16.09.15
833	Betamethasone Valerate IP eq. to Betamethasone 0.10%/w/w+Salicylic Acid IP 3.0%w/w skin ointment	17.07.15
834	Elemental Iron 50mg+Zinc Sulphate Monohydrate IP 61.8mg eq. to Elemental Zinc 22.05mg+Folic Acid IP 0.5mg capsules	17.07.15
835	Cholecalciferol (Vitamin D3) 200IU+Tribasic Calcium Phosphate IP 1.032g uncoated tablets	17.07.15
836	Diphenhydramine HCl 14.08mg+Ammonium chloride 138mg+Sodium Citrate 57.03mg+Menthol 1.14mg+Ethanol (95%) 0.2625ml in 5ml Expectorent	16.07.15
837	Colloidal Iron 250mg+Folic Acid 500mcg+cyanocobalamin (Vitamin B12) 5mcg syrup	17.07.15

Note: For more details, Interested members can visit cdsco website https://cdsco.gov.in

Plastic Waste Management Rules, 2016 amended (Second Amendment of 2022) - reg.

Environment Notification G.S.R.522(E), dated 06th July 2022

(Published in the Gazette of India on 7th July, 2022)

Whereas the draft rules further to amend the Plastics Waste Management Rules, 2016, were published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i) dated the 18th January, 2022, *vide* notification number G.S.R.22 (E) dated the 18th January, 2022, inviting objections and suggestions from all persons likely to be affected thereby within a period of sixty days from the date copies of the Gazette containing the said draft rules were made available to the public;

And whereas, copies of the Gazette containing the said draft rules were made available to the public on the 18th January, 2022;

And whereas, objections and suggestions received within the aforesaid period have been duly considered by the Central Government;

Now, therefore, in exercise of the powers conferred by sections 3, 6, and 25 of the Environment (Protection) Act 1986, (29 of 1986), the Central Government hereby makes the following rules further to amend the Plastic Waste Management Rules, 2016, namely:-

1. Short title and commencement:

(1) These rules may be called the **Plastic Waste Management (Second Amendment) Rules, 2022.**

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

2. In the Plastic Waste Management Rules, 2016 (hereinafter referred to as the said rules), in rule 3,-

(i) after clause (ab), the following clause shall be inserted, namely:-

'(ac) "Biodegradable plastics" means plastics, other than compostable plastics, which undergoes degradation by biological processes under ambient environment (terrestrial or in water) conditions, without leaving any micro plastics, or visible, or distinguishable or toxic residue, which has adverse environment impacts, adhering to laid down standards of Bureau of Indian Standards and certified by the Central Pollution Control Board;';

(ii) in clause (b), after the words "brand labels", the words "or trademark" shall be inserted;

(iii) in clause (c), before the words "means bags made" the following words and brackets "(covered under Category II of plastic packaging – Clause (5.1) (II), given in Schedule – II)" shall be inserted.

(iv) clause (ga), shall be renumbered as "(gb)" thereof and before clause (gb) as so renumbered, the following clause shall be inserted, namely :-

'(ga) "End of Life disposal" means using plastic waste for generation of energy subject to relevant guidelines in force, which includes co-processing (e.g. in cement, steel or any other such industry) or waste to oil, except in cases where feedstock chemicals are produced for further use in the production of plastic which may then be considered under recycling or for road construction as per Indian Road Congress guidelines etc.';

(v) for clause (k),the following clause shall be substituted, namely:-

"(k) "Importer" means a person who imports plastic packaging or products with plastic packaging or carry bags or multilayered packaging or plastic sheets or like;';

(vi) after clause (o), the following clause shall be inserted, namely:-

'(oa) "Plastic Packaging" means packaging material made by using plastics for protecting, preserving, storing, and transporting of products in a variety of ways;';

(vii) after clause (qa), the following clause shall be inserted, namely:-

"(qb) "Plastic Waste Processors" means recyclers of plastic waste as well as entities engaged in using plastic waste for energy (waste to energy) including in coprocessing or converting plastic waste to oil (waste to oil) except in cases where feedstock chemicals are produced for further use in the production of plastic which may then be considered under recycling , industrial composting;';

(viii) after clause (qb), the following clause shall be inserted, namely:-

'(qc) "Post-consumer plastic packaging waste" means plastic packaging waste generated by the endues consumer after the intended use of packaging is completed and is no longer being used for its intended purpose;';

(ix) after Clause (r), the following clause shall be inserted, namely:-

'(ra) "Pre-consumer plastic packaging waste" means plastic packaging waste generated in the form of reject or discard at the stage of manufacturing of plastic packaging and plastic packaging waste generated during the packaging of product including reject, discard, before the plastic packaging reaches the end-use consumer of the product;';

(x) after clause (s), the following clause shall be inserted, namely:-

'(sa) "Recyclers" are entities who are engaged in the process of recycling of plastic waste;';

(xi) after clause (u), the following clause shall be inserted, namely:-

'(ua) "Reuse" means using an object or resource material again for either the same purpose or another purpose without changing the object's structure;';

(xii) after clause (w), the following clause shall be inserted, namely:-

'(wa) "Use of recycled plastic" means recycled plastic used as raw material, instead of virgin plastic, in the manufacturing process;';

(xiii) after clause (aa), the following clause shall be inserted, namely:-

'(aab) "Waste to Energy" means using plastic waste for generation of energy and includes coprocessing (e.g. in cement, steel or any other such industry);'.

3. In in rule 4 of the said rules, -

(i) in sub-rule (1),

(a) in clause (d), after the words "thickness except", the words "as specified by the Central Government" shall be inserted;

(b) in clause (h),-

(A) after the words "made up of compostable plastic", the words "and biodegradable plastics" shall be inserted;

(B) for the letters and figures "IS 17088:2008,", the letters and figures "IS/ISO 17088:2021" shall be substituted;

(C) after the words "seller of compostable plastic", the words "and biodegradable plastics" shall be inserted;

(ii) in sub-rule (3), after the words "compostable plastic", the words "and biodegradable plastics" shall be inserted.

4. In rule 9 of the said rules, -

(i) for sub-rule (1), the following sub-rule shall be substituted, namely:-

"(1) The Producers, Importers and Brand Owners shall fulfil Extended Producers Responsibility for Plastic Packaging as per guidelines specified in Schedule -II.";

(ii) in sub-rule (2), the portion beginning with the words "This plan of collection" and ending with the words "two years thereafter" shall be omitted;

(iii) in sub-rule (4), before the words "Pollution Control Board", the words, "Central Pollution Control Board and State" shall be inserted;

(iv) in sub-rule (5), -

(A) after the words "without registration from" the words "Central Pollution Control Board if operating in more than two states or Union territories," shall be inserted;

(B) after the words "Pollution Control Committees", the words, brackets and figures "as per sub-rule (2) of rule 13" shall be inserted.

5. For rule 10 of the said rules, the following rule shall be substituted, namely.-

"10. Protocols for compostable and biodegradable plastic materials.-

(1) Determination of the degree of degradability and degree of disintegration of plastic material shall be as per the protocols of the Indian Standards listed in Schedule I.

(2) The compostable plastic materials shall conform to the IS / ISO 17088:2021, as amended from time to time.

(3) The biodegradable plastics shall conform to the standard notified by the Bureau of Indian Standards and certified by the Central Pollution Control Board.

(4) Until a standard referred to in sub-rule (3) is notified by the Bureau of Indian Standards, biodegradable plastics shall conform to tentative Indian Standard IS 17899 T:2022 as notified by the Bureau of Indian Standards.

(5) As a transitory measure, provisional certificate for biodegradable plastics, shall be issued by the Central Pollution Control Board, in cases, where an interim test report is submitted, for an ongoing test, which covers the first component of the IS 17899 T:2022 relating to biodegradability given at Sl. No. (i) or Sl. No. (ii) of Table 1 or Sl. No. (i) of Table 2 of the IS 17899 T:2022:

Provided that the provisional certificate shall be valid till 30th June 2023 with the condition that production or import of biodegrdable plastics shall cease after the 31st day of March, 2023.

(6) The interim test report shall be obtained from the Central Institute of Petrochemical Engineering and Technology or a laboratory recognised under the Laboratory Recognition Scheme, 2020, of the Bureau of Indian Standards or laboratories accredited for this purpose by the National Accreditation Board for Testing and Calibration Laboratories, and they shall certify the bio-degradation of plastic is in line with IS 17899 T:2022.

6. In sub-rule (1) of rule 11 of the said rules,-

(i) for clause (a), the following clause shall be substituted, namely:-

"(a) name, registration number of the producer or brand owner and thickness in case of carry bag and plastic packaging :

Provided that this provision shall not be applicable,-

(i) for plastic packaging used for imported goods:

(ii) for cases falling under rule 26 of the Legal Metrology Packaged Commodities Rules, 2011, after the approval of the Central Pollution Control Board:

(iii) for cases where it is technically not feasible to print the requisite information mandated under this Rule, as per specifications given in the "Guidelines for use of Standard Mark and labelling requirements under BIS Compulsory Registration Scheme for Electronic and IT Products" after the approval of the Central Pollution Control Board.";

(ii) in clause (b), "with effect from the 1st January, 2023" for the word "manufacturer", the words "producer or brand owner" shall be substituted.

(iii) after clause (c), the following clause shall be inserted, namely:-

"(d) the importer or producer or brand owner of imported carry bags or multi-layered packaging or plastic packaging, alone or along with the products shall adhere to clause (a) and (b)."

7. In rule 12 of the said rules, in sub-rule (1), before the words, "State Pollution Control Board" the words, "Central Pollution Control Board or" shall be inserted.

8. In rule 13 of the said rules, -

(i) for sub-rule (1), the following sub-rule shall be substituted, namely:-

"(1) No person shall manufacture carry bags or recycle plastic bags or multilayered packaging unless the person has obtained registration from,-

(i) the concerned State Pollution Control Board or Pollution Control Committee of the Union territory, if operating in one or two states or Union territories; or

(ii) the Central Pollution Control Board, if operating in more than two States or Union territories.";

(ii) in sub-rule (2),-

(A) after the word "producer", the words "or importer" shall be inserted;

(B) after the words "make an application" , the words and figures "as per the guidelines specified in Schedule -II," shall be inserted;

(iii) in sub-rule (3), after the words "in Form II", the words and figures "as per the guidelines specified in Schedule –II" shall be inserted.

(iv) Sub-rule (6) shall be omitted;

(v) in sub-rule (7), after the words "terms of registration" occurring at the end, the words and figures "and the registration shall be subject to fulfilment of obligations in accordance with the guidelines on Extended Producer Responsibility for Plastic Packaging specified in Schedule -II." shall be inserted.

9. After rule 17 of the said rules, the following rule shall be inserted, namely:-

"18. Imposition of Environmental Compensation.- The Environmental Compensation shall be levied based upon polluter pays principle, on persons who are not complying with the provisions of these rules, as per guidelines notified by the Central Pollution Control Board.".

10. For Schedule I of the said rules, the following shall be substituted, namely:-

"SCHEDULE-I
[See rule 10]

(1)	(2)
1	IS / ISO 14851: 2019 Determination of the Ultimate Aerobic Biodegradability of Plastic Materials in an Aqueous Medium - method by measuring the Oxygen demand in a closed respirometer (First Revision)

(1)	(2)
2	IS / ISO 14852: 1999 Determination of the ultimate aerobic biodegradability of plastic materials in an aqueous medium - method by analysis of evolved Carbon dioxide
3	IS / ISO 14853: 2016 Plastics Determination of the ultimate anaerobic biodegradation of plastic materials in an aqueous system - method by measurement of biogas production (First Revision)
4	IS /ISO 14855-1: 2012 Determination of the ultimate aerobic biodegradability of plastic materials under controlled composting conditions - method by analysis of evolved Carbon dioxide: Part 1 General method (First Revision)
5	IS / ISO 14855-2: 2018 Determination of the ultimate aerobic biodegradability of plastic materials under controlled composting conditions - method by analysis of evolved carbon dioxide: Part 2 Gravimetric measurement of Carbon dioxide evolved in a laboratory- scale test (First Revision)
6	IS / ISO 15985: 2014 Plastics - Determination of the ultimate anaerobic biodegradation under high-solids anaerobic-digestion conditions - methods by analysis of released biogas (First Revision)
7	IS /ISO 16929: 2019 Plastics - Determination of the Degree of Disintegration of Plastic Materials under Defined Composting Conditions in a Pilot-Scale Test (Second Revision)
8	IS / ISO 17556: 2019 Plastics Determination of the Ultimate Aerobic Biodegradability of plastic materials in soil by measuring the Oxygen demand in a Respirometer or the amount of Carbon Dioxide Evolved (Second Revision)
9	IS / ISO 20200 : 2015 Plastics - Determination of degree of disintegration of plastic materials under simulated composting conditions in a laboratory - Scale test (First Revision)"

11. In the said rules, in Form I,-

(i) in the sub-heading "1. Producers", for serial number 11 and the entries relating thereto, the following shall be substituted, namely:-

"11.	Action plan in line with the guidelines specified in Schedule –II".	

(ii) in sub-heading "II Brand Owners", for serial number 9 and the entries relating thereto, the following shall be substituted, namely:-

"9.	Action plan in line with the guidelines specified in Schedule –II".	

(iii) after sub-heading "II. Brand Owners" and the entries relating thereto, the following shall be inserted, namely:-

"III- Importers

PART – A GENERAL		
1.	Name, Address and Contact number	
2.	In case of renewal, previous registration number and date of registration	
3.	Is the unit registered with the District Industries Centre of the State Government or Union Territory? If yes, attach a copy.	
4. (a)	Total capital invested on the project	
(b)	Year of commencement of production	
5. (a)	List and quantum of products and by-products	
(b)	List and quantum of raw materials used	
6 .(a)	Quantity of plastic sheet or like used for packaging of imported or to be imported products	
(b)	Quantity of plastic sheet or like used for packaging for further supply or self-use	
(c)	Quantity of multilayered packaging for further supply or self-use	

PART – B PERTAINING TO LIQUID EFFLUENT AND GASEOUS EMISSIONS		
7.	Does the unit have a valid consent under the Water (Prevention and control of Pollution) Act, 1974 (6 of 1974)? If yes, attach a copy	
8.	Does the unit have a valid consent under the Air (Prevention and Control of Pollution) Act, 1981 (14 of 1981)? If yes, attach a copy	

PART – C PERTAINING TO WASTE		
9.	Solid Wastes or rejects: (a) Total quantum of waste generated (b) Mode of storage within the plant (c) Provision made for disposal of wastes	
10. (a)	Attach or provide list of person supplying imported (i) plastic sheet or like used for packaging, (ii) multilayered packaging	
(b)	Quantity of imported (i) plastic sheet or like used for packaging along with the quantity used for further supply or self use, (ii) multilayered packaging along with the quantity used for further supply or self use	
11.	Action Plan in line with Guidelines specified in Schedule - II	
	Name and Signature Date : Place :". Designation	

12. In Form IV of the said rules, after serial number (9) and the entries thereto, the following shall be inserted, namely:-

"(10). Data to be provided as per guidelines specified in Schedule -II by 30th April of every year to the concerned State Pollution Control Board or Pollution Control Committee"

13. In Form VI of the said rules, after the table, the following note shall be inserted:-

"Note: The following informations shall be provided to the Central Pollution Control Board by 30th April of every year, namely:- (a) Manufacturer of carry bag, recycled plastic bag, multilayered packaging (Registered under clause (i) of sub-rule (1) of rule 13;

(b) Producer, Importer, Brand Owner (Registered under clause (i) of sub-rule (2) of rule 13; (c) Recycler and plastic waste processor (Registered under clause (i) of sub-rule (3) of rule 13".

14. Paragraph 3 of Schedule – II of the said rules shall be omitted. 15. In Schedule II of the said rules, for sub-paragraph (7.8), the following shall be substituted, namely:-

"(7.8) In case, the obligated entity utilizes plastic packaging made from biodegradable plastics, the provisions of rule 10 shall be applicable and the Extended Producer Responsibility target shall not be applicable."

F.No.17/24/2021-HSMD

Naresh Pal Gangwar, Addl. Secretary, Ministry of Environment, Forest and Climate Change, New Delhi.

Note : *The principal rules were published in the Gazette of India, vide number G.S.R.320(E), dated the 18th March, 2016 and subsequently amended vide notification number G.S.R.285(E), dated the 27th March, 2018, vide notification number G.S.R.571(E), dated the 12th August, 2021, vide notification number G.S.R.647(E), dated the 17th August, 2021 and last amended vide notification number G.S.R.133(E) , dated the 16th February 2022.*

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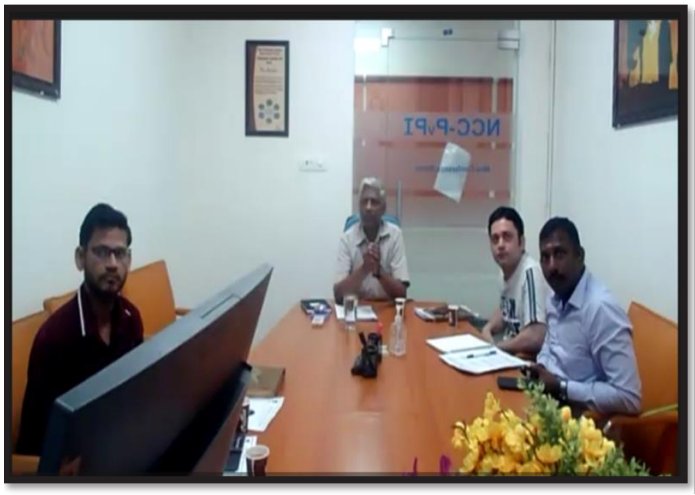
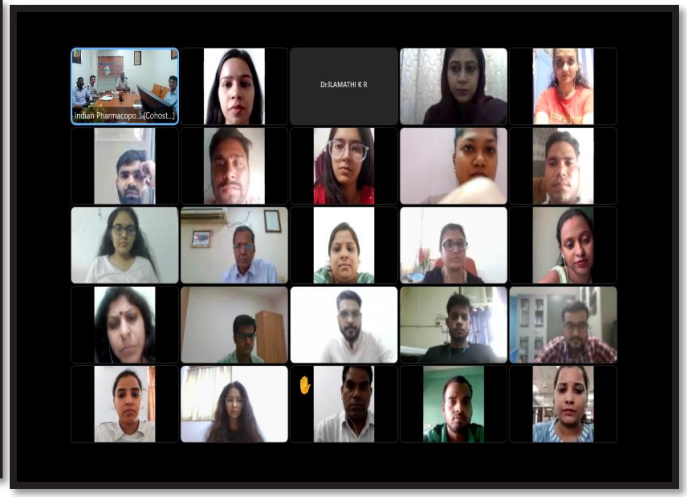
21st Skill Development Programme on Pharmacovigilance of Medical Products





The National Coordination Centre for Pharmacovigilance Programme of India (NCC-PvPI) located at Indian Pharmacopoeia Commission Ghaziabad, organized the 21st Skill Development Programme on Pharmacovigilance for Medical Products from 13th to 17th June, 2022 through virtual mode. The training started with welcome address by Dr. Jai Prakash, Officer-in-Charge, PvPI and extended his warm greetings and best wishes to all the participants on behalf of IPC.

A total of 120 registered participants from Andaman and Nicobar Islands, Andhra Pradesh, Assam, Chandigarh, Chhattisgarh, Gujarat, Himachal Pradesh, Karnataka, Kerala, Madhya Pradesh, Maharashtra, Odisha, Puducherry, Punjab, Tamil Nadu, Telangana, Uttar Pradesh, Uttarakhand, West Bengal participated in this training programme.The participants included Doctor (MD in Pharmacology), PhD scholar's, M Pharma Students, B Pharma Students across the country. Dr. Shashi Bhushan, Dr. R. S. Ray, Mr. Hammad Ali, Mr. Akash Deep Rawat, Mr. Girjesh Vishwakarma, Mr. Tarun Kumar from NCC PvPI supported during the workshop.

During the 5 days Skill Development Programme, 19 technical sessions were conducted on various topics of Pharmacovigilance including Basics of Pharmacovigilance to in-depth Signal detection method and Regulatory intervention/outcomes in an understandable language to the participants. All participants appreciated the Skill Development Programme.

*Note: Please visit IPC website (*www.ipc.gov.in*) for regular updates.*

SC Judgement regarding IGST on Ocean freight not required to be paid by the importer when the goods are imported on CIF basis

Dear Member,

IDMA have received below communication dated 13th June 2022 from Mr Vinay Kansara, Advocate & Consultant, GST, Customs, Central Excise & Service Tax on the above subject (Courtesy: Mr Yogin Majmudar). Same is reproduced below:

It is informed that recently, the Hon'ble Supreme Court in case of UOI Vs. Mohit Minerals Pvt. Ltd. reported in 2022-TIOL49-SC-GST-LB has held that the levy of IGST on ocean freight imposed on the 'service' aspect of the transaction is in violation of the principle of 'composite supply' enshrined under Section 2(30) read with Section 8 of the CGST Act. Since the Indian importer is liable to pay IGST on the 'composite supply', comprising of supply of goods and supply of services of transportation, insurance, etc. in a CIF contract, a separate levy on the Indian importer for the 'supply of services' by the shipping line would be in violation of Section 8 of the CGST Act.

In view of the ratio of the above referred judgement, it is now not required to pay IGST on Ocean freight when the goods are imported on CIF basis.

The gist of the judgement is given in the attached Circular.

Regarding the judgement/Order dated 19-05-2022 in case of Union of India Vs. M/s Mohit Minerals Pvt. Ltd. delivered by the Larger Bench of Hon'ble Supreme Court of India reported in 2022-TIOL-49-SC-GST-LB - Levy of IGST on Ocean freight.

The gist of the issue is as under.

1. Earlier, the Hon'ble High Court of Gujarat in case of Mohit Minerals Pvt. Ltd. Vs. UOI reported in 2020-TIOL-164-HC-AHM-GST has held that no tax is leviable under the IGST Act, 2017 on the ocean freight for the services provided by a person located in a non-taxable territory by way of transportation of goods by a vessel from a place outside India upto the customs station of clearance in India and the Notification No.8/2017–IT(Rate) and the Entry 10 of the Notification No.10/2017–IT(R) both dated 28-06-2017 **were declared as ultra vires the IGST Act, 2017 and unconstitutional as they lack legislative competency.**

2. The Government had preferred Appeal before the Hon'ble Supreme Court against the above referred judgement delivered by the High Court of Gujarat.

3. The Hon'ble Supreme Court while passing the Order dated 19-05-2022 has held as under.

(i) On a conjoint reading of Sections 2(11) [Meaning of 'Import of Service'] and 13(9) [The place of supply of transportation of goods shall be the place of destination of goods] of the IGST Act read with Section 2(93) [Meaning of 'recipient'] of the CGST Act, the import of goods by a CIF contract constitutes an "inter-state" supply which can be subject to IGST where the importer of such goods would be the recipient of shipping service.

(ii) **The impugned levy imposed on the 'service' aspect of the transaction is in violation of the principle of 'composite supply' enshrined under Section 2(30) [Meaning of 'Composite Supply'] read with Section 8 [prescribes the provisions of Tax liability on composite & mixed supplies] of the CGST Act. Since the Indian importer is liable to pay IGST on the 'composite supply', comprising of supply of goods and supply of services of transportation, insurance, etc. in a CIF contract, a separate levy on the Indian importer for the 'supply of services' by the shipping line would be in violation of Section 8 of the CGST Act.**

3.1 The Hon'ble Supreme Court has agreed with the views expressed by the High Court to the extent that a tax on the supply of a service, which has

already been included by the legislation as a tax on the composite supply of goods, cannot be allowed.

4. The contents of Sr. No. 3 are the conclusion arrived at by the Hon'ble Supreme Court **and in view thereof, IGST on Ocean freight is not required to be paid by the importer when the goods are imported on CIF basis**.

5. There is nothing specific in the said judgement about import of the goods on FOB basis and therefore in my view, IGST is to be paid on the Ocean freight when the goods are imported on FOB basis.

6. In view of the above, it is informed in terms of the ratio of the above referred judgement that **IGST on Ocean freight is not required to be paid by the importer when the goods are imported on CIF basis**.

The above views are based on the judgement delivered by the Larger bench of Supreme Court in case of UOI Vs. Mohit Minerals Pvt. Ltd.

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NATIONAL NEWS

Gujarat: Small firms want exclusion from trade margin rationalization

The Central government may soon introduce trade margin rationalization and the Gujarat pharmaceutical industry believes it will affect their market.

AHMEDABAD: The Central government may soon introduce trade margin rationalization and the Gujarat pharmaceutical industry believes it will affect their market.

The central government may bring down prices of widely used medicines by this move and fix margins for wholesalers, distributors and retailers in a phased manner. This will affect smaller companies significantly, because they have higher margins than marketing companies, wholesalers and retailers, as they do not spend on marketing on their own.

The department of pharmaceuticals and the National Pharmaceutical Pricing Authority are preparing a proposal for trade margin rationalization. It is expected that margin cap fixing will begin in cancer and some chronic diseases. Indian Drug Manufacturers' Association (IDMA) president Viranchi Shah said, "The government wants to fix trade margins to ensure customers do not pay very high prices compared to the prices wholesalers or retailers pay. This will bring down prices of medicines."

Trade margin is the difference between the price at which a manufacturer sells the product to a wholesaler or distributor and the price a consumer pays (MRP).

However, small companies say this move will hurt them because big companies do their marketing on their own and add that cost to their selling price to wholesalers, so their selling price is higher. Small Scale Indian Drug Manufacturers' Association (SSIDMA) secretary Atul Shah said, "There is a trade practice where small manufacturing companies give their stock to marketing companies or wholesalers at lower rates and all marketing expenses are done by marketing company or wholesaler. Small companies follow the Propaganda Cum Distribution (PCD) model. So, the retail price for both, the small and big company will remain the same."

Source: Parag Dave, TNN, 10.07.2022

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Diwali target for India-UK FTA possible but not definite, say experts after PM Johnson's exit

From an economic perspective as well, City of London Policy Chair Chris Hayward believes there will be a consistent focus on an enhanced India-UK partnership.

It is always good to have a deadline to work towards while negotiating a free trade agreement (FTA) but the Diwali target set for the India-UK FTA by the outgoing British Prime Minister Boris Johnson does not have to be

set in stone, according to strategic and industry experts here.

At the end of a week of monumental political turmoil which ended with Johnson announcing his resignation to make way for a new Prime Minister in a few months' time, the inevitable focus has been on what this means for India-UK bilateral ties generally and the historic FTA now in its fourth phase of negotiations more specifically.

While there is general consensus that there is unlikely to be any significant shift in foreign policy stance under a new Conservative Party incumbent at 10 Downing Street, a delay of a few months to the October deadline for the conclusion of a draft FTA may well be on the cards.

"India did some very quick deals with the UAE and Australia, in less than 90 days, but those are much lighter in content and comprehensiveness than what we are planning with the UK-India FTA," said Confederation of British Industry (CBI) President Lord Karan Bilimoria, who heads up the UK-India Industry Taskforce as a joint commission to enhance cross-industry collaboration on the ongoing trade negotiations.

"I would much rather have a more comprehensive deal that takes slightly longer to complete. It's good to have a deadline, good to have that target to try and finish by Diwali. But it may not be the end of October but the end of December; my target is the end of this year," said the Indian-origin businessman. Diwali falls on October 24 this year.

He warned of inevitable last-minute issues but remained "very optimistic" about completing a comprehensive pact within this year because of the reports of "good progress" in completing the estimated 26 chapters.

In New Delhi, an official said there are no immediate indications about the impact of the recent political developments in Britain on the advanced India-UK negotiations for a free trade agreement (FTA) which aims at further strengthening bilateral economic ties.

Getting a good, fair and equitable trade deal that would boost exports and create numerous jobs across India is the priority, the official said. When asked about meeting the deadline of concluding talks, the official said: "FTA negotiations are very complex area and they involve a lot of careful assessment of different elements of FTAs and we continue to do that in right earnest both sides and we will put in our best effort to meet these very challenging deadlines".

According to the latest UK Department for International Relations (DIT) statistics, India-UK total trade in goods and services stands at GBP 24.3 billion – with UK exports to India amounting to GBP 8.4 billion and UK imports from India at GBP 15.9 billion.

The target set under the Johnson-Modi Roadmap is to at least double those figures by 2030, with experts of the view that an FTA could take those trade figures even higher.

"Boris Johnson's prime ministership saw an unprecedented political commitment towards boosting ties with India, reciprocated by Prime Minister Narendra Modi," said Rahul Roy-Chaudhury, Senior Fellow for South Asia at the London-based International Institute for Strategic Studies (IISS) think tank.

"While Johnson firmly laid the direction of travel with India, he leaves before the pace of travel has been determined... [and] with Johnson as a caretaker Prime Minister, it remains to be seen how effectively he can conclude a landmark bilateral FTA by October, to be signed by his successor, and whether a much-needed legacy defence technology cooperation can be achieved," he said.

On the legacy of Boris Johnson's nearly three-year term in office, the overwhelming view is that he would leave behind a very strong India-friendly foreign policy focus and little would change in terms of the focus on strengthening relations with India and the wider Indo-Pacific region. (File photo)

Gareth Price, Senior Research Fellow, Asia-Pacific Programme, at the UK-based international affairs think tank Chatham House, said that FTAs by their very nature take a lot of time to negotiate and an obsession with the deadline should not result in a diluted enhanced trade partnership.

"It's just a sort of gut reaction that it's good to have a deadline but I wouldn't bet a lot of money that it would

definitely be met. With the upheaval in the UK, if there are concessions to be made it would be interesting to see whether they can be agreed in that timeframe," said Price.

On the legacy of Boris Johnson's nearly three-year term in office, the overwhelming view is that he would leave behind a very strong India-friendly foreign policy focus and little would change in terms of the focus on strengthening relations with India and the wider Indo-Pacific region.

"There's no question about his love for India. India has been a priority country to him, demonstrated by the launch of the FTA talks… This is such a special centuries-old relationship, which will only strengthen further," said Bilimoria.

"The focus on India was in part a function of Boris Johnson-led government moving away from Europe and so probably whoever succeeds him is going to have similar views. But if it's someone more focused on rebuilding the relationship with Europe, then by default there will be less bandwidth for a focus on India and other countries," reflected Gareth Price.

Anand Menon, professor of European Politics and Foreign Affairs at King's College London and director of the think tank UK in a Changing Europe, does not foresee any significant shift in the UK's Europe stance that could impact its Indo-Pacific focus.

"I don't see much change in foreign policy post-Johnson. I think the biggest legacy that Boris Johnson has on British politics in general is Brexit, which has forced the UK to be more active in foreign policy," said Menon.

"We had Brexit so therefore we had Global Britain and a far more activist British diplomacy than we have had for a long time. That message won't change at all… In a way because foreign policy is such a low priority that no successor is going to spend political energy re-doing it," he said.

From an economic perspective as well, City of London Policy Chair Chris Hayward believes there will be a consistent focus on an enhanced India-UK partnership. "The next Conservative Prime Minister will build upon that work and continue to strengthen our ties with India. It is an incredibly important market to the UK, we would urge that we continue to build on the legacy," said Hayward, who is planning a visit to Mumbai for high-level talks next week.

Source: PTI, 10.07.2022

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Generic drug companies in no hurry to launch new Covid products

After taking progressive measures in the last two years, Indian generic drugmakers are going slow in investing further on Covid-related products as the momentum begins to shift to other therapies, some pharmaceutical industry executives told ET.

Dharmesh Shah, managing director of BDR Pharmaceuticals, said his company is not in a hurry to launch anything related to Covid-19 as cases begin to ebb.

India on Tuesday witnessed a dip in the daily Covid-19 cases as the country reported 13,615 new cases in 24 hours, down from 16,678 cases on Monday.

BDR Pharmaceuticals, a Mumbai-based active pharmaceutical ingredient (API) manufacturing company, has developed the API of antiviral pill Paxlovid and can manufacture the drug but it has decided to wait and watch, Shah said. "We will see if there is any need in the country to launch it," he told ET. "At present, cases are mild and are recovering with the conventional treatment."

BDR Pharmaceuticals was one of the first Indian companies to produce Remdesivir- used to treat Covid-19 in hospitalised patients.

However, Shah said, tonnes of material of antiviral pill molnupiravir got wasted.

"Therefore, we are not in a hurry to launch products," he said. "We are evaluating the situation and will jump only if there is any emergency or in case the country sees a surge." Mankind Pharmaceuticals executive chairman RC Juneja, too, said the company is treading carefully as it has already incurred losses and will have to destroy a lot of products that are nearing expiry. "We have, therefore, decided not to invest further in Covid-related therapies or products unless there is any high demand," Juneja said.

Source: Economic Times, 13.07.2022

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Creation of IPD augurs well for pharma industry

Intellectual Property Rights Division (IPD) rules, 2022, recently notified by Delhi High Court will speed up resolution of IPR cases

In what can be a big relief to the pharmaceutical industry in the country, the Delhi High Court has recently

notified the Intellectual Property Rights Division Rules, 2022, which will replace the erstwhile Intellectual Property Appellate Board (IPAB). Certainly, the creation of Intellectual Property Division (IPD) in the High Court will be a big relief to the pharmaceutical companies in the country which have been looking for an appellate court to resolve their grievances in the Intellectual Property-related disputes.

The IPD will deal with Intellectual Property Right (IPR) matters except cases dealt with by the Division Bench of the Delhi High Court. The statutes under the Copyright Act, 1957; The Designs Act, 2000; The Geographical Indications of Goods (Registration and Protection) Act, 1999; The Information Technology Act, 2000; The Patents Act, 1970; The Protection of Plant Varieties and Farmers' Rights Act, 2001; The Semiconductor Integrated Circuits Layout-Design Act, 2000; and The Trade Marks Act, 1999 are applicable to the new rules. The division will be presided over by Single Judge to deal with disputes and cases concerning Intellectual Property Rights subject matter. Every IPR subject matter or case or proceeding or dispute filed before, or transferred to, the IPD shall be heard and adjudicated by a Single Judge of the Division except those that are to be decided by a Division Bench as per Section 13 of the Commercial Courts Act, 2015.

The Chennai-headquartered IPAB, which was the appellate board for the IPR related disputes in the country, was abolished in 2021 following the Tribunals Reforms (Rationalisation and Conditions of Service) Ordinance, 2021 ('Ordinance'), which is now the Tribunal Reforms Act, 2021. Proposals earlier to relocate the principal office of the IPAB from Chennai resulted in protest from various corners. Now, with the creation of IPD, the cases which will be dealt with by the IPD include all original proceedings, appellate and other proceedings related to IPR including revocation applications, cancellation applications, other original proceedings, appeals and petitions from the various Intellectual Property Offices (IPOs) and all other proceedings which were so far maintainable before the IPAB. All pending proceedings before the IPAB relating to Delhi jurisdiction transferred to the Delhi High Court will also be doing under its jurisdiction.

Of course, the setting up of IPD by the Delhi High Court to deal with IPR disputes augurs well for the pharmaceutical industry as it is an encouraging step taken towards efficient disposal of patent litigations. It is of much significance as there has been a gradual rise in patent litigation in the pharmaceutical sector over the years. The surge in pharma patent litigation in the country is attributed to the amendment introduced to the Patents Act, to bring it in line with Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). In 2005, India introduced product patents for pharmaceuticals due to its commitment under TRIPS. The Indian Patent Office started issuing product patents in 2009. As a result, the innovator foreign drug companies started filing infringement suits against domestic pharmaceutical companies, which led to a rise in patent litigation in the pharmaceutical sector.

The Delhi High Court has been the busiest with patent litigation followed by the Bombay High Court and the Madras High Court. The creation of IPD in the Delhi High Court is a significant step which is in line with global practices in this regard. Such IP Divisions or IP courts, which exclusively deal with IPR matters, already exist in UK, Japan, Malaysia, Thailand and China and the creation of IPD with comprehensive rules governing IPR matters, is a right step taken towards efficient disposal of all cases pertaining to patents in the country. More significantly, at any stage in a proceeding, the Court can constitute a confidentiality club or adopt such measures as appropriate, consisting of lawyers (external and in-house), experts as also nominated representatives of the parties, for the preservation and exchange of confidential information filed before the court including documents, as per the Delhi High Court (Original Side) Rules, 2018. The court can, in any IPR subject matter, also seek assistance of experts (including individuals and institutions) relating to the subject matter of the dispute as may be necessary. The IPD may maintain a panel of experts to assist the court and which panel may be reviewed from time to time. Overall, the creation of Intellectual Property Division with comprehensive, dedicated rules will not only streamline the proceedings, but will also have a significant impact on the jurisprudence surrounding intellectual property in the country.

Source: Sreeja Ramesh, Bizz Buzz, 11.07.2022

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Centre to slash prices of critical drugs for diabetes, heart, kidney diseases

The Central government is planning to bring down the prices of critical drugs by fixing trade margins, said sources in the health ministry.

The move is expected to be announced soon where trade margin will be rationalised in a phased manner as it enables better execution and gives time to the industry to accommodate changes

The difference between the price to trade for manufacturers and the price to patients as the maximum retail price (MRP) is referred to as price margin.

According to a top official in the ministry of health and family welfare, the Centre is making efforts are to reduce prices of drugs used for the treatment of diabetes, cardiovascular diseases, and chronic kidney diseases.

Stating that the move is expected to be announced soon, the sources said that trade margin will be rationalised in a phased manner as it enables better execution and gives time to the industry to accommodate changes.

Sources explained that as the margins in the anti-cancer category were slashed earlier, similarly, the slashing of the trade margins of a particular category of drugs such as anti-diabetic or for kidney diseases will be announced this time.

Drug price watchdog National Pharmaceutical Pricing Authority (NPPA) has been working on the plan for the past several months.

In 2018-19, the NPPA had put a cap on trade margins of 42 select non-scheduled anti-cancer medicines. Union health minister Mansukh Mandaviya had said in the Lok Sabha that the move resulted in reduction of up to 90% of the MRP of 526 brands of these medicines.

This time, the source said, NPPA has conducted a study and the rationalisation will be based on the inputs from the same.

According to the study on TMR analysis conducted by NPPA, a trader's margin moves higher with the price of a tablet. The NPPA found that if a tablet is priced up to ₹2, in the majority of the brands, the margin is up to 50%; whereas if its cost is between ₹15 and ₹25, the margin is less than 40%. At least 2.97% of the medicines in the ₹50-100 per tablet category have trade margins between 50% and 100%, 1.25% in the category have margins between 100% and 200%, and 2.41% have margins between 200% and 500%.

As per the NPPA study, 8% have margins around 200% to 500%, 2.7% have margins around 500-1000%, and 1.48% have more than 1000% margins, in the case of medicines priced above ₹100 per tablet, considered the costliest category.

Source: Mint, 08.07.2022

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Draft drugs, medical devices and cosmetics bill released for feedback

The Centre has proposed separate technical advisory boards for drugs and medical devices

The bill proposes new definitions for clinical trial, over-the-counter drugs, manufacturers, medical devices, new drugs, bioavailability study, investigational new drug and imported spurious drugs, among others

NEW DELHI: The health ministry plans to replace the Drugs and Cosmetics Act of 1940 with an updated law laying down strict regulatory guidelines to keep pace with changing needs and technology.

Given the need to have comprehensive legislation, a committee was constituted for framing the drugs, medical devices and cosmetics bill, 2022 which was released on 8 July for stakeholders to give their suggestions.

The bill proposes new definitions for clinical trial, over-the-counter drugs, manufacturers, medical devices, new drugs, bioavailability study, investigational new drug and imported spurious drugs, among others.

It seeks to bring in regulation for online pharmacies and medical devices and penalties such as imprisonment and compensation in case of injury or death during clinical trials for drugs.

"In the light of the recommendation of the Central government and the felt need to have a comprehensive legislation, a committee was constituted for framing the Drugs, Medical Devices, and Cosmetic Bill. The work of review and updating of Drugs and Cosmetic Rules 1945 was taken up from 2016," the government said in a document seen by Mint. No clinical trial can be carried out without permission, medical management and compensation for injury or death, the draft proposes. "No person shall himself or by any other person on his behalf sell, or stock or exhibit or offer for sale or distribute any drug by online mode (e-pharmacy) except under and in accordance with a licence or permission issued in such manner as may be prescribed," the draft says. The government has proposed empowering the Drugs Control Officer with prior approval of the controlling authority to enter into any premises related to clinical trial to inspect the facilities, record, data, documents, books and drugs.

The Centre has proposed a separate Drugs Technical Advisory Board (DTAB) and Medical Devices Technical Advisory Board (MDTAB) to give suggestions to the government from time to time.

The draft proposes to allow the Centre to waive the requirement of conducting clinical investigation for manufacture or import of a new medical device in public interest.

"We are studying the draft and seeking comments from our members. We are disappointed that the aspirations of a separate Act for medical devices have not been addressed and budding entrepreneurs and startups, developers and engineers will still need to grapple with a complex joint law. The medical devices have a huge potential of investment of more than ₹50,000 crore to meet the market of more than ₹1 trillion. Once we study the fine print, we will be in a better position to comment on the efforts of the health ministry in drafting this bill," said Rajiv Nath, forum coordinator, Association of Indian Medical Device Industry. The Bill includes a chapter on Ayurveda, Siddha, Sowa-Rigpa, Unani and Homeopathy, and their respective Drug Technical Advisory Boards.

Source: Mint, 11.07.2022

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LICENCE NO. MR/Tech/WPP-337/West/2021-23
RNI REGN. NO. 18921/1970, REGN.NO.MCW/95/2021-23
Published and Posted on 7th, 14th, 21st and 30th of every month
This issue posted at Mumbai Patrika Channel Sorting Office on 14.07.2022

Edited, Printed and Published by **Dr.Gopakumar G. Nair** on behalf of **Indian Drug Manufacturers' Association**, Printed at **Ebenezer Printing House**, Unit No. 5 & 11, 2nd Floor, Hind Services Industries, Veer Savarkar Marg, Dadar (West), Mumbai 400 028 and Published from 102-B, Poonam Chambers, "A" Wing, 1st Floor, Dr. A. B. Road, Worli, Mumbai 400 018. Editor: **Dr.Gopakumar G. Nair.**