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IDMA BULLETIN

VOL. NO. 53 | ISSUE NO. 27 (PAGES: 40) | 15 TO 21 JULY 2022 | ISSN 0970-6054 | WEEKLY PUBLICATION

INDIAN PHARMA - GLOBAL HEALTH CARE

INDIAN DRUG MANUFACTURERS' ASSOCIATION

UPDATED ADVANCED PROGRAM IN PHARMACEUTICAL QUALITY MANAGEMENT

ENCOMPASSING ICH, WHO, FDA AND QUALITY 4.0 REQUIREMENTS AND BEST INDUSTRY PRACTICES – VIRTUAL DELIVERY

(Details on Page No. 4)

IDMA and Aptar Pharma Webinar on

"Innovation and Differentiation in Dermal Drug Delivery System"

On Thursday, 28th July 2022 from 4:00 to 5:30 PM

(Details on Page No. 13)

HIGHLIGHTS

UNWAVERING ATTENTION TO DETAIL. FOR ABSOLUTE **PRECISION.**

Dear Partner,

We are firm believers in partnering with those who make us stronger and add value to our customers. Partners such as Tereos and Biogrund who allow us to provide for even the most highly technical and specialised needs, with perfect precision.

Tereos is one of the world's leading sucrose producers, with expert products that allow for a wide variety of pharmaceutical applications. Over the last two decades, Biogrund has built itself as the specialists in top-quality solutions for oral dosage forms, such as film coating, tableting and colouration.

Together, we ensure that customers get exactly what they want, when they want it.

Signet-ure *Precision*

Tereos

COMPRESSUC (Directly Compressible Sucrose)
ICING SUGAR (Milled Sucrose)
CASTER SUGAR (Screened Sucrose)
ALVEOSUCRE (Agglomerated Sucrose)

BIOGRUND

AQUAPOLISH (Film Coating Systems)
HME CLEANER PLUS (Cleaning Agent for Hot Melt Extrusion)
BONUWAX (Ready-to-use Waxes)
ISUPOLISH (Sugar & Sugar-free Coating Systems)

Signet

The Complete Excipients Company

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Indian Drug Manufacturers' Association
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IDMA BULLETIN

Vol. No. 53 **Issue No. 27** **15 to 21 July 2022**

IDMA ACTIVITIES:

MPCB MATTERS:

MoEFCC MATTERS:

FEATURE:

PARLIAMENT NEWS:

NATIONAL NEWS:

Dear Member,

APPQM - EXECUTIVE PROGRAM IN PHARMACEUTICAL QUALITY MANAGEMENT

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

APPQM+ Series 3 Commences 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

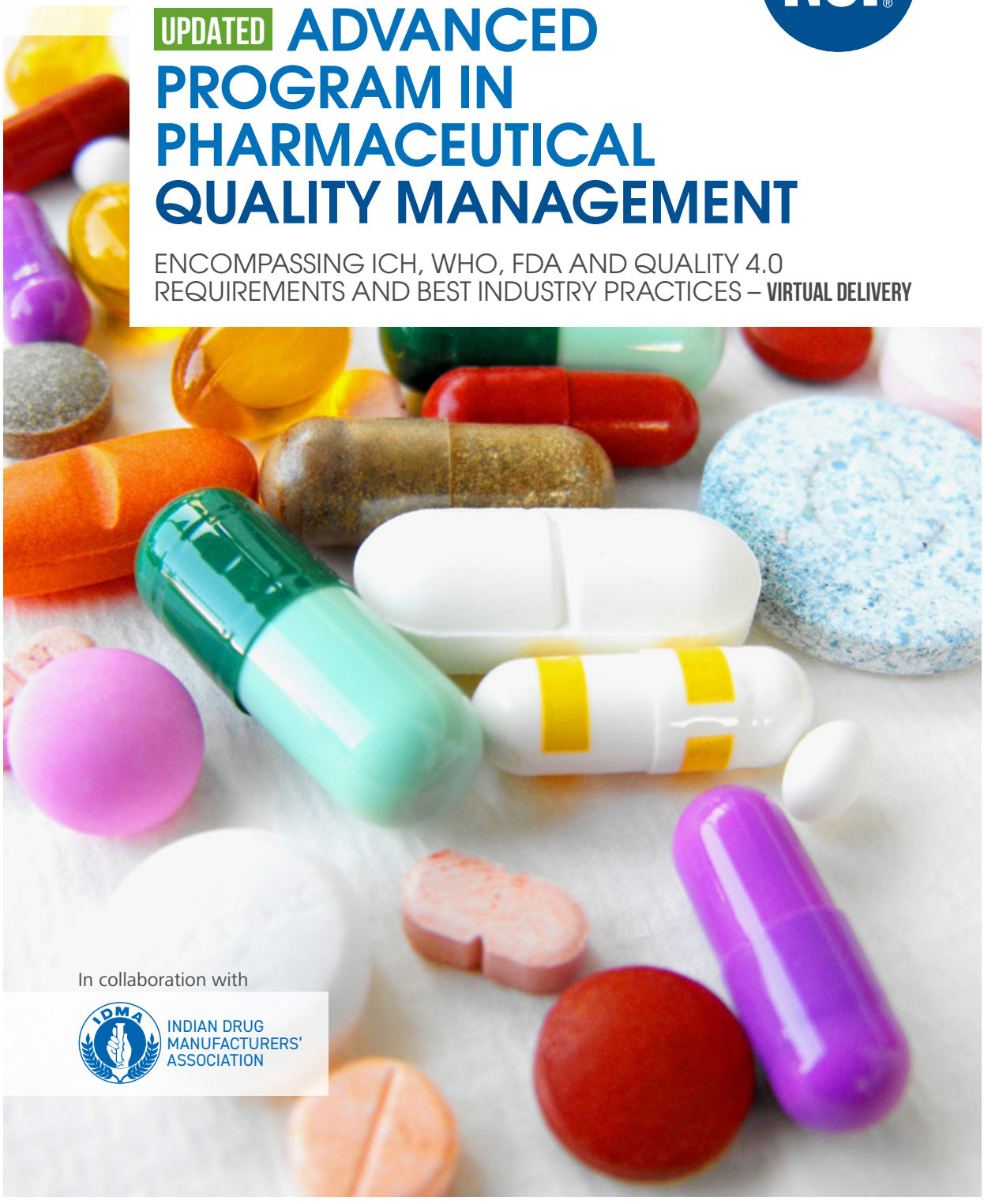
Melvin	**Batul**
actadm@idmaindia.com	technical@idmaindia.com
9821868758	9920045226

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

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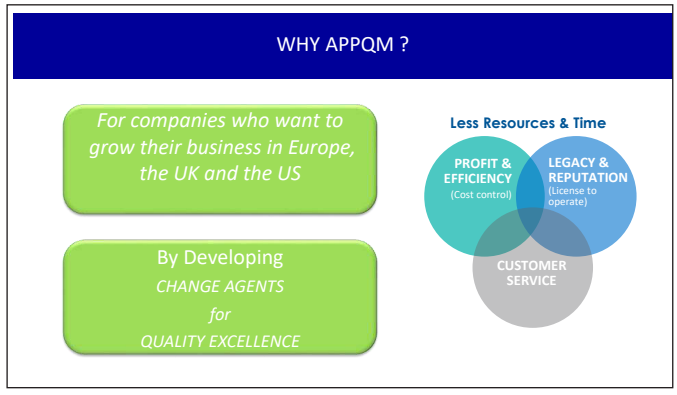
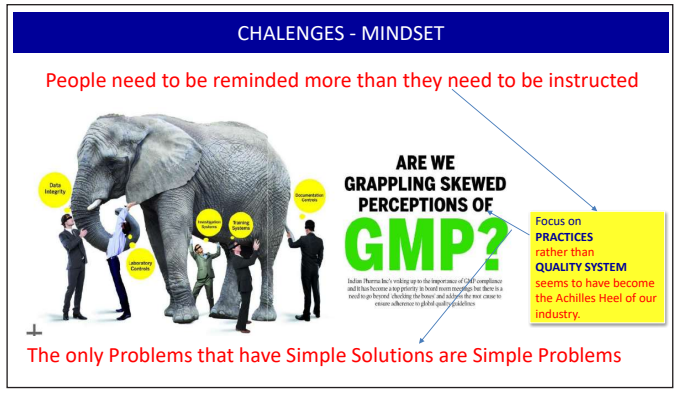
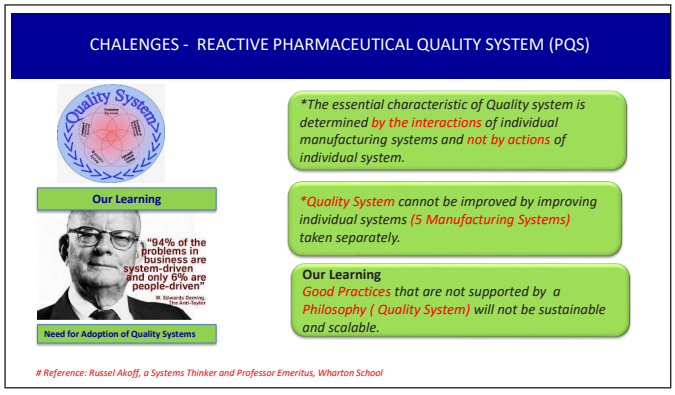
PRESENTATION

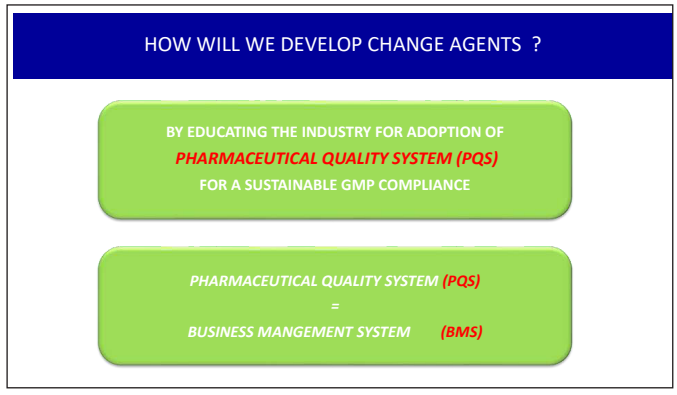
Launch of APPQM Series 3

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.

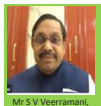
APPQM SERIES 2 VALEDICTORY – APPRECIATION FROM DIGNITARIES

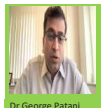

APPQM will help build the quality culture in Indian Pharma Industry
Dr V G Somani, DCGI


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

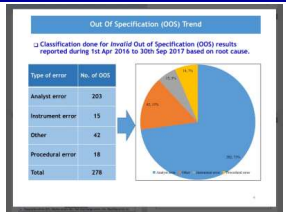

Virtual APPQM Program will be a boon for saving Time, Travel & Cost and yet deliver the same quality education
Dr. Viranchi Shah- National President -IDMA


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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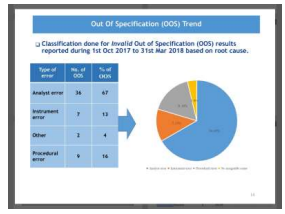

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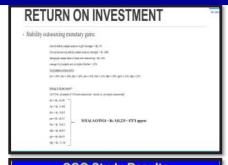
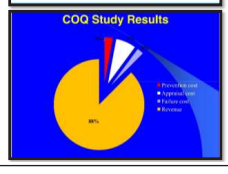
TOTAL SAVING OF Rs. 5 Cr.

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

INDIAN DRUG MANUFACTURERS' ASSOCIATION (IDMA)
102, Poonam Chambers, A Wing, 1st Floor, Dr. Annie Besant Road,
Worli, Mumbai - 400 018. Maharashtra, India.
Tel: +91-22-24974308 / 24944624 E-mail: actadm@idmaindia.com / Website: www.idma-assn.org

Dear Member,

Indian Drug Manufacturers' Association (IDMA) and Aptar Pharma is organizing a Webinar on **"Innovation and Differentiation in Dermal Drug Delivery System"** On **Thursday, 28th July 2022 from 4:00 to 5:30 PM.**

The Moderator of the Webinar : Mr. S R Vaidya, Chairman, MSME Committee, IDMA

Following speakers shall be presenting the webinar:

Dr. Stefan Hellbardt - Vice President, Business Development and Scientific Affairs CHC.

Mr. Marcus Bates - Vice President, Global Business Development, Aptar Digital Health.

Ms. Katja Bertsche - Product Manager CHC, Aptar Villingen, Germany.

Kindly note that there are no registration fees for this webinar but prior registration is compulsory.

Here is your Registration link

REGISTER NOW

Link: https://teams.microsoft.com/registration/PkrXX3rVDkGNfALE3wYiNA,M8Y2FUhaNEmpIW5AtPPojg,H699HZJvpke-twCuPK6LVQ,zULQRW4600Knki5gnKm5VQ,wqNk-gd6oUim7rPOU026pQ,FQFrPt9hM0-UNj6DitPOxg?mode=read&tenantId=5fd74a3e-d57a-410e-8d7c-02c4df062234

Looking forward to your support and participation in making this webinar a grand success.

Thanks & regards,

Daara B Patel *Secretary – General* **Indian Drug Manufacturers' Association** 102, A Wing, Poonam Chamber, Dr.A.B.Road, Worli, Mumbai-400018. Maharashtra. India. Tel No. 022 24974308 / 24944624 Website: www.idma-assn.org	**Prachi Singhai** *Manager-Marketing & Communication, India & S E Asia* **Aptar Pharma** R-854, TTC Industrial Estate, Thane Belapur Road, Rabale, Mumbai, Maharashtra 400701 India (phone) +91 22 6195 1946 I (mobile) 00 91 9892026098 prachi.singhai@aptar.com/ www.aptar.com

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BIRAC has nurtured an ecosystem covering Tier 2 and Tier 3 cities across the country to benefit society till the last mile.

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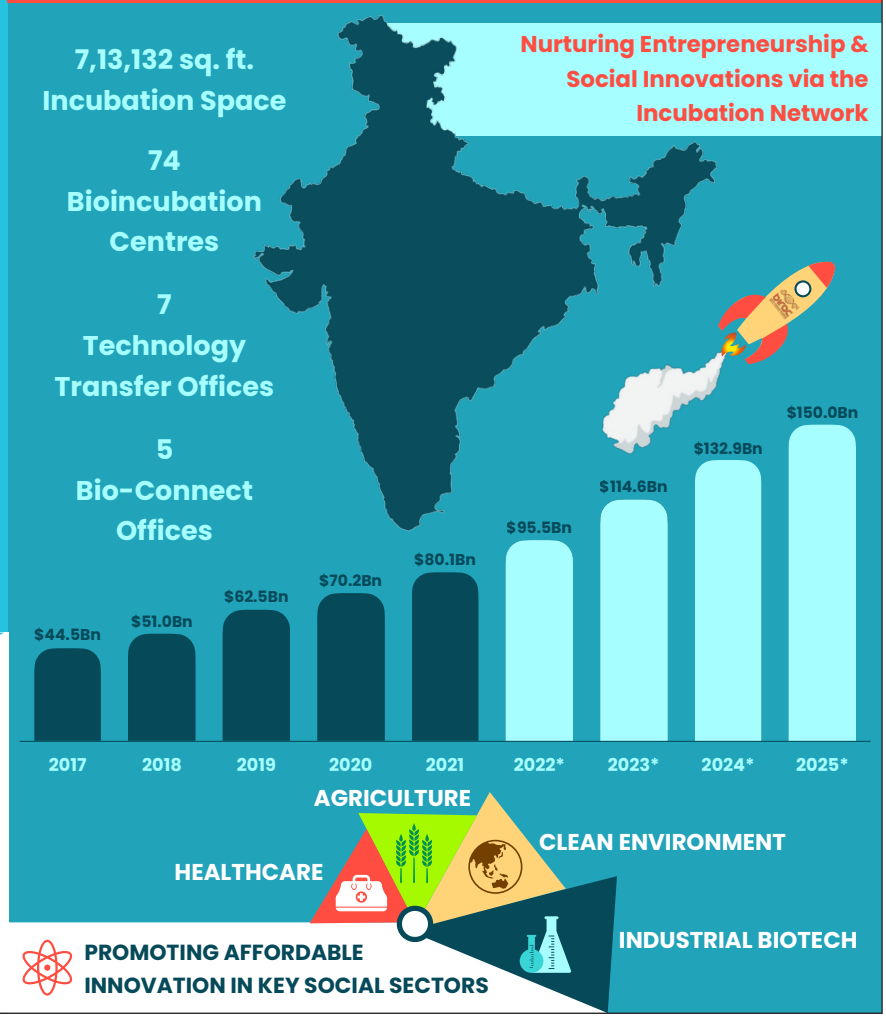
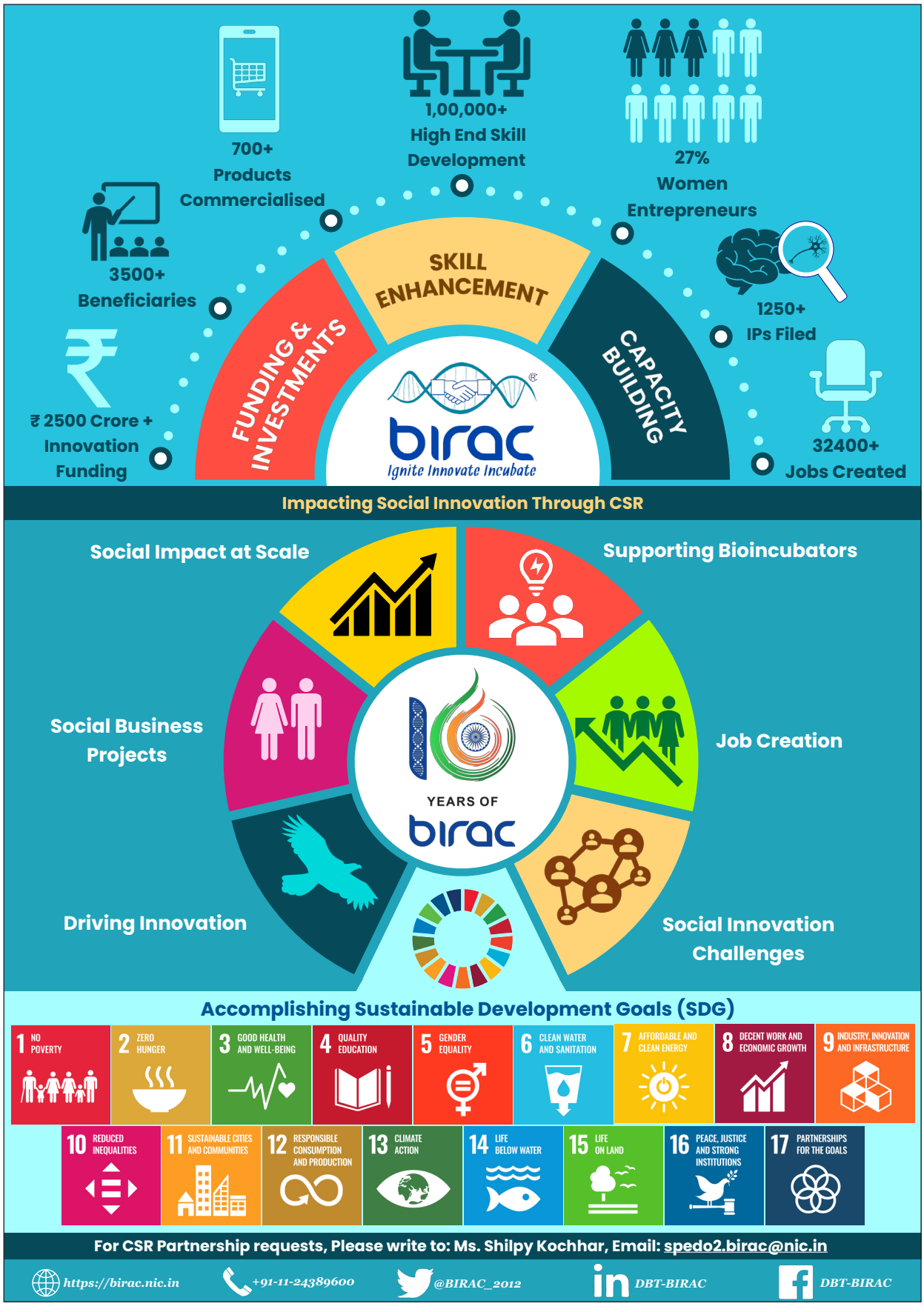
BIRAC: Creating A Cascading Multiplier Effect On The Indian Bioeconomy




700+
Products
Commercialised
1,00,000+
High End Skill
Development
27%
Women
Entrepreneurs
3500+
Beneficiaries
SKILL
ENHANCEMENT
FUNDING &
INVESTMENTS
CAPACITY
BUILDING
1250+
IPs Filed
₹ 2500 Crore +
Innovation
Funding
32400+
Jobs Created
birac
Ignite Innovate Incubate
Impacting Social Innovation Through CSR
Social Impact at Scale
Supporting Bioincubators
Social Business
Projects
Job Creation
YEARS OF
birac
Driving Innovation
Social Innovation
Challenges
Accomplishing Sustainable Development Goals (SDG)
1 NO POVERTY
2 ZERO HUNGER
3 GOOD HEALTH AND WELL-BEING
4 QUALITY EDUCATION
5 GENDER EQUALITY
6 CLEAN WATER AND SANITATION
7 AFFORDABLE AND CLEAN ENERGY
8 DECENT WORK AND ECONOMIC GROWTH
9 INDUSTRY, INNOVATION AND INFRASTRUCTURE
10 REDUCED INEQUALITIES
11 SUSTAINABLE CITIES AND COMMUNITIES
12 RESPONSIBLE CONSUMPTION AND PRODUCTION
13 CLIMATE ACTION
14 LIFE BELOW WATER
15 LIFE ON LAND
16 PEACE, JUSTICE AND STRONG INSTITUTIONS
17 PARTNERSHIPS FOR THE GOALS
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Provision of penal fees for occupiers violating combine consent regime prescribed under Air/Water Act - reg.

No. BO/MPCB/AS(T)/Circular/B- 220712FTS0047, dated 12th July 2022

It is mandatory on the part of industries/entrepreneurs to obtain Consent to Establish and Operate under section 25/26 of the Water (Prevention & Control of Pollution Act) 1974, under section 21 of Air (Prevention & Control of Pollution) Act 1981 and Authorization under Hazardous & Other Waste (Management & Transboundary Movement) Rule 2016. However, it has been noticed that, often industries were found to be violating the aforesaid provisions and the violations noticed are as below:

1. To take effective steps towards establishment of project/unit without obtaining Consent to Establish from the Board
2. To take effective steps without revalidating Consent to Establish from the Board.
3. To start Commercial production/to hand over Occupancy without obtaining Consent to Operate from the Board
4. To carry out expansion activity and applying directly for Consent to Operate without obtaining Consent to Establish of the Board.
5. To operate the activity without valid consent to operate of the Board and applying after lapse of validity period.
6. To store and disposal of Hazardous Waste not consistent with provisions of rules

The MPC Board has published Enforcement Policy for issuance of directions on account of degree of violation by imposing/forfeiting proportionate Bank Guarantee. The matter of such violations was discussed during Consent Appraisal Committee/Consent Committee and was decided to formulate the deterrent policy towards above mentioned other violations. Hence, it is important to discourage the defaulting industries by adopting "Polluter Pays" principal by imposing appropriate cost for violation of provisions of Environment enactments.

The MPC Board in its 178th Board meeting held on 24/02/2022 vide item No. 12 has considered to impose appropriate penal fees towards violation of Environmental enactments, the penal fees shall be imposed as below:

Sr. No.	Violation	Cost of Violation
01	Taking effective steps towards establishment of project/unit prior to obtain Consent to Establish from the Board	**Red Category:** 5 times of one term consent fee X no. of years of violation*
02	Taking effective steps without revalidating Consent to Establish of the Board.	
03	**Industry:** Starting Commercial production prior to obtain to Operate of the Board.	**Orange Category:** 3 times of one term Consent fee X no. of years of violation*
	Infrastructure Project: Handing over possession prior to obtaining Consent to Operate of the Board and Occupancy certificate from Local Body.	
04	Operating the industry/ activity without valid consent to operate of the Board and applying after lapse of validity period.	**Green Category:** 1 time of one term consent fee X no. of years of violation*

*** Calculations of number of years shall be calculated on the basis of number of days of non-compliance.**

The penal fees amount to be paid by PP through online e-payment gateway.

All the Officers of the Board should implement this circular scrupulously without fail.

Ashok Shingare, IAS, Member Secretary, MPCB, Kalpataru Point, 2nd - 4th Floor Opp. Cine Planet Cinema, Near Sion Circle, Sion (E) Mumbai-400 022.

An Area around the boundary of the six states, namely, Gujarat, Maharashtra, Goa, Karnataka, Kerala, and Tamil Nadu, as the Western Ghats Ecologically Sensitive Area notified - reg.

Environment Notification S.O.3072(E), dated 06th July 2022

1. The following draft of the notification, which the Central Government proposes to issue in exercise of the powers conferred by section 3 of the Environment (Protection) Act, 1986 (29 of 1986) is hereby published, in supersession of the notification of the Government of India, Ministry of Environment, Forest and Climate Change published in Gazette of India, Extraordinary, Part II, Section 3, Sub-Section (ii) vide notification number S.O. 5135(E), dated the 3rd October, 2018, as except as respects things done or omitted to be done before such supersession, as required by sub-rule (3) of rule 5 of the Environment (Protection) Rules, 1986, for the infomiation of the public likely to be affected thereby; and notice is hereby given that the said draft notification shall be taken into consideration on or after the expiry of a period of sixty days from the date on which copies of the Gazette of India containing this notification are made available to the Public;

   Any person interested in making any objections or suggestions on the proposals contained in the draft notification may forward the same in writing, for consideration of the Central Government within the period so specified to the Secretary, Ministry of Environment, Forests and Climate Change, Indira Paryavaran Bhawan, CGO Complex, Jor bagh Road, Ali Ganj, New Delhi-110003, or at e-mail address: esz-mef@nic in.

Draft notification

WHEREAS, Western Ghats is an important geological landform on the fringe of the west coast of India and it is the origin of Godavari, Krishna, Cauvery and a number of other rivers and extends over a distance of approximately 1500kilometre from Tapti river in the north to Kanyakumari in the south with an average elevation of more than 600 metre and traverses through six States namely, Gujarat, Maharashtra, Goa, Karnataka, Kerala and Tamil Nadu;

AND WHEREAS, Western Ghats is a global biodiversity hotspot and a treasure trove of biological diversity and it harbours many endemic species of flowering plants, endemic fishes, amphibians, reptiles, birds, mammals and invertebrates and is also an important center of evolution of economically important domesticated plant species such as pepper, cardamom, cinnamom, mango and jackfruit;

AND WHEREAS, Western Ghats has many unique habitats which are home to a variety of endemic species of flora and fauna such as Myristica swamps, the flat-topped lateritic plateaus, the Sholas and wetland and riverine ecosystems;

AND WHEREAS, UNESCO has included certain identified parts of Western Ghats in the UNESCO World Natural Heritage List because Western Ghats is a Centre of origin of many species as also home for rich endemic biodiversity and hence a cradle for biological evolution;

AND WHEREAS, the Western Ghats not only harbour rich biodiversity, but also support a population of approximately fifty million people and include areas of high human population density and therefore, there is a need to conserve and protect the unique biodiversity of Western Ghats while allowing for sustainable and inclusive development of the region;

AND WHEREAS, the Ministry constituted a High Level Working Group to study the ecology, environmental integrity and holistic development of the Western Ghats in view of their rich and unique biodiversity and it was also tasked

with the mandate to take a holistic view of the issue and to bring synergy between protection of environment and biodiversity and needs and aspirations of the local and indigenous people, sustainable development and environmental integrity of the region and to suggest steps and way forward to prevent further degradation of the fragile ecology of the Western Ghats;

AND WHEREAS, the High Level Working Group had since submitted its report to the Ministry on the 15th April, 2013 which was kept in the public domain seeking comments/views of concerned stakeholders and was also sent to the concerned six State Governments of the Western Ghats region namely, Gujarat, Maharashtra, Goa, Karnataka, Kerala and Tamil Nadu for their considered comments/views on the report;

AND WHEREAS, the High Level Working Group has identified approximately thirty-seven percent the Western Ghats as ecologically sensitive which covers an area of 59,940 square kilometer of natural landscape of Western Ghats and represents a continuous band of natural vegetation extending over a horizontal distance if 1,500 kilometre and is spread across six states of Western Ghats region namely, Gujarat, Maharashtra, Goa, Karnataka, Kerala and Tamil Nadu and includes Protected Areas and World Heritage Sites of Western Ghats and the High Level Working Group has recommended prohibition or regulation of identified projects and activities in the Ecologically Sensitive Area which have maximum interventionist and destructive impacts on ecosystems;

AND WHEREAS, the Ministry vide OM No. 1-4/2012-RE(Pt), dated the 20th December 2013, had *inter alia* sought suggestions from the State Governments on modification in the boundary of the Ecologically Sensitive Area as identified by the High Level Working Group on the basis of physical verification;

AND WHEREAS, the State Government of Kerala had earlier accordingly undertaken the exercise of demarcating Ecologically Sensitive Area in the State by physical verification the Ecologically Sensitive Area recommended by the Kerala State Government is spread over of an area of 9993.7 square kilometer, which includes 9107 square kilometer of forest area and 886.7 square kilometer of non-forest area and Ecologically Sensitive Area in that Stateworks out to 9,993.7 square kilometer as compared to 13,108 square kilometer recommended by High Level working Group.

AND WHEREAS, earlier the Ministry issued a draft notification vide S. O. No. 733 (E), dated the 10th March 2014, declaring Ecologically Sensitive Area in the Western Ghats taking into account the Ecologically Sensitive Area demarcated by Kerala Government for the State of Kerala instead of Ecologically Sensitive Area recommended by High Level Working Group for the State, while for other States of Western Ghats region the Ecologically sensitive Area recommended by the High Level Working Group was considered;

AND WHEREAS, while responding to the said draft notification number S.O.733(E), dated the 10th March, 2014 some of the States of Western Ghats region had sought a opportunity to undertake demarcation of Ecologically Sensitive Area by physical verification and the same was accorded by the Central Government vide letter dated the 9th June, 2014 except for the State of Kerala;

AND WHEREAS, the Central Government had convened meetings of the State Environment and Forest Ministers of the Western Ghat region on the 7th July, 2015 and Members of Parliament of Western Ghats region on the 3rd August, 2015 to review the progress of demarcation of Ecologically Sensitive Area by physical verification and also to address the apprehensions / concerns expressed by the State Governments and the various stakeholders of Western Ghats from time to time;

AND WHEREAS, the representatives of the State Governments of Western Ghats region had informed during the meeting held on the 7th July, 2015 that demarcation of Ecologically Sensitive Area by physical verification is in advanced stages of completeness;

AND WHEREAS, it was resolved in both the meetings to clarify that there will be no displacement or dislocation of the local people living in habitations within the Ecologically Sensitive Areas demarcated in the Western Ghats and

practicing of agriculture and plantation activity shall also not be affected due to the provisions contained in the draft notification;

AND WHEREAS, the Central Government convened a meeting with the Members of Parliament of the Western Ghats region on 11th August, 2016 and decided that the Draft Notification dated 4th September, 2015 would be the basis for further discussion to finalize it.

AND WHEREAS, the Central Government convened a meeting with concerned State Govt. representatives in the Ministry on 11th April, 2018 and decided that the Draft Notification dated 27th February, 2017 would be the basis for further discussion and accordingly the draft Notification No. S.O. 5135(E) dated 3rd October, 2018 was issued for stakeholder consultation;

AND WHEREAS, the Central Government convened meetings with concerned State Govt. representatives to discuss the draft at various forum and at the highest level including on 15th February, 2019, 21st May 2020, 23rd November 2021 and 3rd – 4th December, 2021; wherein various objections, comments and suggestions were received from the State Government on the draft notification no. 5135 (E) dated 3rd October, 2018;

AND WHEREAS,in order to address the issues raised by the State Governments, the Ministry of Environment, Forest and Climate Change constituted a Committee to re-examine the suggestions of the six State Governments in a holistic manner, keeping in view the conservation aspects of the disaster prone pristine ecosystem, and the rights, privileges, needs and developmental aspirations of the region;

AND WHEREAS, the Committee observed that the time given for submission of the report of the Committee is inadequate in view of the complexity of the task and consequently the draft notification no. 5135 (E) dated 3rd October, 2018 on 30th June, 2022 could not attain finality.

NOW, THEREFORE, in exercise of the powers conferred by section 3 of the Environment (Protection) Act, 1986 (29 of 1986) and sub-rule (3) of rule 5 of the Environment (Protection) Rules, 1986, the Central Government hereby notifies the identified area of 56,825 square kilometre which is spread across six States, namely, Gujarat, Maharashtra, Goa, Karnataka, Kerala and Tamil Nadu, as the Western Ghats Ecologically Sensitive Area.

2. Boundary and Description of Western Ghats Eco-sensitive Area.-

(1) The boundary and description of Eco-Sensitive Area as recommended by High Level Working Group excluding the State of Kerala is as under:-

(a) the extent of Eco-sensitive area falling in each state is as per Annexure A;

(b) the State-wise map of the portion of the Eco-sensitive area in each State is as per Annexure –B1 to B5;

(c) the State-wise list of villages falling within the Eco-sensitive Area along with respective Districts and Talukas is as per Annexure-C.

(2) The Eco-sensitive Area in the State of Kerala is spread over of an area of 9993.7 square kilometre which includes 9107 square kilometre of forest area and 886.7 square kilometre of non-forest area and the boundary and description of Eco-sensitive Area and the village-wise details of Eco-sensitive area proposed by the State Government are available on the website of the Kerala State Biodiversity Board.

3. Projects and activities to be prohibited or regulated in the Eco-sensitive area.-

(1) The following categories of projects and activities shall be prohibited in Eco-sensitive Area except those proposals which have been received by Expert Appraisal Committees or the Ministry of Environment, Forest and Climate Change or State Level Expert Appraisal Committees or the State Level Environment Impact Assessment Authorities before the 17th April, 2013, the date on which the High Level Working Group report

was uploaded on the website of the Ministry and are pending consideration and such proposals shall be dealt in accordance with the guidelines and rules in existence at that time.

(a) Mining.- There shall be a complete ban on mining, quarrying and sand mining in Ecologically Sensitive Area and all existing mines shall be phased out within five years from the date of issue of the final notification or on the expiry of the existing mining lease, whichever is earlier.

(b) Thermal power plants.-No new thermal power projects and expansion of existing plants shall be allowed in the Ecologically Sensitive Area.

(c) Industry.-All new 'Red' category of industriesas specified by the Central Pollution Control Board or State Pollution Control Board and the expansion of such existing industries shall be banned and the list of 'Red' category of industries shall be as specified by the Central Pollution Control Board:

provided that all existing 'Red' category of industries including health care establishments shall continue in Eco-sensitive Area under the applicable rules and regulations.

(d) Building,construction, township and area development projects.-All new and expansion projects of building and construction with built up area of 20,000 square metres and above and all new and expansion townships and area development projects with an area of 50 hectares and above or with built up area of 1,50,000 square metres and above shall be prohibited and there shall be no restriction on repair or extension or renovation of existing residential houses in the Eco-sensitive Area as per prevailing laws and regulations.

Note:

(1) All existing health care establishments can continue in Eco-Sensitive Area and proposed Primary Health Centres established as per laws and regulations. 2 No restriction in change in ownership of property.

(2) The following categories of projects and activities shall be regulated as given below:-

(a) Hydropower projects- New Hydropower projects shall be allowed as per the Environment Impact Assessment notification, published vide number S.O. 1533 (E), dated the 14th September, 2006, subject to the following conditions, namely:-

(i) uninterrupted ecological flow of atleast thirty percent of the rivers flow in lean season, till a comprehensive study establishes individual baselines for each project;

(ii) a cumulative study which assesses the impact of each project on the flow pattern of the rivers and forest and biodiversity loss;

(iii) the minimum distance between one project and the other is maintained at three kilometre and not more than fifty per cent. of the river basin is affected at any time,

(b) The "Orange/White" category of Industries as specified by the Central Pollution Control Board or State Pollution Control Board shall be allowed with strict compliance of environmental regulations but all efforts shall be made to promote industries with low environmental impacts.

(c) In the case of activities that are covered in the schedule to the Environment Impact Assessment notification number S.O. 1533 (E), dated 14th September, 2006, published by the erstwhile Ministry of Environment and Forests and are falling in the Eco-sensitive Area, except the projects and activities which are specifically prohibited under sub-para (1) shall be scrutinised and assessed for cumulative impacts and development needs before considering for prior environmental clearance by the Ministry under the provisions of the said notification.

(d) In particular and without prejudice to the provisions of the relevant Acts, in cases of diversion of forest land for non-forestry purposes in the Eco-sensitive Area, all information of the project, from application stage to approval shall be placed in the public domain on the website of the Ministry of Environment, Forest and Climate Change and of the Forest Department of the respective States.

(e) The requirements of prior informed consent under the Scheduled Tribes and other Traditional Forest Dwellers (Recognition of Forest Rights) Act, 2006 (2 of 2007) shall be complied with and the consent of Gram Sabha for undertaking projects and activities shall be mandatory.

4. Implementation and Monitoring mechanism.–

(1) The responsibility for monitoring and enforcement of provisions of this notification shall be with the concerned State Governments of Western Ghats region and the State Governments shall ensure placing of required mechanisms for effective monitoring and enforcement of restrictions in the Eco-sensitive Area and while placing such mechanisms, the State Governments shall inter-alia ensure strengthening of existing regulatory institutions and processes, and participation and involvement of local communities in decision making and the details of such mechanisms shall be shared by the concerned State Governments with the Ministry of Environment, Forest and Climate Change.

(2) A Decision Support and Monitoring Centre for Western Ghats shall be established by the Ministry of Environment, Forest and Climate Change in collaboration with the six State Governments of the Western Ghats region which shall assess and report on the status of ecology of Western Ghats on regular basis and provide decision support facility in the implementation of the provisions of this notification and shall also facilitate mechanisms for scientific decision making and strengthening enforcement.

(3) The post clearance monitoring of projects and activities allowed in the Eco-sensitive Area shall be carried out by the concerned State Government, State Pollution Control Board and the Regional Office of the Ministry and all projects in the Eco-sensitive Area which have been given Environmental Clearance or Forest Clearance shall be monitored at least once a year by the concerned Regional Office of the Ministry of Environment, Forest and Climate Change .

(4) All projects in the Eco-sensitive Area which have been given consent to establish or Consent to Operate under the Water (Prevention and Control of Pollution) Act, 1974 (6 of 1974) or the Air (Prevention and Control of Pollution) Act, 1981 (14 of 1981) shall be monitored at least once a year by the concerned State Pollution Control Board and the concerned State Governments shall prepare 'State of Health Report'in respect of Western Ghats region falling within their jurisdiction on an annual basis giving inter-alia the details of steps taken in monitoring and enforcement of provisions of this notification and make the same available in public domain.

5. Action for contravention - In case of any contravention of the provisions of this notification, action under the provisions of the Environment (Protection) Act, 1986 (29 of 1986) and other relevant statutes shall be taken accordingly.

6. The provisions in this notification shall be subject to the final orders of the court in pending litigation.

7. The provisions of this notificatin shall not affect the ownership of the property in the Eco-sensitives Area.

F.No.1-4-2012-ESZ

Dr S Kerketta, Scientist 'G', Ministry of Environment, Forest and Climate Change, New Delhi

NOTE: *Annexures are not reproduced here. Interested members can contact IDMA Secretariat*

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Pathway for the Development and Use of Quality Specifications/Monographs for Herbal Raw Materials in India

***Dr D. B. Anantha Narayana**, CSO, Ayurvidye Trust, Bangalore*

"If one picks up ten Ayurvedic medicinal products and looks at their labels, very few of them would declare the quality standards for the ingredients used in the composition of the product. If one picks up any ten products licensed as drugs, invariably all of them will declare on the label, the quality of the ingredient/ active as either IP or in rare cases as BP or USP. IP means Indian Pharmacopoeia meaning, the ingredient complies with quality specifications specified in the Indian Pharmacopoeia, the official Book of Standards. While quality specifications are published in earlier editions of the Ayurvedic Pharmacopoeia of India (API) for as many as 600 or more raw herbs, often the term API is not declared in the composition section of the products".

Reasons for the above status are many. Some of them are:

1. Most Ayurvedic products are manufactured by firms in MSME sector and data about how many of them test their raw herb materials and comply with the API monograph quality does not exist.
2. For many raw herbs, monographs are not available in API or IP.
3. Enforcement of the labelling provision and compliance to quality requirements need review for creating awareness that expenses incurred in testing raw materials and use of only approved raw materials is not 'a cost, but is an investment in quality'.
4. Material meeting API quality may not be available in which case manufacturer should adopt internal specifications, commonly referred to as 'In-House' (IH). This situation may exist as monographs in API have not been updated.

Current Status

1. Monographs in the API developed over decades, though available for over 600 raw herbs, are not in line with globally acceptable, objectively and scientifically assessable monographs.

   These monographs in API editions, also need multiple updations with respect to botanical identity confirmation, testing for analytical or bio-marker compounds, testing for a chromatographic profile of major group of compounds, contaminant test and their limits, providing photo documentation as a guide to the analyst and providing reference substances (botanical references and phytochemical reference substances).
2. Pharmacopeial standards need to include, in cases where botanical identity test is disputed, use of DNA Barcode test for final confirmation. More so applicable for substitutes, adulterants, and genetic variations. IP was the first Pharamcopoeia to add DNA Bar code testing for 2 herbs and work on adding DNA bar code specification for more are ongoing.
3. Availability of two sets of quality monograph for the same herb in India – one specification in API and one in IP has been a matter of debate. Monographs in API focused only on macroscopy, microscopy, few physiochemical tests, and a simple not mandatory TLC for some of the monographs. Monographs in the IP meet globally acceptable scientific evaluation as detailed above. See Figure 1 for the Journey of such work and Fig 2 for Criteria for inclusion and development of monographs for herbs in IP.
4. Under relevant memorandums of understanding with the Indian Pharmacopoeia Commission/ Ministry of Health, many monographs for raw herbs or processed herbs in IP have been adopted and included in the

*Formerly-member of Scientific Body of Indian Pharmacopeia Commission & Currently-Chair of Scientific Panel of Nutraceuticals –FSSAI. Views expressed are purely personal. Email Id: drandba50@gmail.com

British Pharmacopoeia, European Pharmacopoeia and United States Pharmacopoeia.

5. IP has monographs for herbs or herbal based ingredients used as excipients also. API provides such monograph for very few excipients.
6. It is understood that IP in its latest edition 2022 has 178 monographs (for raw herbs, processed herbs, and few herbal products approved as drugs). API through its many editions has monographs for over 540 raw herbs and about 202 Finished products/ Formulations of ayurveda. In one edition API also published monographs for about 105 herbal extracts that meet acceptable tests similar to those in IP. It is not adequate to publish monographs, but they need to be periodically updated, new and revised Editions of the Pharamcopieae or their supplements need to brought out. IP has in the last decade achieved this.
7. Pharmacopeia Commission for Indian Medicines (PCIM) was established sometime in 2010 by a decision of the Cabinet of Government of India, and the Central Government in 2014 added Homeopathy to this organization and renamed it as the Pharmacopeia Commission for Indian Medicines & Homeopathy (PCIM&H).
8. Thus there is a lack of availability of quality specification for most raw herbs and their processed materials that have regulatory approvals. Pharmacopoeial specifications are legal quality standards which provide minimum quality requirements.

Who needs quality specifications for raw herbs and herbal based raw materials (used as excipients, pharmaceutical aids, additives – diluents, colors, flavors, binders, lubricants etc.).

1. Manufacturers of Ayurvedic medicines
2. Manufacturers of Proprietary Ayurvedic medicines (A guess estimate would lead to need for quality specification for over 750 raw herbs- about 300 most commonly used raw herbs, and about 70 or so herbal based materials that are used as excipients)
3. Food Business Operators using botanicals listed in supplement/ nutraceutical regulations. (About 400 or so raw herbs are listed in these regulations)
4. Manufacturers of 'Ayurveda Aahara' products (recently notified regulations)
5. Manufacturers of Cosmetics
6. Buyers form Abroad who wish to produce herbal products locally in the their countries and also consumers who wish to use them for personal use as post pandemic time usage of ayurvedic herbs have gone up.
7. Exporters of Raw herbs, manufacturers of products containing herbs/ processed herbs for export purposes
8. Research scientists for using quality material in their research including human studies
9. Suppliers / Traders involved in collection, storage and supply of raw herbs
10. Forest Officials who provide permits to move widely collected raw herbs
11. Co-operative farmers/ cultivators of medicinal plants.
12. Ayurvedic Vaidyas who buy small quantities of raw herbs for compounding and preparing recipes in their pharmacies.

Way forward for Consideration at national Level- A Proposal (Non-exhaustive)

1. To sustainably promote herbs known in Ayurveda in the post pandemic era, as more consumers opting to use natural/ herbal-based products. As a nation India needs to fast-track and make available objectively assessable quality standards for most commonly used raw herbs/ processed herbs expeditiously following the normal monograph development process.
2. Indian Pharmacopoeia Commission (IPC) has for many years demonstrated skills and competencies to undertake such work. Consider giving leadership responsibility to IPC along with PCIM working jointly.
3. Urgently provide additional scientific power to both IPC and PCIM consisting of pharmacognosists, botanists, dravya-guna experts, Phytochemists, analytical chemists, instrumentation specialists, man power for drafting & editing specifications and photodocumentaiton specialists. The number of manpower should be commensurate to enable faster turnout of monographs.
4. Consider appropriately to involve privately funded research and analytical laboratories working in this area of testing herbs and herbal products, to provide specific tools, analytical methods and markers to expedite the work.

5. Ministry of AYUSH and its Central Councils and its branches are spread across the country, and they may be given responsibility to collect samples of raw herbs, authenticate them for identity and provide the same to the laboratory for monograph development.
6. Indian Council of Medicinal Research over the last decades, have published monographs for raw herbs in their 18 volumes covering large number of herbs. These were developed by leading laboratories across the nation under supervision of experts. These monographs and the data in them are of high value for use in pharmacopoeial monographs, subject to quickly working on them and confirmation on the test methods and limits. Using this approach would actually avoid repetition and duplication of work. This approach if done scientifically would fast track the work.
7. Measures to support some of the expensive testing involved in the pharmacopoeial monographs by the MSME sector may be reviewed and evaluated. Consider at least for setting up many regional laboratories/or upgrading some of the regional laboratories and equip each of these to provide subsidized testing for Heavy metals levels, pesticide residues and microbial quality which can be used by MSME sector manufacturers.
8. Leading biotechnology institutes may be roped in to assist in developing DNA barcode test and specifications for at least 100 of most commonly used herbs for inclusion as an alternative test for identification tests.
9. Confirmation of botanical identity. Many buyers of herbs for overseas are demanding this test and report of results as a pre-condition for purchase.

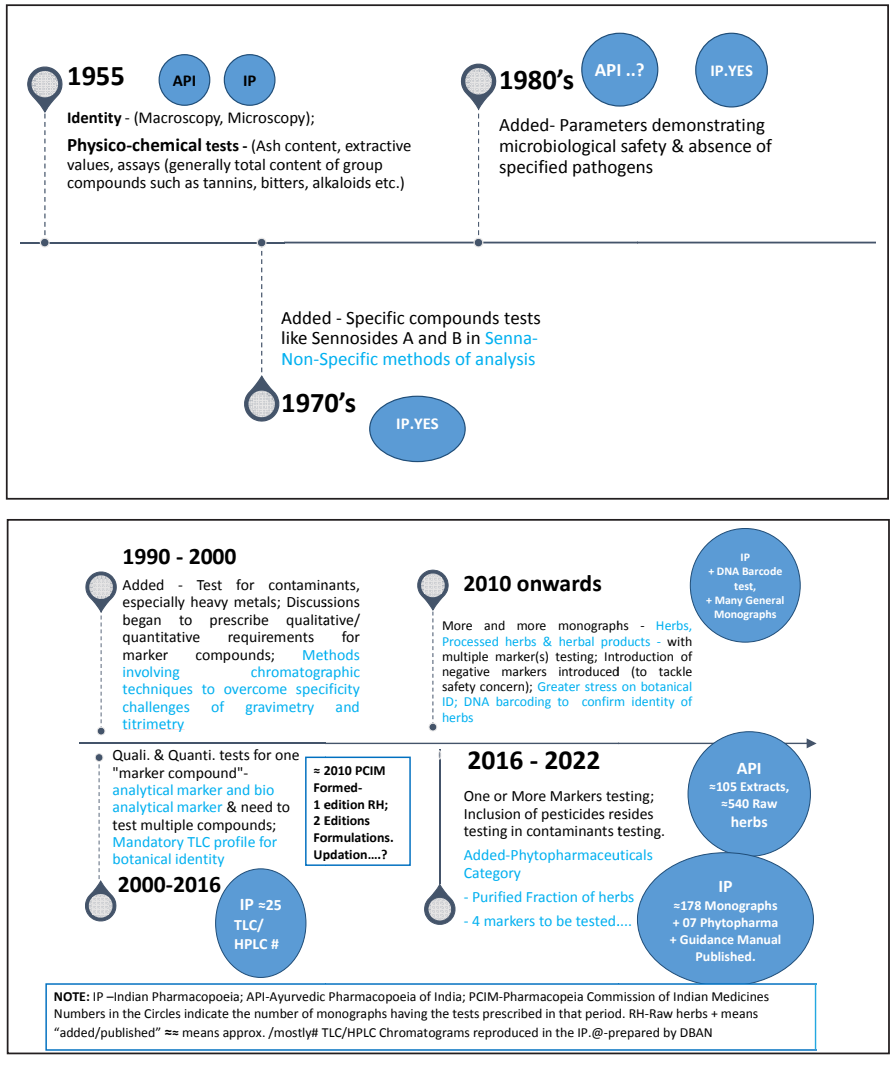

Figure 1. For Herbs: Quality Standards/ Specifications in Pharmacopeias- JOURNEY during DECADES@

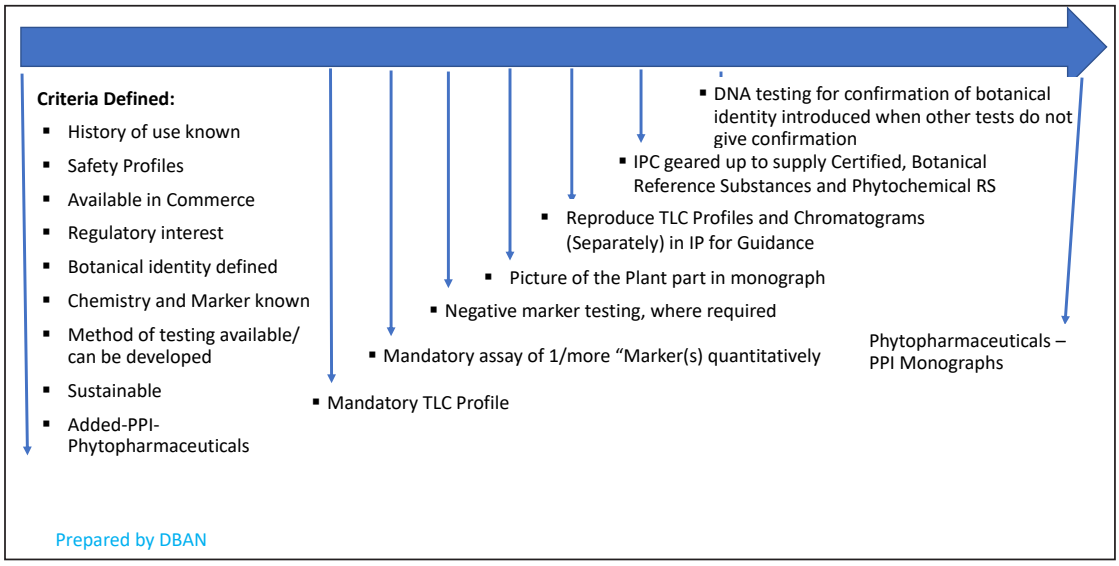

Figure 2. Criteria for monographs in Indian Pharmacopeia - Journey during 2006 to 2022

Acknowledgments: Author thanks Mr. Rojison Koshy and Ms. Sabina Shirsekar for help given in preparing the Figures and text.

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Lok Sabha

In Lok Sabha

Import of PET Bottles

Lok Sabha Unstarred Question No. 96

Shri Adala Prabhakara Reddy:

Dr. Beesetti Venkata Satyavathi:

Shri Sridhar Kotagiri:

Q. Will the Minister of **ENVIRONMENT, FOREST AND CLIMATE CHANGE** be pleased to state:

(a) whether the Government banned the import of plastic waste in the country in 2019;

(b) if so, whether the Government has recently allowed import of PET Bottles, as plastic waste, for processing in the country;

(c) the reason for banning import of plastic waste and now allowing import of PET Bottles; and

(d) the steps taken by the Government to strengthen collection of PET plastic in the country rather than importing such waste given that more than 14 lakh tonnes of PET plastic are consumed annually in the country?

Answered on 18th July 2022

A. (a) to (d) The Hazardous and Other Wastes (Management and Transboundary Movement) Rules, 2016 were amended on 1st March, 2019 to prohibit the import of solid plastic waste into the country including Special Economic Zones (SEZs) and Export Oriented Units (EOUs).The import was banned to boost domestic collection and recycling of plastic waste including Polyethylene terephthalate (PET).

However, the situation was reviewed later and the rules were amended in November, 2021 to allow import of PET. The PET import was allowed to fill the gap in waste availability of PET recycling units which in turn provide raw material to Yarn manufacturing units. There was shortage of plastic waste raw material for recycling units in spite of more than 90% collection of PET waste. The rationale is that the PET recycling industry is anchor for domestic waste management and as long as available domestic waste is being collected and recycled, the growth of the industry should not be hindered by lack of raw material.

The policy provides that import would be allowed only to actual recyclers having valid authorization and Consent to Operate so as to ensure that waste is channelized purposefully. Also the permitted import quantity would be restricted only to fill the gap in recycling capacity and not to replace the domestic waste processing.

The Ministry of Environment, Forest and Climate Change has notified the Guidelines on the Extended Producer Responsibility (EPR) for plastic waste, including PET, by Plastic Waste Management Amendment Rules, 2022. As per the guidelines, the producer, importers and brand-owners have EPR obligation for plastic waste. They shall ensure minimum level of recycling (excluding end of life disposal) of plastic waste collected under EPR. The enforceable prescription of minimum level of recycling of plastic packaging waste collected under EPR will further strengthen circular economy of plastic packaging waste.

Minister of State in the Ministry of Environment, Forest and Climate Change
(Shri Ashwini Kumar Choubey)

Use of Plastic in Packaging Industry

Lok Sabha Unstarred Question No. 214

Shri Vinayak Raut:

Prof. Sougata Ray:

Shri Omprakash Bhupalsinh Alias

Pawan Rajenimbalkar:

Q. Will the Minister of **ENVIRONMENT, FOREST AND CLIMATE CHANGE** be pleased to state:

(a) whether the single use plastic has been completely banned across the country, if so, the details there of State-wise including Maharashtra;

(b) whether it is a fact that Corona Virus has resulted in increased dependence on single use plastic;

(c) the measures taken/being taken by the Government to make the nation free from single-use plastic;

(d) whether the Government noticed the acute shortage and non-availability of alternatives to single use plastics and if so, the details thereof;

(e) the steps taken to ensure the enough availability of alternative items in affordable price; and

(f) the corrective measures taken or proposed to be taken by the Government to ban the use of plastic in the packaging industry to prevent environmental degradation?

Answered on 18th July 2022

A. (a): The Ministry had notified the Plastic Waste Management Amendment Rules, 2021, vide GSR NO. 571 (E) on 12th August 2021, in the Gazette of India, prohibiting the following identified single use plastic items, which have low utility and high littering potential with effect from the 1st July, 2022. Further, over and above the Plastic Waste Management Rules, 2016, as amended, thirty four states/UTs have issued notifications/orders to introduce regulations pertaining to complete or partial ban on plastic carry bags and/or identified single-use plastic items. The details are annexed.

(b) The Government has from time to time issued guidelines/ standard operating procedures (SOPs) on preventive measures to contain spread of COVID 19. These guidelines/SOPs inter alia include use of personal protective equipment and face covers/ masks. The Central Pollution Control Board has issued "Guidelines for Handling, Treatment and Disposal of Waste Generated during Treatment/ Diagnosis/ Quarantine of COVID-19 Patients" including disposal of personal protective equipment including waste masks and gloves.

(c): All thirty six States/UTs have constituted the Special Task Force under Chairpersonship of Chief Secretary/Administrator for elimination of single use plastics and effective implementation of PWMR, 2016. A National Level Taskforce has also been constituted by the Ministry in this regard.The State / UT Governments and concerned Central Ministries/ Departments have also been requested to develop a comprehensive action plan and implement it in a time bound manner. The Government of India provides additional central assistance to the States/ UTs under the Swachh Bharat Mission for solid waste management including plastic waste management. Swachh Bharat Mission Urban 2.0 has specific focus on elimination of single use plastics.

(d) & (e): The comprehensive action plan of the Ministry of Micro, Small and Medium Enterprises for elimination of single use plastics includes providing support to MSME units with respect to technology upgradation, creating awareness, marketing support, infrastructural support for adopting alternatives to banned single use plastic items, through various schemes of the Ministry. The States and UTs have also been asked to provide incentives for promotion alternatives, as part comprehensive action plan template shared with them.

(f):The Ministry of Environment, Forest and Climate Change has also notified the Guidelines on the Extended Producer Responsibility for plastic packaging vide Plastic Waste Management Amendment Rules, 2022, on 16th February, 2022. The prescriptions of mandatory targets for reuse of rigid plastic packaging, minimum level of recycling of plastic packaging waste and use of recycled plastic content in plastic packaging, will promote circular economy and reduce plastic foot print of plastic packaging thus preventing environmental degradation.

Minister of State in the Ministry of Environment, Forest and Climate Change
(Shri Ashwini Kumar Choubey)

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Annexure

Notification for banning manufacture, use, sale import and handling of single use plastic products

(Based on the data available in submitted Annual reports by SPCBs/PCCs)

S. No	Name of State/UT	Complete or Partial Ban	Date of Gazette or Executive Order	Remarks
1	**Andaman & Nicobar Islands**	Complete ban	02.08.2010 **(Gazette)**	Complete ban on manufacture, store, import, distribution, transportation, recycle, sell & use of plastic carry bags.
2	Andhra Pradesh	Not Banned	Not Available	Not Banned
3	**Arunachal Pradesh**	Complete ban	03.07.2012 **(Executive Order)**	Complete ban on manufacture, store, import, transportation, sell& use of polythene/plastic carry bags
4	**Assam**	Complete Ban	30.04.2019 **(Gazette)**	Plastic carry bags, banners, buntings, cups, cling films, flex, flags, plates, sheets (used for spreading on dining tables irrespective of thickness) including the above items made of thermocol and plastic which use plastic micro beads.
5	**Bihar**	Complete ban	11.12.2018 **(Gazette)**	Complete ban on manufacture, store, import, transportation, sell& use of plastic carry bags
6	**Chandigarh**	Complete ban	30.07.2008 **(Gazette)**	Complete ban on manufacture, storage, import, sale, use transportation & disposal of plastic carry bags
7	**Chhattisgarh**	Complete ban	24.12.2014 **(Gazette)**	Complete ban on manufacture, store, import, transportation, recycle, sell & use of polythene/plastic carry bags.
8	**Daman Diu & Dadra Nagar Haveli**	Complete ban	24-01-2014 & 22.09.2017 **(Gazette)**	Forbidding the use, sale/ storage of all kinds of plastic bags
9	**Delhi**	Complete ban	23.10.2012 **(Gazette)**	Complete ban on manufacture, import,store, sell & use of plastic products (poly Propylene, non-woven fabric type carry bags), plastic film or plastic tube to pack or cover any book including magazine & invitation/greeting cards.
10	Goa	**Partial ban**	16.03.2015	Government imposed ban on Manufacture, stock, import, transportation, recycle, sale & use of plastic (carry bags, cups, forks, paper plates, spoons) in ChorlaGhat area Mandi Wildlifesanctuaries .
11	Gujarat	**Partial ban**	28.06.2011 **(Gazette)**	Complete ban on plastic products in Gandhi Nagar
12	**Haryana**	Complete ban	20.08.2013 **(Gazette)**	Complete ban on manufacture, stock, import, transportation, recycle, sell & use of plastic (carry bags, cups, forks, paper plates, straws, spoons& containers for the usage of foodstuffs)

13	**Himachal Pradesh**	Complete Ban	07-07-2009 & 13-08-2009 **(Gazette)**	Complete ban on use of Carry bags (irrespective of size), polythene, non-biodegradable material, disposable plastic cups, plates, and glasses
14	Jammu & Kashmir	Complete Ban	03.01.2017 (SRO 45 order-Notification) Jammu District Magistrate has on 01.10.2020 ordered strict enforcement of SRO 45 notification.	Complete ban on manufacture, stocking, distribution, sale and use of polyethylene carry bags, plastic sheets or like, cover made of plastic sheet, plastic packaging and multilayered packaging less than fifty microns in thickness within territorial limits of the State of Jammu and Kashmir.
15	**Jharkhand**	Complete Ban	17.10.2017 **(Gazette)**	Complete ban on manufacture, import, storage, transport, sell and usage of plastic carry bags in the whole State
16	**Karnataka**	Complete ban	11.03.2016 **(Gazette)**	State government banned the plastic banners, buntings, carry bags (plastic & compostable), cups, cling films, flex, flags, plates, spoons & sheets made of plastic or Thermocol and microbeads usage in the entire state
17	Kerala	01.01.2020 **(Executive Order)**	22.11.2010 **(Executive Order)**	Complete ban on the manufacture, storage, transport and sale of plastic carry bags(irrespective of thickness); plastic sheets(used as table spread); plates, cups and decorative materials made of thermocol/stryrofoam; SUP items like cups, plates, dishes, spoons, forks, straw, stirrer; plastic coated paper cups, plastic coated paper plates, plastic coated paper bowls, plastic coated paper bags; Non woven bags, plastic flags, plastic bunting;plastic water pouches, non branded plastic juice packets ; plastic juice packets; PET/PETE bottles of drinking water of capacities less than 500 ml; garbage bags (plastic); PVC flex materials and plastic packets.
18	Ladakh	**Partial Ban**	**(Order no-40-LA (GAD) of 2020 dated 23.06.2020)**	Ban on the use of plastic water bottles and other plastic made objects in Government offices and other institutions
19	**Lakshadweep**	Complete ban	25.01.2019 **(Gazette)**	Complete ban on use, store & sale of plastic carry bags of all thickness, plastic coated carry bags, plastic flags, plastic sheets/films used for wrapping, plastic sheets used as dining table covers, thermocol cups and plates, plastic coated paper cups and plates, plastic teacups, plastic tumblers, plastic teacups, water pouches/packets/PET plastic water bottles, straws,
20	**Madhya**	Complete	24-05-2017	Production, Storage, Transportation, sale & use

	Pradesh	ban	**(Gazette)**	of plastic carrybags.
21	**Maharashtra**	Complete Ban	23-03-2018 **(Gazette)** Amendment 11th April, 2018	Complete ban in the whole State for manufacture, usage, sale storage,transport, and distribution, wholesale & retail, import of the plastic& compostable bags and the disposable products manufactured from plastic &thermocol (polystyrene) - disposable dish/spoon, cups, bowl, container, fork, plates, glasses, straw, non-woven polypropylene bags, cups/pouches.
22	Manipur	Complete Ban	12.9.2017 Notification no. 56/38/99 for&Envt	Complete ban on use, store & sale of plastic carry bags
23	Meghalaya	Partial Ban	16.2.2017 Notification No. MPCB/TB-144B/2016-2017/79	Use and sale of plastic bags less than 50 microns has been prohibited and public notice has been issued
24	Mizoram	Partial Ban	With effect from 1.8.2019 By Aizwal Municipal Corporation	Complete ban on plastic carry bags below 50 microns
25	**Nagaland**	Complete ban	01.01.2004 **(Gazette)**	Complete ban on use, store & sale of plastic carry bags
26	Odisha	**Partial ban**	29.09.2018 **(Executive Order)**	Ban on use and sale of plastic carry bags, bottled drinking water Polyethylene Terephthalate bottles of less than 200 ml capacity; SUP disposable cutleries like thermocol (polystyrene), dish/spoon, cups, bowl, container, fork, glasses & plates in Bhubaneshwar, Berhampur, Cuttack, Puri, Rourkela & Sambalpur
27	Puducherry	Complete ban	30.07.2019	(i) Polythene/Plastic/Polypropylene carry bags; (ii) Polythene/Plastic/Styrofoam (Thermocol) cups; (iii) Polythene/Plastic/Styrofoam (Thermocol) plates; (iv) Plastic sheet pouches used for cooked food wrapping; (v) Plastic sheets used for spreading on dining table; (vi) Water pouches; (vii) Plastic straw; (viii) Plastic flag.
28	**Punjab**	Complete ban	18.02.2016 **(Gazette)**	Complete ban on Manufacture, stock, distribute, recycle, sale & use of plastic carry bags.
29	**Rajasthan**	Complete ban	01.08.2010 **(Gazette)**	Complete ban on use, store & sale of plastic carry bags
30	**Sikkim**	Complete ban	19.05.2016 **(Gazette)**	Complete ban on sale & use, storage of disposable items (cups, plates, spoons, containers, etc..) made from Styrofoam.
31	**Tamil Nadu**	Complete	01.01.2019	Complete ban on manufacture, sell, use, storage,

		Ban	**(Gazette)**	Transportation and distribution of "Single-use plastics" i.e. plastic carrybags, flags, sheets using for food wrapping, straws, tea cups, tumblers, water packets & pouches
32	Telangana	Not Banned	Not Available	Not Banned
33	**Tripura**	Complete ban	10.03.2015 **(Gazette)**	Complete ban on Sell, use, storage, Transportation & import of plastic carrybags (including polypropylene, non-woven fabric type) plastic tube to pack or cover any book including magazine & invitation/greeting cards.
34	**Uttar Pradesh**	Complete ban	22.12.2015 **(Gazette)**	Sell, use, Storage, Transportation & import of plastic carrybags (including polypropylene, non-woven fabric type) plastic tube to pack or cover any book including magazine & invitation/greeting cards.
35	**Uttarakhand**	Complete Ban	01.01.2017 **(Gazette)**	Sell, use, storage& Transportation, of plastic carry bags.
36	West Bengal	**Partial ban**	**11.01.2018 (Executive Order)**	Completely banned in religious and historical places.

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Indian pharma MSMEs can play vital role in international market: Daara Patel

The Micro, Small and Medium Pharma Enterprises in India need to be capable enough to compete well in the international markets as chances are there for them to become international sellers.

Export opportunities in the pharma sector are increasing in the eastern and western countries and the small scale manufacturers will have a prosperous period in the coming years, feels Daara B Patel, secretary general of the Indian Drug Manufacturers' Association (IDMA).

While addressing the small scale pharma entrepreneurs in Chennai, he said time has come for the world population to think of Indian made drugs. Even now, when people in any country in the world talk about medicines they think about India. One out of the three drugs consumed by a patient in any part of the world and one vaccine out of the three vaccines administered to a child in any country are made in India. So, the future is the prosperous period for Indian pharma and the SMEs can play vital roles.

Encouraging the entrepreneurs to become international players, the pharma association leader said the Indian small scale pharmaceutical manufacturers have to think globally to become exporters. The Indian drug manufacturers association is confident that all the SME entrepreneurs will come forward to become exporters in order to make a prosperous future for the country's pharma sector.

According to him, the Indian pharma sector has more potential to grow globally for which the MSME units can contribute a lot. The industry needs an ecosystem of innovation for utilizing its full potential. In the last two decades' period the Indian pharma witnessed 10% growth. But in the Covid-19 pandemic the industry could utilize only 20% of its total capacity.

Releasing a special edition of IDMA bulletin on its 60th year celebration, Patel informed the industry people that the association has instituted several awards to support the industry and innovation in pharmaceuticals. This year two industry stalwarts, one from Chennai and one from Kolkata have been honored with the 'N I Gandhi Chief Mentor Award'. The CMD of the Chennai based Fourrts India Laboratories, S V Veermani and the managing director of Strassenburg Pharmaceuticals in Kolkata, Deepnath Roy Chowdhury were the recipients this year.

IDMA also honours industry leaders with Corporate Citizen award and students of pharmacy with Best Student Award. All these honours will be extended to all the parts of the country with state boards' support.

Talking about the membership strength of the IDMA, Daara Patel said the association has crossed the numeral 1,100 in membership number. He expressed the hope that before long, one third of the drug manufacturers in the world will be from India.

Source: Peethaambaran Kunnathoor, Pharmabiz, 15.07.2022

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Valid medical prescriptions must for sale of specified ayurveda, unani drugs online: CCPA

The Central Consumer Protection Authority on Thursday directed e-commerce entities to sell specified ayurveda, siddha and unani drugs only after customers upload valid medical prescriptions from registered doctors on the platforms.

The requirement will be applicable for drugs specified under Schedule E (1) of the Drugs and Cosmetics Rules, 1945. Schedule E lists out poisonous substances under the ayurveda (including siddha) and unani systems of medicine. Such drugs are required to be taken under medical supervision.

"Consuming such drugs without medical supervision can lead to severe health complications. E-commerce platforms have been advised that the sale or facilitating the sale of such drugs shall be done only after a valid prescription of a registered Ayurveda, Siddha or Unani practitioner respectively is uploaded by the user on the platform," the Central Consumer Protection Authority (CCPA) said in a statement.

Besides, the word 'caution' is to be printed in both English and Hindi languages on the label of the container of such medicines specified in Schedule E (1).

In February 2016, the Ministry of Ayush issued a public notice informing stakeholders that such drugs are required to be taken under medical supervision and purchasing the same online should be avoided without medical consultation.

Under Section 18 of the Consumer Protection Act, 2019, CCPA said it is empowered to protect, promote and enforce the rights of consumers as a class, and prevent violation of consumers' rights.

The regulator is empowered to prevent unfair trade practices and ensure that no person engages himself in unfair trade practices.

CCPA said it is consistently monitoring the issues affecting consumer welfare.

Recently, the watchdog issued guidelines to prevent unfair trade practices and protect consumer interests with respect to levy of service charges in hotels and restaurants.

It has also issued guidelines for the prevention of misleading advertisements and endorsements.

To safeguard consumer rights while shopping online, CCPA has issued an advisory to all marketplace e-commerce entities to ensure that details of sellers as mandated under sub-rule (5) of rule 6 of the Consumer Protection (E-commerce) Rules, 2020 are displayed on the platforms. Details such as name and contact number of the grievance officer concerned should be provided in a clear and accessible manner, and displayed prominently to users on the platform.

According to the statement, CCPA has also issued safety notices to alert and caution consumers against buying goods which do not have a valid ISI mark and violate compulsory BIS standards.

While the first safety notice was issued with regard to helmets, pressure cookers and cooking gas cylinders, the second safety notice was issued with respect to household goods, including electric immersion water heaters, sewing machines and microwave ovens.

Source: PTI, 14.07.2022

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IPC's efforts to get IP recognized by foreign countries will be provided all support: SV Veeramani

The efforts of the Indian Pharmacopoeia Commission (IPC) to get the Indian Pharmacopoeia (IP), which proves the standards of Indian made drugs, recognized and accepted by foreign countries will be supported by the Pharmaceuticals Export Promotion Council of India (Pharmexcil) as the council feels that promotion of IP worldwide will help increase the country's pharmaceutical exports.

"Pharmexcil will work together with the IPC in that endeavour because IP has been accepted by only four countries as a book of standards and it needs to be accepted by more. IP promotion is also a responsibility of the council," says SV Veeramani, vice-chairman of the Pharmexcil.

According to him, efforts are being made by the council to get the IP accepted by all the countries in the world one by one. Currently, countries such as Afghanistan, Ghana, Nepal and Mauritius only have accepted the Indian Pharmacopoeia as a book of standard to ensure drug quality. Among these, Afghanistan is the first country that accepted the IP by their national ministry of public health.

He said it is high time other countries recognized our IP as a book of quality standards as India has already become the 'pharmacy of the world'. India exports, mainly generics, to more than 250 countries and one out of the three drugs consumed by a patient in any part of the globe is from India. But, Indian Pharmacopoeia is not recognized by these countries. Whereas, the US Pharmacopoeia (USP), the British Pharmacopoeia (BP) and the Pharmacopoeia of the European Union (EP) are accepted by all the countries. Medicines to the USA, UK and to the EU countries are supplied by India, but they are reluctant to recognize IP. Veeramani said the IPC and the Pharmexcil, through the government of India, are taking steps with other countries for acceptance of IP. He pointed out that the forthcoming international regulators' meeting in New Delhi in September would also take this issue as an agenda for discussion.

Talking about the advantages of recognition of IP by foreign countries, the industry doyen said acceptance of Indian pharmacopoeia by foreign countries will help the merchant exporters to do their business easily. The medicinal products in IP can be exported to overseas markets as they are. There is no need to apply a separate production method. Like the supply in the domestic market, medicines manufactured in IP, can be bought and exported to the IP accepted countries which will treat them like their locally manufactured drugs. But, to the non-accepted countries a separate method of production has to be done in their quality and safety perspectives as per each country's pharmacopoeia.

"The superiority complex of the western countries is the major hurdle in accepting the IP by them. Our medicines

are acceptable for them, but standards cannot be accepted. That poses a paradox. However, Pharmexcil is taking all efforts to get the IP accepted by all countries and we hope that it will happen in a gradual manner," Veermani told Pharmabiz.

On the second of this Month, the Indian Pharmacopoeia Commission released the 9th edition of the IP which contained 92 new monographs for drugs, 12 new general chapters, 1,245 monographs for formulations, 930 monographs for active pharmaceutical ingredients (APIs).

Source: Peethaambaran Kunnathoor, Pharmabiz, 19.07.2022

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War effect: India's pharma exports to Russia down 24% in April–May period

Russia is the fourth largest pharma export market for India

Indian pharma exports to Russia have dropped 24 per cent due to the continuing war between Russia and Ukraine. In April-May 2022 exports were $68 million compared with $89 million in the same period last year, as per the data of the Pharmaceutical Export Promotion Council (Pharmexcil), an arm of the Ministry of Commerce.

"The geopolitical situation marked by the continuing war, payment blues have led to decrease in exports but we believe this is a temporary issue," R Uday Bhaskar, Director – General, Pharmexcil told *Business Line.*

Russia has been a significant market for Indian drug-makers with diverse exports including drugs and formulations, bulk drugs, intermediates, biologics, vaccines, Ayush, herbals and surgicals. The total exports to Russia from India increased 1.21 per cent in 2021-22 at $597 million compared to $590 million in 2020-21.

Q1 results may be affected

According to the director of a Hyderabad-based listed pharma company, the first quarter performance of pharma companies with a major presence in the Russian market would have some`adverse' impact in view of the Russia situation.

"Contrary to initial expectations, the war has been prolonging with no end in sight. The first half of the current fiscal will surely witness some kind of impact," he added.

Russian market accounts for about 60 percent of total exports to CIS countries, which accounted for 4.6 percent of India's total pharma exports of $24.6 billion in financial year 2021-22. It's the fourth largest export market for India, accounting for significant revenues for some Indian drug majors including Dr Reddy's Laboratories.

Source: G Naga Sridhar, Business Line, 18.07.2022

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