

IDMA BULLETIN

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WEEKLY PUBLICATION

IDMA Secretariat and Editorial Team
Wishes all our Members and Readers



Independence Day



INDIAN PHARMA - GLOBAL HEALTH CARE

INDIAN DRUG MANUFACTURERS' ASSOCIATION

HIGHLIGHTS

- ★ IDMA congratulates Dr Gopakumar G. Nair, Editor, IDMA Bulletin and Indian Drugs on receiving LLM (Corporate Law & Finance) (Page No. 16)
- ★ Updated List of Applicants Approved under PLI Scheme for Promotion of Domestic Manufacturing of Critical KSMs / DIs / APIs in India as received from DoP (Page No. 17)
- ★ Uniform Code of Pharmaceutical Marketing Practices - Government clarifies Supreme Court issue (Page No. 32)
- ★ Tamil Nadu Scientist Breaks Glass Ceiling, Becomes CSIR's First Woman Director General-Kalaiselvi (Page No. 33)
- ★ Commerce dept recast to bring more focus on policy making (Page No. 33)

WE DO WHAT WE SAY.
AND SAY WHAT WE DO.
THAT'S OUR **RELIABILITY**
YOU CAN RELY ON.



Dear Partner,

Consistency is one of the key factors of our success in the pharmaceutical excipients industry. It is why our customers have been able to trust and depend on us. And esteemed partnerships with the likes of CP Kelco and Nouryon, have only reinforced our adherence to these principles.

CP Kelco is backed by over 200 years of successful operational experience in globally diverse markets. They are trusted the world-over, for their efforts toward responsible business, ethics and environmental practices. Nouryon, formed in 2018, has swiftly become one of the world's top producers of specialty chemicals, with a keen focus on safety and sustainability in all their processes.

Signet takes immense pride in partnering with CP Kelco and Nouryon, the most reliable experts in Hydrocolloid manufacturing, modification and application, as well as Sodium CMC. They provide countless useful products such as Xanthan Gum, Gellan Gum, Pectin and Sodium CMC, that each serve a variety of functions - from viscosity modification to suspension stabilisation, as a thickening agent or gelation.

Signet-ure
reliability



XANTURAL - Xanthan Gum

- Xantural 75 - Fine Particle Size
- Xantural 180 - Coarse Particle Size
- Xantural 11K - Agglomerated Type

KELCOGEL - Gellan Gum

- Kelcogel CG LA - Low Acyl Type
- Kelcogel CG HA - High Acyl Type

GENU PECTIN - Pectin (Citrus)

Nouryon

CEKOL - Carboxymethylcellulose Sodium

- Cekol 30 / 700 P / 2000 P / 4000 P / 10000 P
- Cekol 20000 P / 30000 P / 40000 / 50000 P / 100000
- Majol 25000 S

CHELATES

- Dissolvine Na2-P - Disodium EDTA

Signet

The Complete Excipients Company



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OPINIONS EXPRESSED BY THE AUTHORS OF INDIVIDUAL ARTICLES
DO NOT NECESSARILY REPRESENT THE OFFICIAL VIEW OF IDMA.

IDMA BULLETIN

Vol. No. 53

Issue No. 30

08 to 14 August 2022

IDMA ACTIVITIES:

Advanced Program in Pharmaceutical Quality
Management Series 3 Commences October 2022 4

Monkeypox: *Dr. Nagaraj Rao, Associate Editor, Indian Drugs*..... 13

IDMA Secretariat celebrates 75th Independence Day..... 14

Shri Mehul Shah, Hon. General Secretary, IDMA interacts with
Shri Shivraj Singh Chauhan, the Hon'ble Chief Minister of
Madhya Pradesh at Bhopal on 8th August 2022 15

CONGRATULATIONS:

IDMA congratulates Dr Gopakumar G. Nair, Editor,
IDMA Bulletin and Indian Drugs on receiving LLM
(Corporate Law & Finance) from Jindal Global Law
School, O. P Jindal University from Justice Chandrachud
as Chief Guest at Convocation Ceremony 16

GOVERNMENT COMMUNICATIONS:

Updated List of Applicants Approved under PLI Scheme for
Promotion of Domestic Manufacturing of Critical Key Starting
Materials (KSMs)/Drug Intermediates (DIs)/Active Pharmaceutical
Ingredients (APIs) in India as received from DoP..... 17

PARLIAMENT NEWS:

In Rajya Sabha & In Lok Sabha 19

GOVERNMENT PRESS RELEASE:

Uniform Code of Pharmaceutical Marketing Practices -
Government clarifies Supreme Court issue 32

NATIONAL NEWS:

Commerce dept recast to bring more focus on policy making 33

Tamil Nadu Scientist Breaks Glass Ceiling, Becomes
CSIR's First Woman Director General-Kalaiselvi 33

Advertisements.....2, 35 & 36



UPDATED ADVANCED PROGRAM IN PHARMACEUTICAL QUALITY MANAGEMENT

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

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 October 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 October 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 :


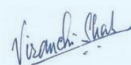


Please fill the [Registration Form](#) and send it to

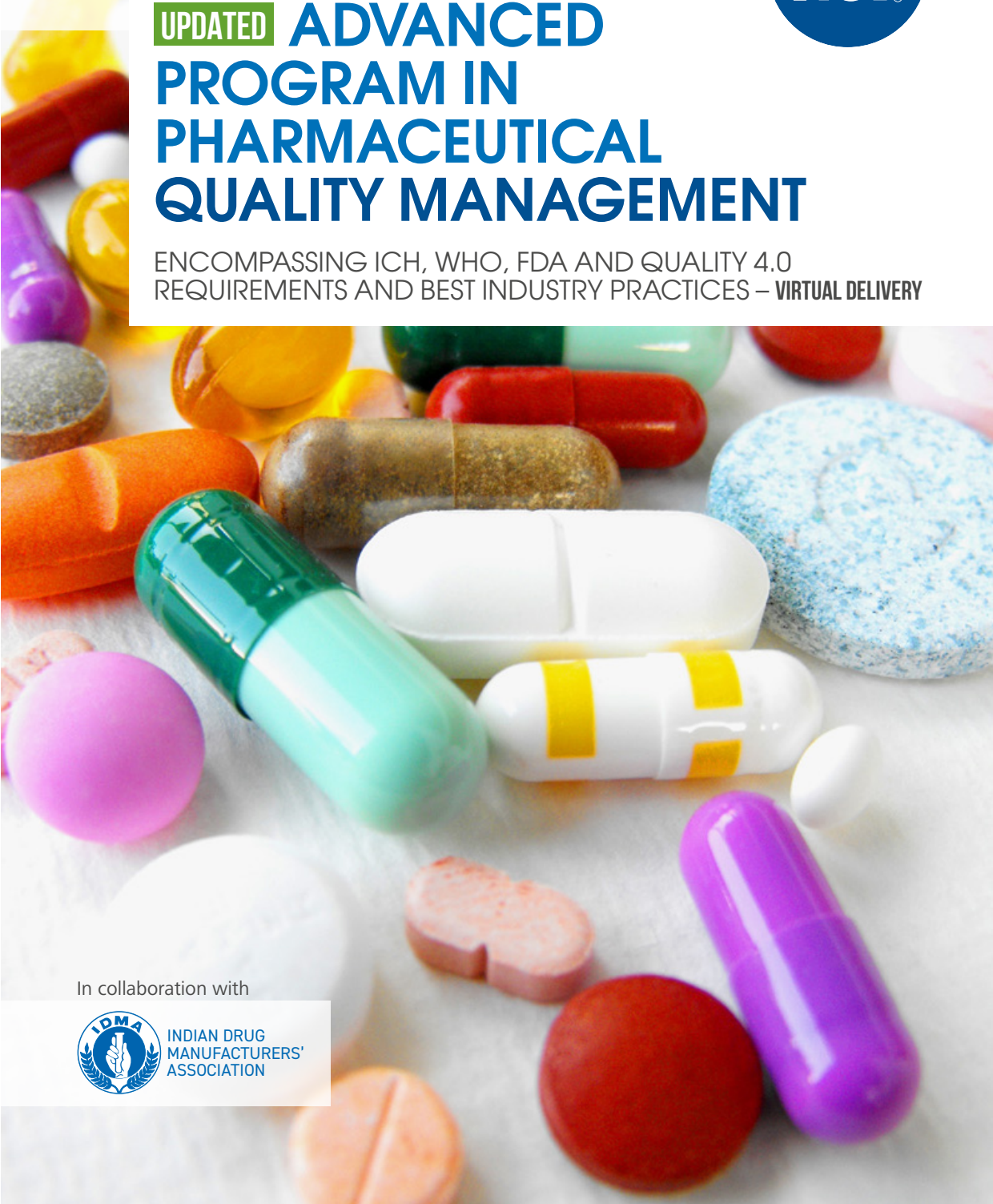
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For further information / queries :
You may also contact Mr. S. M. Mudda
@ mudda.someshwar@gmail.com / 9972029070

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
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The background of the entire page is a close-up photograph of various pharmaceuticals. It includes several capsules in green, white with yellow bands, and purple. There are also various tablets in round, oval, and heart shapes, with colors ranging from pink and orange to blue and white. Some tablets have markings like 'N2' or a cross.

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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Launch of APPQM Series 3

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




ADVANCED PROGRAM IN PHARMACEUTICAL QUALITY MANAGEMENT

MBA STYLE INTERNATIONAL EDUCATION PROGRAM FOR SENIOR LEADERS



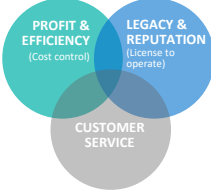
LAUNCH OF APPQM SERIES 3
 IDMA EC Meeting, Sahara Star, Mumbai
13.04.2022
S.M.MUDDA
 PROGRAM DIRECTOR &
 CHAIRMAN, REGULATORY AFFAIRS, IDMA

NSF INTERNATIONAL
789 N. Dixboro Road, Ann Arbor, Michigan 48105 USA

WHY APPQM ?

For companies who want to grow their business in Europe, the UK and the US

Less Resources & Time



By Developing
CHANGE AGENTS
for
QUALITY EXCELLENCE

CHALLENGES - KEY PERSONNEL

DEVELOPING SECOND-LEVEL LEADERSHIP FOR PQS

Current Leadership



- No formal education in best-in-class Quality Management Systems
- Traditional management approach
- Focus on Training-Not on Education
- Risk-Averse, Compliance-oriented and Reactive in Approach

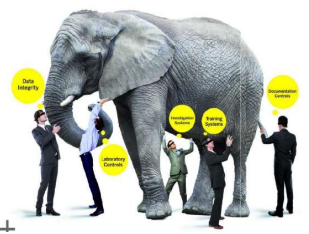
Future Leadership



- Possesses Critical Thinking abilities
- The art and science of simplification
- Structured problem solving
- Risk-based decision making
- Empowered Systems Thinker

CHALLENGES - MINDSET

People need to be reminded more than they need to be instructed




ARE WE GRAPPLING SKEWED PERCEPTIONS OF GMP?

Indian Pharma has a long way to go in the implementation of GMP and it has become a top priority. It has become a top priority for them to a standard for the industry. It has become a top priority for them to a standard for the industry.

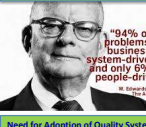
Focus on PRACTICES rather than QUALITY SYSTEM seems to have become the Achilles Heel of our industry.

The only Problems that have Simple Solutions are Simple Problems

CHALLENGES - REACTIVE PHARMACEUTICAL QUALITY SYSTEM (PQS)



Our Learning



"94% of the problems in business are system-driven and only 6% are people-driven"

Need for Adoption of Quality Systems

- *The essential characteristic of Quality system is determined by the interactions of individual manufacturing systems and not by actions of individual system.
- *Quality System cannot be improved by improving individual systems (5 Manufacturing Systems) taken separately.
- Our Learning**
Good Practices that are not supported by a Philosophy (Quality System) will not be sustainable and scalable.

Reference: Russel Akoff, a Systems Thinker and Professor Emeritus, Wharton School

HOW WILL WE DEVELOP CHANGE AGENTS ?

BY EDUCATING THE INDUSTRY FOR ADOPTION OF
PHARMACEUTICAL QUALITY SYSTEM (PQS)
FOR A SUSTAINABLE GMP COMPLIANCE

PHARMACEUTICAL QUALITY SYSTEM (PQS)
=
BUSINESS MANGEMENT SYSTEM (BMS)

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. Muddala

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

Focused 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 implementation of APPQM Learnings:

1. Transformative and Life Changing.

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

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

4. Educating Oneself while Educating Others

5. Has helped transform our quality culture.

6. Best business investment we've ever made.

7. Worth every penny and more.

APPQM SERIES 2 VALEDICTORY – APPRECIATION FROM DIGNITARIES



Dr. V. G. Somani, DCGI

APPQM will help build the quality culture in Indian Pharma Industry



Dr. B. Suresh, Pro-Chancellor, JSS University

APPQM will help develop future quality leaders



Dr. Viranchi Shah, National President- IDMA

Virtual APPQM Program will be a boon for saving Time, Travel & Cost and yet deliver the same quality education



Mr. Mehul Shah, MD, Encube Ethics & Hon. General Secretary, IDMA

Inclusion of Digitization topics will enhance the next series of APPQM



Mr. S. V. Veeraramani, MD, Fountis India

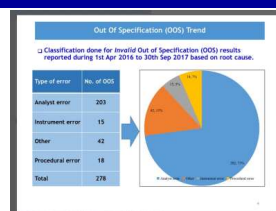
IDMA should aim at developing 1000 Change Agents for quality excellence in coming years



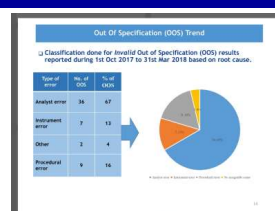
Dr. George Patani, VP (Western Region), IDMA

APPQM will help to remain competitive even while complying with the regulations

Benefits of APPQM –ROI



BEFORE



AFTER

TOTAL SAVING OF Rs. 5 Cr.

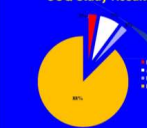
Benefits of APPQM –ROI

RETURN ON INVESTMENT

Stability enhancing monetary gains

- Reduction in OOS results
- Reduction in Material Wastage
- Reduction in Market Complaints
- Reduction in Labor Cost
- Improved process cycle time
- Enhanced Compliance
- Reduced Paper Usage

COQ Study Results



RETURN ON INVESTMENT

100% costed as saved

30% in place of 500 cost

Human error reduction

13% in place of 72

Reduced Paper Usage

Return on Investment-Quantitative

- Bottlenecks in Productivity – (Timeline- 6 months)
- Reduction in Material Wastage – (Timeline- 4 months)
- Reduction in Market Complaints – (Timeline- 1 year)
- Reduction in Labor Cost – (Timeline- 3 months)
- Improved Business Prospects – (However difficult to establish Return on Quality)

Acknowledgments



S. V. Veeraramani, Past National President, IDMA for his continued support & providing his unstinted support.



Dr. B. Suresh, Immediate Past National President, IDMA, for his continued support.



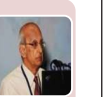
Dr. Viranchi Shah, Joint Secretary, Department of Commerce, Ministry of Commerce & Industry, Govt. of India, for his support.



Mr. Mehul Shah, 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.



Dr. George Patani, Secretary General, IDMA for his continual support, active participation and coordination success of APPQM.



Dr. S. M. Muddala, Chairman, Regulatory Affairs, IDMA and Program Director, APPQM for his Vision & Inspiration. Quality of work determines the Quality of Products.

THANK YOU FOR YOUR ATTENTION

Monkeypox

Dr. Nagaraj Rao, Associate Editor, Indian Drugs

Dear Reader,

Although the COVID-19 pandemic is still a huge cause for worry for governments and populations like, a new threat is raising its head across various countries in the form of monkeypox. Till date, more than 5000 monkeypox cases have been reported from 51 countries worldwide. However, more worrying and abnormal is the fact that these countries seem to have been affected for the first time. More than 90% of the infections are occurring in 31 of the European countries. The United Kingdom has the biggest monkeypox outbreak beyond the African countries, where it is known since decades. British officials note that the disease is spreading in defined sexual networks of gay, bisexual, or men who have sex with men. A recent study on the changing epidemiology of human monkeypox published in PLOS highlights “the mounting concerns about the geographical spread and further resurgence of monkeypox”.

The monkeypox virus is, like the COVID-19 virus, zoonotic and transmitted from animals to humans. The symptoms resemble those of smallpox (which was eradicated in 1980), but these are milder in nature. Earlier, monkeypox was found to occur in central and west Africa, especially close to tropical rainforests. The disease has been raising its head in urban areas and animal hosts include a range of rodents and non-human primates. The monkeypox virus was first identified in 1958 in a macaque colony in Denmark. The virus itself is an enveloped, double-stranded DNA virus belonging to the Orthopoxvirus genus of the Poxviridae family. The two distinct genetic clades of the monkeypox virus are the more severe central African (Congo Basin) clade and the west African clade. Since the virus has a big genome pool, it is considered to have a low rate of mutation. However, the potential influence of mutations cannot be ruled out. The abnormal behaviour of emerging diseases is attributed partly to habitat loss, climate change effects as well as illegal wildlife trade.

Monkeypox is transmitted to human beings through close contact with an infected person or animal, or with material contaminated with the virus. Lesions, body fluids, respiratory droplets and contaminated materials such as bedding used by infected persons are the sources of

Dr. Nagaraj Narayan Rao



obtained Bachelor's degrees in Science (Chemistry) and in the Technology of Pharmaceuticals and Fine Chemicals from the University of Mumbai. After working with Colgate-Palmolive (India) for two years as a laboratory chemist, he obtained his doctorate in science with magna cum laude from the University of Tuebingen, Germany, under the guidance of Prof. Dr. H. J. Roth. He carried out post-doctoral research at the Institute of Biotechnology of the Research Center Juelich, Germany. He was a member of the Editorial Board for the first official German-language version of the European Pharmacopoeia. He was a visiting scientist at Juelich and a visiting faculty at the Institute of Chemical Technology Mumbai from 1993 to 2007 in the field of bioprocess technology. He has authored several original research articles, a patent, review articles and book chapters in the fields of pharmaceuticals, biotechnology, brewery and surface coatings. He was Chief Editor of the “Transactions of the MFAl” for a few years. He contributes a monthly ‘Report from India’ to a leading German technical journal since fourteen years and is a distinguished alumnus of the Research Center Juelich.

Dr. Rao is co-founder of the RRR group of small and medium enterprises, manufacturing organic fine chemicals, formulations for surface coating technologies and fertilizers, process sensors and process units for life sciences, brewery and chemical process industries, as well as representing select overseas companies for cell culture media, bulk drugs and used chemical equipment and plants.

transmission. Fortunately, the vaccines effective against smallpox are also effective to the extent of about 85% against monkeypox. One vaccine has been recently approved for the prevention of monkeypox. An antiviral agent, tecovirimat, developed for the treatment of smallpox has been licensed by the European Medicines Agency for the treatment of monkeypox. The case fatality ratio is around 3-6%.

While monkeypox is not yet known in India, India has recorded several sporadic outbreaks of another pox disease, namely, buffalopox. The buffalopox virus was first isolated in India in 1934. A majority of the people infected have been milkers who have had close contact with buffaloes.

The animal health industry has a crucial role to play in fighting such diseases. The Indian animal healthcare market was pegged at Rs. 6000 crores in 2021. The animal health products are segmented into nutritionals, paracitocides, antibacterials, biologicals and others. In addition to 10 large players, more than 50 smaller manufacturers across the country cater to the needs of this market. They offer a wide range of pharmaceutical tablets, pharmaceutical capsules, antibiotic tablets, injections, pharmaceutical syrups, analgesic tablets, antihistamine tablets, soft gelatin capsules, protein powders and other pharmaceuticals. A paradigm shift in their business approach is noticeable – from therapeutics to preventive to productivity enhancement to overall healthcare of the animals. India's strong presence in the global milk and egg production sectors gives tailwinds to this industry.

The animal health products are regulated by the Veterinary Cell of the Central Drug Standard Control Organisation (CDSCO). The Department of Animal Husbandry and Dairying is responsible for technical reviewing of veterinary products for the farm and companion animal products for registration. The Department of Fisheries is responsible for aqua products, while the Indian Institute of Veterinary Science evaluates biologicals. An excellent document entitled "Guidance for Industry Document for Veterinary Biologicals in India" has been published by CDSCO. The Department of AYUSH is responsible for introducing regulations for herbal and contemporary medicines meant for veterinary use.

The infrastructure created in research, manufacturing and logistics following the onset of the COVID-19 pandemic in India would come to good use in reacting quickly and effectively, should a pandemic such as monkeypox arise.

Happy reading!

Courtesy: Indian Drugs, Editorial, 59 (06), June 2022



IDMA Secretariat celebrates 75th Independence Day



Shri Mehul Shah, Hon. General Secretary, IDMA interacts with Shri Shivraj Singh Chauhan, the Hon'ble Chief Minister of Madhya Pradesh at Bhopal on 8th August 2022



Shri Mehul Shah, Hon. General Secretary, IDMA and Promoter & Managing Director - Encube Ethicals Pvt. Ltd., called upon Shri Shivraj Singh Chauhan, the Honourable Chief Minister of Madhya Pradesh on 8th August, 2022 at CM House, Bhopal. Shri Mehul Shah informed the Chief Minister Shri Shivraj Singh Chauhan on IDMA's work under the Noble direction of Dr. Mansukh Mandaviya and astute leadership of Dr. Viranchi Shah, National President, IDMA. A copy of Diamond Jubilee Coffee Table Book was also presented to him.

Shri Sanjay Kumar Shukla IAS, Principal Secretary, Industrial Policy and Investment Promotion - Government of Madhya Pradesh, and Mr. Vikrant Parashar, EA (Strategy) to MD - Encube Ethicals Pvt. Ltd. had accompanied Shri Mehul Shah.



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CONGRATULATIONS

IDMA congratulates Dr Gopakumar G. Nair, Editor, IDMA Bulletin and Indian Drugs on receiving LLM (Corporate Law & Finance) from Jindal Global Law School, O. P Jindal University from Justice Chandrachud as Chief Guest at Convocation Ceremony



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Updated List of Applicants Approved under PLI Scheme for Promotion of Domestic Manufacturing of Critical Key Starting Materials (KSMs)/Drug Intermediates (DIs)/ Active Pharmaceutical Ingredients (APIs) in India as received from DoP

dated 08th August 2022

List of Applicants Approved under Production Linked Incentive Scheme for Promotion of Domestic Manufacturing of Critical Key Starting Materials (KSMs)/ Drug Intermediates (DIs)/ Active Pharmaceutical Ingredients (APIs) in India

S.No.	Name of the Applicant	Name of the Eligible Product
Target Segment I – Key Fermentation Based KSMs/Drug Intermediates		
1	M/s Aurobindo Pharma Limited (through Lyfius Pharma Pvt. Ltd.)	Penicillin G
2	M/s Karnataka Antibiotics & Pharmaceuticals Ltd.	7 - ACA
3	Orchid Bio-Pharma Limited	
4	M/s Kinvan Pvt. Ltd.	Clavulanic Acid
Target Segment II – Fermentation Based Niche KSMs/Drug Intermediates/APIs		
1	M/s Natural Biogenex Private Limited	Betamethasone
2	M/s Natural Biogenex Private Limited	Dexamethasone
3	M/s Natural Biogenex Private Limited	Prednisolone
4	M/s Symbiotec Pharmed Private Limited	
5	M/s Macleods Pharmaceutical Limited	Rifampicin
6	Karnataka Antibiotics and Pharmaceuticals Limited	Clindamycin Base
Target Segment III – Key Chemical Synthesis Based KSMs/Drug Intermediates		
1	M/s Emmennar Pharma Private Limited	1,1 Cyclohexane Diacetic Acid (CDA)
2	M/s Hindys Lab Private Limited	
3	M/s Alkimia Pharma-Chem Pvt. Ltd. (APCPL)	
4	M/s Meghmani LLP	Para amino phenol
5	M/s Sadhana Nitro Chem Limited	
6	Granules India Limited	Dicyandiamide (DCDA)
Target Segment IV – Other Chemical Synthesis Based KSMs/Drug Intermediates/APIs		
1	M/s Rajasthan Antibiotics Limited	Meropenem

2	M/s Centrient Pharmaceuticals India Private Limited	Atorvastatin
3	M/s Anasia Lab Private Limited	Olmesartan
4	M/s Andhra Organics Limited	
5	M/s RMC Performance Chemicals Private Limited	Aspirin
6	M/s Alta Laboratories Limited (ALL)	
7	M/s Lifetech Sciences	Ritonavir
8	M/s Honour Lab Limited	Lopinavir
9	M/s Hindys Lab Private Limited	Acyclovir
10	M/s Dasami Lab Private Limited	Carbamazepine
11	M/s Dasami Lab Private Limited	Oxcarbazepine
12	M/s Hetero Drugs Limited	
13	M/s Hazelo Lab Private Limited	Vitamin B6
14	M/s Sudarshan Pharma Industries Ltd. (SPIL)	
15	M/s Honour Lab Ltd. (HLL)	
16	M/s Honour Lab Limited	Valsartan
17	M/s Anasia Lab Pvt Ltd	Losartan
18	M/s Hetero Drugs Ltd.	Levofloxacin
19	M/s MSN Life Sciences Pvt. Ltd.	
20	M/s Vital Laboratories Pvt. Ltd.	
21	M/s Vital Laboratories Pvt. Ltd.	Ofloxacin
22	M/s Global Pharma Healthcare Pvt Ltd	
23	M/s Globela Industries Pvt. Ltd.(GIPL)	
24	M/s Kreative Actives Pvt Ltd	Diclofenac Sodium
25	M/s Amoli Organics Pvt Ltd	
26	M/s Vapi Care Pharma Private Ltd	
27	M/s Hetero Drugs Ltd.	Carbidopa
28	M/s Hetero Drugs Ltd.	Levodopa
29	M/s Andhra Organics Ltd	Sulfadiazine
30	M/s Sreepathi Pharmaceuticals Ltd.	Ciprofloxacin
31	M/s Andhra Organics Ltd	Telmisartan
32	M/s Honour Lab Limited	Levetiracetam
33	M/s Globela Industries Pvt. Limited (GIPL)	Norfloxacin
34	M/s Aviran Pharmachem Private Limited (APPL)	Artesunate
35	M/s K P Manish Global Ingredients Pvt. Ltd. (KPMGIPL)	

Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, GoI



In Rajya Sabha & In Lok Sabha

In Rajya Sabha

Change in GST Slabs

Rajya Sabha Starred Question No. *94

Shri Brijlal:

Q. Will the **Minister of Finance** be pleased to state:

- (a) whether Government is contemplating to change the GST slabs, and if so, the details thereof;
- (b) whether Government is also contemplating to relax the mandatory provisions of invoice, and if so, the details thereof; and
- (c) the manner in which common people would be benefited by the change in GST slabs; and
- (d) whether it would also affect the revenue collection of Government, and if so, the details thereof?

Answered on 26th July, 2022

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

Statement Referred to in Reply to the Rajya Sabha Starred Question No. 94 Raised by Shri Brijlal for 26th July, 2022 on Change in GST Slabs

(a) : GST rates/ rate slabs applicable on goods and services are prescribed on the recommendations of the GST Council. GST Council has not made any recommendation for change in the existing GST rate slabs so far. A Group of Ministers (GoM) has been constituted by the GST Council in its 45th meeting held on 17th September, 2021. One of the terms of reference of the GoM is to *“review the current rate slab structure of GST, including special rates, and recommend rationalization measures, including merger of tax rate slabs, required for a simpler rate structure in GST”*.

(b) : At present, there is no such proposal. Currently, E-invoicing is mandatory for taxpayers with aggregate turnover of more than Rs. 20 crore in a financial year with effect from 01.04.2022.

(c) and (d) : The GST Council takes into account all relevant factors while making any recommendation. These include calibrating the interest of common man and the

needs of revenue. A simplified rate structure would ease compliance and provide greater transparency.

Minister of Finance (Shrimati Nirmala Sitharaman)

Guidelines for Prescribing Generic Medicines in Public Hospitals

Rajya Sabha Starred Question No. 104

Prof. Manoj Kumar Jha:

Q. Will the Minister of **Health and Family Welfare** be pleased to state:

- (a) Whether there is a mechanism or guideline of Ministry to track or monitor the doctors in public health facilities for not prescribing generic medicines, if so, the details thereof;
- (b) whether the Ministry has taken or proposed any action to the States against the doctors who are not prescribing generic medicines in public health facilities, if so, the details thereof, State-wise for the year 2021-22; and
- (c) the actions that have been taken against or suggested by the Ministry in instances where patients are asked to purchase medicines from outside, and the details thereof, State-wise for the years 2021-22 and 2020-21?

Answered on 26th July, 2022

A. (a) to (c) A Statement is laid on the Table of the House.

Statement Referred to in Reply to Rajya Sabha Starred Question No. 104* for 26th July, 2022

(a) to (c) Clause 1.5 of Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 prescribes that every physician should prescribe drugs with generic names legibly and preferably in capital letters and he/she shall ensure that there is a rational prescription and use of drug. Further, the erstwhile Medical Council of India (MCI) had issued Circulars dated 22.11.2012, 21.04.2017 and 18.01.2013 vide which all the Registered Medical Practitioners have been directed to comply with the aforesaid provisions.

The National Medical Commission Act, 2019, empowers the appropriate State Medical Councils or Ethics and Medical Registration Board (EMRB) of the Commission, in case of States/UTs where Medical Council is yet to be established, to take disciplinary action against a doctor for violation of the provision of the aforesaid Regulations. As and when complaints are received against the violation of code of ethics for doctors, such complaints are referred by EMRB (previously by erstwhile MCI) to the concerned State Medical Councils where the doctors/medical practitioners are registered. The details of number of complaints received by the Government/ MCI for not prescribing drugs with generic name by the Doctors across the country is not maintained centrally. States have been advised to ensure prescription of generic drugs and conduct regular prescription audits in public health facilities.

Practice of prescription audit is one of the prerequisites for getting certified under the National Quality Assurance Standards (NQAS).

Under National Health Mission (NHM), support is provided for provision of essential generic drugs free of cost in public health facilities. The support is not only for drugs but also for various components necessary for effective implementation of Free Drug Service Initiative viz. strengthening/ setting up robust systems of procurement, quality assurance, IT backed supply chain management systems like Drugs and Vaccines Distribution Management Systems (DSDMS) developed by CDAC, warehousing, prescription audit, grievance redressal, Information, Education and Communication (IEC), training.

**The Minister of Health and Family Welfare
(Dr Mansukh Mandaviya)**

Funds for R&D in drug discovery and manufacturing

Rajya Sabha Unstarred Question No. 973

Dr. Kanimozhi NVN Somu:

- (a) whether Government has initiated any funds for R&D in drug discovery and manufacturing; and
- (b) if so, the details thereof and the list of Indian drugs and medicines approved by FDA, USA and EU?

Answered on 26th July, 2022

- A.** (a): R&D and innovation in pharma sector is done by number of institutions and organizations under

various scientific Ministries/ Departments, which have their own budgetary provisions. Department of Pharmaceuticals has set up seven National Institutes of Pharmaceutical Education & Research (NIPERs) as institutes of national importance, to nurture and promote quality and excellence in pharmaceutical education and research in India. An outlay of Rs. 1,500 cr. has been approved for strengthening/ up-gradation of these NIPERs for the period 2021-22 to 2025-26.

Department of Pharmaceuticals has also set up an Inter- Departmental Committee (IDC) to periodically review and coordinate research work undertaken by various organizations under different Ministries/ Departments so as to ensure optimum utilization of funds and avoid overlapping and duplication of efforts and resources.

NIPERs, after detailed inter departmental consultations have formulated a programme on 'Drug Discovery for Affordable Healthcare' in mission mode and has sought funds from National Research Foundation (NRF). Council of Scientific and Industrial Research (CSIR) through its constituent laboratories has been pursuing R&D activities for drug discovery and development with the total funds committed for ongoing research in the area to the tune of about Rs 53.56 Crore. Department of Biotechnology (DBT), along with its Public Sector Undertaking (PSU) Biotechnology Industry Research Assistance Council (BIRAC) has facilitated implementation of R&D projects for drug discovery in the areas of Tuberculosis (TB), Anti-Microbial Resistance (AMR), Diabetes, Cancer, Rare Diseases, etc., through the regular schemes of DBT and BIRAC. Department of Scientific & Technology (DST) has recently invited proposals for research in rare diseases with focus to bring generic drugs which are off- patent and to develop process chemistry for drugs under patent to make it affordable once patent expires.

(b): Central Drugs Standard Control Organization (CDSCO) under the Ministry of Health & Family Welfare approve new drugs in the country as per provisions of Drugs & Cosmetic Act, 1940 & Rules, made there under. The comprehensive list of all approved drugs is available at https://cdsco.gov.in/opencms/en/Approval_new/Approved-New-Drugs/

In USA, the list of all drugs approved by USFDA is available at <https://www.accessdata.fda.gov/>

[gov/scripts/cder/daf/](https://www.ema.europa.eu/en/medicines/download-medicine-data#european-public-assessment-reports-(epar)-section) and in EU, the European Medicines Agency (EMA) publishes medicine-related data on its website and European public assessment reports (EPARs) of all medicines authorized in European Union is available at [https://www.ema.europa.eu/en/medicines/download-medicine-data#european-public-assessment-reports-\(epar\)-section](https://www.ema.europa.eu/en/medicines/download-medicine-data#european-public-assessment-reports-(epar)-section)

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

Bulk Drug Park in the country

Rajya Sabha Unstarred Question No. 974

Dr. Ameer Yajnik:

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

- the details of Bulk Drug Parks operating in the country;
- whether Government is planning to set up more Bulk Drug Parks in the country;
- if so, the details thereof, State-wise; and
- the manner in which Bulk Drug Parks will reduce the manufacturing cost of bulk drugs in the country and enhance the competitiveness of the domestic bulk drug industry?

Answered on 26th July, 2022

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

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

Under the scheme, financial assistance would be provided for creation of Common Infrastructure

Facilities (CIF) like (i) Central Effluent Treatment Plant(s) (CETP) (ii) Solid waste management (iii) Storm water drains network (iv) Common Solvent Storage System, Solvent recovery and distillation plant (v) Common Warehouse (vi) Dedicated power sub-station and distribution system with the necessary transformers at factory gate (vii) Raw, Potable and Demineralized Water (viii) Steam generation and distribution system (ix) Common cooling system and distribution network (x) Common logistics (xi) Advanced laboratory testing Centre, suitable for even complex testing/ research needs of APIs, including microbiology laboratory and stability chambers (xii) Emergency Response Centre (xiii) Safety/ Hazardous operations audits centre and (xiv) Centre of Excellence etc. in any upcoming Bulk Drug Park promoted by State Government/State Corporation.

The common infrastructure facilities created under the scheme will help reduce the manufacturing cost of bulk drugs and also enhance the competitiveness of the domestic industry.

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

Remdesivir production

Rajya Sabha Unstarred Question No. 978

Prof. Manoj Kumar Jha:

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

- the current production of Remdesivir in the country;
- the buffer stocks of Remdesivir for preparedness to deal with any future requirements;
- the remaining shelf-life of the stock of Remdesivir; and
- the quantity of Remdesivir exported in the years 2020, 2021 and 2022?

Answered on 26th July, 2022

- A.** (a) to (d): As per information provided by the Central Drugs Standard Control Organisation (CDSCO), Ministry of Health & Family Welfare, the quantity of Remdesivir Injection exported by the manufacturers permitted by CDSCO, during 2020, 2021 and 2022, is as under:

Firm Name	Quantity of Remdesivir Injection exported (Vials/Unit)		
	2020	2021	2022
Cipla Ltd.	2,94,999	12,11,795	68,640
Zydus	1,77,994	21,31,609	Nil
Jubilant	1,49,009	7,54,705	3,950
Dr. Reddy's	Nil	17,977	Nil
Mylan	211068	19,66,085	1,75,378
Hetero	852058	18,59,851	2,00,366
Syngene	5000	1,72,678 (from Jan 2021-17.04.2022)	

Further, it has been informed by CDSCO that as there is no demand presently in market for Remdesivir, the current production is Nil. However, the production can be scaled up in case of urgent need.

Further, MoH&FW has informed that about 6,69,083 vials in Central Buffer Stock are available with M/s HLL Lifecare Limited to meet the requirement, if any. These vials are having the Shelf-life ranging from January, 2023 to September, 2025.

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

In Lok Sabha

Impact of War on Indian Industry and Commerce

Lok Sabha Starred Question No. 144

Shri Shyam Singh Yadav

Dr. Vishnu Prasad M. K.

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

- whether the Government has made any estimation of the scale of impact of Ukraine-Russia war on Indian industry and commerce;
- if so, the details thereof;
- whether the Government intends to inject any financial stimulus in the economy in the wake of Ukraine-Russia war; and
- if so, the details thereof?

Answered on 27th July, 2022

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

Statement Referred to in Reply to Parts (A) To (D) of Lok Sabha Starred Question No. 144 For Answer on 27th July, 2022 Regarding "Impact of War on Indian Industry and Commerce".

(a)&(b): As per the feedback received from the industry, exports of some products from India are affected such as pharmaceuticals, telecom instruments, tea, coffee, marine products, etc. The bilateral trade with Russia has, however, improved in comparison to corresponding period last year. The precise implication of the war scenario can be assessed only after the situation stabilizes.

In spite of global economic adversities, the High Frequency Indicators (HFIs) in the first quarter of 2022-23 are reflecting sustained growth momentum in the economy as compared to the previous quarter.

(c)&(d): The Government has provided for fiscal stimulus in the budget of FY 2022-23 with Gross Fiscal Deficit to GDP ratio budgeted at 6.4 per cent.

**The Minister of Commerce and Industry
(Shri Piyush Goyal)**

Ban on Chinese Products

Lok Sabha Starred Question No. 155 (H)

Shri Gopal Chinnaya Shetty:

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

- whether the Government has taken/proposes to take any steps to impose ban on Chinese products;
- if so, the details thereof; and
- if not, the reasons therefor?

Answered on 27th July, 2022

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

Statement Referred to In Reply to Parts (A) To (C) of Lok Sabha Starred Question No. 155(H) for Answer on 27th July, 2022 Regarding "Ban on Chinese Products".

(a) to (b): India and China, are both members of the WTO, and any trade restriction imposed must be WTO compliant. Government has from time to time reviewed and taken WTO compliant measures to address the concerns raised by various stakeholders to have a holistic

global trade strategy. India has not imposed any country specific ban on imports. However, as per the import policy of the Government, all goods imported into India are subject to domestic laws, rules, orders, regulations, technical specifications, environment and safety norms that are notified from time to time and Government takes appropriate action including ban on goods if these are found to violate these regulations or have implications for national security. The import policy of Government for goods is 'free' except when regulated by way of 'Prohibition', 'Restriction' and 'Exclusive Trading' through State Trading enterprises (STEs) on the grounds of (i) public morals, (ii) protection of human, animal or plant life and health, (iii) protection of patents and copy rights, (iv) protection of national treasures of artistic, historical and archaeological value, (v) conservation of exhaustible resources; (vi) prevention of trade in fissionable materials, (vii) of traffic in arms, ammunition and implements of war.

The Directorate General of Trade Remedies (DGTR) is empowered to recommend restrictions on import of a product by imposition of additional duty or quantitative restrictions (QRs) if Indian industry is 'seriously injured' or 'threatened with injury' on account of surge in imports or unfair trade practices. Currently, 61 Anti-dumping measures and 4 countervailing duty measures are in force on Chinese products.

Some examples of industry specific measure are as below:

- (i) For toys, the Government has issued Toys (Quality Control) Order, 2020 on 25 Feb 2020 through which toys have been brought under compulsory Bureau of Indian Standards (BIS) certification with effect from 1 Jan 2021. This QCO is equally applicable to domestic manufacturers as well as foreign manufacturers who intend to export their toys to India. As per this QCO, it is mandatory for toys to conform to Indian standards and bear the standard ISI mark under licence from BIS and no person shall manufacture, import, distribute, sell, hire, lease, store or exhibit for sale any toys without the ISI mark. This will curb import of substandard toys.
- (ii) Similarly, compulsory registration under "Electronics and IT Goods (Requirement of Compulsory Registration) Order 2012" addresses safety standards for 63 notified electronic products including mobile phones. The stock,

sale, import, manufacture, etc. without having valid Registration and Standard Mark of these items is prohibited.

- (iii) In the chemicals and fertilizer sector, the Government has issued the Quality Control Orders (QCO) dated 16.6.2020 whereby in accordance with Section 16 of the Bureau of Indian Standards Act 2016, 14 chemicals shall conform to the corresponding Indian standards and shall bear the Standard Mark under a licence from the Bureau as per Scheme-I of Schedule-II of the Bureau of Indian Standards (Conformity Assessment) Regulations, 2018.
- (iv) In the Electrical machinery sector such as Air conditioners, the Government has issued the Air Conditioner and its related Parts, Hermetic Compressor and Temperature Sensing Controls (Quality Control) Order, 2019, which specifies that specified goods shall conform to the corresponding Indian standards and shall bear Standard Mark under a licence from the Bureau as per Scheme I of Schedule-II of the Bureau of Indian Standard (Conformity Assessment) Regulations, 2018. To support and expand domestic capacities, the Government has implemented policies to promote domestic manufacturing like the Production Linked Incentive (PLI) Schemes in line with the Atmanirbhar Bharat policy to reduce dependence on imports, at an estimated outlay of Rs. 1,97,000 cr fully funded by the Central Government covering inter-alia sectors such as drug intermediates and Active Pharmaceutical Ingredients, medical devices, telecom and networking products, automobile and auto components, advance chemistry cell battery, white goods, textile products, specialty steel, drone and drone components, etc. In addition, in order to promote semi conductor industry, the Government has formulated a scheme amounting to Rs. 76,000 cr.

(c): Does not arise in view of (a) and (b) above.

**The Minister of Commerce and Industry
(Shri Piyush Goyal)**

Foreign Trade Policy

Lok Sabha Unstarred Question No. 1672

Shri S. Jagathrakshakan:

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

- whether the Government is planning to extend the present Foreign Trade Policy (FTP) 2015-20 again, at least by six months, due to pandemic-induced uncertainties;
- if so, the details thereof; and
- if not, the reasons therefor?

Answered on 27th July, 2022

A. (a) and (b): No such proposal is under consideration at present.

(c): The existing Foreign Trade Policy 2015-20 which was announced for a period for five years, was extended by a year due to COVID-19 till 31st March, 2021 and thereafter up to 30.09.2021. Due to continuing impact of COVID-19 again Foreign Trade Policy 2015-20 was extended up to 31st March, 2022. Thereafter, Foreign Trade Policy, 2015-20 was extended up to 30.09.2022 due to global supply chain uncertainties in the wake of conflict between Russia and Ukraine. At present, preparation of new Foreign Trade Policy (FTP) is ongoing.

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

Trade with GCC

Lok Sabha Unstarred Question No. 1678

Shri Naba Kumar Sarania:

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

- whether India's trade with the Gulf Cooperation Council(GCC) is growing at a fast pace;
- if so, the details of India's total exports to the Gulf countries during the last five years;
- the details of requirements for India's trade with Gulf Cooperation Council (GCC);
- whether NRIs constitute half of the Gulf countries and if so, the details thereof;
- whether Startup Bridge has been launched between Invest India and Invest Qatar to accelerate Startup sector in both the countries and if so, the details thereof; and

- whether Assam tea is being exported to such Gulf countries and if so, the details thereof?

Answered on 27th July, 2022

A. (a): Bilateral Trade between India and the GCC grew from US\$ 87.35 billion in FY 2020-21 to US\$ 154.66 billion in FY 2021-22, registering an increase of 77.06% on a year-on-year basis. Since FY 2017-18, on a compounded annual growth rate basis, bilateral trade between India and the GCC has grown by 10.57%.

(b): Details of India's exports to the GCC during the last five financial years is as follows:

India's Exports to GCC						
Values in USD Billion						
S. No.	Country	2017-2018	2018-2019	2019-2020	2020-2021	2021-2022
1	BAHRAIN	0.56	0.74	0.56	0.53	0.90
2	KUWAIT	1.37	1.33	1.29	1.05	1.24
3	OMAN	2.44	2.25	2.26	2.36	3.15
4	QATAR	1.47	1.61	1.27	1.28	1.84
5	SAUDI ARABIA	5.41	5.56	6.24	5.86	8.76
6	UAE	28.15	30.13	28.85	16.68	28.04
	GCC Total	39.39	41.62	40.47	27.76	43.93

Source: DGCIS

(c) : India and the six GCC countries are members of the multilateral trading system, the World Trade Organisation (WTO). India and the UAE recently concluded a bilateral Comprehensive Economic Partnership Agreement (CEPA) that entered into force on 01 May 2022. Like any other partner country in the WTO/ bilateral Free Trade Agreements, trade with GCC countries also entails adhering to relevant customs laws and procedures of India and the respective partner countries under the existing trade Agreements, which includes, inter alia, customs duties, technical standards, sanitary and phytosanitary measures, export and import licencing measures, labelling, packaging and marketing requirements, and any other relevant rules and regulations of India and the partner countries.

(d): As per last figures provided by local authorities in Gulf countries, the estimated number of non-resident Indians (NRIs) currently residing in Gulf countries is as follows:

S. No.	Country	Estimated No. of NRIs residing in the country (In Lakh)
1.	Bahrain	3.20
2.	Kuwait	10.29
3.	Muscat	6.26
4.	Qatar	7.80
5.	Saudi Arabia	21.60
6.	United Arab Emirates	35

(e): Yes. A Startup Bridge has been launched in collaboration with Invest India, the Embassy of India in Doha, Qatar, and Invest Qatar. The India-Qatar Startup Bridge was launched by the Hon'ble Vice President, Shri M. Venkaiah Naidu during the India-Qatar Business Forum held in Doha on 5th June 2022. The collaboration of these two fast-paced and ever-growing ecosystems will result in long-term economic growth and prosperity for both countries. More information of this StartUp Bridge is available on the following website of Startup India: <https://www.startupindia.gov.in/content/sih/en/international/india-qatar-bridge.html>

(f) : As merchant exporters of tea export blended teas by mixing teas from different regions, including Assam, in order to cater to the requirements of different buyers located in various countries, including the GCC countries, the exact volume of Assam tea exports to the GCC countries cannot be estimated.

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

Trade with China

Lok Sabha Unstarred Question No. 1689

Shri N. Reddeppa:

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

- the details of trade with China during the last five years, year and commodity-wise;
- whether the Government is taking measures to reduce our dependence on imports from China,

especially since the Galwan clash;

- if so, the details thereof; and
- if not, the reasons therefor?

Answered on 27th July, 2022

A. (a) : The details of commodity-wise trade between India and China from 2017-18 to 2021-22 is at Annexure-I.

(b) & (c): The Government has launched Production Linked Incentive (PLI) schemes in 14 sectors which will make Indian manufacturers globally competitive, attract investment in the areas of core competency/ cutting-edge technology, enhance exports, integrate India in global supply chain and reduce dependency on imports. The sectors in which PLI has been announced are i) Key Starting Materials/Drug Intermediates and Active Pharmaceutical Ingredients (APIs), ii) Large Scale Electronics manufacturing, iii) Manufacturing of Medical Devices, iv) Electronic/ Technology Products, v) Pharmaceutical drugs, vi) Telecom & Networking Products, vii) Food Products, viii) White Goods (ACs & LED), ix) High Efficiency Solar PV Module, x) Automobiles and Auto components, xi) Advance Chemistry Cell battery, xii) Textile products, xiii) Specialty Steel and (xiv) Drones and Drone Components. All these are the sectors in which substantive imports take place.

Technical Regulations (TRs) have been framed for several products for maintenance of standards/ quality of imported products. This will check import of substandard products.

Several trade remedial actions have been taken against imports from China to protect the domestic industry from serious injury (Anti-Dumping measures in force-61, Countervailing Duty measures in force-4) against unfair trade.

The government procurement portal GeM has made it mandatory for sellers to mention 'country of origin' on products they wish to sell through the platform, a move aimed at promoting Aatma Nirbhar Bharat (Self-reliant India). Also, all e-commerce companies operating in India have to mention country of origin of products being offered for sale.

(d): Does not arise in view of (c) above.

Commodity wise total trade with China (2017-18 to 2021-22)

(In USD million)

HS Code	Commodity	Total trade 2017-18	Total trade 2018-19	Total trade 2019-20	Total trade 2020-21	Total trade 2021-22
01	LIVE ANIMALS.	0.07	0	0.01	0.05	0
02	MEAT AND EDIBLE MEAT OFFAL	0.17	0	0.01	0.05	0
03	FISH AND CRUSTACEANS, MOLLUSCS AND OTHER AQUATIC INVERTEBRATES.	162.33	722.2	1338.62	862.2	1104.23
04	DAIRY PRODUCE; BIRDS' EGGS; NATURAL HONEY; EDIBLE PROD. OF ANIMAL ORIGIN, NOT ELSEWHERE SPEC. OR INCLUDED.	0	0.95	2.08	1.54	11.5
05	PRODUCTS OF ANIMAL ORIGIN, NOT ELSEWHERE SPECIFIED OR INCLUDED.	8.96	13.66	9.07	8.07	11.26
06	LIVE TREES AND OTHER PLANTS; BULBS; ROOTS AND THE LIKE; CUT FLOWERS AND ORNAMENTAL FOLIAGE.	3.55	4.23	4.07	3.82	9.62
07	EDIBLE VEGETABLES AND CERTAIN ROOTS AND TUBERS.	67.83	57.17	92.22	81.72	117.43
08	EDIBLE FRUIT AND NUTS; PEEL OR CITRUS FRUIT OR MELONS.	71.05	15.26	21.76	18.95	18.13
09	COFFEE, TEA, MATE AND SPICES.	54.09	179.72	482.15	689.48	578.56
10	CEREALS.	0.14	1.3	1.08	119.08	511.87
11	PRODUCTS OF THE MILLING INDUSTRY; MALT; STARCHES; INULIN; WHEAT GLUTEN.	15.35	20.4	18.02	13.13	21.75
12	OIL SEEDS AND OLEA. FRUITS; MISC. GRAINS, SEEDS AND FRUIT; INDUSTRIAL OR MEDICINAL PLANTS; STRAW AND FODDER.	37	33.09	64.29	131.76	72.29
13	LAC; GUMS, RESINS AND OTHER VEGETABLE SAPS AND EXTRACTS.	71.39	121.57	73.96	65.73	70.88
14	VEGETABLE PLAITING MATERIALS; VEGETABLE PRODUCTS NOT ELSEWHERE SPECIFIED OR INCLUDED.	41.37	42.14	58.81	78.04	71.08
15	ANIMAL OR VEGETABLE FATS AND OILS AND THEIR CLEAVAGE PRODUCTS; PRE. EDIBLE FATS; ANIMAL OR VEGETABLE WAXES.	452.75	415.59	410.79	885.56	567.93

16	PREPARATIONS OF MEAT, OF FISH OR OF CRUSTACEANS, MOLLUSCS OR OTHER AQUATIC INVERTEBRATES	1.69	1.98	2.78	3.05	2.62
17	SUGARS AND SUGAR CONFECTIONERY.	18.72	24.99	22.34	56.29	92.82
18	COCOA AND COCOA PREPARATIONS.	1.88	1.99	2.14	1.62	1.53
19	PREPARATIONS OF CEREALS, FLOUR, STARCH OR MILK; PASTRYCOOKS PRODUCTS.	1.39	1.65	1.79	1.17	2.24
20	PREPARATIONS OF VEGETABLES, FRUIT, NUTS OR OTHER PARTS OF PLANTS.	31.85	39.82	45.31	35.32	37.02
21	MISCELLANEOUS EDIBLE PREPARATIONS.	20.95	20.76	22.96	30.54	35.16
22	BEVERAGES, SPIRITS AND VINEGAR.	8.72	1.03	3.21	5.58	2.43
23	RESIDUES AND WASTE FROM THE FOOD INDUSTRIES; PREPARED ANIMAL FODER.	61.45	56.84	69.74	88.53	122.4
24	TOBACCO AND MANUFACTURED TOBACCO SUBSTITUTES.	3.12	2.71	6.24	5.98	4.89
25	SALT; SULPHUR; EARTHS AND STONE; PLASTERING MATERIALS, LIME AND CEMENT.	782.61	845.6	753.02	736.05	1094.83
26	ORES, SLAG AND ASH.	1290.08	1255.53	2388.14	4425.36	2587.92
27	MINERAL FUELS, MINERAL OILS AND PRODUCTS OF THEIR DISTILLATION; BITUMINOUS SUBSTANCES; MINERAL WAXES.	2511.65	3903.01	2635.17	1255.7	2787.56
28	INORGANIC CHEMICALS; ORGANIC OR INORGANIC COMPOUNDS OF PRECIOUS METALS, OF RARE-EARTH METALS, OR RAD. ELEM. OR OF ISOTOPES.	785.65	1113.78	852.13	770.82	1112.49
29	ORGANIC CHEMICALS	9197.77	11845.46	10672.87	11390.59	14878
30	PHARMACEUTICAL PRODUCTS	168.08	193.16	212.01	259.23	269.82
31	FERTILISERS.	1072.77	2054.32	1823.56	1553.53	2956.53
32	TANNING OR DYEING EXTRACTS; TANNINS AND THEIR DERI. DYES, PIGMENTS AND OTHER COLOURING MATTER; PAINTS AND VER; PUTTY AND OTHER MASTICS; INKS.	685.42	763.02	884.69	885.2	1252.01

33	ESSENTIAL OILS AND RESINOIDS; PERFUMERY, COSMETIC OR TOILET PREPARATIONS.	276.17	232.06	248.55	274.27	344.61
34	SOAP, ORGANIC SURFACE- ACTIVE AGENTS, WASHING PREPARATIONS, LUBRICATING PREPARATIONS, ARTIFICIAL WAXES, PREPARED WAXES, POLISHING OR SCOURING PREP.	93.61	128.63	125.11	137.43	161.41
35	ALBUMINOIDAL SUBSTANCES; MODIFIED STARCHES; GLUES; ENZYMES.	110.45	130.79	151.33	151.39	240.73
36		0.07	0.11	0.01	0	0
37	PHOTOGRAPHIC OR CINEMATOGRAPHIC GOODS.	21.72	22.46	26.58	35.69	54.64
38	MISCELLANEOUS CHEMICAL PRODUCTS.	1476.13	1433.45	1353.74	1555.52	1870.26
39	PLASTIC AND ARTICLES THEREOF.	2916.43	3827.12	3557.88	3479.73	4833.28
40	RUBBER AND ARTICLES THEREOF.	392.02	361.15	346.85	277.55	368.46
41	RAW HIDES AND SKINS (OTHER THAN FURSKINS) AND LEATHER	133.96	113.84	95.73	71.11	93.61
42	ARTICLES OF LEATHER, SADDLERY AND HARNESS; TRAVEL GOODS, HANDBAGS AND SIMILAR CONT. ARTICLES OF ANIMAL GUT (OTHER THAN SILK-WORM) GUT.	380.67	401.19	342.11	109.64	194.45
43	FURSKINS AND ARTIFICIAL FUR, MANUFACTURES THEREOF.	2.54	3.46	2.61	1.13	1.84
44	WOOD AND ARTICLES OF WOOD; WOOD CHARCOAL.	176.55	187.06	159.14	113.01	172.06
45	CORK AND ARTICLES OF CORK.	0.2	0.76	1.03	0.28	0.45
46	MANUFACTURES OF STRAW, OF ESPARTO OR OF OTHER PLAITING MATERIALS; BASKETWARE AND WICKERWORK.	2.12	2.84	3.42	2.39	3.53
47	PULP OF WOOD OR OF OTHER FIBROUS CELLULOSIC MATERIAL; WASTE AND SCRAP OF PAPER OR PAPERBOARD.	18.46	23.27	31.07	30.36	25.36
48	PAPER AND PAPERBOARD; ARTICLES OF PAPER PULP, OF PAPER OR OF PAPERBOARD.	589.98	601.09	615.79	653.72	744.85
49	PRINTED BOOKS, NEWSPAPERS, PICTURES AND OTHER PRODUCTS OF THE PRINTING INDUSTRY; MANUSCRIPTS, TYPESCRIPTS AND PLANS.	25.12	21.58	24.15	13.76	30.19

50	SILK	203.15	148.49	138.19	62.32	81.36
51	WOOL, FINE OR COARSE ANIMAL HAIR, HORSEHAIR YARN AND WOVEN FABRIC.	40.75	58.7	50.74	23.13	46.63
52	COTTON.	1133.91	1907.82	896.07	1345.19	1356.24
53	OTHER VEGETABLE TEXTILE FIBRES; PAPER YARN AND WOVEN FABRICS OF PAPER YARN.	248.68	201.38	172.26	159.84	238.7
54	MAN-MADE FILAMENTS.	393.68	472.7	575.3	600.31	985.46
55	MAN-MADE STAPLE FIBRES.	358.13	369.94	411.91	405.02	480.91
56	WADDING, FELT AND NONWOVENS; SPACIAL YARNS; TWINE, CORDAGE, ROPES AND CABLES AND ARTICLES THEREOF.	108.37	124.13	111.13	116.14	162.03
57	CARPETS AND OTHER TEXTILE FLOOR COVERINGS.	57.05	56.36	48.98	31.18	32.36
58	SPECIAL WOVEN FABRICS; TUFTED TEXTILE FABRICS; LACE; TAPESTRIES; TRIMMINGS; EMBROIDERY.	90.99	85.63	86.22	67.78	109.18
59	IMPREGNATED, COATED, COVERED OR LAMINATED TEXTILE FABRICS; TEXTILE ARTICLES OF A KIND SUITABLE FOR INDUSTRIAL USE.	596.53	552.21	475.95	327.22	535.21
60	KNITTED OR CROCHETED FABRICS.	460.52	416.3	390.3	361.83	477.11
61	ARTICLES OF APPAREL AND CLOTHING ACCESSORIES, KNITTED OR CROCHETED.	209.66	240.18	235.39	161.08	212.11
62	ARTICLES OF APPAREL AND CLOTHING ACCESSORIES, NOT KNITTED OR CROCHETED.	167.08	161.12	185.05	189.3	139.25
63	OTHER MADE UP TEXTILE ARTICLES; SETS; WORN CLOTHING AND WORN TEXTILE ARTICLES; RAGS	198.69	205.43	198.67	251.59	188.13
64	FOOTWEAR, GAITERS AND THE LIKE; PARTS OF SUCH ARTICLES.	507.18	450.59	427.51	216.72	326.7
65	HEADGEAR AND PARTS THEREOF.	14.1	17.39	20.6	18.29	19.73
66	UMBRELLAS, SUN UMBRELLAS, WALKING- STICKS, SEAT-STICKS, WHIPS, RIDING-CROPS AND PARTS THEREOF.	33.84	35.77	32.27	20.63	22.21
67	PREPARED FEATHERS AND DOWN AND ARTICLES MADE OF FEATHERS OR OF DOWN; ARTIFICIAL FLOWERS; ARTICLES OF HUMAN HAIR.	167.92	160.62	206.81	308.61	508.68

68	ARTICLES OF STONE, PLASTER, CEMENT, ASBESTOS, MICA OR SIMILAR MATERIALS.	418.32	550.54	481.07	389.53	513.95
69	CERAMIC PRODUCTS.	377.46	357.07	369.37	308.13	397.31
70	GLASS AND GLASSWARE.	564.17	638	631.37	499.46	708.89
71	NATURAL OR CULTURED PEARLS,PRECIOUS OR SEMIPRECIOUS STONES,PRE. METALS,CLAD WITH PRE.METAL AND ARTCLS THEREOF;IMIT. JEWELRY;COIN.	786.29	746.16	201.77	200.59	358.27
72	IRON AND STEEL	1945.14	1741.27	1635.24	3407.93	2727.68
73	ARTICLES OF IRON OR STEEL	1533.71	1809.49	1670.74	1379.35	1764.69
74	COPPER AND ARTICLES THEREOF.	1769.19	476.41	444.27	946.84	1567.9
75	NICKEL AND ARTICLES THEREOF.	26.28	45.41	117.69	61.75	76.55
76	ALUMINIUM AND ARTICLES THEREOF.	781.52	1187.63	1017.84	1138.14	2296.66
78	LEAD AND ARTICLES THEREOF.	2.13	15.33	11.83	1.7	0.81
79	ZINC AND ARTICLES THEREOF.	295.08	71.2	91.52	20.77	25.82
80	TIN AND ARTICLES THEREOF.	290.71	5.81	4.11	3.16	3.98
81	OTHER BASE METALS; CERMETS; ARTICLES THEREOF.	214.36	246.16	220.92	174.95	375.19
82	TOOLS IMPLEMENTS, CUTLERY, SPOONS AND FORKS, OF BASE METAL; PARTS THEREOF OF BASE METAL.	298.05	339.97	336.55	394.51	499.56
83	MISCELLANEOUS ARTICLES OF BASE METAL.	424.77	407.89	407.25	332.89	523.21
84	NUCLEAR REACTORS, BOILERS, MACHINERY AND MECHANICAL APPLIANCES; PARTS THEREOF.	14255.75	14214.64	14126.44	14738.28	20907.33
85	ELECTRICAL MACHINERY AND EQUIPMENT AND PARTS THEREOF; SOUND RECORDERS AND REPRODUCERS, TELEVISION IMAGE AND SOUND RECORDERS AND REPRODUCERS, AND PARTS.	29151.99	21207.08	19966.48	21045.9	30726.25
86	RAILWAY OR TRAMWAY LOCOMOTIVES, ROLLING-STOCK AND PARTS THEREOF; RAILWAY OR TRAMWAY TRACK FIXTURES AND FITTINGS AND PARTS THEREOF; MECHANICAL	132.03	183.93	207.74	183.34	164.82

87	VEHICLES OTHER THAN RAILWAY OR TRAMWAY ROLLING STOCK, AND PARTS AND ACCESSORIES THEREOF.	1543.43	1619.84	1361.15	1490.29	1854.67
88	AIRCRAFT, SPACECRAFT, AND PARTS THEREOF.	40.39	23.52	27.64	11.41	11.94
89		1208.98	78.81	73.17	83.27	84.68
90	OPTICAL, PHOTOGRAPHIC CINEMATOGRAPHIC MEASURING, CHECKING PRECISION, MEDICAL OR SURGICAL INST. AND APPARATUS PARTS AND ACCESSORIES THEREOF;	1818.45	1738.02	1507.17	1926.94	2731.82
91	CLOCKS AND WATCHES AND PARTS THEREOF.	97.93	50.25	49.2	30.82	55.56
92	MUSICAL INSTRUMENTS; PARTS AND ACCESSORIES OF SUCH ARTICLES.	33.92	39.36	31.27	35.22	37.12
93		0.08	0.02	0.08	0.05	0
94	FURNITURE; BEDDING, MATTRESSES, MATTRESS SUPPORTS, CUSHIONS AND SIMILAR STUFFED FURNISHING; LAMPS AND LIGHTING FITTINGS NOT ELSEWHERE SPECIFIED OR INC	1219.62	1005	912.04	603.48	730.73
95	TOYS, GAMES AND SPORTS REQUISITES; PARTS AND ACCESSORIES THEREOF.	491.67	457.12	408.9	297.04	252.1
96	MISCELLANEOUS MANUFACTURED ARTICLES.	317.62	348.1	359.98	317.56	376.13
97	WORKS OF ART COLLECTORS' PIECES AND ANTIQUES.	111.36	3.74	37.01	4.74	0.71
98	PROJECT GOODS; SOME SPECIAL USES.	614.22	555.81	441.56	350.29	202.17
99	MISCELLANEOUS GOODS.	1.25	0.04	0.1	0.08	0.13
	Total trade with China	89714.23	87071.84	81873.5	86399.4	115419.96

(Source: DGCIS)

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



Uniform Code of Pharmaceutical Marketing Practices - Government clarifies Supreme Court issue

The Government has put in place a Uniform Code for Pharmaceutical Marketing Practices (UCPMP) for Pharmaceutical companies, which is in operation since 01.01.2015, to prevent unethical practices by the pharmaceutical companies. This code governs the conduct of pharmaceutical companies in their marketing practices, duly covering the various aspects such as medical representatives, textual and audio-visual promotional materials, samples, gifts, etc. Further, the code establishes relationship with healthcare professionals, wherein the provisions related to travel facilities, hospitality and cash or monetary grants to physicians or their families have been elaborated.

The code also details the mode of operation of the code, responsibilities of the Pharmaceutical Associations in constituting the Ethics Committee for Pharmaceutical Marketing Practices (ECPMP) for handling the complaints and Apex Ethics Committee for Pharmaceutical Marketing Practices (AECMP) for review, procedure of lodging a complaint, procedure of handling of complaints by the Pharmaceutical Associations and various penalty provisions.

The code has been adopted by the all the major associations of pharmaceutical companies and the Department on various instances has reviewed implementation of the code by the Pharmaceuticals associations.

The complaints of violation of the voluntary UCPMP by pharma companies which are perceived by the Department are forwarded to the concerned associations for taking necessary action.

The Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 formed under Indian Medical Council Act, 1956 (102 of 1956), provides for conduct for doctors and professional association of doctors in their relationship with pharmaceutical and allied health sector industry. Under this, any complaint of professional misconduct of a medical practitioner or professional is to be addressed by the respective State Medical Councils.

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

The Department has not received any representations in the recent past from civil societies and patents group to make the UCPMP code mandatory. Further, in the writ petition (Civil) No. (s).323/2021 filled by federation of the Medical and Sales Representatives Associations of India & others against Union of India and others, the matter is under consideration of Hon'ble Supreme Court of India.

This information was given by Minister of State for Chemicals and Fertilizers, Shri Bhagwanth Khuba in a written reply in Lok Sabha today.

Source: PIB Delhi, 05.08.2022



Have you renewed your **Membership** for the years

2021-2022 & 2022-2023

If not, please do so; kindly contact IDMA Secretariat at:
Email: actadm@idmaindia.com / accounts@idmaindia.com
Tel.: 022 - 2494 4624 / 2497 4308 / Fax: 022 - 2495 0723

Commerce dept recast to bring more focus on policy making

The commerce department has restructured the organisation separating multilateral and bilateral trade-negotiating divisions to allow greater focus on ongoing talks for free-trade deals.

It has also taken away from the Directorate General of Foreign Trade (DGFT) its power to make foreign trade policy, leaving it only with the function of regulation and promotion of foreign trade.

The Trade Policy Division has been bifurcated to Trade Negotiation Wing-Bilateral and Trade Negotiation Wing Multilateral (TNM) to be headed by additional secretaries in the departments.

The move is significant at a time when India is negotiating free-trade agreements (FTAs) with countries like the United Kingdom, European Union, Canada, and Australia.

“The Trade Policy Wing/Division of DGFT, from the date of this order, will function as foreign trade policy division within the Trade Policy Wing of DoC (Department of Commerce) and will be responsible for foreign trade policy and all connected matters,” a government notification reviewed by Business Standard showed.

Earlier, foreign trade policy used to be prepared by the DGFT. The ministry has now created wings of trade regulation and global trade promotion that will function under the DGFT.

A commerce Ministry official confirmed that the reorganisation had been conducted based on a report submitted by Boston Consulting Group. “So both the Special Economic Zone (SEZ) and foreign trade policies will be under one additional secretary. The idea is to anchor related policies at one location instead of keeping it scattered. However, the idea is also to induct domain experts into the department. If that does not happen, the restructuring will be of little use,” he said.

The DGFT has been already working on the much-delayed foreign trade policy, which is now expected to be released by the end of September.

Another former trade official said there might be a logic in separating the two divisions so that they don't interfere in each other's domains since in bilateral and multilateral negotiations, the considerations are different. “But one should not confuse form for substance. Our exports are not strong and resilient for reasons which are deep rooted in the economy. That cannot be changed by such restructuring. Sometimes, we diagnose the problem wrongly,” he added.

The government has been seeking to reorganise the work structure of DGFT for quite some time. In 2016, consultancy firm Frost & Sullivan submitted a report restructuring of DGFT, but it did not take off.

“The effort was to convert DGFT into a corporatised agency like the Japan External Trade Organization. Governments in developed countries like Japan don't carry out trade promotion functions. They do it through a corporatised body supported by the government. But our government decided against it as in our environment it would become like yet another government agency without any arm's length functioning. There could also be duplication of work through the government and the corporatised body,” the former trade official said.

“Another idea was to hand over the implementation and adjudication function of DGFT to customs authorities because even now there is a dual responsibility. But the revenue department was not ready for it,” he added.

Source: Asit Ranjan Mishra, Business Standard, 08.08.2022



Tamil Nadu Scientist Breaks Glass Ceiling, Becomes CSIR's First Woman Director General - Kalaiselvi

Known for her work in the field of lithium ion batteries, Kalaiselvi is at present director of the CSIR-Central Electrochemical Research Institute at Karaikudi in Tamil Nadu

New Delhi: Senior scientist Nallatham by Kalaiselvi has become the first woman director general of the Council of Scientific and Industrial Research (CSIR), a consortium of 38 research institutes across the country.



Her appointment is for a period of two years with effect from the date of assumption of charge of the post or until

further orders, whichever is earlier, a personnel ministry order said on Sunday, August 7.

Kalaiselvi succeeds Shekhar Mande, who superannuated in April. Rajesh Gokhale, Secretary, Department of Biotechnology, was given the additional charge of the CSIR upon Mande's retirement.

Known for her work in the field of lithium ion batteries, Kalaiselvi is at present director of the CSIR-Central Electrochemical Research Institute at Karaikudi in Tamil Nadu.

She will also hold the charge as secretary, Department of Scientific and Industrial Research. Kalaiselvi has risen through the ranks in CSIR and had broken the proverbial glass ceiling by becoming the first woman scientist to head the Central Electrochemical Research Institute (CSIR-

CECRI) in February, 2019.

She had started her career in research as an entry-level scientist at the same institute. Hailing from Ambasamudhram, a small town in Tirunelveli district of Tamil Nadu, Kalaiselvi did her schooling in Tamil medium, which, she said, helped her grasp the concepts of sciences in college.

Kalaiselvi's research work of more than 25 years is primarily focused on electrochemical power systems and in particular, development of electrode materials, and electrochemical evaluation of in-house prepared electrode materials for their suitability in energy storage device assembly. Her research interests include lithium and beyond lithium batteries, super-capacitors and waste-to-wealth driven electrodes and electrolytes for energy storage and electrocatalytic applications.

She is currently involved in the development of practically viable Sodium-ion/Lithium-sulfur batteries and super-capacitors. Kalaiselvi also made key contributions to the National Mission for Electric Mobility. She has more than 125 research papers and six patents to her credit.

Source: The Wire, 07.08.2022



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