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

IDMA BULLETIN

VOL. NO. 53 | ISSUE NO. 23 (PAGES: 44) | 15 TO 21 JUNE 2022 | ISSN 0970-6054 | WEEKLY PUBLICATION

INDIAN PHARMA - GLOBAL HEALTH CARE

INDIAN DRUG MANUFACTURERS' ASSOCIATION

HIGHLIGHTS

EXCELLENCE

THAT IS IT'S OWN STANDARD.

Dear Partner,

Excellence is the link between all we do at Signet, from our products to services and to our partners such as Meggle. Seen as the world's best producers of pharmaceutical lactose, Meggle's reputation of excellence precedes them.

Not only does Meggle possess an impressive portfolio of several lactose based products used for a variety of dosage forms and dry powder inhalation; but also the complete range of production capabilities, from sieving and milling to spray drying and co-processing.

With partners like Meggle, Signet's excellence is achieved with ease. And the demands of our clients, we always exceed.

Signet-ure *excellence*

MEGGLE EXCIPIENTS & TECHNOLOGY

GRANULAC / SORBOLAC
- Milled Lactose Monohydrate

PRISMALAC / CAPSULAC / SACHELAC / SPHEROLAC
- Sieved Lactose Monohydrate

FLOWLAC
- Spray-dried, DC Lactose

DURALAC H
- Anhydrous, DC Lactose

TABLETTOSE
- Agglomerated, DC Lactose

INHALAC
- Lactose for Inhalation

CELLACTOSE 80
- Co-processed blend of Lactose & Powdered Cellulose

MICROCELAC 100
- Co-processed blend of Lactose & MCC

RETA M
- Co-processed blend of Mannitol & HPMC

RETALAC
- Co-processed blend of Lactose & HPMC

COMBILAC
- Co-processed blend of Lactose, MCC & Starch

LACTOSE MONOHYDRATE - LOW ENDOTOXIN

Signet

The Complete Excipients Company

A Publication of
Indian Drug Manufacturers' Association
102-B, 'A-Wing', Poonam Chambers,
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actadm@idmaindia.com/ website: www.idma-assn.org

Published on 7th, 14th, 21st and 30th of every month

Annual Subscription
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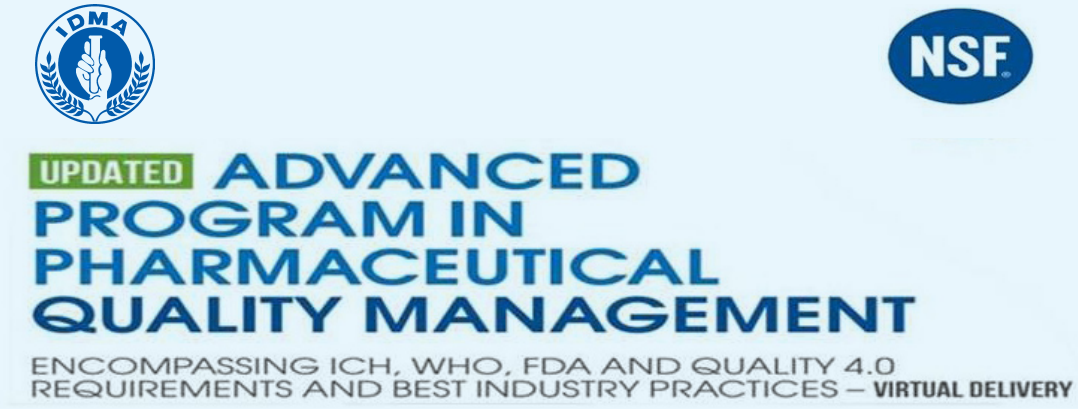
IDMA BULLETIN

Vol. No. 53 **Issue No. 23** **15 to 21 June 2022**

IDMA ACTIVITIES:

GOVERNMENT NOTIFICATIONS:

NATIONAL NEWS:



3rd June 2022

Dear Member,

APPQM - EXECUTIVE PROGRAM IN PHARMACEUTICAL QUALITY MANAGEMENT

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

APPQM+ Series 3 Commences September 2022

Why APPQM in INDIA?

We live in a world of 'Brutal Disruption'. Covid pandemic – what next? **Prosperity awaits those who do the basics to PhD level.**

When launching the first series of the APPQM, we at IDMA along with NSF Health Sciences, UK boldly stated that APPQM, the unique, World-Class education program will just do that and ***Develop Change Agents For Quality Excellence.***

Well, Series One & Two lived up to the expectations of the industry. Over 40 delegates attended Series One & 28 delegates attended Series Two.

Both the series were a resounding success and this is what the delegates thought:

- ✓ Transformative
- ✓ World-class
- ✓ Best business investment we've ever made
- ✓ Worth every penny and more
- ✓ Has helped transform our quality culture
- ✓ Educating oneself while Educating others
- ✓ The course was really pragmatic and foundational in understanding the core Quality Systems framework

'Work Placement Projects' have been completed by APPQM delegates. These have generated $ millions in savings for their parent companies, improved their operational efficiency (profit), regulatory compliance and reduced risk.

APPQM+ Series 3

Based on the success of Series 1 & 2, we are pleased to announce the launch of APPQM+ Series 3 that is expected to commence in September 2022 and covers special sessions on Digitization.

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

- ✓ Challenges Facing the Pharmaceutical Industry
- ✓ How APPQM can help
- ✓ Benefits of the Program
- ✓ Course Format
- ✓ Details of Key Topics of the 5 Course Modules and the List of Tutors

Additional Benefits:

This virtual education program offers the following additional benefits.

- ➢ Safety of Individuals during this COVID-19 pandemic.
- ➢ Reduction in Course Fees (from £8000 for Physical Class to £3300 for Virtual Class)
- ➢ Saving of time especially travel time to venue in Bangalore and travel & hotel stay expenses

Please don't get left behind and register for the third series of APPQM to have a competitive edge in the global market and to be future ready.

Registration Fee for APPQM+ Series 3

The Registration Fee for APPQM+ Series 3 is Rs.4,00,000/- (Rupees Four Lakh Only) Plus 18% GST Per Participant.

You can initially block the seats by paying an advance amount of Rs.1,00,000/- (Rupees One Lakh Only) and balance 15 days before commencement of the program.

Registration Procedure :

Please fill the enclosed Registration Form and send it to

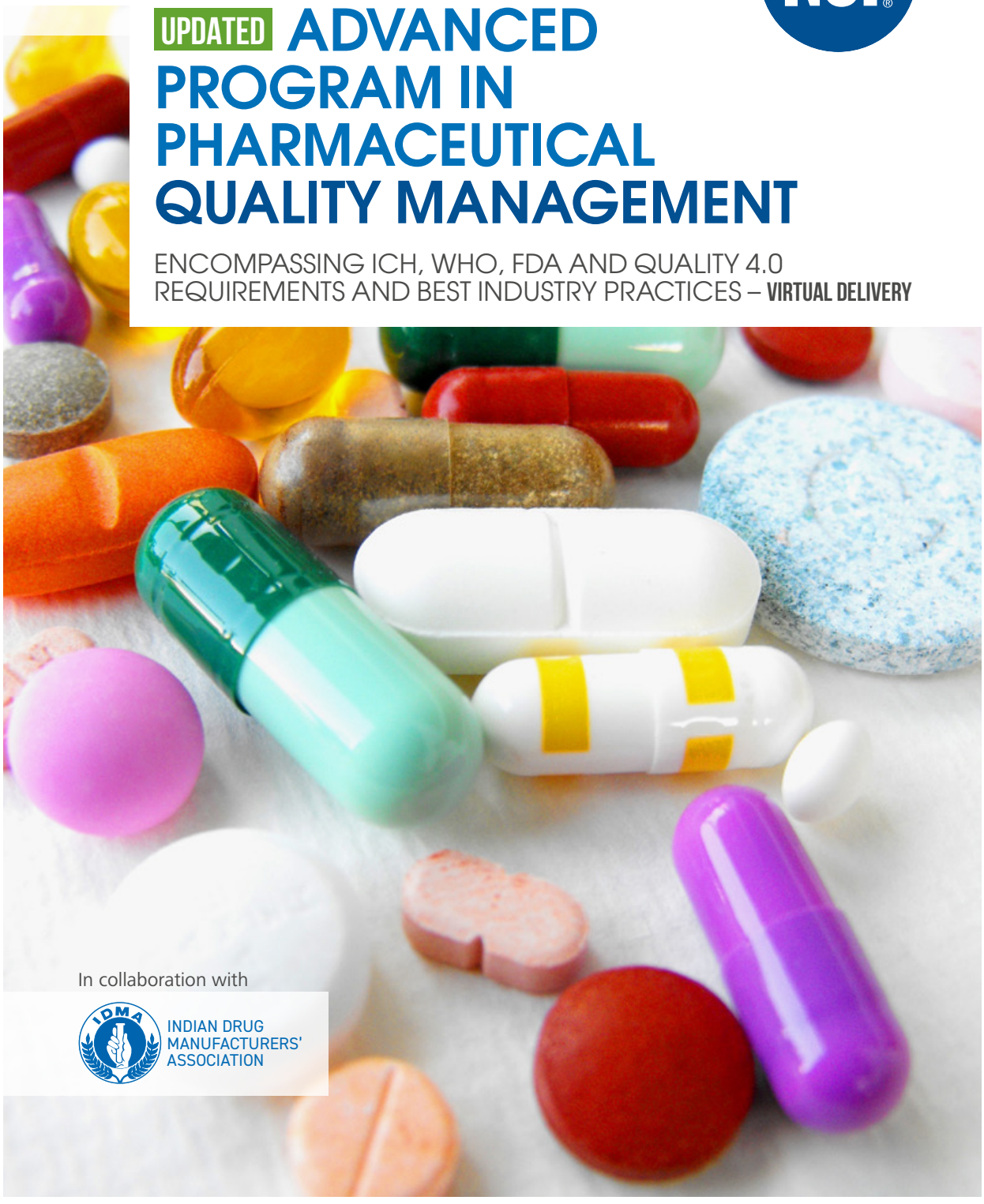
Melvin actadm@idmaindia.com 9821868758	**Batul** technical@idmaindia.com 9920045226

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

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

Sincerely Yours,

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


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

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

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

CHALLENGES FACING THE PHARMACEUTICAL INDUSTRY

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

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

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

HOW THIS TRAINING CAN HELP

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

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

WHY CHOOSE NSF?

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

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

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

BENEFITS OF THIS TRAINING

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

For example by:

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

Attendees will also:

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

COURSE FORMAT

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

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

▶▶

COURSE MODULES

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

MODULE ONE: Pharmaceutical Quality Management Systems – Best Industry Practices

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

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

MODULE TWO: Managing Change; Change Control and Deviations

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

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

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

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

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

▶▶

MODULE FOUR: Data Analysis for Business Improvement

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

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

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

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

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

NEXT STEPS YOUR CALL TO ACTION

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

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

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

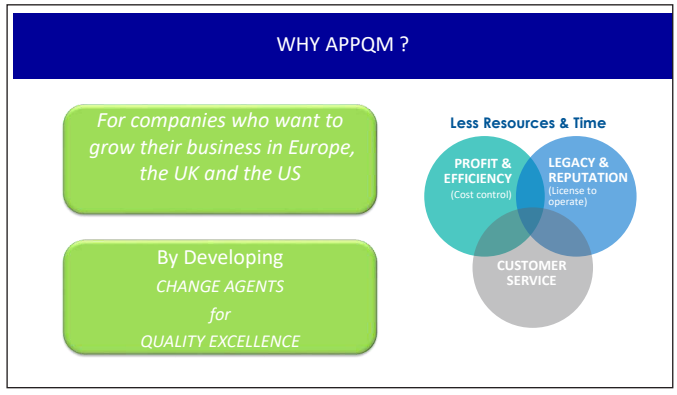
NSF INTERNATIONAL

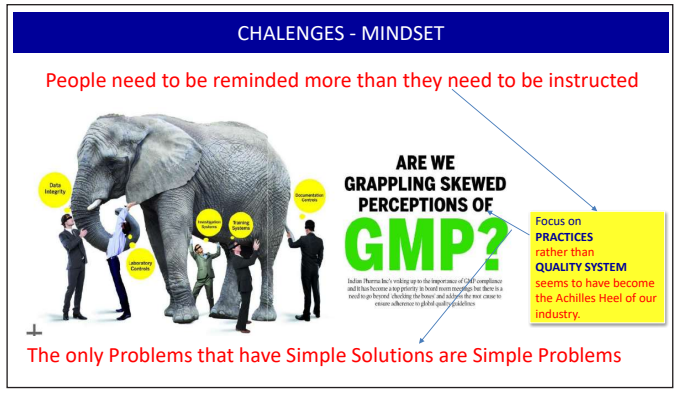
www.nsf.org | www.nsf.org/locations LinkedIn

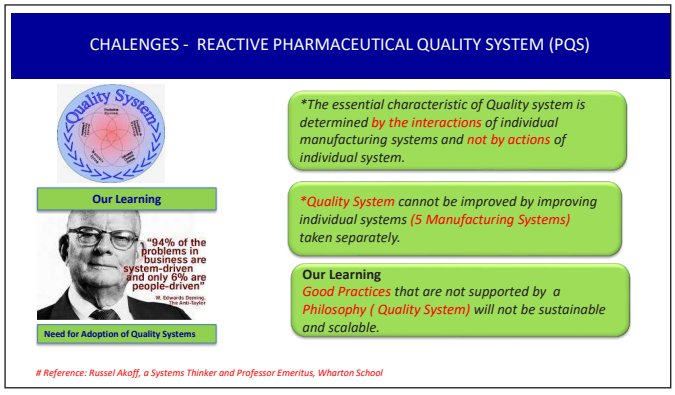
PRESENTATION

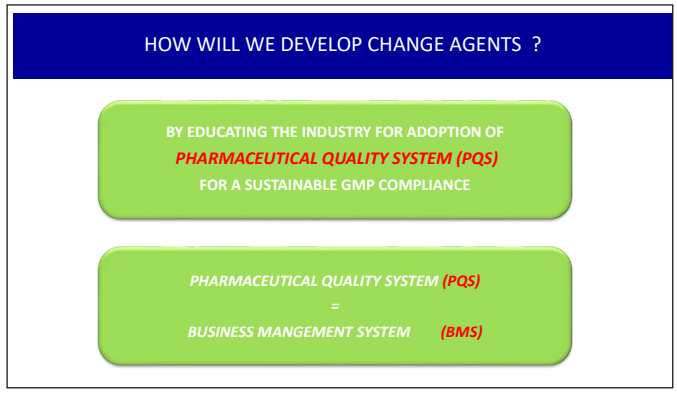
Launch of APPQM Series 3

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	*Mr. Martin Lush	*Dr. Ajaz Hussain
Chairman, Regulatory Affairs, IDMA and a strong Proponent of Quality Systems	Ex- Global VP, NSF International, UK and a leading consultant & tutor	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

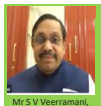
Dr. B Suresh, Pro-Chancellor, JSS University

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

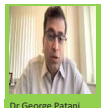
Inclusion of Digitization topics will enhance the next series of APPQM

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



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

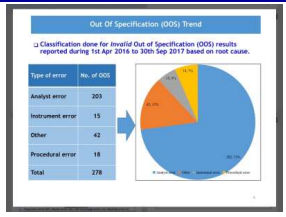
Mr S V Veerramani, MD, Fourrts India



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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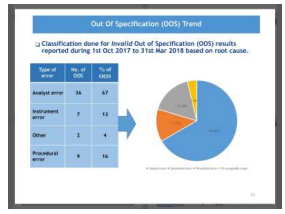

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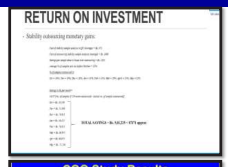
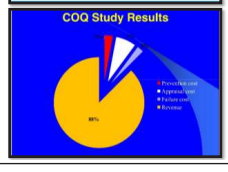
TOTAL SAVING OF Rs. 5 Cr.

Benefits of APPQM -ROI





Acknowledgments

S.V.Veerramani	Mahesh Doshi	Sudhanshu Pandey,	S. M. Mudda	Dsara B Patel	R.S.Iyer
Past National President, IDMA for mentoring this program & providing his unstinted support.	Immediate Past National President, IDMA for his continued support	Joint Secretary, Department of Commerce, Ministry of Commerce & Industry, Govt. of India, for his support	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	Secretory General IDMA for his continual support, active participation and coordination success of APPQM	Renowned Quality Guru and our Inspiration "Quality of Work Determines The Quality Of Products"

THANK YOU FOR YOUR ATTENTION

IPR Policy Vs Regulatory Policy

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

Dear Reader,

Let us get ready to face the global healthcare challenges with positive attributes and approaches to regulatory pathways.

Resisting evergreening and extreme imbalances in Intellectual Property and patent practices may be a good option to continue from the Uruguay Round, TRIPs and the Doha Declaration perspective. However, it is time for us to sit up and take note that we have come a long way in the pharmaceutical field from the India of the 70s and 80's, to now attract global attention as the "Pharmacy of the World". We must now move on to consolidate our position and "pride of place" by voluntarily opting for regulatory upgradation by increasingly co-operating with CDSCO and the leading state FDAs to move up the ladder on global quality assurance, offering a global regulatory model and not just GMPs but also overall Good Manufacturing and Quality Assurance Governance Standards setting an example to the world.

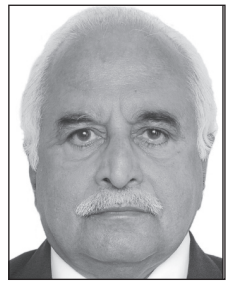
In earlier times, finance was a major constraint for upgrading the quality standards and maintaining good laboratory practices. Today both the Government of India as well as private equities are ready and forthcoming to help the merit-driven pharma industry for upgradation. Let us move forward and consolidate the global leadership. It is there for us to take and we must "strike when the iron is hot".

Indian regulators have chosen to opt for ICH, which is a very welcome initiative. Let us hope that we will become fully compliant in the near future. In his valedictory address at the 60th Annual Celebrations of IDMA on 15th April 2022, the Honorable Minister for Commerce and Industry, Shri Piyush Goyal, appealed to the pharma industry and IDMA to go for full PICs membership to claim and consolidate Global acceptance and get "Open-door" invitations for Indian Pharmaceuticals. Let us shelve our inhibitions and reservations and move forward to provide the Indian Pharma Industry the welcome it awaits from the "rest of the developed countries and the emerging countries by being fully equipped not only with the US and EU approvals, but also with ICH, PICs and other regulatory compliance labels.

While we endeavor to move to our goal of achieving higher quality and regulatory standards, we must support our manufacturing capabilities and new product launches with better research methodologies and higher standards of data integrity. Our research organizations must play a key role in helping us build robust processes and products which will result in lesser regulatory issues in the days ahead.The focus on robust processes and products will further ensure that innovation is not stifled due to the more stringent regulatory procedures. Hence our R&D teams must essentially also be part of this transformation to improve the regulatory standards.

The world is waiting, let us get ready to remove the last of the hurdles and make "Vasudhaiva Kutumbakam" a reality by getting all the gates (hitherto locked under TBT-Technical Barriers to Trade) opened and make global pharma open "flood-gates" for Indian Pharma to conquer.

Courtesy: Indian Drugs, Editorial, 59 (04), April 2022



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

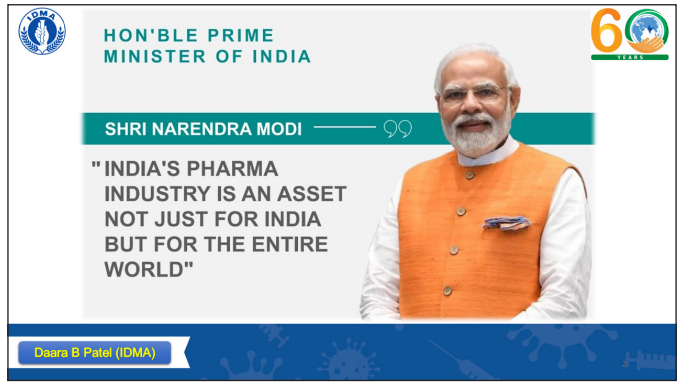
Having moved into the Intellectual Property field, he was the Dean of IIPS (Institute of Intellectual Property Studies) at Hyderabad in 2001/2002. Later, he set up his own boutique IP firm, Gopakumar Nair Associates, as well as Gnanlex Hermeneutics Pvt. Ltd., having done his L. L. B. from Mumbai University.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

IDMA Delegation at Korea International Pharmaceutical & Bio-Pharma Exhibition held on 14th to 17th June 2022, Korea

PRESENTATION

Indian Pharma Industry's Role during Covid-19 (Global Perspective)

Mr. Daara B Patel, *Secretary- General, IDMA*



ABOUT IDMA

- Indian Drug Manufacturers' Association (IDMA) has been, since its inception in 1961, the engine leading the Indian Pharmaceutical Industry to greater heights and glory and ensuring near self-sufficiency of affordable quality medicines for our people and also globally.
- We have a membership of 1000 plus and 8 State Boards
- IDMA, as the apex national body of Pharmaceutical and API manufacturers in our country is the only Association comprising of small, medium and large scale pharmaceutical manufacturers situated throughout the length and breadth of our country.
- IDMA engages with the Regulators & Government Authorities on policy matters and regulatory issues and has been on various platforms & committees that consider policy formations and amendments.

Daara B Patel (IDMA)

ABOUT IDMA – Training Programs

- IDMA has been successfully organizing Pharmaceutical Analysts Convention (PAC) for the last 20 years with active participation of Regulatory Authorities, both Central and States.
- IDMA also organizes other Webinars, Conference, Seminars & Training Programs regularly.
- IDMA has organized two (2) Series of "Advanced Program in Pharmaceutical Quality Management" (APPQM) in collaboration with NSF Health Sciences, UK. Developed 68 Change Agents for the Pharma Industry.
- **The Third (3) Series is an updated APPQM+ which begins on1st September 2022.**

UPDATED ADVANCED PROGRAM IN PHARMACEUTICAL QUALITY MANAGEMENT
ENCOMPASSING ICH, WHO, FDA AND EQUALITY 4.0 REQUIREMENTS AND BEST INDUSTRY PRACTICES – VIRTUAL DELIVERY

Daara B Patel (IDMA)

ABOUT IDMA - IDMA PUBLICATIONS

IDMA Bulletin	Indian Drugs	Annual Publication
Weekly communication medium with members and other interested readers now in 53rd year	Monthly scientific and technical journal, now in its 59th year – Also online with dedicated website: www.indiandrugsonline.org	A reference compendium with a wealth of information and data on the Indian Pharmaceutical Industry including New Drugs approved by DCG(I) Latest Edition 60th Edition released in April 2022

Daara B Patel (IDMA)

ABOUT IDMA - AWARDS

- ✓ **IDMA – APTAR INNOVATION OF THE YEAR AWARD**
- ✓ **IDMA – N I GANDHI – CHIEF MENTOR AWARD**
- ✓ **IDMA QUALITY EXCELLENCE AWARDS** for Bulk Drug and Formulation manufacturing units.
- ✓ **IDMA MARGI PATEL CHOKSI MEMORIAL BEST PATENT AWARDS** for Best patents granted in India and globally for greater emphasis on innovative Research
- ✓ **IDMA CORPORATE CITIZEN AWARD** to recognize and appreciate humanitarian CSR activities
- ✓ **IDMA RESEARCH AWARDS** and the **BEST REVIEW ARTICLE AWARD** for the Best Original Research Papers and Review Article published in 'Indian Drugs'
- ✓ **IDMA J B MODY BEST STUDENT AWARDS** for the top-ranking B. Pharm students of Indian Universities

Daara B Patel (IDMA)

ABOUT INDIAN PHARMA INDUSTRY

India is Considered & Appreciated As Pharmacy of the World

- We supply to more than 200 countries, everybody is looking at India for affordable, efficacious quality medicines.
- India is the world's largest supplier of generic medications, accounting for 20% of the worldwide supply by volume.
- **We meet about approximately 60% of the global covid-19 vaccination demand.**
- We cater to 50% of global demand for various vaccines
- 40% of Generic medicines required by the US is supplied by India
- We meet 25% of all medicines required by UK.

Daara B Patel (IDMA)

ABOUT INDIAN PHARMA INDUSTRY

- The domestic pharmaceutical industry includes a network of 3,000 drug companies and 10,500 manufacturing units.
- **India also has a large pool of scientists and engineers with the potential to steer the industry ahead to greater heights.**
- Presently, over 80% of the antiretroviral drugs used globally to combat AIDS are supplied by Indian pharmaceutical manufacturers.

Daara B Patel (IDMA)

ABOUT INDIAN PHARMA INDUSTRY

- The Indian pharmaceutical sector is worth US$ 44 billion & ranks 3rd in terms of volume & 13th in terms of value worldwide (competitive prices).
- Indian pharmaceutical market will reach US$ 65 billion by 2024 & further expand to reach US$ 120-130 billion by 2030.
- **IDMA Members' Export Record – approximately 75% in formulations and 85% in APIs**

Daara B Patel (IDMA)

ABOUT INDIAN PHARMA INDUSTRY

EXPORTS

- Indian pharmaceutical exports stood at US$ 24.44 billion in FY21 and US$ 22.21 billion in FY22 (until February 2022).
- India is the 12th largest exporter of medical goods in the world. The country's pharmaceutical sector contributes 6.6% to the total merchandise exports.

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RECENT DEVELOPMENTS IN INDIA – COVID RELATED

- In March 2022, Themis Medicare Ltd. (Themis), announced the approval of its antiviral drug VIRALEX by the Drug Controller General of India (DCGI).
- In November 2021, Zydus Lifesciences Ltd. has entered into a manufacturing license and technology transfer agreement for its plasmid DNA-based COVID-19 (ZyCoV-D) vaccine **with Korea-based Enzychem Lifesciences (Enzychem).**
- In November 2021, US-based Akston Biosciences announced that it would start the clinical trial of its second-generation COVID-19 vaccine 'AKS-452' in India soon.
- In August 2021, Glenmark collaborated with SaNOtize to introduce spray for COVID-19 treatment in India and other Asian markets.

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RECENT DEVELOPMENTS IN INDIA – COVID RELATED

- In May 2021, Cipla launched a real-time COVID-19 detection kit 'ViraGen' that is based on multiplex polymerase chain reaction (PCR) technology.
- In May 2021, Indian Immunologicals Ltd. (IIL) and Bharat Immunologicals & Biologicals Corporation (BIBCOL) inked technology transfer pacts with Bharat Biotech to develop the vaccine locally to boost India's vaccination drive.
- In May 2021, Eli Lilly & Company issued non-exclusive voluntary licenses to pharmaceutical companies—Cipla Ltd., Lupin Ltd., Natco Pharma & Sun Pharmaceutical Industries Ltd.—to produce and distribute Baricitinib, a drug for treating COVID-19.

Daara B Patel (IDMA)

INDIA's Role During Covid-19 Pandemic

INDIA'S VACCINES - A LIFE SAVER

- **January 1 & 2, 2021** - India approved Covishield [Oxford–AstraZeneca vaccine (manufactured under license by Serum Institute of India)] & Covaxin (first indigenous vaccine developed locally by Bharat Biotech) (respectively).
- India began administration of COVID-19 vaccines in 15 days post-approval. COVID-19 vaccine was first administered to health workers, followed by senior citizens & adults with existing comorbidities.
- The other approved vaccines as of now (total: 8) are Sputnik V (manufactured under license by Dr. Reddy's Laboratories), Moderna vaccine, Johnson & Johnson vaccine, Covovax (Novavax, USA) ZyCoV-D & Corbevax (vaccines locally developed by Zydus Lifesciences & Biological-E resp.).
- As of 25 May 2022, India has administered over 1.9 billion doses overall, including first, second and precautionary (booster) doses of the currently approved vaccines. More than 80% of its 1.36 bn population fully vaccinated as of now and for this over 100,000 centers run by Govt of India.

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https://en.wikipedia.org/wiki/COVID-19_vaccination_in_India

INDIA's Role During Covid-19 Pandemic

INDIA'S VACCINES - A LIFE SAVER

VACCINE MAITRI (*English:* VACCINE FRIENDSHIP) is a humanitarian initiative undertaken by the Indian Government to provide COVID-19 vaccines to countries around the world.

- As of 6 March 2022, India had delivered around **163 mn doses of vaccines to 96 countries**. The Government started providing vaccines to requiring countries from 20 January 2021.
- 14.3 mn doses were gifted to 46 countries by the Government of India.
- 200,000 doses of COVID-19 vaccines were gifted by India to the UN peacekeepers to be distributed to all peacekeeping missions

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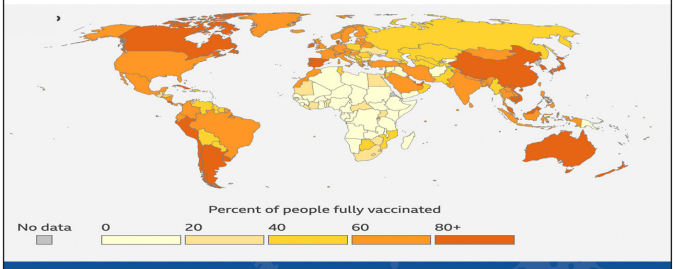
INDIA Stands Tall

ENSURING VACCINE PROTECTION



Daara B Patel (IDMA)

INDIA's Role during Covid-19 Pandemic

INDIA HAS EMERGED AS A "FIRST RESPONDER" TO THE GLOBAL CRISIS

As you are aware, India has played a humongous role during the two-year-long running COVID-19 pandemic. India supplied 'Made-in-India' vaccines to at least 98 countries.
INDIA supported the world during Covid-19 Pandemic by:

- Vaccines – 98 countries
- Medicines
  - (1) Hydroxychloroquine – 53 countries
  - (2) Remedisivir – 11 Lakh injections to more than 100 countries
  - (3) Favipiravir – 18 countries
  - (4) Anti viral medicines like Famciclovir, Tocilizumab, Itolizumab, Doxycycline + Ivermectin, etc.
- Sanitizers
- PPE Kits
- Oxygen in bulk containers to Hospitals
- **Laudable initiatives for Repurposing of Drugs for use against Covid-19**

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INDIA's Role During Covid-19 Pandemic

- **Central & State Governments along with Manufacturers & IDMA increased the Production Capacity Utilization from 20% in March 2020 to 80% in June 2020.**

- **Total Commitment & Dedication by All Stakeholders**
  Department of Pharmaceuticals (DoP), Ministry of Health, Ministry of Commerce, DCG(I), various CDSCOs, AIOCD, Transporters Associations, Police along with the big three Associations i.e. IDMA, OPPI & IPA ensured that people get the medicines required.

Daara B Patel (IDMA)

India's Collaborations with Korea

The South Korean pharmaceutical market is the tenth largest globally, although the industry is highly fragmented, with almost all the domestic pharmaceutical companies having a strong portfolio of generic products rather than expensive, branded drugs.

India is planning to promote its generic exports to the South Korean market. With India entering into the Comprehensive Economic Partnership Agreement with South Korea, traders maintain there is good scope for improving bilateral trade between the two nations, particularly in the case of active pharmaceutical ingredients (API).

Improved intellectual property rights, changing demographics and government support have contributed towards making the South Korean pharmaceutical industry attractive for multinational companies.
Indian and South Korean pharma companies can leverage their strengths to become a force to reckon with in Asia.

Daara B Patel (IDMA)

IDMA Collaborations

IDMA has signed MoUs :

- China Pharmaceutical Industry Association (CPIA)
- DuBiotech
- Toyoma Pharmaceutical Association (TPA)
- National Chamber of Pharmaceutical Manufacturers, Sri Lanka etc.

IDMA is looking forward to sign MoUs with

1) Korean Pharmaceuticals Industry Association
2) Korean Cosmetics Industry Association

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Indian Pharmaceutical Industry

STRENGHTHS :

- A very matured Industry
- Resilience
- Qualified and Experienced Pharma Professional
- Research Driven Organizations
- Increased Industry Academia - Involvement & Interaction
- Enhanced Government Support

YOU ASK WE MANUFACTURE

The day is not far when the World will say:
if it is medicines it is
INDIA

Daara B Patel (IDMA)

THANK YOU

감사합니다

(GAM SA HAM NI DA)

Daara B Patel (IDMA)

Report on IDMA & IPA Interactive Meeting with Dr Mandeep Bhandari, IAS, Jt. Secretary, Ministry of Health, Government of India

IDMA & IPA Interactive Meeting with Dr Mandeep Bhandari, IAS, Jt. Secretary, Ministry of Health, Government of India was held on 13th June 2022 at IDMA Office, Mumbai.

There were about 22 participants for this meeting.

The meeting commenced with welcome address by Mr. Mahesh Doshi, Past National President IDMA, followed by a quick introduction of the members present for the meeting. Mr. Mehul Shah, Hon General Secretary, IDMA address the gathering and then handed over the proceedings to Mr. S M Mudda, Chairman, Regulatory Affairs Committee, IDMA. The following points were discussed :

1. Decriminalisation of the Drugs Act and Rules
2. Suggestions in Response to Draft Schedule M. GSR 999(E) dated 5.10.2018 to substitute existing Schedule M of the Drugs and Cosmetics Rules, 1945.
3. API v/s. FP SHELF LIFE
4. Labelling Requirements
5. Pathway for handling Kokate Committee approved FDCs
6. Marketer Responsibilities
7. QR Codes for APIs, 300 Finished Product Brands
8. Standards for Drugs

With other some points from IPA.

Mr. Sudarshan Jain, Secretary - General, IPA presented IPA's points as below:

1) Regulatory Reforms
2) Composition and functioning of Subject Matter Expert Committee(SES)
3) OTC Policy
4) Rare Disease
5) Emergency Use Authorisation

The deliberations were very interactive and the response by Dr.Mandeep Bhandari IAS was reassuring.

Mr. Mehul Shah delivered his vote of thanks at the end of the meeting. He thanked Dr. Mandeep Bhadari for his valuable time and for providing very useful insights with regards to the industry concerns. He thanked Dr. Manish Singhal, Asst. Drug Controlled (India) and Dr. Chandra, Drug Inspector from CDSCO, West Zone, Mumbai for their presence and support. He thanked Mr. Sudarshan Jain and all at IPA for coming together to address these common industry issues.

Report on IDMA Interactive Meeting with Ms. Heran Gerba, Director General (DG), Ethiopia Food and Drug Authority (EFDA)

An Interactive Meeting was organized with Ms. Heran Gerba, Director General (DG), Ethiopia Food and Drug Authority (EFDA) on Thursday, 16th June 2022 at 03.00 p.m. in IDMA J B Mody Conference room, IDMA office, Mumbai.

The Meeting was chaired by our National President Dr. Viranchi Shah.

30+ members attended the meeting. Dr. Viranchi Shah gave the welcome address and welcomed the Ethopian FDA delegates.

1. Ms. Heran Gerba, Director General of Ethiopian Food & Drug Administration

   and members of her team
2. Yibeltal Abeje, Medicine & Registration Expert
3. Dejene Daba, Registration Expert
4. Getu Bogale, EFDA Branch Head

Brief introduction of the Ethopian Members was given by Mr. Mukund Mehta, then the proceedings were handed over to Mr. Amish Desai Encube ethicals.

Ms. Heran Gerba gave a presentation (as reproduced below) and provided the inputs for the meeting with IDMA members.

The interactive meeting and the deliberations between the Ethiopian Food & Drug Administration (EFDA) and IDMA Members was excellent and we got to learn and understand more about the Ethiopian procedures and Regulations with regards to doing business with Ethiopia.

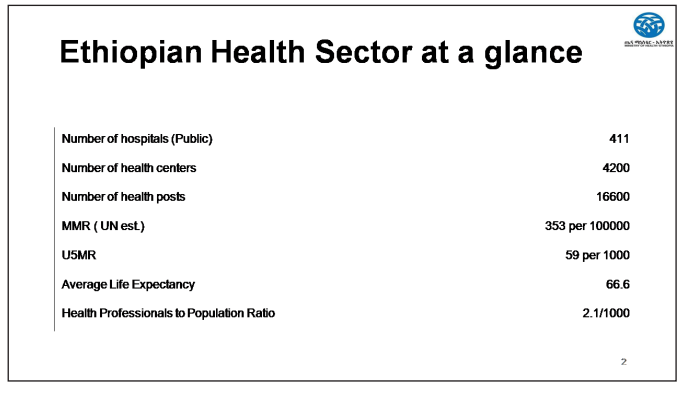
Mr. Tushar Korday then gave the Vote of Thanks , he then on behalf of our National President, Dr. Viranchi Shah and IDMA Members, thanked Ms. Heran Gerba, Director General of Ethiopian Food & Drug Administration and members of her team.

It was indeed an interesting and encouraging meeting wherein we were made aware of the latest happenings in Ethiopia and many of IDMA issues were clarified and the suggestions made by the IDMA members were well received.

PRESENTATION

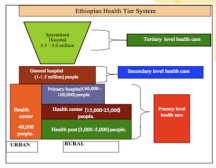
Investing in the Health Sector in Ethiopia

Ms Heran Gerba, *Director General (DG), EFDA*



Why Invest in the Health Sector in Ethiopia?

- Government commitment to Universal Health Coverage (UHC) and global commitments such as SDGs
- An epidemiologic shift with high morbidity and mortality from the triple burden of diseases.
  - *Data from the GBD study shows that 52% of the total mortality is due to NCDIs* while it comprises of 15% share from the national health expenditure (NHA-7, 2016/17).
- Increasing demand from the community for high quality healthcare
- High political commitment to improving health infrastructure.
- Large population with high need for services and products
- Increased number of health professionals' training institutions (public and private sectors) and programs
- Introduction of insurance schemes (e.g., Community Based Health Insurance system (55%) , third-party road accident)
- Efforts to introduce Social Based Health Insurance system



3

Contnd..

Because Ethiopian hospitals do not have enough capacity for specialty services – both in terms of facilities and healthcare professionals

>6,000 patients seeks overseas treatment per year

Reasons for overseas treatment include:

1. Advanced Cardiac Surgeries / interventional cardiac procedures
2. Organ transplant (Renal and Liver)
3. Fertility treatment - IVF (In Vitro Fertilization)
4. Advanced orthopedics procedures
5. Oncology services (Diagnostic , radiotherapy and chemotherapies)
6. Ophthalmologic
7. Neurosurgery
8. Rehabilitation Medical Services

Ethiopians spend **>USD 100 million annually** for overseas treatment – presenting a **great opportunity to capture this growing market segment**

4

Modalities of Private Sector Investment /engagement

- Foreign or local direct investment
- Public Private Partnership (PPP)
- Joint venture
- Outsourcing

5

Priority investment areas in the health sector

- Tertiary Health care services
- Advanced Diagnostic Services
- Medical Product Manufacturing
- Human Resource Development
- Pre-Hospital Emergency Care
- Healthcare Technologies & Innovation

6

Pipeline PPP in health sector

- **Diagnostic (Laboratory and Imaging) pilot PPPs (Approved by board)**
- **Oxygen plants in selected federal university hospitals (Approved by board)**
- **Oncology services (On feasibility assessment)**

1/5/2022 7

Local Medical Product Industry

Includes

- Pharmaceuticals
- Biological products
- Vaccines
- Diagnostics & laboratory instruments
- Medical supplies
- Medical equipment
- Contract research organizations-eg. Bioequivalent centers

1/5/2022 8

Invest in Medical Product Industry!

Why?

- Market
- Rising and Expanding Economy
- Industrial Parks(IP)
- Human Resources
- Regulatory system
- Economic and Trade Cooperation
- Wide range of incentive packages
- Initiative to improve the medical product industry ecosystem

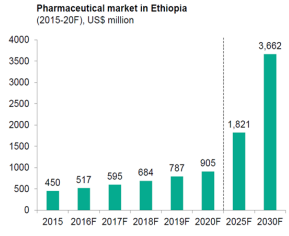
9

Market

10

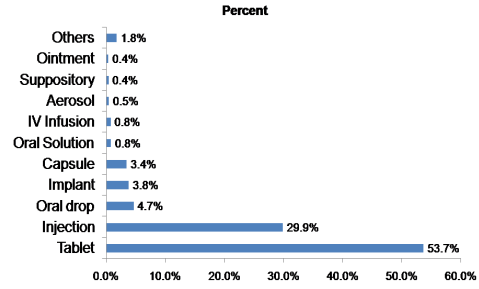
ETHIOPIAN PHARMACEUTICAL MARKET OVERVIEW

- In 2015, the Ethiopian pharmaceutical market was estimated to be **$ 450M** and it has been growing at 15% to reach an estimated value of $ 1.8Bn by 2025.
- According to the market research company Fitch Solutions, the estimated size of the market in 2021 is $1.12Bn
- Public sector purchase by EPSS is estimated to be **75%** of the total pharma.
- The Ethiopian pharmaceutical market is highly dependent on import **>90%**.

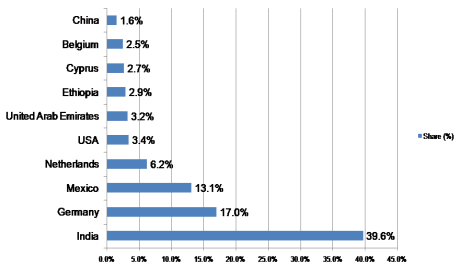


Ref: EPSA, Frost &Sullivan, NSPA Pharma & Fitch Solutions – Ethiopia Pharmaceuticals & Healthcare Report: Q42020

Market Share by dosage Form



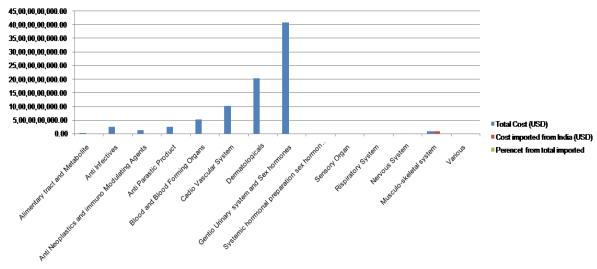
Market Share by Country of origin



IMPORTED MEDICINE FROM 2017-2021 BY PRIVATE IMPORTERS

S.No.	Therapuetic Category	Total Cost (USD)	Cost imported from India (USD)	Perencet from total imported
1	Alimentary tract and Metabolite	234,687,974.25	13,910,490.35	5.93%
2	Anti Infectives	2,552,642,218.07	5,586,309.36	0.22%
3	Anti Neoplastics and immuno Modulating Agents	1,276,321,109.04	1,278.36	0.00%
4	Anti Parastic Product	2,552,642,218.07	5,051,489.11	0.20%
5	Blood and Blood Forming Organs	5,105,284,436.14	3,062,267.03	0.06%
6	Cadio Vascular System	10,210,568,872.29	3,062,267.03	0.03%
7	Dermatologicals	20,421,137,744.57	122,297.74	0.00%
8	Gentio Urinary system and Sex hormones	40,842,275,489.14	4,547,263.16	0.01%
9	Systemic hormonal preparation, sex hormon, and Insulin	20,379.83	12,861.63	63.11%
10	Sensory Organ	421,646.60	290,083.27	68.80%
11	Rispiratory System	17,316,240.25	17,230,503.60	99.50%
12	Nervous System	2,136,236.55	416,317.56	19.49%
13	Musculo-skeletal system	810,862,030.99	809,780,950.13	99.87%
14	Various	9,597.60	8,989.72	93.67%

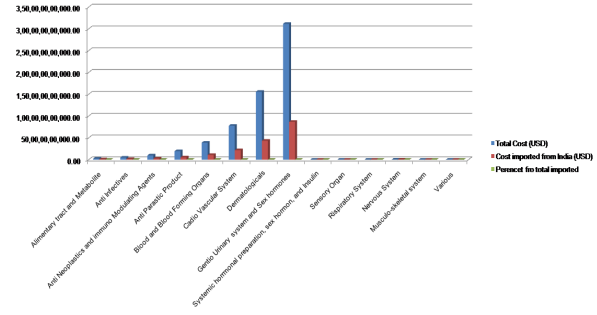
Total Cost imported by private importers from India



IMPORTED MEDICINE FROM 2017-2021 BY EPSS

S.No.	Therapuetic Category	Total Cost (USD)	Cost imported from India (USD)	Perencet fro total imported
1	Alimentary tract and Metabolite	2,434,534,094.83	678,636,667.66	27.88%
2	Anti Infectives	4,869,068,189.66	1,357,273,334.75	27.88%
3	Anti Neoplastics and immuno Modulating Agents	9,738,136,379.32	2,714,546,669.49	27.88%
4	Anti Parastic Product	19,476,272,758.64	5,429,093,338.98	27.88%
5	Blood and Blood Forming Organs	38,952,545,517.28	10,858,186,677.97	27.88%
6	Cadio Vascular System	77,905,091,034.55	21,716,373,355.94	27.88%
7	Dermatologicals	155,810,182,069.10	43,432,746,711.88	27.88%
8	Gentio Urinary system and Sex hormones	311,620,364,138.21	86,865,493,423.75	27.88%
9	Systemic horrmonal preparation, sex hormon, and Insulin	14,151,160.51	10,620,006.55	75.05%
10	Sensory Organ	10,498,774.45	5,919,325.58	56.38%
11	Rispiratory System	8,379,172.62	3,181,226.95	37.97%
12	Nervous System	44,016,326.60	25,574,292.23	58.10%
13	Musculo-skeletal system	10,447,818.33	5,681,009.47	54.38%
14	Various	6,335,777.42	964,782.61	15.23%

Total Cost imported by EPSS importers from India



Industrial Parks(IP)

- More than 15 owned by governments and 10 privately owned and are governed by EIC & IPDC
- Kilinto Industrial Park (KPIP) is dedicated to the pharmaceutical, vaccine and other biological products and medical device manufacturers.
- KPIP will provide one window service and host :
  - *Banks*
  - *Logistic firms*
  - *R&D facilities*
  - *Training center*
  - *Regulatory, calibration institution/companies etc.*

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Human Resources

- Has a large pool of highly educated workforce
  - *approximately half a million students being enrolled in local universities annually.*
- More than 814 TVET institutions and more than 58 universities
  - *Close to hundred thousand science, engineering and health discipline students graduate every year*
- The labour market is well structured, enabling employees to be hired on different terms;
  - *i.e consultancies, contracts, fixed-term employment or permanent employment.*

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Kilinto Industrial Park....

- Total area of park is 279 ha and 60% of these amount will be serviced by the GoE and availed to interested investors
- Located in Addis Ababa, the capital of the country
- Industrial cluster/ specialization – Pharmaceuticals
- Installed with adequate water and power supply, roads and bridges, fences, sewerage line, waste water treatment plant

Pharmaceutical manufacturing

- Ethiopia is one of the first African countries to develop ***National strategy for pharmaceutical manufacturing*** with a strategy to grow exports in addition to substituting imports and improving access to medicines

Economic and Trade Cooperation

Ethiopia is a signatory to the following trade agreements:

Treaty Establishing the Common Market for Eastern and Southern Africa (COMESA) (1993)

Agreement Establishing Intergovernmental Authority on Development (IGAD) (1996)

African, Caribbean, and Pacific Group States (ACP)-EU) Economic Partnership Agreement (2000)

Ethiopia has acceded to the African Continental Free Trade Agreement (AfCFTA),

Ethiopia has signed and ratified the Abuja Treaty that aims to establish an Africa Economic Community among the continent's 54 countries.

22

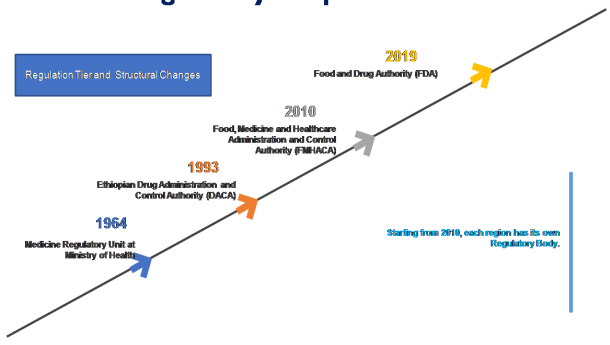
Financing Options

Development bank of Ethiopia

More than 15 commercial banks

23

Regulatory Preparedness

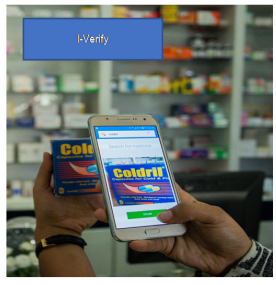


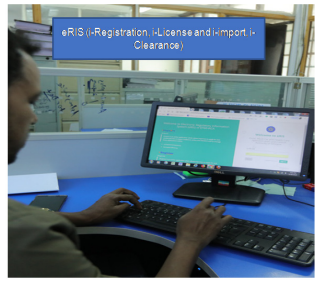
Regulatory Preparedness…

In terms of System

- All registration and Licensing process is through the electronic information system
- There is no need of applying in person for registration,
- A more robust electronic information gathering system for vigilance activities are in placed,
- Priority is given to Local Pharma products in all the regulatory activities,

Regulatory Preparedness…





Regulatory Preparedness…

In terms of infrastructure

- A center of Excellence is under process of establishment near to the industry park for any regulatory assistance and guidance,
- EFDA will be providing a one window service at Kilinto Industry park for better performance,

Regulatory Preparedness…

In terms of Efficiency,

- The average registration time required for local products is below 6 Months, and compared to other African countries, it is the fastest,
- As of this presentation is prepared no backlogs are waiting for registration, laboratory testing and GMP Inspection,
- EFDA is revising in collaboration with MoH and the Association for some guidance and polices toward importation of API, Excepients and other packing materials

Regulatory Preparedness…

Interms of Scale of Recognition (Nationally & Internationally)

- EFDA is working to reach Maturity level III or above by based on WHO GBT
  - This help recognition of EFDA regulatory measures NRA with similar/lower Maturity level and WHO
  - Eg. Marketing authorization issued by EFDA may be recognized by other countries

Regulatory Preparedness…

- The Medicine Facility Inspection Directorate of EFDA, which is responsible for regulating the Manufacturing Industries is accredited for ***ISO 17020:2012 for all the inspection activities,***
- The Medicine Quality Control Directorate of EFDA is accredited for *ISO 17025:2015 for most of the physico chemical testing parameters*

Regulatory Preparedness…

Interms of Regional Cooperation

- IGAD harmonization initiative :
  - Joint assessment of dossier and GMP inspection
    - Facilitate obtaining marketing authorization by member countries
    - Ultimate goal of this initiative is "Mutual recognition"

Regulatory Preparedness…

- Ethiopia is one of the signatories for African Medicine Agency,
- EFDA is participating in WHO Collaborative Registration Process (esp. in Vaccine)
- Implementing Risk and Trust based Regulatory Systems (like accepting data's from SRA, Mutual Recognition

Regulatory preparedness

EFDA is working to reach Maturity level III or above by based on WHO GBT	IGAD Harmonization initiative	African Medicine Agency	WHO Collaborative registration procedure
• *This helps in the recognition of EFDA's regulatory measures by NRA with similar/lower Maturity level* • *Eg. Marketing authorization issued by EFDA may be recognized by other countries*	• *Joint assessment of dossier and GMP inspection* • Facilitate obtaining marketing authorization by member countries • Ultimate goal of this initiative is "Mutual recognition"	• *Established* • *Ethiopia will be signatory member* • *The treaty will be ratified soon* • *Will create access to more than 1.1 billion market*	• *46 countries participating including Ethiopia* • *31 African countries* • *Prequalified products will be recognized by 46 countries* • *e..g SINOPHARM VACCINE*

33

Incentive Packages

Incentives Designed for Kilinto Pharmaceutical Industrial Park

- **Corporate income tax exemptions** (partially contingent on export performance):
  - **API production** up to **14** years
  - **Formulations/final medicines** up to **12** years
  - Pharmaceutical **packaging** up to **8** years
- **Personal incomes tax exemptions for expatriate employees up to 5 – 10** years (and long term visas)
- **Duty and other tax exemptions on inputs**
- **Zero tax on exports**
- **Joint warehousing, calibration,** and **testing services**

Other Support Measures

- **Public procurement;**
  - 25% price preference and 30% prepayment for firms manufacturing in Ethiopia
  - Potential for long term procurement guarantee
- **Export facilitation**
  - More accessible and competitive logistics
  - Information consolidation and market linkages
- **Regulatory system**
  - Fast-track medicine registration
  - Regional regulatory harmonization

34

Incentive Packages…

- Loss carry forward – Up to 5 years
- Personal income tax exemption
  - 5-10 years for expat experts
  - Long term employment visa work permit
- 100% customs duty exemption and other tax exemption during importation
  - Raw materials/inputs
  - Capital goods/ machineries
  - Spare parts
  - Vehicle necessary for the investment
- 100% export duty exemption

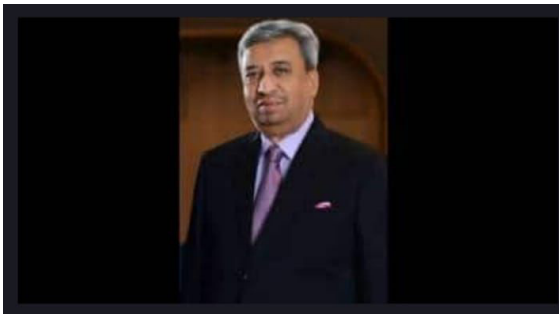
Incentive Packages…

- Strong investment policy focused on pharmaceuticals which is led by Prime Minister Office,
  - Tax exemptions: corporate income tax, personal income tax, duties, export taxes,
  - One-stop shop for government services,
  - Price preference in public procurement which accounts for a huge market

Some Establishment under constructions

Some Establishment under constructions…

IDMA congratulates Mr Pankaj R. Patel, Chairman, Zydus Lifesciences on being appointed as a part-time non-official Director in the Central Board of RBI



Zydus Lifesciences chairman Pankaj R. Patel has been appointed as a part-time non-official director in the Central Board of the Reserve Bank of India (RBI), the company announced in indices filing on June 14.

"The Appointments Committee of the Cabinet (ACC) approved the proposal of appointment of Mr. Patel under section 8 (1)(c) of the RBI Act, 1934 for a period of four years from the date of notification of his appointment, or until further orders, whichever is earlier," the statement said.

Patel is already on the board of Invest India, a Member of the Mission Steering Group under the National Health Mission, Drug Technical Advisory Board under the Ministry of Health & Family Welfare.

● ● ●

Medical Devices Rules, 2017 amended (Fourth Amendment of 2022)

Drugs & Cosmetics Notification G.S.R.450(E), dated 15th June 2022

Whereas a draft of certain rules further to amend the Medical Devices Rules, 2017, was published as required under sub-section (1) of section 12 and sub-section (1) of section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940) vide notification of the Government of India in the Ministry of Health and Family Welfare (Department of Health and Family Welfare) number G.S.R.228(E), dated the 29th March, 2022, in the Gazette of India, Extraordinary, Part II, section 3, sub-section (i), inviting objections and suggestions from persons likely to be affected thereby before the expiry of a period of forty-five days from the date on which the copies of the Official Gazette containing the said notification were made available to the public;

And whereas copies of the said Official Gazette were made available to the public on 30th March, 2022;

And whereas objections and suggestions received from the public on the said draft rules have been considered by the Central Government;

Now, therefore, in exercise of the powers conferred by sections 12 and 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, after consultation with Drugs Technical Advisory Board, hereby makes the following rules further to amend the Medical Devices Rules, 2017, namely:-

1. (1) These rules may be called the **Medical Devices (Fourth Amendment) Rules, 2022**.

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

2. In the Medical Devices Rules, 2017, in Fourth Schedule, in Part III, in Appendix II, in paragraph 7.4 relating to biological safety, in clause no. (i), the following proviso shall be inserted, namely:—

"Provided that the requirement of Transmissible Spongiform Encephalopathies (TSEs) or Bovine Spongiform Encephalopathy (BSE) Certificates is not necessary, if the source is from an animal species from a country of origin recognised as having negligible Bovine Spongiform Encephalopathy risk in accordance with the recommendations of the World Organisation for Animal Health.".

F.No.X.11014/25/2021-DR

Dr. Mandeep K Bhandari, Joint Secretary, Ministry of Health and Family Welfare, Department of Health and Family Welfare, New Delhi.

Note: *The Medical Devices Rules, 2017 was published in the Gazette of India, Extraordinary, Part II, section 3, sub section (i) vide notification number G.S.R.78(E), dated the 31st January, 2017 and was last amended vide notification number G.S.R.356(E), dated the 18th May, 2022.*

● ● ●

Notification Number Z-28016/178/2019-PMSSY-IV dated the 11th March, 2020 amended

Health & Family Welfare Notification S.O.2734(E), dated 13th June 2022

(Published in the Gazette of India on 14th June, 2022)

In exercise of powers conferred by Section 4 of the All India Institute of Medical Sciences Act, 1956 (25 of 1956) as amended by All India Institute of Medical Sciences (Amendment) Act, 2012 (37 of 2012), the Central Government hereby nominates Vice Chancellor, Assam Central University to be member of Institute Body of All India Institute of Medical Sciences, Guwahati in place of Prof. Dilip Chandra Nath, Vice Chancellor, Assam

University, Silchar (Assam), and for that purpose makes the following amendment in the notification of Government of India, Ministry of Health & Family Welfare, Number Z-28016/178/2019-PMSSY-IV dated the 11th March, 2020 published in the Gazette of India Part II, section 3 , Sub-Section (ii) vide SO 1183 (E) dated the 20th March, 2020:

In the said notification, for serial number 1 and the entry relating thereto, the following should be substituted, namely: -

"Member under clause (aa) of Section 4:

"1. Vice Chancellor, Assam Central University"

The terms of office of member shall be governed by the provisions contained in Section 6 of the All India Institute of Medical Sciences Act, 1956.

F.No.Z-28016/178/2019-PMSSY.IV

Nilambuj Sharan, Economic Advisor, Ministry of Health and Family Welfare, New Delhi.

● ● ●

Terephthalic Acid (Quality Control) Order, 2021 amended (1st Amendment of 2022)

Chemicals & Fertilizers Order S.O.2730(E), dated 13th June 2022

(Published in the Gazette of India on 14th June, 2022)

In exercise of the powers conferred by section 16 of the Bureau of Indian Standards Act, 2016 (11 of 2016), the Central Government after consulting the Bureau of Indian Standards, is of the opinion that it is necessary or expedient so to do in the public interest, hereby makes the following Order to amend the Terephthalic Acid (Quality Control) Order, 2021, namely:-

1. Short title and commencement

(1) This Order may be called **the Terephthalic Acid (Quality Control) Amendment Order, 2022**.

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

2. In the Terephthalic Acid (Quality Control) Order, 2021, in paragraph 1, for sub-paragraph (2), the following sub-paragraph shall be substituted, namely:-

"(2) This order shall come into force on the 22nd day of December, 2022."

F.No.PC-II 46016/6/2020-Tech.CPC Pt-2

N K Santoshi, Dy. Director General, Ministry of Chemicals and Fertilizers, Department of Chemicals and Petrochemicals, New Delhi.

Note : *The principal order was published in the Gazette of India, Extraordinary, Part II, Section 3, Sub section (ii), dated the 28th December, 2021, vide notification number S.O.5437(E), dated 24th December, 2021.*

● ● ●

Ethylene Glycol (Quality Control) Order, 2021 amended (1st Amendment of 2022)

Chemicals & Fertilizers Order S.O.2731(E), dated 13th June 2022

(Published in the Gazette of India on 14th June, 2022)

In exercise of the powers conferred by section 16 of the Bureau of Indian Standards Act, 2016 (11 of 2016), the Central Government after consulting the Bureau of Indian Standards, is of the opinion that it is necessary or expedient so to do in the public interest, hereby makes the following Order to amend the Ethylene Glycol (Quality Control) Order, 2021, namely:-

1. Short title and commencement

(1) This Order may be called the Ethylene Glycol (Quality Control) Amendment Order, 2022.

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

2. In the Ethylene Glycol (Quality Control) Order, 2021, in paragraph 1, for sub-paragraph (2), the following sub-paragraph shall be substituted, namely:-

"(2) This order shall come into force on the 22nd day of December, 2022."

F.No.PC-II 46016/6/2020-Tech.CPC Pt-2

N K Santoshi, Deputy Director General, Ministry of Chemicals and Fertilizers, Department of Chemicals and Petrochemicals, New Delhi

Note : *The principal order was published in the Gazette of India, Extraordinary, Part II, Section 3, Sub section (ii), dated the 28th December, 2021, vide notification number S.O.5435(E), dated 24th December, 2021.*

● ● ●

Toluene (Quality Control) Order, 2021 amended (1st Amendment of 2022)

Chemicals & Fertilizers Order S.O.2727(E), dated 13th June 2022

(Published in the Gazette of India on 14th June, 2022)

In exercise of the powers conferred by section 16 of the Bureau of Indian Standards Act, 2016 (11 of 2016), the Central Government after consulting the Bureau of Indian Standards, is of the opinion that it is necessary or expedient so to do in the public interest, hereby makes the following Order to amend the Toluene (Quality Control) Order, 2021, namely:-

1. Short title and commencement

(1) This Order may be called **the Toluene (Quality Control) Amendment Order, 2022.**

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

2. In the Toluene (Quality Control) Order, 2021, in paragraph 1, for sub-paragraph (2), the following sub paragraph shall be substituted, namely:-

"(2) This order shall come into force on the 22nd day of December, 2022."

F.No.PC-II 46016/6/2020-Tech.CPC Pt-2

N K Santoshi, Deputy Director General, Ministry of Chemicals and Fertilizers, Department of Chemicals and Petrochemicals, New Delhi

Note : *The principal order was published in the Gazette of India, Extraordinary, Part II, Section 3, Sub section (ii), dated the 28th December, 2021, vide notification number S.O.5436(E), dated 24th December, 2021.*

● ● ●

Phthalic Anhydride (Quality Control) Order, 2021 amended (1st Amendment of 2022)

Chemicals & Fertilizers Order S.O.2728(E), dated 13th June 2022

(Published in the Gazette of India on 14th June, 2022)

In exercise of the powers conferred by section 16 of the Bureau of Indian Standards Act, 2016 (11 of 2016), the Central Government after consulting the Bureau of Indian Standards, is of the opinion that it is necessary or expedient so to do in the public interest, hereby makes the following Order to amend the Phthalic Anhydride (Quality Control) Order, 2021, namely:-

1. Short title and commencement

(1) This Order may be called the Phthalic Anhydride (Quality Control) Amendment Order, 2022.

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

2. In the Phthalic Anhydride (Quality Control) Order, 2021, in paragraph 1, for sub-paragraph (2), the following sub-paragraph shall be substituted, namely:-

"(2) This order shall come into force on the 22nd day of December, 2022."

F.No.PC-II 46016/6/2020-Tech.CPC Pt-2

N K Santoshi, Deputy Director General, Ministry of Chemicals and Fertilizers, Department of Chemicals and Petrochemicals, New Delhi.

Note : *The principal order was published in the Gazette of India, Extraordinary, Part II, Section 3, Sub section (ii), dated the 28th December, 2021, vide notification number S.O.5434(E), dated 24th December, 2021.*

● ● ●

n- Butyl Acrylate (Quality Control) Order, 2021 amended (1st Amendment of 2022)

Chemicals & Fertilizers Order S.O.2729(E), dated 13th June 2022

(Published in the Gazette of India on 14th June, 2022)

In exercise of the powers conferred by section 16 of the Bureau of Indian Standards Act, 2016 (11 of 2016), the Central Government after consulting the Bureau of Indian Standards, is of the opinion that it is necessary or expedient so to do in the public interest, hereby makes the following Order to amend the n- Butyl Acrylate (Quality Control) Order, 2021, namely:-

1. Short title and commencement

(1) This Order may be called the **n- Butyl Acrylate (Quality Control) Amendment Order, 2022.**

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

2. In the n- Butyl Acrylate (Quality Control) Order, 2021, in paragraph 1, for sub-paragraph (2), the following sub-paragraph shall be substituted, namely:-

"(2) This order shall come into force on the 22nd day of December, 2022."

F.No.PC-II 46016/6/2020-Tech.CPC Pt-2

N K Santoshi, Deputy Director General, Ministry of Chemicals and Fertilizers, Department of Chemicals and Petrochemicals, New Delhi.

Note : *The principal order was published in the Gazette of India, Extraordinary, Part II, Section 3, Sub section (ii), dated the 28th December, 2021, vide notification number S.O.5438 (E), dated 24th December, 2021.*

● ● ●

Announcing the Change of Identity to JB Our Core Values Remain Unchanged

GOOD PEOPLE *for* GOOD HEALTH

Nikhil Chopra, *CEO & Whole-time Director, JB*

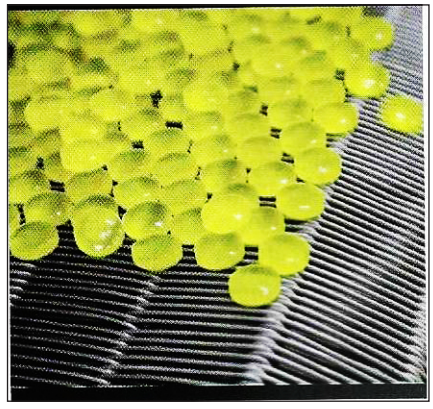
While we are changing in many ways, we are not changing the solid foundation of JB. Our new identity has a simple, solid look that reflects the way we think and conduct ourselves. It is a symbol of our belief in being 'Good People for Good Health'. "

The fastest growing pharmaceuticals company in India - JB Chemicals & Pharmaceuticals Limited has emerged in a new avatar as JB. While its look has changed, the values remain. Endowed with goodness at its core, JB retains its value - 'Good people for good health.

In sync with the evolving healthcare industry, and the changing need of customers, JB has re-visioned the cause of spreading good health in India. JB aims to support healthcare providers and enrich patients' lives in innovative new ways while remaining committed to its core values of integrity, trust and reliability built over 45 years.

Announcing the change of identity to JB - Good People for Good Health, Mr Nikhil Chopra, CEO & Whole-time Director, JB, said, "In 45 years, we at JB have built a strong foundation of integrity, trust and reliability: Now we are taking the next leap forward towards becoming more agile, lean and simple. Our offerings and capabilities are becoming more diverse to cater to the evolving needs of our customers, our manufacturing processes are becoming more robust, and lean, our vision of looking at healthcare industry is becoming more progressive, globally. We are adapting ourselves to become more responsive to the needs of the healthcare world."

Mr Chopra further says, "While we are changing in many ways, we are not changing the solid foundation of JB. Our new identity has a simple, solid look that reflects the way we think and conduct ourselves. It is a symbol of our belief in being 'Good People for Good Health"'



JB has emerged as the fastest growing Indian Pharmaceutical company. It has figured among the top 25 pharma companies with a remarkable growth rate of 29% in the Financial Year 2021¬22. The five household brands of JB have featured in the top 300 of the Indian Pharmaceutical Market (IPM) with 4 brands (including Azmarda) in the top 100 in the cardiac therapy segment. JB currently ranks at 12 in the gastro¬intestinal segment in IPM. It has over 350 brands with 20 key therapeutic categories.

Its brands are available across 600,000 pharmacies in India, literally, in almost every PIN code.

Catering to the evolving needs of customers (patients), JB has been adapting to the emerging new technologies and acquiring the leading pharma brands. The recent acquisition of Sanzyme has helped JB gain ranks and figures in the top-25 brands of the Indian Pharmaceutical Market. Likewise, by the acquisition of Azmarda in April 2022, JB is likely to surge more ranks in the Indian Pharmaceutical Market.

Its seven manufacturing facilities in India comply to the world's highest standards meeting the rigorous international regulatory requirements around the world. It is one of the few Indian pharma companies employing the OROS (Osmotic-controlled release oral delivery system) technology. JB has set an unmatched technological lead in lozenges as a drug delivery format and is today one of the world's top 5 manufacturers of medicated and herbal lozenges.

JB has over 40 highest global accreditations for the manufacturing process, including certification from the US, UK, EU, Australia, South Africa, Russia/CIS and Australia. It is a leading partner for global pharma innovators and Global MNC majors. It exports a wide

range of formulations to over 40+ regulated and semi-regulated markets.

The 5 household brands of JB featured in the top 300 of the Indian Pharmaceutical Market (IPM) are - Rantac (anti-ulcerate) with IPM rank at 45 and gastro-intestinal segment rank at 6; Cilacar (anti-hypertensive) with rank at 52 and cardiac segment rank at 4; Cilacar-T (anti-hypertensive) with rank at 203 and cardiac segment rank at 22; Metrogyl (amoebicide) with IPM rank at 194; Nicardia (anti-hypertensive) with rank at 240 and cardiac segment rank at 30.

Source: India Forbes, 17.06.2022

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IDMA urges FSSAI to delink FoSCoS licensing from product details submission

The Indian Drug Manufacturers' Association (IDMA) has urged Food Safety and Standards Authority of India (FSSAI) to delink license granted from Food Safety Compliance System (FoSCoS) from product details submission.

It will fast-track FoSCoS license grant, thus facilitating ease of doing business for Food Business Operators (FBOs) manufacturing and selling health supplements, nutraceuticals, and food for special medical purposes, stated the industry body.

IDMA has recently submitted a representation to Arun Singhal, CEO, FSSAI as well as its chairperson Rajesh Bhushan appealing them to take steps to delink FoSCoS license grant from the submission of individual product-related details.

FSSAI launched FoSCo on June 1, 2020 replacing the Food Licensing & Registration System (FLRS), which was launched in 2012 for issuance of pan-India FSSAI licenses and registration. The prime objective of FoSCoS is to enhance the user performance of the application, and make the required data submission process effective and simple in an effort to promote ease of doing business amongst the FBOs.

On the basis of one particular objective listed by FoSCoS Guidance Document, March 2020: 'Achieve and enable the application to have standardized product approach rather than text box approach for manufacturers' the FSSAI has enabled collection of product details, including complete composition, even of excipients, of marketed products as a pre-condition for issuing a FoSCoS license.

As per the guidance document, the complete product information regarding composition, excipients and their quantities are needed to be specified.

This is not only an impractical requirement but proving to be a bottleneck in grant of FSSAI central license. FBOs have painstakingly developed their own 'proprietary' blend which has potential to become public and hence a potential breach of the Intellectual Property (IP) rights, said Dr RK Sanghavi, chairman – Nutraceutical Committee, IDMA.

The guidance document further says the product information being provided should be identically matching (mirrored) in applications done by the marketeer as well as the manufacturer.

Taking exception to this, Dr Sanghavi said "For applicants of FoSCoS licenses this has become a bottleneck and grant of licenses are being withheld for both manufacturers as well as marketeers for no fault of theirs and resulting in huge financial losses for these FBOs.

It says marketeers of products under FSS (Nutra) Regulations need to upload details such as licenses, etc. of the manufacturers. "This is becoming a huge exercise since many large sized companies outsource their products from various manufacturers and even change the latter at any point of time for the same product," he added.

The FBOs have been receiving queries in piecemeal rather than a one-time query to resolve all conflicts in application done for grant of FoSCoS license. They are at their wits end with repeat communications from FSSAI regarding details appearing in the license applied. Also, most of the queries are related to deficiencies and clarifications being addressed regarding the listed products whilst applying for FoSCoS license, he stated.

When a license has been granted and the manufacturer FBO intends to launch a new product, the modification is required to update details for which fees are additionally charged each time.

The concerned FSSAI officials on receiving applications for license modification for product addition start examining even the previously listed products already featuring in the system and re-start a cumbersome series of queries for approving the modification – on matters of nil relevance for which the application has been made. The FBOs are being forced to employ a full-time team to keep on applying for license modification and solving even queries raised regarding previously submitted and accepted data, said chairman of Nutraceutical Committee, IDMA.

An averagely operational manufacturing FBO could be churning out 1-2 products per fortnight if not more often, or more frequent. This could entail endless and time-consuming license modifications – possibly – every month, mandated under the new regime of FoSCoS license grant and with all the accompanying hiccups as elaborated above, he stated.

"Grant of license need not be confused with developing or marketing of products' appropriateness. There are already set regulations in place to ensure the same and the Enforcement Department within the FSSAI is suitably empowered to haul up the errant FBOs in this respect. The FoSCoS licensing should be de-linked from product details submission. Such a practice is not even prevalent within the drug industry wherein the licensing is separate and has no direct linking to products permitted for manufacturing and/or marketing. If it is the intent of FSSAI to collect and collate data on available products in the country, the same can be done via another mechanism or platform. For ensuring ease of business for FBOs, fast-tracking of FoSCoS license grant is one of the mantras and it requires FoSCoS licensing to be de-linked from the submission of individual product-related details," said Dr Viranchi Shah, national president, IDMA.

Source: Laxmi Yadav, Pharmabiz, 21.06.2022

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UK MHRA joins international partnerships to set global standards for medicines and medical devices regulation

The UK is set to play a greater international role in making sure medicines and medical devices are regulated safely and efficiently worldwide, the Medicines and Healthcare products Regulatory Agency (MHRA) announced after being accepted as a full member of three international work-sharing partnerships.

Two of these, the International Medical Device Regulatory Forum (IMDRF) and the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) are focused on improving the harmonisation and convergence of medicines and medical devices regulation globally.

Through these partnerships, the MHRA will share expertise with other leading organisations, support the development of regulatory guidelines and drive greater harmonisation of regulation around the world. This will help deliver timely access to innovative medical products not just in the UK but globally.

The MHRA has also been accepted as a member of the US-based Medical Devices Innovation Consortium (MDIC). This public-private partnership brings together representatives of regulatory bodies, industry, non-profits, and patient organisations from different countries to improve the processes for development, assessment, and review of new medical technologies. This enables transformational medical technology to get to the people who need it sooner, by shortening the path from innovation to safety to access.

Dr Glenn Wells, Chief International and Partnerships Officer at the MHRA, said: "We are delighted to join these three international organisations to collaborate on regulatory alignment that will help deliver safer, innovative, and more cost-effective medicines and medical devices to the people who need them sooner.

"We are currently building a world-leading regime for regulating medicines and medical devices in the UK that prioritises patient safety while fostering innovation, and we look forward to sharing expertise with partner organisations for the benefit of patients not just in the UK but worldwide."

The MHRA is one of the world's leading regulators of medicines, medical devices, and blood components for transfusion. Recognised globally as an authority in its field, the agency plays a leading role in protecting and improving public health and supports innovation through scientific research and development.

Before the UK's exit from the EU, the MHRA was part of both the IMDRF and ICH under the EU system, became observer nations after Brexit, and is now a full sovereign member.

Source: Pharmabiz, 18.06.2022

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Fixing the ills of Healthcare

After steering the country through the pandemic, the health ministry is concentrating on the gaps exposed

The Sudden, Gathering storm of a pandemic, the gradual outbreak, its spikes and troughs, and the immediate health needs of millions in acute distress—the Union ministry of health and family welfare (MoHFW) has been constantly under the spotlight for the past two years.

Most of the health resources of the Ministry, too, were deployed to manage the pandemic. Nonetheless, amidst the turmoil, the ministry has successfully initiated a variety of other schemes in the past three years.

Leading the Ministry from 2021 is Union minister Mansukh Mandaviya, a believer in 'quick' communication who has separate WhatsApp groups with State Health Ministers and Senior Ministry officials. Mandaviya was honoured by Unicef for contributing to women's menstrual hygiene by using the chain of Jan Aushadhi Kendras to sell 100 million biodegradable sanitary pads.

Keeping future outbreaks in mind, the ministry has set up the Centre for One Health in Nagpur, which will carry out surveillance of bacterial, viral and parasitic infections. To bolster defences further, the PM Ayushman Bharat Health Infrastructure Mission Scheme will focus on preparing health systems for pandemic responses. "The management of the pandemic, especially the recent Omicron wave. has shown the world the power of strong political will, self-reliance through Atma Nirbharta and innovation powered by technology," says Mandaviya.

After enduring the pain and distress of the second Covid-19 wave, there was the undeniable success of the vaccination drive. On October 21, 2021, the ministry celebrated the landmark achievement of the one billionth Covid-19 vaccine dose being administered in India. The world's fastest vaccination drive took nine months and, at its peak, 25 million (mostly free) doses were being given in 70,000 centres. More doses were given in rural India—a feat made possible by door-to-door campaigns and networks of field workers. The fight against non-communicable diseases such as cancer, stroke and diabetes has received an infra-structure boost, with 640 district clinics and over 5,000 clinics at community healthcare centres. In addition, 194 cardiac care units (CCUs) and 239 day care cancer centres have also been set up across the country.

The MoHFW has made the National Digital Health Mission a priority, funded it handsomely and has brought in schemes like the hospital information system, the Nikshay-TB programme and Mera Aspataal, a patient feedback system. India also launched its tele-medicine programme, eSanjeevani, connecting 150,000 health and wellness centres to patients. During the pandemic, 15 million consultations were done through it. To address the burden of mental health disorders, the government has put aside funds to start a National Tele-Mental Health Programme 23 dedicated centres will provide free tele-counselling.

The urban poor have little access to health facilities, and the National Urban Health Mission is setting up a network of primary and community health centres to cater to their needs. Already, out of pocket expenditure (OOPE) for healthcare (expenditure borne directly by a patient) in India has declined from 64.2 per cent in 2014 to 48.8 per cent in 2018. Experts say that the increase in the budget's healthcare allocation to 2.5 per cent of the GDP would further reduce OOPE. Furthermore, in recent years, India has witnessed a notable decline in the Maternal Mortality Ratio as well as the Neonatal Mortality Rate.

However, there are challenges ahead, and many have been doggedly persistent for decades: a less than ideal number of doctors and trained nurses, and the need for more hospital beds.

Keeping this in mind, there is a push to direct health resources where the disease burden is the greatest—the urban poor, village and block levels and remote areas—through a mixture of technology, field visits, improved community health infrastructure and setting up district-level medical colleges. The crucial goal here is to make healthcare accessible. Accessibility is healthcare's golden ratio now.

Source: Sonali Acharjee, India Today, 06.06.2022

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(IDMA GSTIN:27AAATI3594D1ZO)

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LICENSED TO POST WITHOUT PREPAYMENT
LICENCE NO. MR/Tech/WPP-337/West/2021-23
RNI REGN. NO. 18921/1970, REGN.NO.MCW/95/2021-23
Published and Posted on 7th, 14th, 21st and 30th of every month
This issue posted at Mumbai Patrika Channel Sorting Office on 21.06.2022

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