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IDMA BULLETIN

VOL. NO. 53 | ISSUE NO. 21 (PAGES: 64) | 01 TO 07 JUNE 2022 | ISSN 0970-6054 | WEEKLY PUBLICATION

INDIAN PHARMA - GLOBAL HEALTH CARE

INDIAN DRUG MANUFACTURERS' ASSOCIATION

HIGHLIGHTS

- ★ **IDMA representation to IPC on General Monograph of Capsules for Soft Gelatin capsules – Disintegration Limit (DT) revision (From 60 minutes to 30 minutes)** *(Page No. 13)*
- ★ **IDMA representation to Reserve Bank of India on Line of Credit with Sri Lanka** *(Page No. 14)*
- ★ **NAFDAC, Nigeria - Drug and Related Product Labelling Regulations 2021** *(Page No. 38)*

‘EXACT’ IS A SCIENCE. AND AN ART. THAT’S ACCURACY FOR US.

Dear Partner,

We serve a multitude of clients, fulfilling just as many needs along the way. And in spite of variables, we have been tremendously accurate in doing so. This wouldn’t be possible without partners like Asahi Kasei, Morimura and Mitsubishi Chemical Corporation.

Specialists in the production of microcrystalline cellulose spheres and pregelatinized starch, Asahi Kasei is renowned for their meticulous and forward-thinking approach. Morimura brings their tremendous experience of over 140 years in supplying a top quality plasticiser that is used for a host of pharmaceutical applications. While Mitsubishi Chemical Corporation is the foremost name in the production of highly refined sucrose fatty acid esters (non-ionic emulsifiers) that meets the highest global standards.

We truly believe in the accuracy of information and guidance offered by Asahi Kasei, Morimura and Mitsubishi Chemical Corporation. As should you. For that’s how we ensure the very same for you.

Signet-ure ACCURACY

AsahiKASEI

CELPHERE
- Microcrystalline Cellulose Spheres

PC-10
- Partly Pregelatinized Corn Starch

SWELSTAR
- Pregelatinized Potato Starch

MORIMURA BROS., INC.

CITROFLEX
- Triethyl Citrate

MITSUBISHI-CHEMICAL CORPORATION

SURFHOPE SE PHARMA
- Sucrose Stearate

Signet

The Complete Excipients Company

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IDMA BULLETIN

Vol. No. 53 **Issue No. 21** **01 to 07 June 2022**

IDMA ACTIVITIES:

INDIAN PHARMACOPEIA COMMISSION:

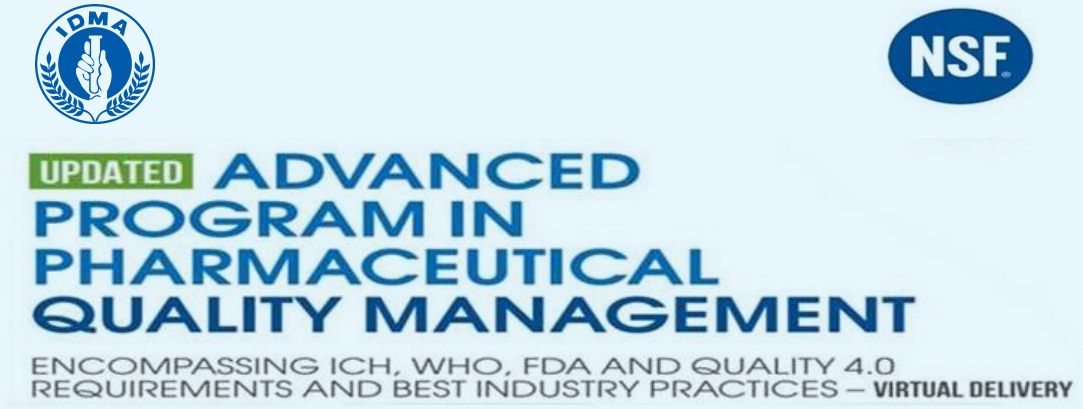
GOVERNMENT COMMUNICATIONS:

GOVERNMENT NOTIFICATIONS:

DGFT MATTERS:

NPPA MATTERS:

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 July 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 July 2022 and covers special sessions on Digitization.

Please refer to the enclosed brochure and the video link for details of the Program covering: (Enclosure 1)

- ✓ 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 : (Enclosure 2) and send it to

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

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

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

Sincerely Yours,

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

NSF®

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

IDMA 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

▶▶

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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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)

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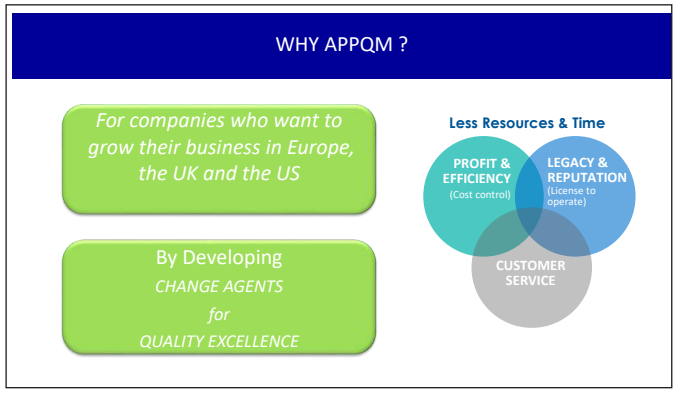
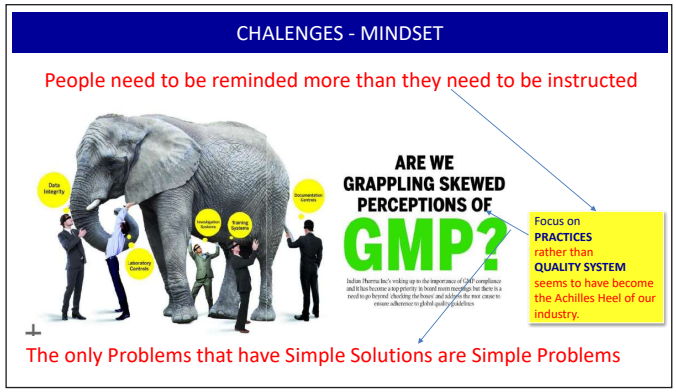
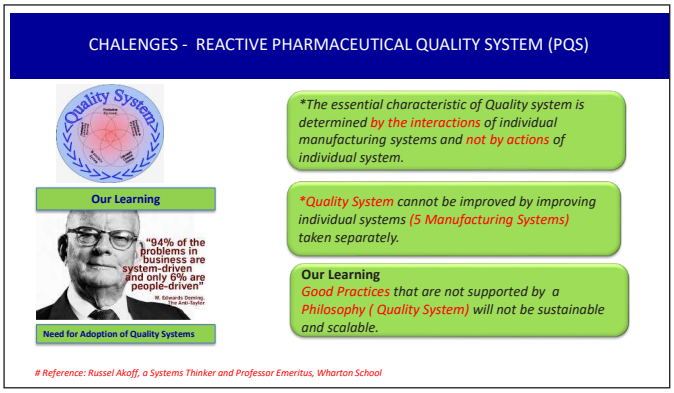
PRESENTATION

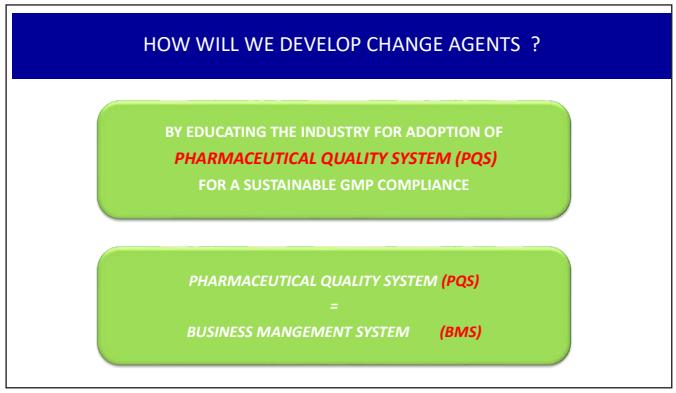
Launch of APPQM Series 3

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









APPQM IS DESIGNED FOR INDIAN COMPANIES

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

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

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

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

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

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

HOW APPQM IS DIFFERENT FROM OTHER TRAINING PROGRAMS ?

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

APPQM- Program Modules

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

APPQM SERIES 1 & 2 DELEGATES SURVEY FEEDBACK

APPQM SERIES 1 & 2 DELEGATES SURVEY FEEDBACK

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

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

Transformative and Life Changing.

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

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

Educating Oneself while Educating Others

Has helped transform our quality culture.

Best business investment we've ever made.

Worth every penny and more.

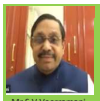
APPQM SERIES 2 VALEDICTORY – APPRECIATION FROM DIGNITARIES


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


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

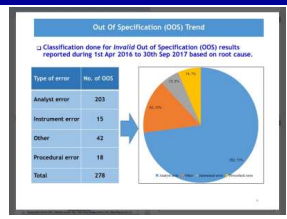

Virtual APPQM Program will be a boon for saving Time, Travel & Cost and yet deliver the same quality education
Dr. Viranchi Shah- National President -IDMA


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


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


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

Benefits of APPQM –ROI



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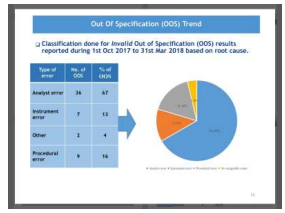

AFTER

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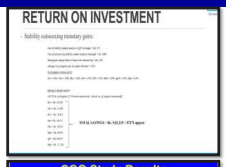
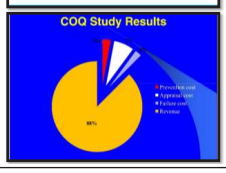
Benefits of APPQM -ROI





Acknowledgments

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

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

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

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

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

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

THANK YOU FOR YOUR ATTENTION

IDMA representation to IPC on General Monograph of Capsules for Soft Gelatin capsules– Disintegration Limit (DT) revision (From 60 minutes to 30 minutes) – reg.

IDMA have submitted the following representation on 12th May 2021 to Dr. Rajeev Singh Raghuvanshi, Ph.D., Secretary-Cum-Scientific Director, Indian Pharmacopoeia Commission, Ministry of Health & Family Welfare, Ghaziabad on the above subject:

Respected Sir,

Greetings from Indian Drug Manufacturers' Association (IDMA).

We appreciate the efforts of Indian Pharmacopoeia Commission (IPC) for continuous progress initiated through collaboration with various Associations with regards to the Indian Pharmacopoeia which helps in regulating the quality of pharmaceutical products in India.

IDMA is with you in all your endeavors to make IPC a pharmacopeia that would be recognized globally. However keeping in mind the concerns of the Industry and our members, we would like to put forth the following suggestions:-

- It is requested that for any changes in the IP monograph, discussions with the stakeholders should be done based on acquired data and it is advisable to refrain from merely following the BP & USP pharmacopoeias.
- The Indian Pharmacopoeia Laboratory (IPC) is accredited for both chemical and biological testing and had tested market samples and control samples in two groups i.e of Ethical therapeutic medicinal products and Nutraceutical in which category of vitamins and dietary supplements are included.
- The category 1 products meet the stringent standards for limit of DT, whereas the nutraceutical products had 25% failure to pass the stringent limit of DT.
- In order to meet the stringent limit of DT for soft Gelatine capsules there is need for modification in the product composition and the stake holders have a reservation to do the changes in product composition as it would take the product out of market and there will be shortage of medicines.
- It was discussed and suggested that the DT time of 60 minutes may please be retained in General monograph of soft gel capsules, and the stringent limit of 30 minutes to be included in individual monographs.
- The semi-digested food (chyme) takes minimum 45-60 minutes to travel to the stomach and hence the drug can be available for dissolution and absorption only after 45-60 minutes.
- For dissolution water is required over the small intestine lining. This water comes from three enzymes of small intestine i.e. pancreatic juice, intestinal juices and bile. These juices are secreted only after the chyme enters the small intestine. Thus faster DT is not an important determinant as the timing of chyme entering the intestine decides the dissolution indirectly.
- Reformation of the existing widely used products violates schedule M, where the Clinical and BE (Bio Equivalency) studies which was performed prior to marketing of products will be needed to be repeated so that the reduction of DT limit does not create dose dumping or any adverse reaction in clinical patients.
- It is recommended that Dietary supplements and Ethical medicinal products be set apart, and FSSAI can decide the Limit for DT test rather than link it to IP.
- Majority of the stakeholders have opposed the change in DT limit and informed IPC to hold the change until a proper statistically validated protocol based study is performed and shared with all the stakeholders.
- We appreciate that IPC has agreed to hold this change till all the members are in agreement with the change in limit of DT.

- IDMA suggests that any changes to the softgelatin product monographs which are invalidated can lead to product withdrawals from the market which will result in product shortage and ultimately affect the patients adversely.

We request you to kindly peruse the above suggestions from IDMA and look forward to your positive response.

Thanking you,

Yours sincerely,
For Indian Drug Manufacturers' Association

Dr. Viranchi Shah
National President

Dr. Vinay G Nayak
Chairman, Quality Management
& Technical Committee

● ● ●

IDMA representation to Reserve Bank of India on Line of Credit with Sri Lanka – reg.

IDMA have submitted the following representation on 18th May 2022 to Mr. Vivek Srivatsava, Chief General Manager, Reserve Bank of India on the above subject:

Respected Sir,

Pharma companies are exporting products regularly to Sri Lanka. However due to economic crisis in Sri Lanka and US $ position of the country, all existing and future transactions are put on hold.

We understand that India has announced One Billion US Dollar Line of Credit in Indian Rupees to Sri Lanka through SBI for purchasing essential goods from India. Medicines fall under this category. Accordingly many companies are trying to utilize this Line of Credit for exporting medicines to Sri Lanka. Our counterparts in Sri Lanka have also confirmed that for pending orders, whether tenders or Primary, they would procure goods through Indian Credit Line Facility.

There are certain formalities outlined by Sri Lankan authorities under this Line of credit in Indian Rupees and for the same they have requested us to send copies of duly filled documents, formats. One such document is an agreement for receiving payment in Indian Rupees from Sri Lanka Bank by exporter's bank and by exporter entity.

However, our bankers like Kotak Bank, HDFC Bank, ICICI Bank and even State Bank of India are saying that they do not have any circular or any direction from Reserve Bank of India or Commerce Ministry or any other government department on the subject and as such they cannot issue the above mentioned agreement.

As you are aware,

- pharma products have defined shelf life and the goods are waiting to be dispatched. Once the stock cross certain shelf life it would be difficult to sell those stock with short expiry. Even, the stocks manufactured for export purposes would not be possible to sell in domestic market.
- The stocks are lying on port and industry is suffering demurrage, interest cost on working capital.
- Insurance companies are not giving credit risk coverage.
- Banks are not confirming USD Letter of Credits.
- Even the said situation is affecting the stock position in Sri Lanka as it is dwindling fast. There is no process of reinstating the essential medicine availability in Sri Lanka.
- Patients at large are suffering due to shortage of medicines in Hospitals/markets of Sri Lanka.

In this situation, the gesture of Indian Government to help our neighbour is not getting fulfilled and the whole purpose of creating a Line of Credit is getting defeated.

Your urgent intervention in the matter is solicited in advising/issuing the circular/guidelines to the commercial banks so that exporters can ship the pending orders without any ambiguity.

We would be happy to meet you in person and explain the issue in greater detail.

Thanking You,

Yours sincerely,

For Indian Drug Manufacturers' Association

Dr Viranchi Shah
National President

● ● ●

IDMA representation to National Medicines Regulatory Authority, Srilanka on Increasing India - Sri Lanka trade in Pharmaceutical Sector and Request to review the policy of allowing multiple partners in Sri Lanka for registered Indian manufacturers - reg.

IDMA have submitted the following representation on 3rd May 2022 to Dr. Rasitha Wijewantha, Chairman, National Medicines Regulatory Authority, Srilanka on the above subject:

Respected Sir/ Madam,

Greetings from Indian Drug Manufacturers' Association (IDMA).

IDMA is an Indian association of Pharmaceutical companies having more than 1000+ members from across India. We have our central office in Mumbai, 8 state boards covering all important Pharma clusters, and one office in New Delhi. Our members are engaged in the manufacture, sale, and export of good quality cost-effective medicines.

Sri Lanka is a close friend and associate of India and the Indian pharmaceutical industry. We wish to strengthen our ties with the Sri Lanka counterparts in order to promote more Indo-Sri Lanka trade in the pharmaceutical sector, as also to help the Sri Lankan manufacturers through knowledge sharing.

We understand that when an Indian manufacturer is engaged with an existing Sri Lankan importer, and the manufacturer wishes to engage additionally with a new agent in Sri Lanka, there are some issues. As per the current policy, the NMRA insists on an NOL from the existing Sri Lankan importer, in order to enable the new Sri Lankan agent to engage and register some new products in Sri Lanka. This actually deters new Sri Lankan players from entering into a contract with established Indian companies. This hampers the possibilities for the Indian manufacturer to engage more actively with newer importers for differentiated ranges. If this policy is relooked, we are sure that there could be much more engagement from Indian manufacturers with more Sri Lankan counterparts.

As per the information available to us, no other country in South East Asia has such a policy.

It is therefore our humble request, in the interest of bilateral trade, that this policy for insisting on an NOL from existing partners be relooked. We wish to propose that a registered Indian manufacturer may please be allowed to appoint with multiple partners in Sri Lanka without the need to obtain NOL, as far as the products are different from the existing partner.

We also wish to engage more actively with the Sri Lankan counterparts and work closely in order to take the Indo-Sri Lanka pharma trade to new heights and also to help the Sri Lanka pharma industry to progress through knowledge sharing.

We look forward to your support in the matter.

Thanking you.

Yours faithfully,

For Indian Drug Manufacturers' Association,

Dr Viranchi Shah
National President

IDMA representation to FSSAI on License Modification under the FoSCoS - reg.

IDMA have submitted the following representation on 10th May 2022 to Mr Arun Singhal, CEO, Food Safety and Standards Authority of India (FSSAI) with a copy to Shri Rajesh Bhushan, IAS, Chairperson, FSSAI on the above subject:

Dear Mr. Singhal,

Greetings from Indian Drug Manufacturers' Association (IDMA).

Food Licensing & Registration System (FLRS), launched in 2012 for issuance of pan-India FSSAI Licenses and Registration, has been an online application launched by Food Safety and Standards Authority of India (FSSAI) to facilitate Food Business Operators (FBOs) in India to apply for License/Registration Certificate and track their applications during the course of processing.

FSSAI launched Food Safety Compliance System ("FoSCoS") on 1st June 2020 hereby replacing the existing online registration system of FLRS. Since it is the regulatory body FSSAI that itself issues the FoSCoS license the latter is synonymous with FSSAI license. FoSCoS is conceptualized to provide one point stop for all engagements of an FBO with the department for any regulatory compliance transaction.

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 (FoSCoS Guidance Document, March 2020: Version 1.0; https://foscos.fssai.gov.in/assets/docs/FoSCoSGuidanceDocumentV1.0.pdf): '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!

This is not only an unpractical requirement but proving to be a bottleneck in grant of FSSAI Central License. The concerns expressed by FBOs which pertain to the mandating the product-related information meticulous details submission, are many.

- The complete product information regarding composition, excipients and their quantities are needed to be specified. **This is indeed frightening since the 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.**
- The product information being provided should be identically matching (mirrored) in applications done by the marketeer as well as the manufacturer. **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.**
- 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.**
- 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. **FBOs 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.**
- 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 FBOs are thus not burdened with extra workload but also recurring expenses for the same cause.**
- 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!**

- 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.**

All-in-all the current methodology of processing of licenses is turning out to be another unacceptable scenario as was prevalent under the illegal product approval era. 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.

It is urged that 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 intent of FSSAI to collect and collate data on available products in the country the same can be done via another mechanism or platform. Let us not slide back to a quasi-Product Approval system – the same that had already set back the Nutraceutical Market growth by 4-5 years by stunting its growth and progress – at the cost of consumer's health.

For ensuring ease of business for FBOs, fast-tracking of FoSCoS License grant is one of the mantras and it requires to be de-linked from the submission of individual product-related details.

Thanking you.

Yours sincerely,

For Indian Drug Manufacturers' Association

Dr Viranchi Shah
National President

Dr R K Sanghavi
Chairman – Nutraceutical Committee

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IDMA representation to NPPA with regards to NPPA webinar on Proposed IPDMS Version 2

IDMA have submitted the following representation on 19th April 2022 to Mr. Rajesh Kumar T, Deputy Director (LEGAL/IT), NPPA, Department of Pharmaceuticals on the above subject:

Ref: Video Conference on 30th March 2022, at 3.30 pm

Dear Sir,

Greetings from Indian Drug Manufacturers' Association (IDMA)!

We thank you for the invitation to attend the NPPA webinar on 30th March 2022 regarding IPDMS Version 2 (V2). We are happy to note that many of the suggestions made by us vide our representations dated 6 November 2019 (Annexure I), 13/07/2021 (Annexure II) and 13/10/2021 (Annexure III) on the problems faced while entering data in IPDMS Version 1 have been incorporated, which will ensure ease of use during entry. However, a few critical suggestions remain unaddressed. Table I below contains the suggestions from IDMA that have been incorporated and those that remain unaddressed. We request you to incorporate the unaddressed suggestions on priority.

Table I: IDMA suggestions and NPPA response

	IDMA Suggestion	NPPA Response
1	All registered users of IPDMS V1 should migrate to V2 automatically.	Incorporated
2	The WPI change w.r.t preceding year (%) for a scheduled formulation, should appear automatically (auto-populate) on the screen.	Incorporated
3	The Ceiling Price (Notified)(Rs.), for a scheduled formulation, should appear automatically (auto-populate) on the screen.	Incorporated
4	In Product Registration, all submitted product details including the composition, pack, packing and the manufacturing source should appear automatically (auto-populate) on the screen.	Incorporated
5	For all the forms I to V, all the selections especially for products, should appear in an alphabetical drop down order in IPDMS V2, for scheduled and non-scheduled formulations.	Incorporated
6	It is cumbersome to populate data for over 100 Scheduled formulations in IPDMS, please enable a facility to upload the data from a Company's ready data file in Excel format for all forms.	Incorporated
7	In 2015 NLEM the categories of some formulations changed from scheduled to non-scheduled and vice versa, more changes are expected in NLEM 2021. Whenever the category changes, there is no provision in IPDMS V1 to edit the category. We have to re-enter the formulation in the new category all over again and the old formulation continues to be reflected in the old category wrongly, since we cannot delete it. An editing facility should be provided, to change the category from scheduled to non-scheduled or vice versa. The old product category should be archived and only the new product registration should be reflected and allowed to be entered. This would ensure that data would be maintained only for one formulation in one category.	**Not incorporated**
8	Please provide an editing facility for data correction for all scheduled and non scheduled formulations in all forms in IPDMS V2, even after submission. Since all the corrections are saved in the IPDMS with a time stamp, an archive of the trail of corrections would be maintained in the IPDMS V2, and available for access to the industry also.	**Not incorporated**
9	In the section **"Update Registration Details",** under "Product Source", when we click "Add New Product", there is a provision for entering "Product Capacity". Individual production capacity for a product cannot be determined, and it becomes more complicated for loan licence and third party operations. This should be deleted from IPDMS V2 as it has no relevance and is not mentioned in DPCO 2013.	**Not incorporated**

10	**Form I** In V2, under "List of Relevant Documents", in Point 7, it has been mandatorily asked to submit the CA/CMA certificate for production data of six quarters. No such clause is mentioned in Form I of DPCO 2013. Secondly, every company registered with IPDMS files Form III, which contains authentic quarterly data of production and sales for past multiple quarters. Quarterly data from Form III can be tracked for such formulations.	**Not incorporated**
11	**Form II** The entry "Effective Batch No." should be in MM/YY format as is printed on the label and not in DD/MM/YY format as in IPDMS V1 and V2.	Incorporated
12	**Form III** Para 21 (1) of DPCO 2013 specifies that the Government shall monitor the production and availability, **quarterly**. But under "Form III for Quarterly Return of Production/ Import and Sales of NLEM Drugs" in IPDMS V2, there is a new provision to enter the monthly data of production. This is not as per DPCO Form III and the workload of the companies would increase as the number of entries would triple. This is an unnecessary addition and only quarterly figures should be sought.	Incorporated
13	**Form IV** Now that IPDMS V2 has enabled a provision for online updation of Form IV, the data should be auto-populated if entered earlier and the contents should only be as specified in Form IV of DPCO 2013.	**Not incorporated**
14	**Form V** Highest entries are in Form V among scheduled and non-scheduled formulations hence a) Auto populate all product data for data entry b) Enable multiple scheduled formulations data upload from an Excel file for ease of submission c) **At each stage of saving and final submission, there should be an option for Excel, PDF and printing.** d) "Effective Batch No." should be in MM/YY format not in DD/MM/YY format	**Incorporated except point C**
15	**Change Password** Should be renamed as Password Authentication section. Allow access to an authorized user of a company, and modification in the name of that authorized user, in case the company decides to allocate this responsibility to another person. A provision should also be allowed for an additional authorized person if the company requires so as, the data processed is huge. In any case the records will be saved in the IPDMS. Please send the OTP by SMS and email, the SMS takes much time.	Incorporated modification and additional user, **OTP by Email to be incorporated.**

15	Submission of data in IPDMS in Form V should be considered as an intimation of data to the trade channels. NPPA may align the data provided in Form II & V with NPPA's APP "**PHARMA SAHI DAM"** for trade as well as for public information. This will substantially reduce load at the company level in communicating to all concerned.	**Not incorporated**
16	Reports No reports were shown to us in V2. In V1 only three reports are available, which are inadequate. 1. Form II Status submission report- contains the status of submission of the Form II for all the scheduled formulations by a company. No other details are provided. This report continues to reflect formulations that were shifted from scheduled to non-scheduled formulations as scheduled formulations. 2. Form V Status submission report- contains the status of submission of the Form V for all the scheduled and non-scheduled formulations by a company. No other details are provided. 3. Form V Consolidated report- status of submission of the Form V for all the scheduled and non-scheduled formulations by a company. Includes last entered product, price and production details including own and purchased formulations. The reports in IPDMS V2 should be designed in such a way that every detail entered in the IPDMS since its inception, should be easily retrievable for editing, storage, printing and submission by the concerned company across product details, period, prices and product sources. E.g. in IPDMS V1, if one wants to print the price entered for a particular scheduled formulation for the last 5 years, one has to first identify the report year wise where that scheduled formulation is saved, and then generate and print the form submitted individually for every year separately. Instead IPDMS V2 should enable a report across whatever time period and details are specified for one, many or all formulations for a company. It would not be possible for us to submit actual templates for the reports but above guidelines should be followed.	**Not incorporated**

In the past it was noted that our members had to submit certain data or documents which were termed "voluntary" but over a period of time the same has been made "mandatory" even though they are not included in DPCO 2013.

You will appreciate that critical information is shared online by our members through the IPDMS including Form I/II/III/IV/V from time to time and constitutes an official submission for pricing regulatory matters. Hence it is imperative that all the data sought and reports generated are in consonance with the provisions of DPCO 2013 and user friendly.

We request you to implement the above suggestions to ensure better compliance and whenever required our members can visit your office to use and experience the software first hand and provide you with feedback and key user insights.

Yours faithfully,

For Indian Drug Manufacturers' Association,

Dr Viranchi Shah,
National President

INDIAN DRUG MANUFACTURERS' ASSOCIATION

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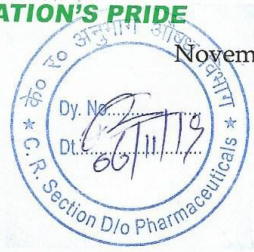
akmadan.idma@gmail.com
Website : www.idma-assn.org

INDIAN PHARMACEUTICALS NATION'S PRIDE

November 06, 2019



The Deputy Director,
Department of Pharmaceuticals,
Shastri Bhawan, New Delhi 110 001.

Kind Attn.: **Ms. Remya Prabha G., Deputy Director**

Sub: Record of the first meeting of the Forum of Pharma Associations (FOPA) on 23/08/19

Ref: Office Memorandum dated 05/09/19

Dear Madam,

Greetings from Indian Drug Manufacturers' Association

We refer to our representationmade at the 1st FOPA (Federation of Pharma Associations) meeting organized by Department of Pharmaceuticals at Delhi on 23/08/19 and the subsequent office memorandum dated 05/09/19 on the details of the discussions therein. Dr Amit Rangnekar, Chairman, IDMA Pricing /Consumer Affairs Committee and Mr Ashok Madan, Executive Director, IDMA Delhi had represented us at the meeting.

We had highlighted the problems faced in entering/updating/modifying data in the NPPA-IPDMS database. This was mentioned in Para 4 (iv) in the record of discussions issued vide office memorandum dated 05/09/19.

You will appreciate that critical informationis shared online by the companies through the IPDMS including Form I/II/III/IV/V as well as details of products, facilities and prices from time to time. Once submitted this data becomesan official submission from the company for pricing matters.

However, there are various operational issues faced during IPDMS entry which lead to confusion and errors. Once these are resolved, it would facilitate considerably ease of doing business and ensure better complianceby the industry. The details of formulations under NLEM 2015 have also not yet been updated in the IPDMS.

Secretary DOP and Chairperson NPPA had specifically advised us to send them the details in this regard and the same are **enclosed below, along with images from the actual entries in the IPDMS as annexures 1 to 9.**

1

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Ph.: 022-24944624, 24974308 Fax: 022 – 24950723 Email: idma1@idmaindia.com

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IPDMS Entry issues

Url: http://nppaipdms.gov.in/Loginform

	Section	Issue	Suggested Solution	Annexure attached
1	**Update Registration Details**	**Radio buttons** for selection are sometimes on the left and sometimes on the right. Leads to confusion, errors.	Please keep all radio buttons throughout the IPDMS only on one side, preferably left.	1,2,3,4
2	**Form II/ Form V**			
A	**Select product source**	The **Product Source Det**ails appear in the order in which they were entered, they do not appear alphabetically. Each screen has only 10 entries visible, If one has 40-50 product sources, one has to go through different pages to edit a source, which is time consuming and leads to errors. In many cases the product source has 2-3 companies with the same first name but different second name Eg XYZ Pharmaceuticals, XYZ Healthcare, XYZ Lifesciences. If these 3 sources appear on different pages it may lead to errors.	All the product sources could appear as a drop down menu in alphabetical order for selection, would save time and minimize errors.	5
B	**Select formulation**	Under **Search Product Name**, we have to enter the first 3-4 letters of a brand and then search. The brand suffixes, prefixes and pack sizes are not visible while entering. Leads to errors or duplication.	Product Source should appear automatically. To change source it should be visible alphabetically	6
		Under **Add New Product**, Under **Product Details**, when we go to the FROM-Select Product Source, the selected source should appear automatically as it	Pack size/ Unit/ Pack of the product should be automatically visible Since all brands, their product source, composition, pack,	6

2

		has already been entered in the database. In case of a change, provision for entry should be enabled.	packing are pre-entered they should appear as a drop down in alphabetical order for all entries.	
		Under Add New Product, Under Product Details, when we go to the Select Formulation, the formulationscovered in NLEM 2015 have not been included in the selection, only products of NLEM 2011 are visible. As products of NLEM are scheduled formulations whenever we enter we have to choose the option "Not in List".	**Products included in NLEM 2015 should be updated in the "Select Formulation". Eg Paracetamol 250 mg included in NLEM 2015 is still not updated while Losartan Pottasium 25 mg and 50 mg as well as Cefixime 100 mg which were excluded from NLEM 2015 are still reflected.**	7
C	**Product Details**	Under **Add New Product,** there are 3 entries- Search Product Name, Select Product, Product Name.	All 3 entries pertain to selecting a product name and can be combined as one entry. Since all products are entered in the database, all products should be visible alphabetically for selection. This would save 3 steps and confusion with suffixed brand strengths.	6
D	**Effective Batch No**	We need to select a date, month and year whereas only month and year are requiredon the actual label.	MM/YY format should appear in scroll up/down format, date is irrelevant	8
3	**Form II Scheduled Formulations**			
	Add New Product	At the bottom the WPI needs to be entered every time.	Should appear automatically year wise for selection to avoid entry errors.	9

The issues found during IPDMS entrylead to errors, and hence we would also request you to help resolve the post entry IPDMS issues as under:

A. IPDMS does not provide options for editing. i.e. if an erroneous data is entered and saved, the system does not allow the same to be rectified. This leads to wrong data being available in the system. For any correction, the same will have to be informed to NPPA for doing the needful, which takes a long time. Option for correction should be provided to the user.

B. Provision for uploading excel sheet into the system for pricing would be helpful to user as well as ensure ease of updating the prices.

We request you to kindly resolve all the points above on IPDMS entry and post entry issues. It would be our pleasure to meet you at your earliest convenience and present the technical details if required.

Thanking you,

Yours sincerely,

D. N. Roy Chowdhury

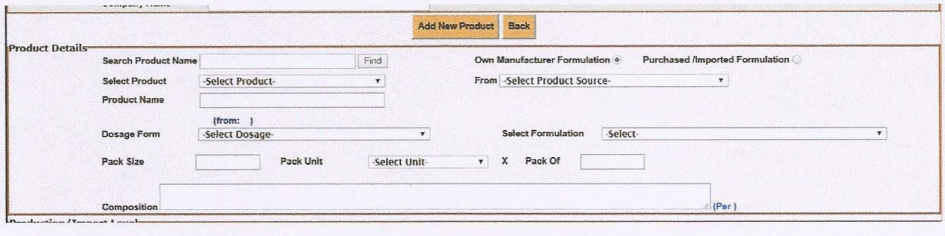
Deepnath Roy Chowdhury
National President

CC: **Ms. Shubhra Singh, IAS** — Submitted on 06/11/2019.
Chairperson,
National Pharmaceutical Pricing Authority
1, Jai Singh Marg, New Delhi 110 001.

Encl: Annexures 1 to 9 - images from actual entries in the IPDMS

IMAGES FROM ACTUAL ENTRIES IN THE IPDMS ***Annexures I to IX***

Annexure I



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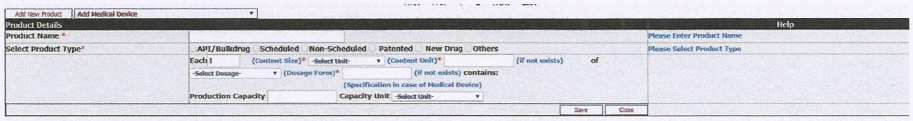

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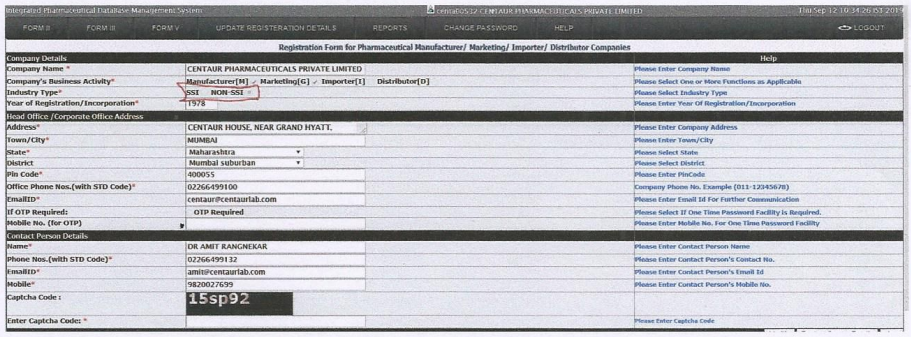

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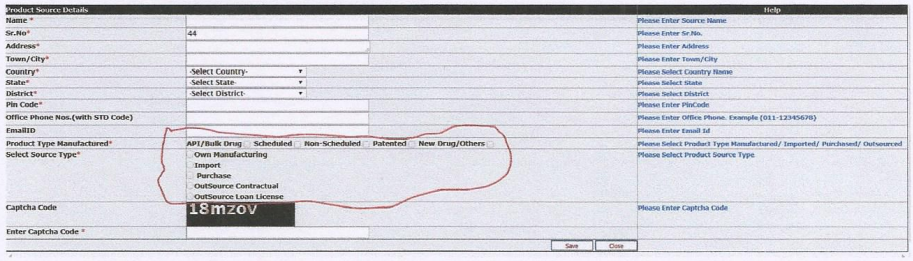

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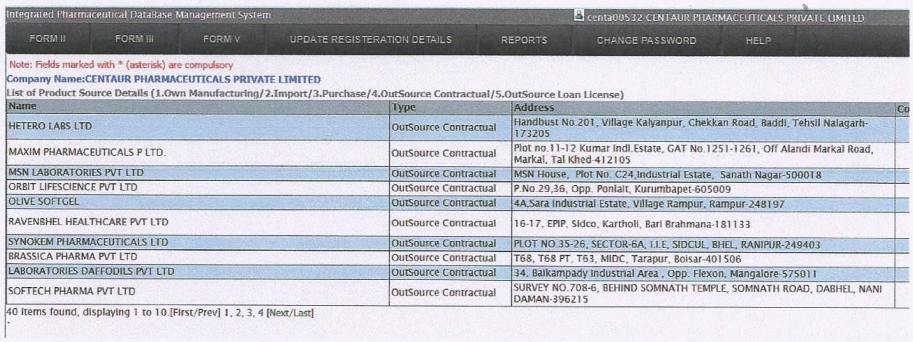
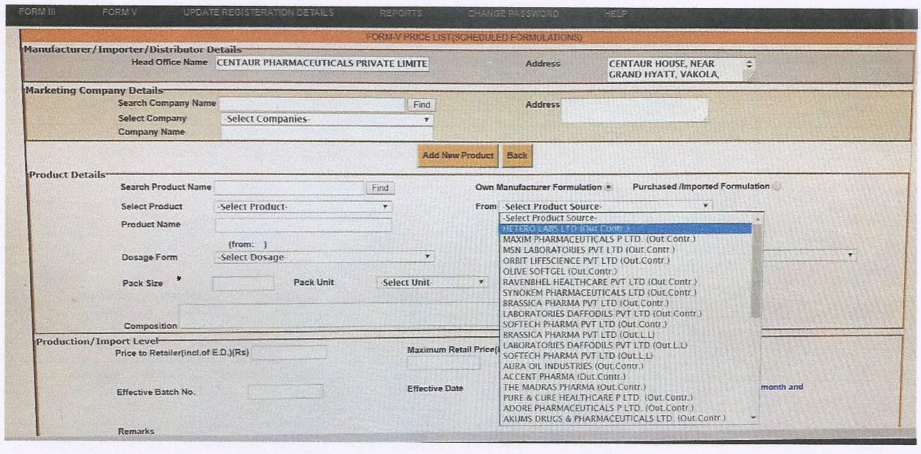
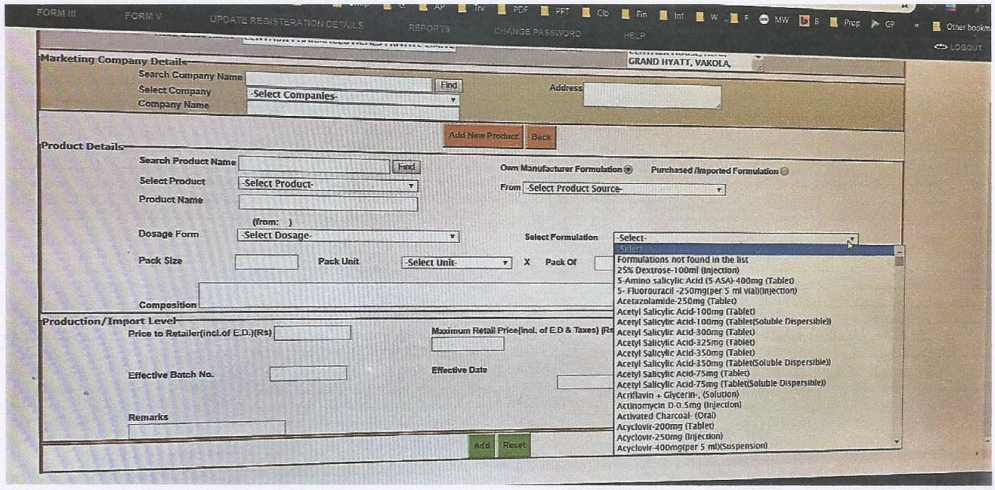


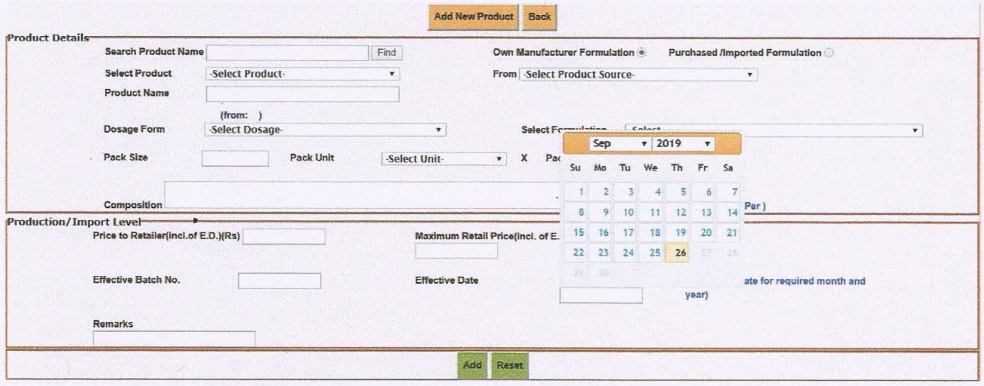
Annexure VI



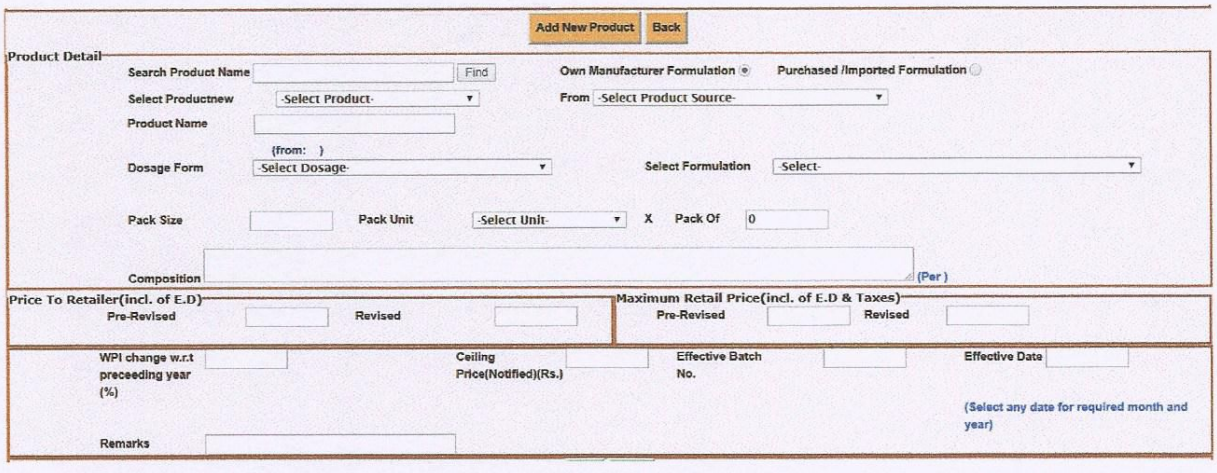
Annexure VII



Annexure VIII



Annexure IX



INDIAN DRUG MANUFACTURERS' ASSOCIATION
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PARTNERS IN GLOBAL HEALTHCARE

13 July 2021

TO
MR RAJESH KUMAR T
DEPUTY DIRECTOR (LEGAL/IT)
NPPA, NEW DELHI.

Sub: Discussion on Proposed IPDMS V 2 in NPPA
Ref: Video Conference on 1st July, 2021 at 11.00 AM

Dear Sir

Greetings from IDMA!

We thank you for organizing the above video conference, to introduce the pharmaceutical industry to IPDMS V 2, the proposed online service for filing Form I, II, III, IV, and V of DPCO 2013, by Pharmaceutical Manufacturer/ Marketing/ Importer/ Distributor Companies.

IDMA had made a detailed presentation regarding various issues faced with IPDMS V 1, to Dr. P D Waghela, Secretary, Department Of Pharmaceuticals and the Chairperson NPPA Ms. Shubra Singh on 23.08.2019 during the 1st meeting of the Federation of Pharmaceutical Associations (FOPA) in New Delhi. Dr. Waghela and Madam Shubhra Singh had specifically requested us to submit a representation which is attached for your perusal and we are pleased to note that many of our suggestions have been incorporated in IPDMS V 2 which seems an improvement on V 1 in terms of user friendliness and ease of use.

Our prima facie observations of IPDMS V 2 were as under:

1. We are glad to note that registered users of V 1 would migrate to V 2 automatically.

2. In Form II, the WPI change w.r.t preceding year (%) and the Ceiling Price (Notified)(Rs.), for a scheduled formulation should appear automatically (auto-populate) on the screen as they have been notified and are in force. In V1 we have to enter separately which is a duplication of work.

3. In Product Registration, we are entering all product details including the composition, pack, packing and the manufacturing source. These details should appear automatically (auto-populate) on the screen while we are updating the price details. In V 1 we have to reselect each detail and they are not in an alphabetical order either. This maybe avoided, as it is duplication of work. Similarly, for any change in composition of the formulations, which maybe due to change in Government regulations, the companies should be provided an editing facility, which would archive the old product registration and only the new registration is reflected. This would avoid wrong entry of prices in the IPDMS.

4. In Form II, and in Form V for scheduled and non-scheduled formulations, under the tab “select formulations” the composition needs to be selected. It should be automatically selected from the product registration file Since changes in price takes effect every April due to WPI change for scheduled formulations and as and when due for Non-Scheduled formulations as per the provisions of Para 20 of DPCO 2013. It is cumbersome to populate data for all the Scheduled formulations in IPDMS. Hence, the facility to upload the data from a Company’s ready data file (word or Excel), would go a long way in facilitating ease of uploading data in IPDMS.

5. In Form II, and in Form V for scheduled and non-scheduled formulations, the entry for “Effective Batch No.” should be in MM/YY format as is printed on the label and not in DD/MM/YY format as in V 1.

6. Under “Form III for Quarterly Return of Production/ Import and Sales of NLEM Drugs” we observed that monthly data of production now needs to be keyed in. This could inconvenience the user as number of entries would triple to 12 against 4 earlier. This is an unnecessary addition. We request you to revert to the old system of quarterly figures as per para 21 (1) of DPCO 2013 which specifies that the Government shall monitor the production and availability, quarterly.

7. Provision should be enabled to allow corrections in Form V even after submission, as in any case there would be a trail maintained at your end.

8. The submission of data in IPDMS in Form V may be considered as intimation of data to the trade channels. NPPA may align the data provided in Form II & V with NPPPA’s APP **PHARMA SAHI DAM** for trade as well as public information. By aligning the information the need for issuing overcharging notices to the manufactures can be avoided to a greater extent. Manufacturers will also undertake the required steps to inform the trade channels as per the guidelines.

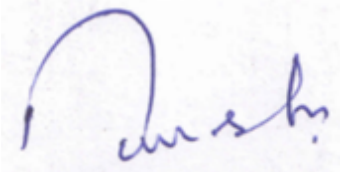
9. Since the proposed system would be accessed only by authorized user of a company, we request you to allow modification in the name of the authorized user, in case the company decides to allocate this responsibility to another authorized person.

You will appreciate that critical information is shared online by our members through the IPDMS including Form I/II/III/IV/V from time to time and constitutes an official submission for pricing regulatory matters.

Sir, as discussed during the call, we request that a few of our members be allowed to use the software in your presence in your office so that our actual users may provide inputs for ease of use of the software and a better end user experience.

We look forward to your invitation to IDMA, in this regard.

Yours sincerely,
For Indian Drug Manufacturers’ Association,



Mahesh H Doshi
National President

INDIAN DRUG MANUFACTURERS' ASSOCIATION
102, POONAM CHAMBERS, 'A' WING, DR. A.B. ROAD, WORLI, MUMBAI 400 018, INDIA

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PARTNERS IN GLOBAL HEALTHCARE

October 13, 2021

To,
Mr. Surendra Singh
Director (Admin)
NPPA, NEW DELHI.

Sub: Discussion on Proposed IPDMS V2 (Version 2)
Ref: Personal meeting on 17th September, 2021 at 330 pm in the NPPA office, New Delhi

Dear Sir,

Greetings from IDMA!

IDMA had made a detailed presentation in the past to the NPPA / DOP / NITI Aayog (***Annexure I***) regarding various operational issues faced with IPDMS V1. We are glad that many of the inputs suggested by IDMA have been incorporated in the IPDMS V2 which was demonstrated to the industry on 1st July 2021.

IDMA had conveyed further observations on IPDMS V2 vide representation dated 13th July, 2021 (***Annexure II***) and had requested for a physical demonstration of the IPDMS V2 for the pharmaceutical industry. We are grateful that the meeting was organized on 17th September 2021 at the NPPA New Delhi office, and was attended by Dr Amit Rangnekar, Chairman, Pricing Committee, IDMA .

We were assured during the demonstration that based on our earlier queries, the following has been incorporated in the IPDMS V2:

A. All registered users of IPDMS V1 would migrate to V2 automatically.

B. In Form II, the WPI change w.r.t preceding year (%) and the Ceiling Price (Notified)(Rs.), for a scheduled formulation, would appear automatically (auto-populate) on the screen once they have been notified.

C. In Product Registration, all the submitted product details including the composition, pack, packing and the manufacturing source would appear automatically (auto-populate) on the screen.

D. For all the forms I to V, all the selections especially for products, would appear in an alphabetical drop down order in IPDMS V2, for scheduled and non-scheduled formulations.

We were directed by your good self to submit our observations and further recommendations for IPDMS V2 to make it user friendly and effective, which are as under.

1. With the impending NLEM 2021, the category of some formulations would change from scheduled to non-scheduled and vice versa. Whenever the category changes, there is no provision in IPDMS V1 to edit the category. We have to re-enter the formulation in the new category all over again and the old formulation continues to be reflected in the old category wrongly, since we cannot delete it. There should be a provision to change the category from scheduled to non-scheduled or vice versa. Ideally an editing facility should be provided, which would archive the old product registration and only the new registration would be reflected and allowed to be entered. This would ensure that data would be maintained only for one formulation in one category.

2. Many of our members enter over 100 scheduled formulations in April after the WPI price revision. It is cumbersome to populate data for all the Scheduled formulations in IPDMS. Please enable a facility to upload the data from a Company's ready data file in Excel format.

3. An editing facility should be provided in all the forms in IPDMS V2 in case any correction is required, even after submission. Since all

the corrections are saved in the IPDMS with time stamp, an archive of the trail of corrections would be maintained in the IPDMS V2, and available for access to the industry also.

4. In the section **"Update Registration Details",** under "Product Source", when we click "Add New Product", there is a provision for entering "Product Capacity". This should be deleted from IPDMS V2 as it has no relevance and is not mentioned in DPCO 2013.

5. Form I

Under "List of Relevant Documents", in Point 7, it has been mandatorily asked to submit the CA/CMA certificate for production data of six quarters. No such clause is mentioned in Form I of DPCO 2013. Under Form III production and Sales data are already submitted on a quarterly basis.

6. Form II

a. Multiple scheduled formulations are entered after the WPI price revision in April, hence a facility to upload the data from an Excel file should be provided for ease of submission.

b. The column number 5 "WPI change wrt preceding year" and column number 10 "Ceiling Price (Notified) Rs." should both be auto-populated as they are announced by the NPPA and already in effect. In IPDMS V1 we have to enter these two columns when updating the price revision for every scheduled formulation which is unnecessary.

c. The entry "Effective Batch No." should be in MM/YY format as is printed on the label and not in DD/MM/YY format as in IPDMS V1 and V2.

7. Form III

Para 21 (1) of DPCO 2013 specifies that the Government shall monitor the production and availability, quarterly. But under "Form III for Quarterly Return of Production/ Import and Sales of NLEM Drugs" in IPDMS V2, there is a new provision to enter the monthly data of production. This is not as per DPCO Form III and the workload of the companies would increase as the number of entries would triple. This is an unnecessary addition and only quarterly figures should be sought.

8. Form IV

Now that IPDMS V2 has enabled a provision for online updation of Form IV, the data should be auto-populated if entered earlier and the contents should only be as specified in Form IV of DPCO 2013.

9. Form V

a) All the product data should be auto populated for data entry.
b) Multiple scheduled formulations are entered after the WPI price revision, a facility to upload the data from an Excel file should be provided for ease of submission.
c) Multiple non-scheduled formulations are entered from time to time, facility to upload the data from an Excel file should be provided for ease of submission.
d) The entry for "Effective Batch No." should be in MM/YY format as is printed on the label and not in DD/MM/YY format as in IPDMS V2.

10. Reports

a) Currently in IPDMS V1 there are only three reports available
   I. Form II Status submission report- contains the status of submission of the Form II for all the scheduled formulations by a company. No other details are provided. This report continues to reflect formulations that were shifted from scheduled to non scheduled formulations as scheduled formulations.
   II. Form V Status submission report- contains the status of submission of the Form V for all the scheduled and non-scheduled formulations by a company. No other details are provided.
   III. Form V Consolidated report- status of submission of the Form V for all the scheduled and non-scheduled formulations by a company. Includes last entered product, price and production details including own and purchased formulations.

b) The reports in IPDMS V2 should be designed in such a way that every detail entered in the IPDMS since its inception, should be easily retrievable for editing, storage, printing and submission by the concerned company across product details, period, prices and product sources.

c) E.g. in IPDMS V1, if one wants to print the price entered for a particular scheduled formulation for the last 5 years, one has to generate and print every years submission separately. Instead

IPDMS V2 should enable a report across whatever time period and details are specified for one, many or all formulations.

11. **Change Password**

Under this section there is a provision to change the password for IPDMS V1. Instead in IPDMS V2 this section should be renamed as Password Authentication section. IPDMS V2 should allow access to an authorized user of a company, should also allow modification in the name of that authorized user, in case the company decides to allocate this responsibility to another person. A provision should also be allowed for an additional authorized person if the company requires so as, the data processed is huge. In any case the records will be saved in the IPDMS.

12. **Important Note**:

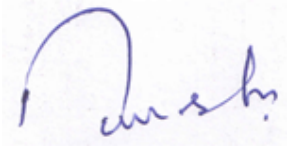
a) The submission of data in IPDMS in Form V should be considered as an intimation of data to the trade channels. NPPA may align the data provided in Form II & V with NPPA's APP "**PHARMA SAHI DAM"** for trade as well as for public information.

b) In the past it was noted that our members had to submit certain data or documents which were termed "voluntary" but over a period of time the same was made "mandatory" even though they were not included in DPCO 2013.

c) You will appreciate that critical information is shared online by our members through the IPDMS including Form I/II/III/IV/V from time to time and constitutes an official submission for pricing regulatory matters. Hence it is imperative that all the data sought and reports generated are in consonance with the provisions of DPCO 2013 and user friendly, for better compliance.

If required, once the above suggestions are implemented, few of our members can again come over to your office to use and experience the software first hand and provide key user insights.

Yours Sincerely,
For Indian Drug Manufacturers' Association,



Mahesh H Doshi
National President

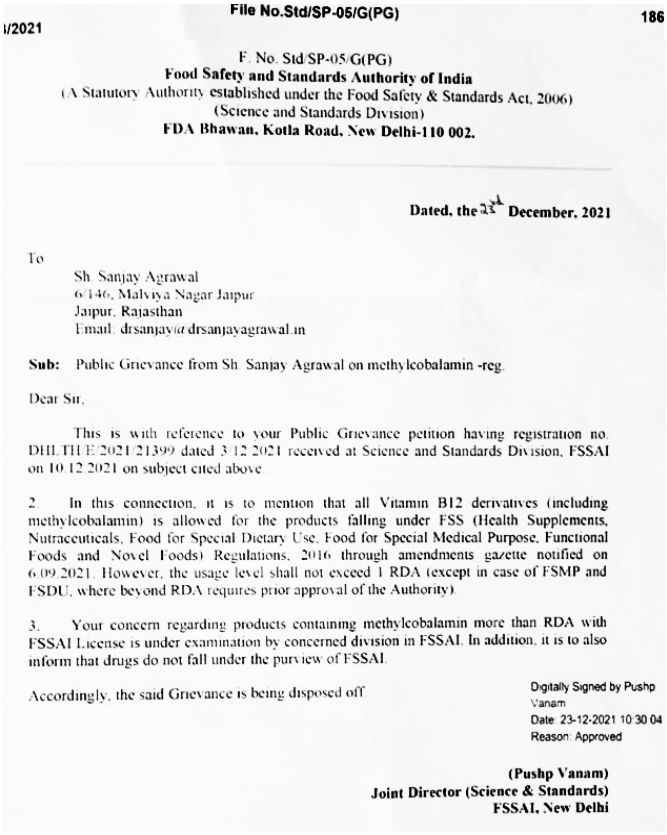
● ● ●

Methylcobalamin – RDA concerns

To,
All Food Business Operators
IDMA – Members

Dear All,

Recommended Dietary Allowances or RDA for Methylcobalamin has become a burning issue and the following correspondence from FSSAI is being considered as a basis by Food Business Operators (FBOs) in forming current, albeit conflicting, opinion regarding the same.



File No.Std/SP-05/G(PG) 186

1/2021

F. No. Std/SP-05/G(PG)
Food Safety and Standards Authority of India
(A Statutory Authority established under the Food Safety & Standards Act, 2006)
(Science and Standards Division)
FDA Bhawan, Kotla Road, New Delhi-110 002.

Dated, the 23rd December, 2021

To
Sh. Sanjay Agrawal
6/146, Malviya Nagar Jaipur
Jaipur, Rajasthan
Email: drsanjay@drsanjayagrawal.in

Sub: Public Grievance from Sh. Sanjay Agrawal on methylcobalamin -reg.

Dear Sir,

This is with reference to your Public Grievance petition having registration no. DHLTH/E/2021/21399 dated 3.12.2021 received at Science and Standards Division, FSSAI on 10.12.2021 on subject cited above.

2. In this connection, it is to mention that all Vitamin B12 derivatives (including methylcobalamin) is allowed for the products falling under FSS (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Foods and Novel Foods) Regulations, 2016 through amendments gazette notified on 6.09.2021. However, the usage level shall not exceed 1 RDA (except in case of FSMP and FSDU, where beyond RDA requires prior approval of the Authority).

3. Your concern regarding products containing methylcobalamin more than RDA with FSSAI License is under examination by concerned division in FSSAI. In addition, it is to also inform that drugs do not fall under the purview of FSSAI.

Accordingly, the said Grievance is being disposed off.

Digitally Signed by Pushp Vanam
Date: 23-12-2021 10:30:04
Reason: Approved

(Pushp Vanam)
Joint Director (Science & Standards)
FSSAI, New Delhi

In this regards, kindly note –

- This is a personal correspondence to the aggrieved in response to the filed Public Grievance Petition to the PMO (Prime Minister's Office).
- Point No 2 mentions that Vitamin B_{12} derivatives (including Methylcobalamin) are permitted as per gazette notified on 6th September 2021.
- Point No 2 also mentions that applicable RDA of 1x is not to be exceeded except in cases of FSMP (Foods for Special Medical Purposes) and FSDU (Foods for Special Dietary Use).
- ***However,* the Point No 3 categorically specifies that for Methylcobalamin the defining of RDA is under examination.**
- Above all, this correspondence is not addressed to the FBOs as an addendum to regulations.

Besides, this there is never a single circular or gazette notification issued capping the RDA of Methylcobalamin.

It is interesting to survey the various circulars pertaining the RDA announcing by the FSSAI (Food Safety and Standards Authority of India) on the basis of ICMR (Indian Council of Medical Research) / NIN (National Institute of Nutrition) recommendations.

Date	Circular / Notification Details	Vitamin B_{12} RDA
Before 2019	NIN, 2009	1 mcg
27/02/19	F.No.Stds/Nutra(DCGI)/FSSAI-2017	1 mcg
07/01/20	F.No.Stds/Nutra(DCGI)/ FSSAI-2017	1 mcg
16/07/21	F.No. Stds/SP-05/Orders/FSSAI	2.5 mcg
02/08/21	F.No. Stds/SP-05/Orders/FSSAI	2.2 mcg

Here it must be understood medically why Cyanocobalamin's RDA has been capped to 2.2 mcg whilst Methylcobalamin needs to be considered for recommending in higher amounts.

- The Vitamin B_{12} action on DNA is the most important and is possible at available concentrations of 7-17.6 mcg.
- At intakes of approximately 1 mcg Cyanocobalamin the absorption is 50% and this makes the available Vitamin B_{12} only 0.5 mcg.
- This is the reason for the widespread deficiency of vitamin B_{12} since the minimum need of the body i.e., 7 mcg is not catered to.
- However, Cyanocobalamin RDA has been determined by ICMR / NIN as 2-2.2 mcg. This is because Vitamin B_{12} is absorbed from ileum after binding with Intrinsic Factor (IF) but the IF is saturated by 2 mcg of Vitamin B_{12}. **Hence,**

there is no purpose in administering >2 mcg of Cyanocobalamin.

- **Methylcobalamin can ensure higher amounts of Vitamin B_{12} absorption since it can bypass the IF but only if provided in higher concentrations.**
- Since 1-2% absorption can occur for 500 mcg and above recommendations higher intakes of Methylcobalamin up to 2000 mcg are necessary for this derivative of Vitamin B_{12} to attain blood levels necessary for its action on DNA.

[Paul C & Brady DM. Comparative Bioavailability and Utilization of Particular Forms of B_{12} Supplements With Potential to Mitigate B_{12}-related Genetic Polymorphisms. Integrative Medicine 2017; 16(1): 42-49.]

The European Food Safety Authority (EFSA) has published a 'Scientific Opinion of the Panel on Food Additives and Nutrient Sources added to food' titled *"Scientific Opinion on 5'-deoxyadenosylcobalamin and methylcobalamin as sources for Vitamin B12 added as a nutritional substance in food supplements"* which was adopted on 25 September 2008 (copy enclosed). After a detailed study, the Panel has concluded that:

" … the use of 5'-deoxyadenosylcobalamin and methylcobalamin as a source of vitamin B12 in food supplements for the general population at the proposed uses and use levels *[below the guidance value of 2000 µg/day defined by EVM (Expert group on Vitamins & Minerals)]* ***is not of safety concern."***

Thus, it is meaningless and, in fact, detrimental to consumer's well-being if Methylcobalamin's requirements are considered to be the same as for Cyanocobalamin since it is a Vitamin B_{12} derivative!!

The RDA are for Vitamin B_{12} as Cyanocobalamin and cannot be applicable to all derivatives. There are several examples of derivatives requiring different amounts as compared to the parent substance / drug.

- Ambroxol is active metabolite of bromhexine.
  - Ambroxol Dose: 30 mg 3 times daily; Bromhexine Dose: 8-16 mg 3 times daily.
- Cetirizine is active metabolite of hydroxyzine.
  - Cetirizine Dose: 10 mg once daily; Hydroxyzine Dose: 50-100 mg 4 times daily.

Similarly Methylcobalamin is the active derivative of Vitamin B_{12} which has been usually administered as Cyanocobalamin till the availability of Methylcobalamin in the late 20th century.

Vitamin B_{12} deficiency in vegetarians is significant at 62%, 25% to 86%, 21% to 41%, and 11% to 90% in pregnant women, children, adolescents, and older individuals, respectively. This is because Cyanocobalamin as an ingredient in oral forms such as tablet, capsule or powder product has never been adequately effective to prevent or overcome Vitamin B_{12} deficient states – always injectable form necessary. Methylcobalamin has revolutionized by becoming the first oral form to *reliably* fulfil the Vitamin B_{12} requirements, and without the need for injections, because it is being recommended in amounts ranging from 500-2000 mcg/day.

The regulatory justification of higher limits for Methylcobalamin is additionally based on the following stated under the category of Health Supplements [6(1)(c)] (which includes vitamins) as per the FSS (Nutra) Regulations, 2022 (effective from 1st April 2022) page no 7 –

"Limits as specified in schedule. In case daily minimum and maximum usage levels have not been specified, the FBO shall adopt the usage level based on relevant scientific data and retain the documentary evidence of such data. FBO shall submit such data to the Food Authority, as and when called for."

There is not a single circular or advisory or notification from the FSSAI's office mentioning that RDA of Methylcobalamin is same as Cyanocobalamin. It's all a conclusion based on the single correspondence by a non-Scientific Panel member from the FSSAI office addressing the Public Grievance petition filed by an enquiring individual and the same being possibly hurriedly compiled on pressure from the PMO. **Members of IDMA engaging in Nutraceutical vertical of healthcare need to take cognizance of the facts given and not keep on asking authorities to declare the RDA.**

Let us ensure reliable health benefits of Vitamin B_{12} via Methylcobalamin for especially the vegetarian consumer which constitutes up to 40% of Indians!

DR R K SANGHAVI

CHAIRMAN – Nutraceutical Committee

NAFDAC, Nigeria Notice on Unprofessional Act of Pharma Manufacturers/Exporters- reg.

IDMA have submitted the following representation on 5th May 2022 to Prof. S B Adebayo, Director, Ports Inspection (NAFDAC)on the above subject:

Ref: Your letter dated 3rd May 2022

Respected Sir/ Madam,

We acknowledge with a great concern, your letter dated 3rd May 2022, regarding the Unprofessional act of some Indian manufacturers/ exporters in connivance with some Nigerian importers.

It appears from the letter that your office has observed a significant number of cases of mismatch between the registered designs/formulations of some products imported into Nigeria from India vis-à-vis the designs/formulations submitted and registered by Nigerian importers at the time of registration of relevant products. It also appears from your letter, that as per your information, such Indian manufacturers/ exporters work in connivance with some Nigerian importers and they have been jointly involved in making these changes in designs/ formulations without their Nigerian counterparts getting these amendments approved by NAFDAC through the prescribed process. It may also be noted that, as per information available from some of our members, many products are being manufactured under CMO model where the brand names, artworks etc. are provided by the importers.

At the onset, we assure you of our best possible co-operation in all matters wherever you need our assistance or support. IDMA is the largest association of Indian Pharmaceutical manufacturers, and perhaps one of the largest pharma manufacturer's associations globally. We are headquartered in Mumbai, have a liaison office in New Delhi, and have 8 State Boards at different locations within India, based on the density of pharma manufacturers. Our members are committed to providing affordable- good-quality medicines globally.

Nigeria is an important partner for India. India and Nigeria share very close cultural ties and political alignment and are allies in several areas. Nigeria is a very important consumer of Indian Pharmaceuticals in Africa. India continues its best efforts to be a reliable global source of cost-effective quality medicines, including those for the Nigerian market. We believe, India and Nigeria have similar National goals of Affordability, Availability, and Accessibility of quality healthcare for their population, and IDMA members assure NAFDAC of a constructive role in reaching these goals.

India proudly stands 3rd in the Global production and exports of medicines with almost 50% of our products being exported to the US and Europe. We have the largest number of US FDA-approved manufacturing sites outside the US, we have a large number of companies having approvals from the EU, PIC/s, and other stringent regulatory authorities. India has a long history of being a respected source of good quality affordable medicines and medical services, created over years of hard work by our stakeholders.

As the first and immediate step, we will sensitize our members in this context. We shall circulate your letter and request our members to initiate steps to rectify the designs and formulations so as to meet the approved ones. In case there are discrepancies, we shall advise them to either revise them in line with what is registered with NAFDAC or where applicable contact their local agents/ representatives in order to initiate procedures to rectify the same with NAFDAC. To enable them to do so without depending on intermediaries, we would request NAFDAC to provide **password-protected gated access** to NAFDAC website for the manufacturers to view their current registered formulation and artworks, it would help to identify the gaps and initiate activities to reconcile. Password-protected gated access will also allow the manufacturers as well as importers to seek your guidance on the present Rules and Regulations and thus help them to align their pack designs, etc. with the prescribed norms. This gated access to the registered manufacturer can also display a list of registered products, along with their current renewal status, on NAFDAC Website. We feel this will be helpful to all stakeholders.

We propose to form a joint working group with NAFDAC for a long-term engagement, in the common interest of India and Nigeria. This working group can help to take the NAFDAC directives to Indian manufacturers and exporters and at the same time facilitate, in case the

issues faced by the Indian side, with respect to matters of registrations, inspections, etc. by suitably presenting these issues to NAFDAC.

IDMA is ready to engage with any other stakeholders in Nigeria including associations and regulators, for mutual benefits.

We once again assure you that we will do our best to take the NAFDAC message to our members.

We remain at your disposal for any other support or assistance.

Yours faithfully,

For Indian Drug Manufacturers' Association,

Dr Viranchi Shah
National President

Dear Member,

With regards to above representation, IDMA have received the positive response from NAFDAC dated 06th May 2022, as reproduced below for your reference.

Dear Sir,

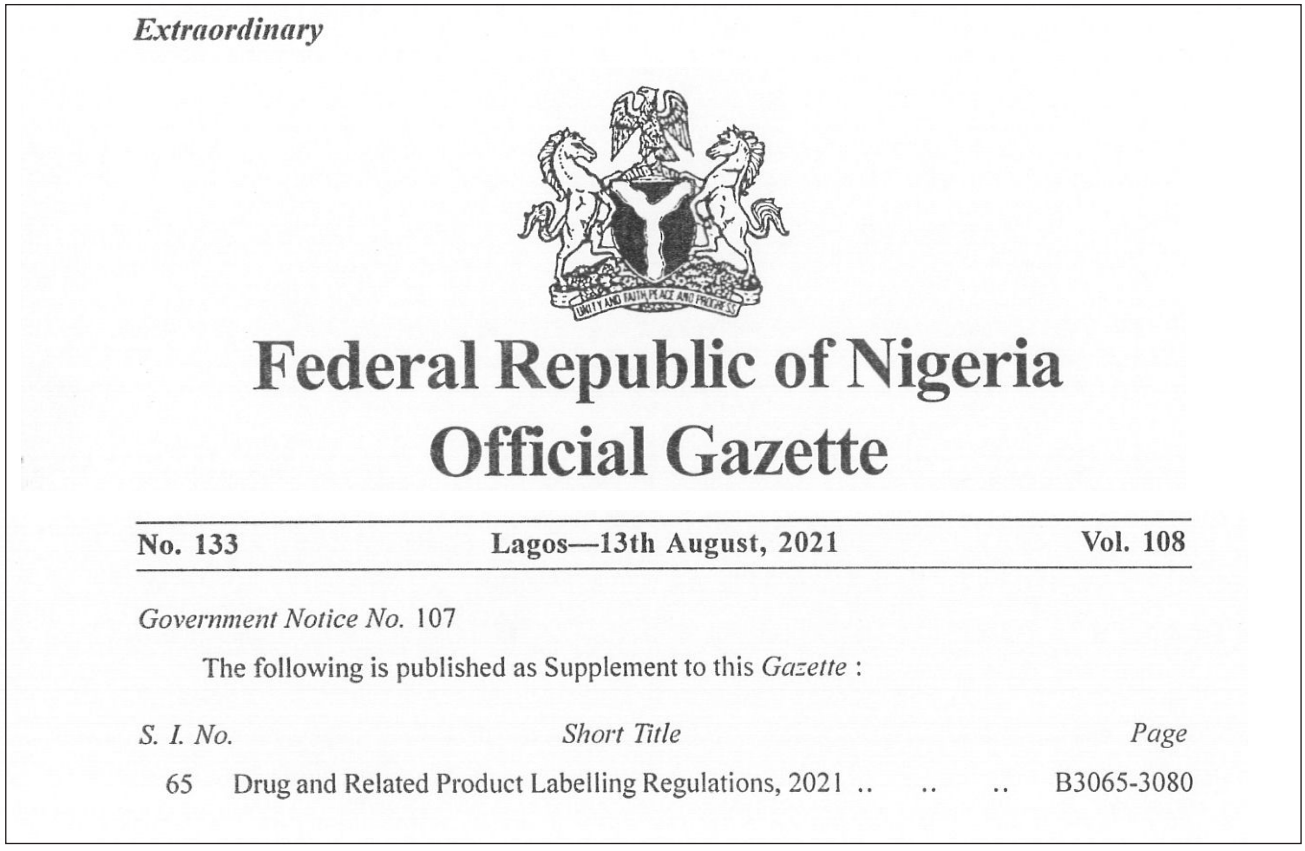
We acknowledge and appreciate your mail and your swift response and readiness to collaborate with NAFDAC. I am directed to inform you that we appreciate your suggestions and assure you that we shall work with you on them.

Best Regards

***Dunoi AFAM**, B.Pharm (Univ. of Benin, Nigeria); MPH (Univ. of Liverpool, UK)*
Deputy Director
Ports Inspection

• • •

NAFDAC, Nigeria - Drug and Related Product Labelling Regulations 2021 - reg.



Extraordinary

Federal Republic of Nigeria
Official Gazette

No. 133 **Lagos—13th August, 2021** **Vol. 108**

Government Notice No. 107

The following is published as Supplement to this *Gazette* :

S. I. No.	*Short Title*	*Page*
65	Drug and Related Product Labelling Regulations, 2021	B3065-3080

B 3065

NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL ACT (CAP. N1 LFN), 2004

DRUG AND RELATED PRODUCT LABELLING REGULATIONS, 2021

ARRANGEMENT OF REGULATIONS

Regulation :

S. I. No. 65 of 2021

NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL ACT (CAP N1, LFN), 2004

DRUG AND RELATED PRODUCT LABELLING REGULATIONS, 2021

[*7th Day of July*, 2021] Commencement.

In exercise of the powers conferred on it by sections 5 and 30 of the National Agency for Food and Drug Administration and Control Act (Cap. N1, LFN) 2004 and section 12 of the Food, Drug and Related Products (Registration, Etc.) Act (Cap. F33, LFN) 2004 and all other powers enabling it in that behalf, the Governing Council of the National Agency for Food and Drug Administration and Control with the approval of the Minister of Health makes the following Regulations—

Scope of application.

1. These Regulations shall apply to all labelling of drug and related products, manufactured, imported, exported, sold, distributed or used in Nigeria.

Prohibition.

2. A person shall not manufacture, import, export, distribute, advertise, display for sale or use any drug or drug product unless it is labelled and it is in accordance with these Regulations.

Reference to national or international bodies.

3. Label of a drug or drug product shall not make reference either directly or indirectly, to a national or international body, except as permitted, prescribed or specified by the Agency.

Labelling information.

4.—(1) All information required to be indicated on the label of a product, shall be prominent, legible and distinct.

(2) Every statement shall appear in font size and style type, which is adequate for clarity and on sufficient contrasting background without obscuring designs or vignettes or crowding within printed or graphic matter.

(3) All information for drug or related product shall be in English Language, and may include any other languages.

(4) Labelling shall be informative and accurate.

(5) Labelling shall not be false or misleading.

(6) All information and statements required by these Regulations shall appear on the part or panel of the label which is presented or displayed under customary conditions of purchase.

(7) The label space shall not be used to present information, statement or graphics not required by these Regulations in such a manner that will make the label space insufficient for the prominent placing of such information or statements required under these Regulations.

(8) Special labeling requirements and drug safety information shall be clearly stated.

Name and address of Manufacturer. Holder of Certificate of Registration. Packer on label.

5.—(1) The label of a drug shall be conspicuous, indicating the name and manufacturing location, address of the manufacturer, and the name of the holder of certificate of registration.

(2) Where a drug is manufactured under a contract of manufacturing arrangement, the name and manufacturing address shall be indicated by a phrase that reveals the connection with the entity such as "Manufactured by....., for.....", 'Manufactured for.....by.....", or any other wording that expresses the facts.

(3) The name of the person represented as manufacturer under regulations 5(1) and 5(2), may be the same as either the name of establishment under which the entity is registered at the time the labelled product is manufactured or the registered name of the parent, subsidiary or affiliated company, where the related companies are under common ownership and control, the corporate name may be followed or preceded by the name of the particular division.

(4) The site address of the manufacturer of a drug shall be complete on labels of all packaging components, for example Primary, Secondary and Tertiary), unless the immediate container of the drug contains 5ml (or equivalents) or less of the drug product, in which case the address needs not be shown on the inner label.

Display of generic and brand name.

6.—(1) The packaging components of a drug product shall bear the name, active ingredients, strength and dosage form of the drug.

(2) Where a drug is branded, the generic (common) and brand (proprietary) names shall be reflected on all packaging components (primary, secondary and tertiary).

(3) The name shall prominently appear on the principal display panel of the package to aid accurate identification.

(4) To satisfy the requirement for prominence, the generic or common name shall be printed in letters that are as large and visible as those of the brand (proprietary) on both the principal display panel and other labeling components.

(5) Where a drug contains a single active ingredient, the common or generic name shall appear in conjunction and in close proximity to the brand name, if any, of the drug.

(6) The generic or common name shall appear directly below the brand or proprietary name on all labeling components except in a running text of pack insert, where generic or common name is required to appear at least once in the same font and style, type, size as the brand proprietary name.

(7) The representation of the generic or common name on principal display panel and all labeling components shall be in the format; name, followed

by pharmaceutical dosage form, the compendia standard, if applicable and the strength (mg or g) for example "XYZ tablets 200mg".

(8) A product shall not be labeled or designated with claim of compliance with official compendia standard, except it complies with the specifications of the official compendia.

(9) Where a drug contains more than one active ingredient, all the common names shall appear on the principal display panel of the drug, unless the drug is packaged in a container too small to bear the information, then it shall appear on the information panel.

(10) In the case of a drug product containing two or more active ingredients, if the label indicates the brand (proprietary) name and there is no common name corresponding to such combination, the quantitative ingredient information required on the label by these Regulations shall be placed conspicuously on the panel. The prominence of the quantitative ingredient information shall bear a reasonable relationship to the prominence of the brand name.

(11) Where the generic or common name is required to accompany or to be used in association with the brand (proprietary) name in a running text, the common or generic name shall be placed in direct conjunction with the brand name.

Declaration of net content of drug.

7.—(1) The outer label of a drug shall indicate the net content of the drug in the container in terms of unit weight, measure or number.

(2) The declaration of net content of drug in tablet, capsule, ampoule, vial or other unit dosage form shall be expressed in numerical count; the declaration of net content for DRUG in other dosage forms shall be in terms of weight if the drug is solid, semi-solid, or viscous, or in liquid measure or volume, if the drug is liquid.

(3) Declaration of weight of the contents shall be expressed in terms of metric units *i.e.* kilogram, gramme, and subdivisions.

(4) Declaration of liquid measure or volume of the contents shall be expressed in the liter and milliliter, cubic centimeter and subdivisions.

(5) Declaration of net content of a co-packaged drug product shall state the quantity of each component in conjunction with other components of the co-pack using the plus sign (+) with the statement of quantity enclosed within brackets and "Co-pack" or "Combipack" preceding the statement of content, for example: 1 Co-pack (3 tablets +2 capsules) or 1 Combipack (1 vial + 5ml ampoule +1ml ampoule); if there are more than one co-packs in a pack, the number of co-packs within a pack shall be described in numerical counts such as 2 x 1 Co-pack.

Brand name or Trademark.

8.—(1) The brand name or trade mark shall be displayed on the label and shall not give a wrong impression of the nature, quality or substance of the drug product.

(2) Where the brand name or trade mark registration is in conflict with any Regulations or requirements of the Agency, the latter shall supersede and prevail.

(3) The brand name of a drug product shall not sound or look like already registered drug product.

(4) Where a drug product has been registered under a brand name or as a range of drug products with similar active ingredients, at least one of the active ingredients must be common to the parent and the brand name shall bear a differentiating suffix.

Registration number assigned by the Agency.

9.—(1) The outer and inner labels of a drug shall clearly show the registration number of the Agency (NAFDAC REG. NO.) assigned to it as indicated on the certificate of registration in a manner prescribed by the Agency.

(2) Where a drug product has tertiary, secondary and primary packaging materials and the content of a unit pack is reasonably considered to be dispensed or sold to an end-user as a whole or is for a single use, the NAFDAC REG. No. shall be shown on the tertiary and secondary packaging materials only.

Identification mark.

10.—(1) Where tablets, capsules, caplets and similar dosage forms bear identification marks the identification marks shall be traceable to the certificate of registration holder or the manufacturer of the drug product.

(2) The following classes of drug products are exempted from the requirements in sub-regulation (1)—

(*a*) drug products intended for use in a clinical trial investigation or bio-equivalence studies ;

(*b*) radiopharmaceutical drug products ;

(*c*) drug products with product size, shape, physical characteristics which make imprinting technologically infeasible or impossible ; and

(*d*) drug administered solely in controlled healthcare settings.

(3) Exemptions request shall be made in writing to the Agency.

Labelling of dispensing measure.

11. All packages for oral pediatric liquid drug products, shall have included in them, an appropriate measuring device graduated as applicable.

Package insert.

12. All prescription, only drug shall be accompanied by a package insert with relevant information as required in these Regulations and any other information as may be required by the Agency.

Labelling of parenteral preparations.

13.—(1) The Labelling of injectable drug products shall provide adequate information to health care practitioners and other users to ensure safe and

proper use of the therapeutic agent and where all the information required may not be contained on the immediate container, they shall be included in the package insert.

(2) The Labelling shall state the following—

(*a*) the name of the product ;

(*b*) percentage content of the drug in liquid preparations ;

(*c*) amount of active ingredients (for drug powder form) ;

(*d*) volume of liquid to be added for reconstitution of the drug powder ;

(*e*) the route of administration ;

(*f*) storage conditions ;

(*g*) batch or lot number ;

(*h*) manufacture and expiry dates ;

(*i*) the full name and address of the manufacturer ;

(*j*) preparations intended for use in dialysis, haemofiltration, irrigation or any other use, shall bear the statement "Not intended for intravenous injection"; and

(*k*) injection for veterinary use shall be so labeled, including the withdrawal period.

Declaration of non-nutritive sweeteners.

14.—(1) The labels of all packaging components for Over-The-Counter products containing an approved non-nutritive sweetener as an inactive ingredient, shall bear a conspicuous declaration as to the identity and quantity of the non-nutritive sweetener in milligram per dosage unit and shall also bear boldly and conspicuously, any precautionary warnings for the non-nutritive sweetener as may be prescribed by the Agency.

(2) The package inserts providing information concerning prescription drug containing an approved non-nutritive sweetener as an inactive ingredient shall bear a conspicuous declaration as to the identity and quantity of the non-nutritive sweetener in milligram per dosage unit and shall also bear boldly and conspicuously any precautionary warnings for the non-nutritive sweetener as may be prescribed by the Agency.

Warning for children.

15. The labels of all drug shall state prominently a warning statement to the following effect; "Keep this medicine out of reach of children".

Labelling of prescription DRUG.

16.—(1) In addition to compliance with the provisions in regulations 1 to 15 of these Regulations, the following shall apply—

(*a*) all prescription DRUG shall be properly labeled with the information on the package label as follows—

(*i*) the brand name, where applicable,

(4) Where the bottle, jar or other "immediate container" of the drug product has an outer wrapper or carton, such outer wrapper or carton shall bear all the information required to be specified on the label.

(5) Over-The-Counter Drugs shall not be labelled as treatment, preventive or cure for any of the diseases, disorders or abnormal states as identified in Schedule I of Food and Drug Act (Cap F32, LFN) 2004.

Drug in 5cm container.

18.—(1) Notwithstanding the provisions of these Regulations, a drug packed in a container that is 5cm or its equivalents or less, shall indicate the following—

(*a*) the brand name, where applicable ;

(*b*) the generic or common name ;

(*c*) lot or batch number ;

(*d*) net content ;

(*e*) manufacture and expiry dates ;

(*f*) manufacturer's name ; and

(*g*) registration number assigned to it in a manner prescribed by the Agency.

(2) For drug in blister packs packed in a container, each of the blister strips shall indicate the following—

(*a*) the brand name, where applicable ;

(*b*) the generic or common name ;

(*c*) the strength of the drug ;

(*d*) lot or batch number ; and

(*e*) expiry date.

(3) Any drug in a bulk package, except tablets, capsules or other dosage unit forms, intended for processing, repackaging or use in the manufacture of another drug shall be exempted from the labeling provisions of these Regulations, provided that, the label of the bulk drug contains the following information—

(*a*) the brand name (where applicable) ;

(*b*) the generic or common name ;

(*c*) net content ;

(*d*) lot or batch number ;

(*e*) manufacture and expiry dates ;

(*f*) name and location address of manufacturer, distributor or vendor ;

(*g*) storage conditions ; and

(*h*) the statement "Caution: For Bulk Drug Manufacturing Purposes Only".

Declaration of content of ingredients under composition.

19.—(1) List of all ingredients, active and inactive, shall be listed on product labeling and appear together without any intervening written, printed, or graphic matter.

(2) Full ingredient listing shall be provided on package label of Over-the -Counter drug products.

(3) Where label space cannot permit stating all ingredients, inactive ingredients may be designated with quantity sufficient ; (*qs*) on the package label and the full ingredient listing provided in the package insert.

(4) where the drug is in tablet or capsule form or other unit dosage forms, declaration of the quantity of an ingredient contained therein shall express the quantity of such ingredient in each such unit such as "Each film coated tablet contains……".

(5) Where the drug is not in a unit dosage form, any declaration of the quantity of an ingredient contained therein shall express the amount of such ingredient in a specified unit of weight or measure of the drug, or the percentage of such ingredient in such drug and such declaration shall be in terms that are informative to the end user.

(6) Statement of the percentage of an active ingredient in a drug product shall, where the—

(*a*) active ingredients and the drug product are both solids, means weight-in-weight ;

(*b*) active ingredient is a liquid and the drug product is a solid; means percentage volume in weight ;

(*c*) active ingredient is a solid and the drug product is a liquid, percentage weight in volume ; and

(*d*) both the active ingredient and the drug product are liquids, means percentage volume in volume ;

(7) Where an ingredient is a derivative or preparation of a substance and the common or generic name of such ingredient does not indicate that it is a derivative or preparation of the parent substance, the labeling shall, in conjunction with the listing of the common or generic name of such ingredient, declare that such article is a derivative or preparation of such parent substance.

(8) For sterile DRUG, a quantitative list of preservatives present in it shall be indicated where applicable by their generic or common names.

(9) Certain specific warning or precautionary statement shall be included in the product labeling due to some inactive ingredients as may be determined by the Agency.

(10) Ingredient shall not be designated with compendia standard without truly being in compliance with such standard.

Expiry dating and batch or lot numbers.

20.—(1) Expiry date of a product shall—

(*a*) be determined by an appropriate stability testing described in the product registration submission and approved by the Agency based on the determined shelf life of the product ;

(*b*) be related to the storage conditions stated on the labelling, as determined by stability studies ;

(*c*) appear on the immediate container and the outer package, if any, unless it is easily legible through such outer package ; and

(*d*) bear the shortest shelf-life component of a co-packaged product.

(2) Batch or Lot number of—

(*a*) all product label shall indicate the batch or lot number in conjunction with the expiration dating ; and

(*b*) the label of a drug product shall be capable of yielding the complete manufacturing history of the drug product.

Score line information requirement for scored tablets.

21. To the extent as may be determined as appropriate by the Agency, a drug product formulated as a scored tablet shall state in the labelling, (package insert or package label), to the effect that—

(*a*) the break-line is functional and that tablet can be divided into equal halves to satisfy certain dosage requirement as indicated under dosage information ; or

(*b*) the break-line is not functional hence its presence is for ease of swallowing and not to divide into equal halves.

Offences and penalties.

22.—(1) Any person who contravenes any of the provisions of these Regulations commits an offence and is liable on conviction, in the case of—

(*a*) an individual, to imprisonment for a term not exceeding 1 year or to a fine not exceeding ₦800,000.00 or to both ; and

(*b*) a body corporate, to a fine not exceeding ₦5,000,000.00

(2) Where an offence under these Regulations is committed by a body corporate, firm or other association of individuals every—

(*a*) director, manager, secretary or other similar officer of the body corporate;

(*b*) partner or officer of the firm ;

(*c*) trustee of the body concerned ;

(*d*) person concerned in the management of the affairs of the association ; or

(*e*) person who purports to act in a capacity referred to in paragraphs (*a*) to (*d*) of this sub-regulation,

is liable to be proceeded against and punished for the offence in the same manner as if,the person committed the offence, unless the person proves that the act or omission constituting the offence took place without his knowledge, consent or connivance.

23. A person convicted of an offence under these Regulations shall forfeit to the Federal Government— Forfeiture after conviction.

(*a*) any asset or property constituting proceeds derived from or obtained, directly or indirectly, as a result of the offence ; and

(*b*) any of the person's property or instrumentalities used in any manner to commit or to facilitate the commission of the offence.

24. The Agency is exclusively responsible for the enforcement of these Regulations. Enforcement of these Regulations.

25.—(1) The Drug Labelling Regulations 2005 is revoked. Revocation.

(2) The revocation of these Regulations specified in sub regulation (1) of this regulation shall not affect anything done or purported to be done under the revoked Regulations.

26. In these Regulations— Interpretation.

"*Active ingredient*" means any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure or any function of the body of humans. The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in the drug product in a modified form intended to furnish the specified activity or effect ;

"*Address*" means a place where the business of the manufacturer, sale, distribution, storage and display of drug and related products are carried out, which includes the house number, plot number, street name town or city, state and country ;

"*Agency*" means The National Agency for Food and Drug Administration and Control ;

"*Batch*" means a defined quantity of material manufactured in one process, a series of processes or in a given part of a continuous process so that it may be expected to be homogeneous ;

"*Common name*" means with reference to a drug, the name in English Language by which the drug is commonly known ;

"*Co-packaged drug product*" means a *product* that contains two or more separate *DRUG* in their final dosage forms that are intended to be

used together for a common or related therapeutic purpose and that are contained in a single package or unit ;

"*Drug*" includes any substances of vegetable, animal or mineral origin or any preparation or admixture thereof manufactured, sold or advertised for use in—

(*i*) the diagnosis, treatment, mitigation, in man or animal,

(*ii*) restoring, correcting or modifying organic function in man and animal,

(*iii*) disinfections or the control of vermin, insects or pest, or

(*iv*) contraception ;

"*Expiry date*" means the date given on the individual container (usually on the label) of a product up to and including the Active Pharmaceutical Ingredient (API) and Finished Pharmaceutical Product (FPP) are expected to remain within specifications, if stored correctly and it is established for each batch by adding the shelf-life to the date of manufacture ;

"*Fixed dose combination product*" means a product consisting of combination of two or more active ingredients in a single dosage form, the active ingredients usually combined in a fixed ratio ;

"*Generic name*" means the official non-proprietary name of a drug product or substance assigned by national or international bodies such as INN secretariat ;

"*Generic product*" means pharmaceutically equivalent (equivalent in dosage form, *product* in dosage, strength, route of administration, quality) or pharmaceutically alternative products that may or may not be therapeutically equivalent to the innovator product, therapeutically equivalent products are interchangeable ;

"*Identification mark*" means any single letter or combination of letters and numbers including words, company, mark, symbol, logo or monogram or a combination of letters, numbers and marks or symbols assigned by a drug firm to a specific drug product ;

"*Inactive ingredient*" means any component of a drug product other than an active ingredient ;

"*Ingredient*" means any substance in the drug, whether added to the formulation as a single substance or in admixture with other substances ;

"*Inner label*" means primary packaging material label ;

"*Label*" means any tag, brand, mark, pictorial or other descriptive matter, written, printed, stenciled, marked, embossed or impressed on, or attached to a package or container of drug ;

"*Labelling*" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article";

"*Lot or Batch number*" means the number or a combination of numbers and letters specifically given to a drug which is linked to the manufacturing history of the drug;

"*National reference product or the comparator product*" means a pharmaceutical product with which a generic product is intended to be interchangeable in clinical practice;

"*Outer label*" means secondary packaging material label;

"*Over-The-Counter drug*" means any drug other than a prescription drug;

"*Package*" includes any suitable container in which any drug is wholly or partly placed or packed;

"*Package insert*" means an accompanying written or printed paper consisting of product information inserted in product pack or container;

"*Parenteral use*" means administration of a drug by means of hypodermic syringes, needles or other instrument through or into the skin or mucous membrane;

"*Prescription drug*" means a drug which can only be made available to a patient through a written prescription signed by a duly qualified and registered medical or dental practitioner or veterinary surgeon and dispensed by a registered and licensed pharmacist and such drug shall not be made available or sold to the general public without the said prescription;

"*Primary packaging material*" means packaging material that come in direct contact with the product such as bottle, blister, aluminum foils;

"*Principal display panel*" means the part of a package or label that is most likely to be displayed, presented, shown or examined under customary conditions of display for retail sale;

"*Proceeds*" means any property derived or obtained, directly or indirectly, through the commission of the offence;

"*Proprietary or brand name*" refers to the exclusive name of a drug product owned by a company and registered under trademark law;

"*Secondary packaging material*" means packaging material in which primary packaging material is enclosed;

"*Scored tablets*" means tablet with a debossed line that runs across the planar surface of the tablet;

"*Tertiary packaging material*" means outer carton in which multiples of saleable units are packed such as shipper carton;

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"*Therapeutic agent*" means a chemical substance that is used for the treatment or mitigation of a disease condition or ailment ; and

"*Withdrawal period*" means the period between the last dose of a drug and the time when the drug or its metabolite is depleted to acceptable Maximum Residue Limit (MRL) in the edible products (meat, milk or egg) of the animal.

Citation.

27. These Regulations shall be cited as the Drug and Related Product Labelling Regulations, 2021.

MADE at Abuja this 7th day of July, 2021.

DR. OSAGIE E. EHANIRE, MD, FWACS
Honourable Minister of Health

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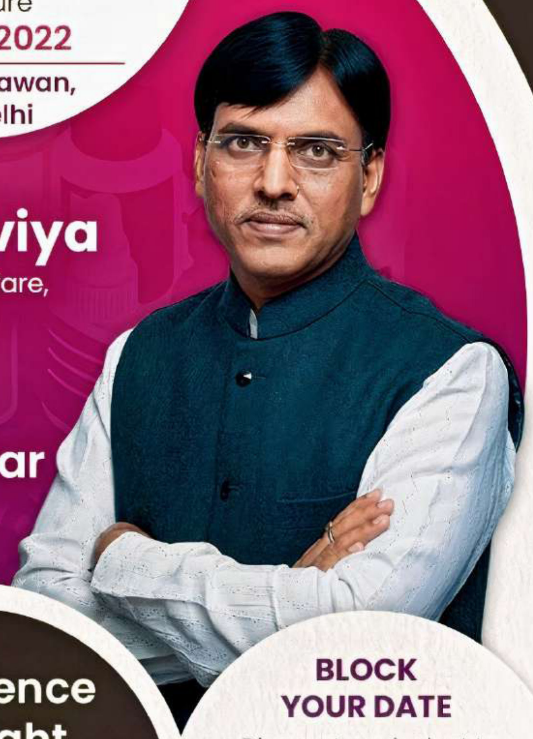

Chief Guest

Dr. Mansukh Mandaviya

Hon'ble Minister of Health & Family Welfare, and Chemical & Fertilizers, Government of India

Guest of Honour

Dr. Bharati Pravin Pawar

Hon'ble Minister of State, Health and Family Welfare, Government of India

Who should attend

- Pharmaceutical Leadership
- R&D Scientists
- QC Analysts
- Regulatory Affairs Professionals
- Analytical CROs
- Researchers & Academicians

Conference Highlight

Release of IP 2022

by

Hon'ble Health Minister

BLOCK YOUR DATE

Discount equivalent to registration fee on purchase of IP 2022 shall be available for registered participants. Registration fee cannot be transferred or clubbed to avail this discount

INDIAN PHARMACOPEIA 2022

Registration Charges

(Last Date for Registration 22nd June, 2022)

Industry	₹ 2500/-
Academia/Students	₹ 1000/-

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Tentative Schedule

9:00 AM - 10:00 AM	Registration
10:00 AM - 11:30 AM	Welcome & Inauguration of Conference and Release of IP 2022 by Hon'ble Health Minister
12:00 PM - 5:00 PM	Scientific Session on Role of IP 2022 Standards in improving Quality of Medicines Presentations by Industry Leaders & Panel Discussion

Contacts:

Phone: **8240312292, 9654507397**

Email: **lab.ipc@gov.in**

Indian Pharmacopoeia Commission

Sector 23, Raj Nagar, Ghaziabad, 201002

Website: www.ipc.gov.in.

5th Edition of the Brasil Investment Forum (BIF) 2022

PXL/HO/Cir-018/2022-23, date: 01st June 2022

We are pleased to inform our members that the Brazilian Trade and Investment Promotion agency (Apex-Brasil) is organizing the 5th Edition of the Brasil Investment Forum (BIF) 2022 during 14th and 15th of June, 2022 in VIRTUAL format. This forum is organized with the support from the Embassy of Brazil in New Delhi and the Ministry of Foreign Affairs.

We understand that BIF is the largest event of its kind in Latin America and during 2021 edition it gathered over 6,000 registrations from more than 100 countries, and 200 strategic meetings took place.

BIF is an exclusive two-day VIRTUAL event discussing business and investment opportunities in Brazil. It will be a great opportunity for members to interact with thousands of Brazilian companies, investors, executives and decision-makers from around the world gathered at a single event. Members can also get a chance to know investment opportunities in Brazil, covering dozens of industries and all 27 Brazilian states and stay up to date with the country's business environment.

For further information, members can visit BIF's website: www.brasilinvestmentforum.com.

Please note that the registration is FREE and can be done at https://bif2022.pathable.co/sign-up.

Member companies having business operations in Brazil and the ones looking forward to expanding in this region may take advantage of this and explore the opportunities in these sectors to enhance India's Pharma exports.

With regards,

Uday Bhaskar
Director General

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Appoints the 25th day of May 2022, as the day on which the provisions of section 1 of the NIPER (Amendment) Act, 2021 (43 of 2021) shall come into force

Chemicals & Fertilizers Notification S.O.2503(E), dated 24th May 2022

(Published in the Gazette of India on 1st June, 2022)

In exercise of the powers conferred by sub-section (2) of section 1 of the National Institute of Pharmaceutical Education and Research (Amendment) Act, 2021 (43 of 2021), the Central Government hereby appoints 25th day of May, 2022 as the day on which the provisions of the said Act shall come into force.

F.No.50020/2/2018-NIPER

Rajneesh Tingal,
Joint Secretary,
Ministry of Chemicals and Fertilizers,
Department of Pharmaceuticals,
New Delhi.

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Alignment of Appendix 4R with the Finance Act, 2022 with effect from 01.05.2022

DGFT S.O. 2538(E), Notification No.12/2015-2020, dated 01st June 2022

1. In exercise of the powers conferred by Section 5 of the Foreign Trade (Development and Regulation) Act, 1992 read with Para 1.02 of the Foreign Trade Policy 2015-20, the Central Government hereby notifies an Appendix 4R which is aligned with the Finance Act, 2022. This Appendix 4R shall be effective from 01.05.2022.
2. This new Appendix 4R, with effect from 01.05.2022, containing the eligible RoDTEP export items, rates and per unit value caps, wherever applicable is available at the DGFT portal www.dgft.gov.in under the link 'Regulatory Updates >RoDTEP'.

Effect of this Notification: Consequent to Finance Act, 2022, certain changes in the Customs Tariff Schedule shall take effect from 01.05.2022. Accordingly, after alignment, a new RoDTEP schedule (Appendix 4R) is being notified for implementation with effect from 01.05.2022.

File No. 01/61/180/155/AM21/PC3

Santosh Kumar Sarangi, Director General of Foreign Trade, Ex-Officio Additional Secretary, Ministry of Commerce & Industry, Department of Commerce, Directorate General of Foreign Trade, New Delhi.

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NPPA fixes the Maximum Retail Price of Oxygen Concentrators at the first point of sale (price to distributor) under para 19 of Drugs (Price control) order, 2013

NPPA Order S.O.2465(E), dated 30th May 2022

1. The National Pharmaceutical Pricing Authority, Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Government of India vide S.O.2161 (E) dated 3rd June 2021 and S.O.4909 (E) dated 30th November 2021 issued notifications under Para 19 of the DPCO, 2013 regarding capping the trade margin of Oxygen Concentrators at first point of sale (price to distributor) for fixation of Maximum Retail Price of the product. In continuation to the above notifications, capping the trade margin of Oxygen Concentrator at first point of sale (price to distributor) upto 31st May 2022 is further extended upto 30th June 2022 or till further order.
2. The Notes (b) to (n) of the Notification S.O. 2161(E) dated 3rd June 2021 shall remain in force during the currency of this order.

PN/230/98/2022/F/
F. No. 8(98)/ 2022/DP/NPPA/Div.II

Rajesh Kumar T, Deputy Director, Ministry of Chemicals and Fertilizers, Department of Pharmaceuticals, National Pharmaceutical Pricing Authority, New Delhi.

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Indian pharma industry must capitalise on MNCs' China plus one strategy, says OPPI DG

Indian pharma market set to grow from current $44 billion to $130 billion by 2030

With all multinational corporations trying to ring fence their supply chain in the aftermath of COVID-19 pandemic and opting for China plus one strategy, India should capitalise on this opportunity to become the alternative to China, a top pharmaceutical industry executive said.

"We [India] have the talent to capture the China plus one strategy of all MNCs. We need to be that plus one. India is not alone in the race. A lot of Asian countries are eyeing for it. India should be the real one in that plus one," K.G. Ananthakrishnan, director general, Organisation of Pharmaceutical Producers of India (OPPI) said while urging the Indian pharmaceutical industry to scale up in quality and digitalisation.

He said the Indian pharmaceutical market is set to grow from its current levels of $44 billion to $130 billion by 2030 growing at a CAGR of 12.3%. By 2047, when India would celebrate the 100 th Independence Day, the Indian pharma industry should grow to the size of half-a-trillion dollar, or $600 billion, he added while addressing at PharmaLytica, a three-day exhibition organised by Informa Markets in Mumbai.

"This target can be achieved by having a global outlook, looking at Asian geographies along with existing completive advantage in various industries, favorable factors of production, conducive business environment, and incentivized government policies," he said.

Emphasising the importance of quality Sudarshan Jain, Secretary General, Indian Pharmaceutical Alliance said, "India has to move up in innovation and R&D will play an important role going forward."

He said the role played by Indian pharmaceutical companies during COVID has changed the perception of the entire world.

"The world could not believe that we suppled medicines and vaccines to 200 countries continuously during the 25 months of the COVID pandemic. We increased digital capabilities during COVID-19 times and that was how we maintained the supplies, Mr. Jain said adding more emphasis should now be given to quality to garner a larger pie of the global pharma business.

He said digital transformation across the entire value chain was vital for enhanced patient care, greater transparency, cost-effectiveness, improved production and drug development.

"The next five years will witness lot of changes. Latest technologies such as artificial intelligence (AI), AR/VR, Block Chain would come into play," he added.

About 300 brands are showcasing their products and solutions at the annual three-day exhibition which is supported by the Pharmaceuticals Export Promotion Council of India, Indian Drug Manufacturers' Association (IDMA) and Cosmetics Ingredients & Packaging India (CiPi).

Rahul Deshpande, senior group director, India, Informa Markets said, "Today pharma is recognised as a well-entrenched sector for our country's economy and is anticipated to grow threefold in the decade. While it is expected to be a $65 billion industry by 2024, with weighty contributions toward generics, the pharmaceutical industry is all set to further extend its R&D capabilities and offer cutting-edge products in a post-pandemic world."

Source: Lalatendu Mishra, The Hindu, 01.06.2022

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India, Egypt to partner for pharma trade, research, regulatory cooperation

Recently, officials from the two countries met to discuss partnerships for pharmaceutical trade, regulatory cooperation, AYUSH, and pharmaceutical education and research.

India is eyeing Egypt as a gateway to North Africa for its pharmaceutical export.

Senior officials from India and Egypt have held one round of talks and are set to meet again in a conference later this month as India eyes Egypt as a gateway to North Africa for its pharmaceutical exports, and the African nation

seeks to leverage Indian businesses to strengthen its API industry and domestic drugs production.

However, they have to overcome a challenge: India is not among the countries currently approved by Egyptian authorities for good manufacturing practices.

Recently, officials from the two countries met to discuss partnerships for pharmaceutical trade, regulatory cooperation, AYUSH, and pharmaceutical education and research. India's department of pharmaceuticals has sought comments from the Central Drugs Standard Control Organization (CDSCO), National Institute of Pharmaceutical Education and Research (NIPER) and the ministry of AYUSH to take this forward.

"India is the top import partner for South Africa for formulations. Egypt is looking to become a hub for the supply of vaccines, pharmaceuticals and medical devices for the domestic market as well as for other African countries.

They are looking forward to attracting Indian pharma companies to look at Egypt as a manufacturing base catering to the African and regional markets for medicines, serum and vaccines. Egypt follows the Good Manufacturing Practice (GMP) model of registration, and India is not among the 22 reference countries accepted by the Egyptian authorities," a person familiar with the matter said.

At the first meeting of the India-Egypt Joint Working Group held in March, it was decided that India would share its best practices in terms of pharmaceutical trade, AYUSH, pharma research, regulatory cooperation, education and investment. "This entire cooperation is beneficial to India in terms of building resilience and diversifying its global supply chains," the official said.

Dr Sondos Mohamed Moshtohry, International Cooperation Officer- chairman of Egyptian Drug Authority (EDA), headed the Egyptian team while the Indian delegation was led by senior officials from the department of pharmaceuticals and its key partners.

"The respective agenda points have been taken forward by each individual. We have sought comments from our different stakeholders such as CDSCO, NIPERS and the ministry of AYUSH," said the official adding that the upcoming "Africa Health ExCon" meeting on 5-7 June will play a key role in taking in building strong bilateral ties.

During April-September 2021, India was Egypt's fifth largest trading partner. It was the largest importer of Egyptian goods and the seventh largest exporter to Egypt during the same time.

"Because we follow Atmanirbhar strategy in India, so everyone wants reliable and diversified sources. Therefore, Egypt is looking to India as a significant partner to boost its pharmaceutical industry," said the official.

Queries emailed to the spokesperson of the ministry of chemical and fertilizers and the embassy of Egypt remained unanswered till press time.

Source: Priyanka Sharma, Mint, 02.06.2022

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Indian Drug Manufacturers' Association
102, A Wing, Poonam Chamber, Dr.A.B.Road, Worli, Mumbai - 400018. Maharashtra. India.
Tel No. 022 24974308 / 24944624, Mob No. 9619802299, E-mail : admin@idmaindia.com

Invitation to participate in ChemTECH + Biopharma World Expo from June 8-11, 2022 at Jio World Centre, Bandra BKC, Mumbai

Dear Members,

We are pleased to inform you that IDMA is the supporting partner for the **30th onground Edition of ChemTECH + BioPharma World Expo which is taking place from June 8-11, 2022 at Jio World Centre, Bandra BKC, Mumbai.**

ChemTECH + BioPharma World Expo 2022 is witnessing Exhibit display by over 275 Exhibitors along with 15,000+ Business Visitors and 5 concurrent conferences on EPC, Specialty Chemicals, Refining & Petrochemicals, Industry Automation & Process Control, Surface Engineering & Corrosion Control.

This Exhibition is providing an excellent opportunity to all the companies to upgrade their plant post Covid-19 pandemic as the event is providing the biggest congregation of technological and product display along with the industry leaders across the entire value chain of process industry.

Please find the concurrent conferences and industry leaders who are part of the event

EPC 8th & 9th June , 2022	Chairman CAB : **Mr. B Narayan,** Group President Projects & Procurement, Reliance Industries Ltd Co- Chairman CAB : **Mr. Subramanian Sarma,** Whole time Director, Sr. EVP (Energy), Larsen & Toubro	**Learnings from the Pandemic: Adopting to the New Normal**
Specialty Chemicals 8th June, 2022	Convener: **Dr Raman Ramachandran,** MDP Chairperson & Professor of Practice, K J Somaiya Institute of Management	**Green Growth of Specialty Chemicals Industry** **Roadmap to Net Zero**
Refining & Petrochemicals 9th June, 2022	Chairman CAB : **Dr SSV Ramakumar,** Director (R&D) & Member of Board, Indian Oil	**Future Refining Towards Net Zero**
Industry Automation & Control 10th June, 2022	Chairman CAB : **Mr U K Bhattacharya,** Director Projects, NTPC Ltd - Chairman, IAC + PVF World Expo 2022	**Industry 5.0: Envisioning New Paradigms in Automation**
Surface Engineering & Corrosion Control 10th June, 2022	Chairman CAB : **Mr R K Srivastava,** Director Exploration, ONGC Ltd Convener : **Mr K L Batra,** Advisor Chugoku Paints	**Corrosion Prevention Technology & Innovation**

Kindly note that there are no visitor registration Fees. Please find the **Link for FREE Business Visitor Registration- https://chemtech-online.com/pre-register-as-visitor/**

Looking forward to your usual excellent support and requesting you all to kindly attend the Exhibition and take benefits from the same.

Thanks & regards,

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