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IDMA BULLETIN

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INDIAN PHARMA - GLOBAL HEALTH CARE

INDIAN DRUG MANUFACTURERS' ASSOCIATION

HIGHLIGHTS

- ★ **Report on Schemes for Strengthening of Pharmaceutical Industries (SPI)** *(Page No. 24)*
- ★ **Report on Pharmac South- 7th Edition - held on 8th & 9th July 2022 at Chennai trade centre, Tamil Nadu** *(Page No. 26)*
- ★ **Govt launches 3 schemes to strengthen MSMEs in pharmaceutical sector** *(Page No. 56)*

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Signet

The Complete Excipients Company

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IDMA BULLETIN

Vol. No. 53 **Issue No. 28** **22 to 30 July 2022**

IDMA ACTIVITIES:

GOVERNMENT COMMUNICATIONS:

PARLIAMENT NEWS:

PRESS RELEASE:

NATIONAL NEWS:

Dear Member,

APPQM - EXECUTIVE PROGRAM IN PHARMACEUTICAL QUALITY MANAGEMENT

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

APPQM+ Series 3 Commences September 2022

Why APPQM in INDIA?

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

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

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

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

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

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

APPQM+ Series 3

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

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

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

Additional Benefits:

This virtual education program offers the following additional benefits.

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

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

Registration Fee for APPQM+ Series 3

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

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

Registration Procedure :

Please fill the Registration Form and send it to

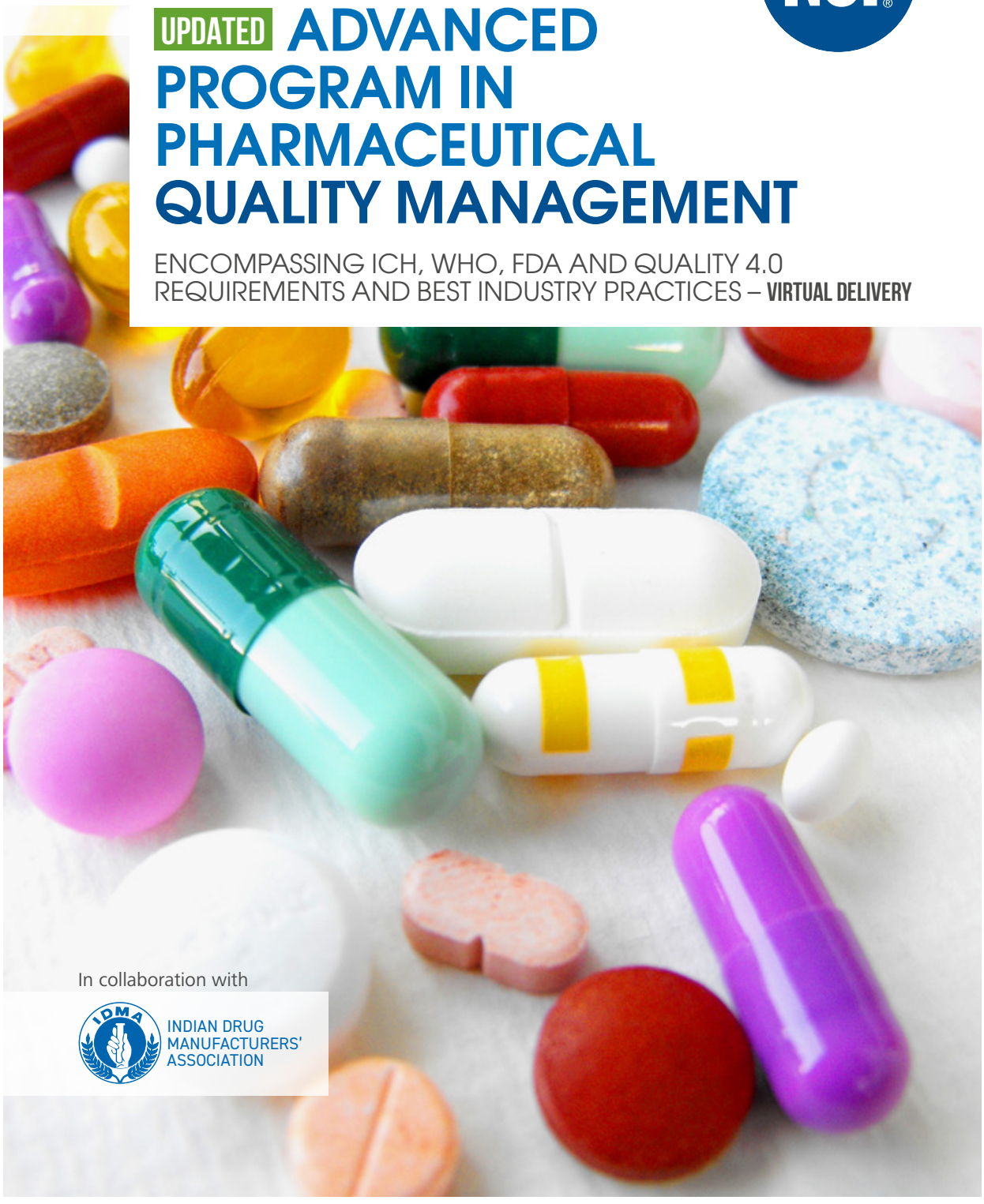
Melvin	**Batul**
actadm@idmaindia.com	technical@idmaindia.com
9821868758	9920045226

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

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

Sincerely Yours,

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


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

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

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

CHALLENGES FACING THE PHARMACEUTICAL INDUSTRY

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

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

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

HOW THIS TRAINING CAN HELP

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

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

WHY CHOOSE NSF?

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

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

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

BENEFITS OF THIS TRAINING

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

For example by:

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

Attendees will also:

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

COURSE FORMAT

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

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

▶▶

COURSE MODULES

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

MODULE ONE: Pharmaceutical Quality Management Systems – Best Industry Practices

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

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

MODULE TWO: Managing Change; Change Control and Deviations

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

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

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

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

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

▶▶

MODULE FOUR: Data Analysis for Business Improvement

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

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

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

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

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

NEXT STEPS YOUR CALL TO ACTION

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

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

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

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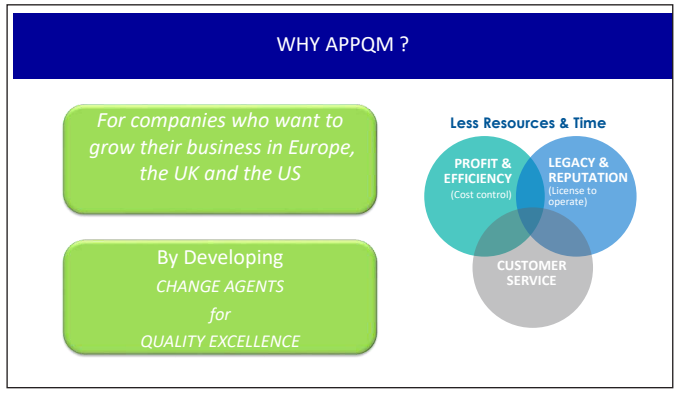
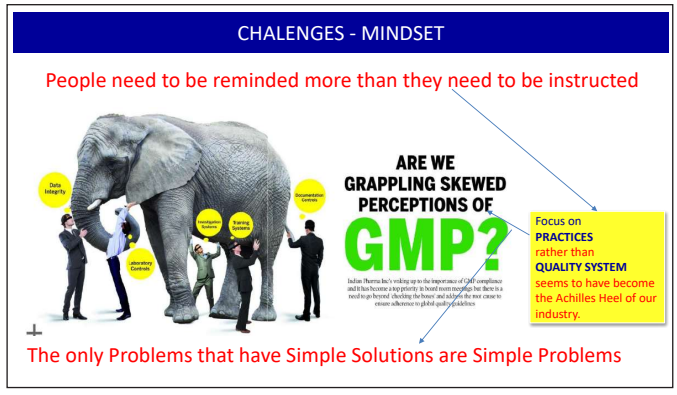
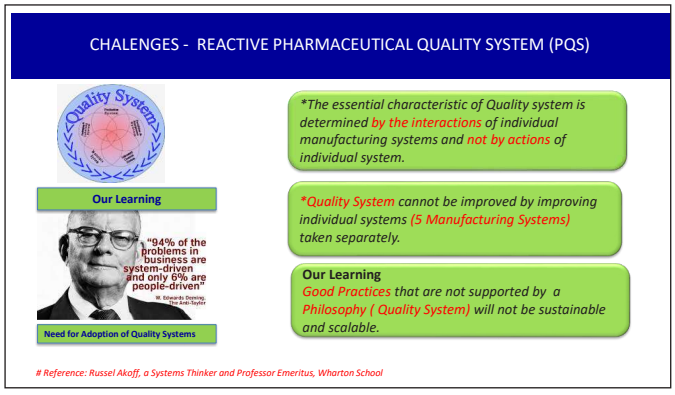
PRESENTATION

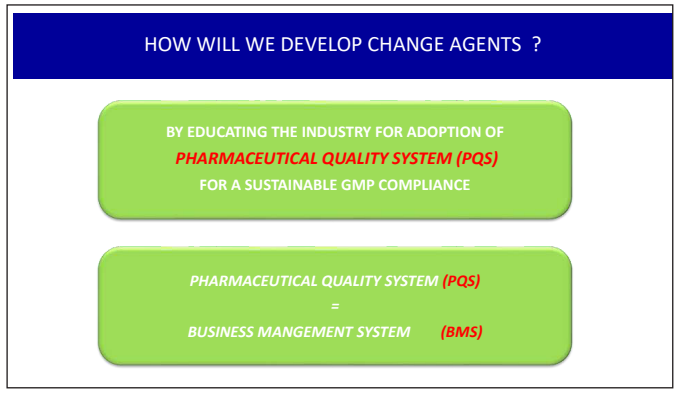
Launch of APPQM Series 3

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









APPQM IS DESIGNED FOR INDIAN COMPANIES

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

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

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

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

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

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

HOW APPQM IS DIFFERENT FROM OTHER TRAINING PROGRAMS ?

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

APPQM- Program Modules

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

APPQM SERIES 1 & 2 DELEGATES SURVEY FEEDBACK

APPQM SERIES 1 & 2 DELEGATES SURVEY FEEDBACK

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

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

Transformative and Life Changing.

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

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

Educating Oneself while Educating Others

Has helped transform our quality culture.

Best business investment we've ever made.

Worth every penny and more.

APPQM SERIES 2 VALEDICTORY – APPRECIATION FROM DIGNITARIES

APPQM will help build the quality culture in Indian Pharma Industry

Dr V G Somani, DCGI

APPQM will help develop future quality leaders

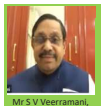
Dr. B Suresh, Pro-Chancellor, JSS University

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

Dr. Viranchi Shah- National President -IDMA

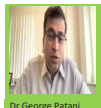
Inclusion of Digitization topics will enhance the next series of APPQM

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



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

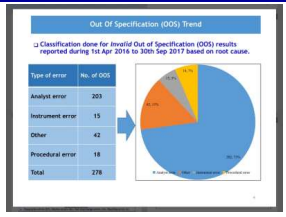
Mr S V Veerramani, MD, Fourrts India



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

Dr George Patani ,VP (Western Region), IDMA

Benefits of APPQM –ROI



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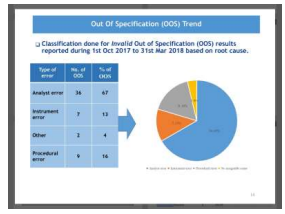
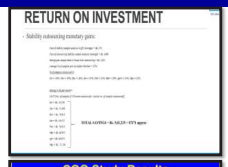
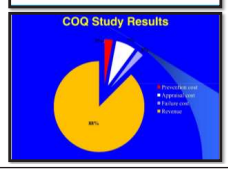


AFTER

TOTAL SAVING OF Rs. 5 Cr.

Benefits of APPQM -ROI





Acknowledgments

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

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

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

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

Dhara 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 regarding Manufacturers to affix Bar Code or Quick Response Code on the packaging label to store data or information legible with software application to facilitate authentication

IDMA have submitted the following representation on 13th July 2022 to the Under Secretary (Drugs), Ministry of Health & Family Welfare, Government of India, New Delhi on the above subject:

Ref: MoHFW notification GSR 448 (E) dated 14th June 2022

We are in receipt of the above draft rules amendment of Drugs Rules, 1945, Rule 96 Sub Rule 5 (A) mandating Barcode or Quick Response (QR) code on the packaging label of the Top 300 brands of drugs with effect from 1st May 2023.

As per the proposed sub-rule 5A, manufacturers of the formulations specified in schedule H2 of the rule, shall print or affix Barcode or QR code on its primary packaging label or, in the case of inadequate space in primary package label, on the secondary package label that store data or information legible with software application to facilitate authentication.

The store data or information shall include the particulars, namely-

(i) Unique product identification code,

(ii) Proper and generic name of the drug,

(iii) Brand name,

(iv) Name and address of the manufacturer,

(v) Batch number,

(vi) Date of manufacturing,

(vii) Date of expiry,

(viii) Manufacturing licence number.

It is further conveyed that, objections and suggestions will be considered by the Central government, within 30 days from the date of the gazette notification.

Background:

In 2018 the then DCGI had formed a working group by inviting a member from every association including IDMA to finalise the modalities for the implementation of authentication measures on the Top 300 medicines. One meeting of the working group was held in Delhi on 20.07.2018 and minutes of the meeting are attached herewith (Annexure I). During the meeting, many pharmaceutical associations had expressed their inability to incorporate this sophisticated technology in their manufacturing processes due to numerous reasons while some of the pharmaceutical companies that had introduced bar coding systems in some of their brands, shared that the response was limited. We request that a working group be formed of members from industry associations that have brands among the Top 300 so that they can give practical inputs and ensure smooth implementation.

In this context we would like to submit our objections and suggestions as under:

1) The draft regulation requires printing or affixing of bar code or QR code on primary packaging label or, in case of inadequate space in primary package label, on the secondary package label. Technically QR code is a machine readable label, used to store data. It is not a tool for anti-counterfeiting application. Anybody can generate and print a QR code.

   Additionally, if QR / BAR codes are printed on the secondary packaging like saleable cartons, and the cartons are not destroyed at the trade/retail level, it can lead to counterfeiting without the knowledge of the manufacturer / marketer.

2) Excluding the unique product identification code, all other information (07 out of 08 as per the aforesaid notification) are already available on the label of the medicinal products as per the requirements of Rule 96. Typically, unique product identification code is GTIN (Global Trade Item Number) taken from

GS1. Hence this QR code cannot be claimed as a mechanism to facilitate authentication.

3) For true authentication, a patient scans a **QR code** embedded in the label of the medicine, via a smart phone. The patient is then directed to a site where the patient enters their mobile number and gets an OTP (One time password). Once the patient enters the OTP they receive a text message authenticating the requisite product information. Once that particular QR code is utilised by the patient, it is not available for further authentication. In this way the patient gets an authentication for the medicine and the company gets a record of the complainant, which does not happen with a basic QR code.

4) Countries like Russia, UK, Germany, Denmark, Sweden, Poland, US have maintained repositories. The data of the codes or **Unique identification numbers** (UIN) in a batch are sent to the importer who loads the codes in the **repository** maintained by the government of that country. These governments have softwares to identify if there is any duplication of the UIN. Such a system is essential if authentication measures are to be truly effective. Hence we suggest a **Central Portal** should be made by the government where manufacturers can upload the printed codes batch wise so that if there are issues with counterfeits the manufacturers can be absolved of the necessity to confirm that the counterfeit drug is not manufactured by them.

5) The substrate (surface or material) where the QR code is printed in primary packaging, poses a challenge. In case of aluminium strips / blister strips the readability of the QR code is difficult and grading is not possible due to reflection and a knurled surface. This is the limitation for implementation in aluminium strips / blisters.

6) Our member companies who have implemented authentication measures like serialization said that the response is very low. We suggest **awareness programmes** should be initiated by the government so that the authentication measures are known and utilised.

7) There have been multiple recent amendments to Rule 96/97 of the Drugs & Cosmetics Act 1945, due to which the printing space on the label of smaller packs like injections, blisters, eye drops, oral drops has shrunk considerably and fitting the authentication measures is a challenge. The above gazette does specify that in case of inadequate space in primary package label, the secondary package label can facilitate authentication. However, the fact remains that continuous changes in the label requirements can cause confusion among companies, doctors, trade, as well as patients and our suggestion is that once these authentication measures are implemented, further label changes should be frozen for the next 5 years.

8) In many government hospitals / medical colleges it is **mandatory to prescribe generic medicines and not brands.** If this policy is further extended to other states, incurring expenditure on authentication may not be feasible.

9) The Top 300 Brands list is dynamic and existing brands may slip out of the list or new products may be added every month, so a **periodic annual revision, effective every 1st April** is suggested.

10) In the last 3 years there has been an unprecedented increase in the prices of inputs under all cost heads like APIs, packing materials, intermediates, excipients, starting materials, solvents and transportation. The industry is allowed to increase prices annually, by upto 10% for non scheduled formulations and as per the WPI for scheduled formulations, but the input costs have risen exponentially.

11) Each authentication measure would entail additional costs like an annual **software licence fee, recurring SMS charges, serialisation charges per individual unit, and multiple sophisticated printers and cameras** for every manufacturing line. Each brand among the Top 300 brands has huge volumes and is manufactured on **multiple lines** and at **multiple locations.**

12) For the Top 300 brands, the manufacturers use combi- packs, that is multiple strips / blisters in one carton. It will be difficult to have codes printed on such packs and this will further hamper the aggregation process. In case each blister has to be put in a **mono carton**, to accommodate the QR codes, then there is a **loss of productivity** in manufacturing and excessive cost of the mono carton as well as the QR code infrastructure are incurred.

13) For each code created, the change in artwork and packing materials, and **changed parts** and **tools** {wherever applicable) there would be an additional cost for which there is no estimate as of now.

14) A huge cost will also be incurred for **small manufacturers** to get the entire system (hardware and software) running along with validation costs.

15) Also, with additional infrastructure and processes the **production output** will be affected for the initial few months as part of the learning curve.

16) From the above it is obvious that the authentication measures would entail a significant additional cost and we suggest a proportionate price increase should be allowed by the NPPA for all scheduled and non scheduled formulations in the list of Top 300 brands where the authentication measures would be implemented.

In light of the above representation we request that the notification be put on hold till the various apprehensions raised above, are taken care of.

Thanking you.

Yours sincerely,
For Indian Drug Manufacturers' Association,

Dr Viranchi Shah
National President

Minutes of the Meeting on the introduction of authentication for the Top Pharmaceutical brands in the country
held at 15:00 hrs at FDA Bhawan, New Delhi
under the Chairmanship of Dr. S. Eswara Reddy, DCGI

1) List of participants annexed.

2) DCGI welcomed the representatives of the Pharmaceutical industry associations, manufacturer/marketers of the top 300 pharmaceutical brands and the senior officials of the CDSCO to the meeting. At the outset, he requested the participants to freely express their views on the introduction of authentication of pharmaceutical brands and assured that their concerns would be addressed. Thereafter, DCGI made a short presentation on the agenda of the meeting.

In his presentation, DCGI explained the public concerns on the quality of medicines marketed in the country and the lack of technology based mechanism to authenticate the drugs available in the market. He further stated that high value/volume brands are prone for introduction of spurious products. He also brought the attention of the participants to the draft notification issued by Ministry of Health & Family Welfare for track and trace dated 03/06/2015 and stated that the notification wasn't implemented due to concerns raised by the industry.

Therefore, a system for authenticating the identified products is required. Unlike the earlier trace and track system, it is now proposed to authenticate the primary packing only. This will remove the concerns raised by the industry and make the system easy to operate. He pointed out that some firms are already implementing the authentication systems and requested that they should share their best practices and issues with others for successful implementation. He stressed that any system adopted should be easily accessible to the layman. He also stated that an expert committee under the Chairmanship of the Commissioner, FDCA, Gujarat, has also recommended authentication as a solution. Based on risk classification, the top 300 brands have been shortlisted from that data obtained from Pharmatrack managed by AIOCD AWACS.

He requested the participants to offer their views and comments on the technology solutions to be adopted, feasibility of having a common server, service provider and short SMS code. He stressed upon the need to establish a communication channel with the Central and State regulators on authentication failures.

3) The views/comments of the industry representatives are given below:

- 2-D barcode used for export formulation has caused a lot of hardships due to parent child linkage and therefore simple authentication is acceptable.
- MSME cannot afford additional cost as they are operating on thin margins and was also requested that subsidy should be provided to MSME for the additional cost borne by the manufacturers

- Any authentication failures should be thoroughly investigated and brought to a logical end.
- Maintaining secrecy of information and replication of the serial numbers are the challenging issues
- Ideally, a central portal and robust system to maintain the secrecy should be developed.
- The concept is acceptable in principle subject to addressing the IT concerns, cost effectiveness and operability.
- A working group should be formed to recommend the details.
- The authentication system if extended to all the brands will not be economically feasible and request hand holding for MSME.
- Several companies who have introduced authentication system voluntarily shared their experiences and stated that the number of people using their system for authentication is very low. There are systemic inherent deficiencies in serialization solutions.
- Whatever system finalized should be affordable.
- Some of the firms have stated that parenteral formulation such as vials, ampoules have very less space on the label and therefore a study should be conducted on the feasibility of printing the serialised number for authentication and the mono carton should be treated as the primary pack, wherever applicable.
- Technical issues while printing on sachet, combi pack, blister pack etc. need to be addressed.
- The definition of the brand may be clarified.
- It was suggested to examine the feasibility of introducing QR Code, Data matrix code etc instead of the proposed serialization number to overcome the safety concerns.
- The representatives of contract manufacturers have expressed that the introduction of the serialization would increase their cost and make their business unviable.

- The majority of the participants have requested to specify the transit time for switching on to the new system and provide an SOP for addressing the issue of multiple hits in case the serialization system is adopted.

4) DCGI summarized the proceedings as below:
   - Thanked the participants for the wonderful response to the meeting notice and for accepting the proposal voluntarily.
   - The major objectives are to create fear in the minds of the counterfeiters and build up image of the Indian pharma industry.
   - Introduction of authentication system will actually increase the workload of regulators.
   - The concerns on the space, dosage form etc. will be addressed.
   - MoHFW/CDSCO will have to undertake consumer education on the authentication process
   - A working group will be constituted with representatives of the associations and CDSCO. The member associations in the pharmaceutical forum were requested to nominate one person each and also can bring an IT expert along with them. The committee should submit the report within 3-4 months from the date of its constitution.
   - The Terms of reference are to identify the weakness in the proposed model of authentication and suggest suitable solutions.
   - The technology proposed to be used for authentication, technology provider, service provider has to be decided by the pharmaceutical forum and CDSCO has no role in this regard.

   The meeting ended with the vote of thanks to the chair.

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IDMA representation to NPPA regarding Stakeholder Consultations on Trade Margin Rationalization (TMR) held on 20th May 2022

IDMA have submitted the following representation on 28th May, 2022 to Shri KK Pant, IAS, Chairman, National Pharmaceutical Pricing Authority on the above subject:

Greetings from Indian Drug Manufacturers' Association.

We thank you for inviting IDMA and giving us the opportunity to share our views on the above subject.

While the Indian pharmaceutical industry grew in higher double digits in the past year, inflationary pressures across all cost heads have severely eroded the margins of manufacturers. Hence abundant precaution is required while formulating guidelines on Trade Margin Rationalization to avoid any disruption in the marketplace, that can adversely impact the availability and affordability of medicines.

Below are our views based on the agenda outlined during the PowerPoint presentation at the stakeholder consultation :

1. Approach and Implementation

a) With over 50,000 stockists and 800,000 retailers the complexities are huge.

b) Hence TMR should be implemented in a phased manner so as not to cause any disruption in the market.

c) The date for the commencement of TMR should be conveyed at least 3 months in advance.

d) A proper amendment should be made in the DPCO 2013 to include TMR.

2. Percentage of Trade Margin

a) The current margin structure has been in force for many decades now and has led to smooth business relations between the trade and the industry.

b) TMR should be excluding GST.

3. Methodology

a) TMR should be applied only to non-scheduled formulations and should exclude drugs under Para 19 of DPCO 2013.

b) TMR should be applied prospectively and not retrospectively.

c) TMR should not be applicable to stocks existing in the market prior to the implementation of TMR.

d) Prices of products under TMR should be increased in accordance with para 20 of DPCO 2013.

e) For easy implementation TMR should not be applicable to formulations with prices below Rs 100.

f) TMR should exclude formulations for government institutional business.

g) The interests of MSMEs involved in indirect marketing should be protected through appropriate mechanisms. In certain MSMEs, there is a model where marketing expenses are taken care of by promoting companies. We request that the survival of such small companies may please be protected through a suitable mechanism.

h) Price to the distributor is a new concept and needs clarity. Traditionally in the ethical pharma business, the billing from the company is to the stockist and hence PTS (Price to Stockist) should be considered as the first point of sale.

4. Post TMR implementation

a) A mechanism to monitor TMR should be announced by the NPPA to ensure clarity, transparency, and smooth migration.

b) All price changes are updated in the IPDMS under Form V non-scheduled formulations from time to time, so there should be no separate submission of TMR data.

Looking forward to your favourable consideration.

Thanking you with kindest regards,

For Indian Drug Manufacturers' Association

National President
Dr. Viranchi Shah

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IDMA representation to CBDT for seeking clarification in respect of Section 194R of the Income Tax Act, 1961 ('the Act') - reg.

IDMA have submitted the following representation on 12th July 2022 to the Chairman, Central Board of Direct Taxes, Ministry of Finance, Government of India, New Delhi on the above subject:

Greetings from Indian Drug Manufacturers' Association (IDMA).

With reference to the above mentioned subject, Indian Drug Manufacturers' Association (IDMA) representing the leading pharmaceutical companies, hereby submits a Representation for the following issues for your kind consideration and favourable action/response in respect of the newly introduced Section 194R of the Act.

We request that No TDS should be charged on the following :-

1. Free medicine samples provided by pharmaceutical companies to healthcare professionals / hospitals / doctors;
2. Brand reminders provided with the Company's logo to various doctors / medical practitioners/hospitals / stockists / vendors / distributors/ retailers, etc.

The detailed representation in respect of the above two issues is attached.

We request you to kindly peruse through our detailed representation and we look forward to your kind favourable consideration of the same at the earliest.

We would be pleased to meet you in person and explain the points in detail. Also, please feel free to contact us if you require any further details/clarifications.

Thanking you.

Yours sincerely,

For Indian Drug Manufacturers' Association,

Dr Viranchi Shah
National President

Encl.: (1) IDMA Representation
(2) Appendix 1
(3) Appendix 2
(4) Appendix 3
(5) Appendix 4

IDMA Representation Section 194R introduced by the Finance Act 2022 –Recommendations from the Indian Drug Manufacturers' Association

Introduction

The Indian Drug Manufacturers' Association ('IDMA'), established in 1961, is the industry association of leading pharmaceutical companies based out of India which has over 1000 plus members. IDMA works with the Government of India on the industry's development plans, represents the industry on prominent issues such as pricing, regulatory affairs, and other policy matters. It also plays a crucial role in keeping business leaders, media, and the public informed about the industry.

Section 194R of the Income-tax Act, 1961 ('the Act'), effective from 1 July 2022, provides for tax deduction at the rate of ten percent of the value or aggregate of value of any benefit or perquisite, whether convertible into money or not, provided to a resident arising from carrying out of a business or exercising of a profession by such resident. The Central Board of Direct Taxes ('CBDT') has issued guidelines vide CBDT Circular no 12 of 2022 dated 16 June 2022 for removal of difficulties under Section 194R of the Act.

From a taxpayer's perspective, there are several measures which can significantly help remove uncertainty and practical challenges faced by the pharmaceutical industry with respect to the newly introduced provisions of Section 194R read with the CBDT Circular. This brief document summarizes some of our key suggestions and industry views that may be considered. We will be happy to share our thoughts in greater detail on any specific points that you may require. We also request for a personal hearing in the matter to explain the issues for the pharmaceutical industry at large.

I. Free samples are benefit or perquisite and therefore subject to TDS under Section 194R [CBDT Circular Question no 4]
Recommendation: Free medicine samples provided by pharmaceutical companies to healthcare professionals / hospitals / doctors should be outside the purview of Section 194R of the Act
Challenges and rationale for recommendation:
1. Free medicine samples are not in the nature of any benefit or perquisite to the doctors: • Extract of the Explanatory Memorandum to Finance Bill 2022: "As per clause (iv) of section 28 of the Act, the value of any benefit or perquisite, whether convertible into money or not, arising from business or exercise of profession is to be charged as business income in the hands of the recipient of such benefit or perquisite. However, in many cases, such recipient does not report the receipt of benefits in their return of income, leading to furnishing of incorrect particulars of income" • Accordingly, the object of the new TDS provision is to capture those benefits which are admittedly benefits for the recipient causing enrichment and taxable under Section 28(iv) of the Act but were escaping the tax net. • Free medical samples provided to hospitals / doctors are not 'benefits' or 'perquisites' in the hands of doctors. Such free medical samples are statutorily required to be used by the doctors for clinical evaluation purposes/ testing the efficacy of the drugs by giving them to patients free of cost and cannot be sold or monetized by them. Accordingly, such free medical samples are not consumed by the doctors for any personal benefit neither they can earn any income by selling such samples to the patients. Such free medical samples are passed on the patients free of cost and the benefit if at all any is accruing to the patients which cannot be subjected to TDS under Section 194R as such benefit is not arising to the patients from any business or profession. • It is a known fact that the free sample of medicines supplied to doctors is done for promotion of the product of the pharmaceutical company. When a new product is launched, the doctors through the free sample provided, test the efficacy of the new drug launched in the market, give necessary inputs regarding the use and effectiveness etc. of the product • Provision of free samples help impart knowledge to other doctors about the new medicine / product coming into the relevant for practice of their profession. Therefore, distribution of free samples are directly related to business promotion activity of the pharmaceutical company and no benefit / perquisite arises to the doctors from such samples. • Providing samples of pharmaceutical products is not prohibited under either the Indian Medical Council (Professional Conduct, Etiquette and Ethics), Regulations 2002 ("MCI Code") or the Uniform Code of Pharmaceutical Marketing Practices by the Department of Pharmaceuticals, 2014 ("UCPMP") or 2019 Organization of Pharmaceutical Producers of India ("OPPI") Code of Practice. The UCPMP prescribes guidelines under which medical samples should be dispensed which ensure that they are used strictly for clinical evaluation purposes and each sample shall be marked "free medical sample – not for sale". • Even the draft Uniform Code for Medical Device Marketing Practices ("UCMDMP") published for stakeholder consultation on 16 March 2022 lays down guidelines to ensure that medical devices are distributed as samples for evaluation purposes only. • The Drugs and Cosmetics Rules, 1945 also recognizes the practice of providing drugs for distribution to medical professionals as a free sample by providing specific labelling requirements, requiring such sample to be labelled with the words 'Physician's Sample – Not to be sold' • Considering the above referred strict conditions under which product samples are distributed to doctors, distribution of such free samples cannot be regarded as benefit or perquisite for the doctors. We once again reiterate that the doctors are required to administer them / pass on the benefit to the patients free of cost and cannot be monetized in any manner whatsoever. Such free samples are not meant for personal consumption of the doctors such as other gift items like car, jewellery, travel, accommodation etc.

2. Practical challenges for implementation:

- The receipt of free medicine samples is not treated as income taxable under Section 28(iv) of the Act for the doctors as the said samples are not consumed by them and passed on to the patients or discarded in other cases. Accordingly, the doctors may refuse to provide their PAN number to the pharmaceutical companies or even receive any such free samples from the companies.
- If the doctors refuse to receive free medical samples from the pharmaceutical companies, it will be extremely challenging for any company to introduce new drugs into the market or test its efficacy or even increase knowledge about their products in the market. Such measures in turn will impact the patients and humanity at large and therefore should be addressed at the earliest.
- Alternatively, if the TDS is grossed up by the pharmaceutical company, then it will significantly increase the additional cost burden on the industry which may in turn lead to increase in the price of the medicines and therefore again have an impact on the patients and humanity at large.
- In view of all the above, we resubmit that applicability of TDS under Section 194R will cause immense practical difficulties for both the pharmaceutical companies and the doctors and accordingly suitable clarification be issued at the earliest for excluding free medicine samples from the TDS ambit.

3. Recommendation:

- Free medicine samples provided by pharmaceutical companies to healthcare professionals / hospitals / doctors should be outside the purview of Section 194R of the Act as the same does not benefit doctors/ medical practitioners.
- In case a blanket exclusion of free medical samples from the purview of Section 194R, is not possible then it is recommended that CBDT may mandate pharmaceutical companies and Healthcare professionals to follow guidelines laid down by OPPI, UCPMP and UCMDMP in respect of free medical samples which obligate dispensation of medical samples in a way which ensures that they are used strictly for clinical evaluation purposes and each sample shall be marked “free medical sample” and not for sale etc. The extract of the guidelines has been enclosed as Appendix 1-4.

III Brand Reminders

Recommendation: Brand reminders such as items provided with the Company’s logo etc. should be outside the ambit of TDS under Section 194R as they are provided for the benefit of the provider of items itself.

Challenges and rationale for recommendation:

- Various pharmaceutical companies provide small value items such as pens, calendars, notepads, files, etc. to various doctors / hospitals / stockists / vendors / distributors/ retailers, etc. which contain the logo of such companies. Such brand reminders are provided to maintain brand memory on a continuous basis
- In such cases, the item / incentive predominantly benefits the provider as it increases its visibility and promotes its brand and the benefit arising to the recipient, if any, is purely tangential and negligible. Further these brand reminders are small value items for daily use with minimum life cycle and having practically no independent utility for the recipient. These are provided by various pharmaceutical companies as per industry practice.
- Such promotional expenditure is incurred only to aid promotion of provider’s products and create market awareness about the medicines or drugs of the pharmaceutical company and not intended to provide any benefit to the recipient of such items.
- Again, the receipt of such brand reminder items is not taxable as income under Section 28(iv) of the Act for the recipient in absence of any benefit or perquisite arising to him. Accordingly, the recipient may refuse to provide their PAN number to the pharmaceutical companies or even receive any such free items from the companies.
- If the parties refuse to receive free brand reminders from the pharmaceutical companies, it will be extremely challenging for any company to create market awareness, promote its medicines or drugs or even increase knowledge about their products in the market. Such measures in turn will impact the patients and humanity at large and therefore should be addressed at the earliest.

- Alternatively, if the TDS is grossed up by the pharmaceutical company, then it will significantly increase the additional cost burden on the industry which may in turn lead to increase in the price of the medicines and therefore again have an impact on the patients and humanity at large.
- In view of all the above, we resubmit that brand reminders by pharmaceutical companies which are nominal in value and has a limited usage/ validity are not benefit or perquisite for the recipient and accordingly should also not be subjected to Section 194R of the Act.

Recommendation

- Brand reminders such as items provided with the Company's logo etc. should be outside the ambit of TDS under Section 194R as they are provided for the benefit of the provider/ Sponsors.
- The brand reminders have nominal value, limited utility and the benefit arising to the recipient, if any, is purely tangential and negligible. Accordingly, it is recommended that CBDT prescribes certain threshold that brand reminders accepted within the stipulated threshold should not be subjected to withholding under Section 194R. Even, MCI guidelines prescribes threshold for accepting brand reminders to physicians.
- Further, CBDT may also consider laying down conditions as prescribed under Explanation 3 to Section 37(1)to trigger applicability under Section 194R which are incurred in violation of any Rule or law

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APPENDIX 1

Extract from OPPI guidelines on Samples

8. SAMPLES:

8.1 Samples Permitted:

In accordance with local laws, regulations, Guidelines and Code, free samples of a pharmaceutical product may be supplied to healthcare professionals directly or to persons duly authorised by them to or to receive such samples on their behalf in order to enhance patient care. Samples should not be resold or otherwise misused.

8.2 Control and Accountability:

Companies should have adequate systems of control and accountability for samples provided to healthcare professionals including how to look after such samples whilst they are in possession of medical representatives.

APPENDIX 2

Extract from Uniform Code of Pharmaceuticals Marketing Practices (UCPMP) on distribution of free samples

5. Samples

5.1. Free samples of drugs shall not be supplied to any person who is not qualified to prescribe such product.

5.2. Where samples of products are distributed by a medical representative, the sample must be handed directly to a person qualified to prescribe such product or to a person authorized to receive the sample on their behalf.

5.3. The following conditions shall be observed in the provision of samples to a person qualified to prescribe such product:

i. Such samples are provided on an exceptional basis only (see (ii) to (vii) below) and for the purpose of acquiring experience in dealing with such a product;

ii. *Such sample packs shall be limited to prescribed dosages for three patients for required course of treatment;*

iii. *Any supply of such samples must be in response to a signed and dated request from the recipient;*

iv. *An adequate system of control and accountability must be maintained in respect of the supply of such samples;*

v. *Each sample pack shall not be larger than the smallest pack present in the market;*

vi. *Each sample shall be marked "free medical sample - not for sale" or bear another legend of analogous meaning;*

vii. *Each sample shall be accompanied by a copy of the most up-to-date version of the Product Information (As required in Drug and Cosmetic Act, 1940) relating to that product.*

5.4. A pharmaceutical company shall not supply a sample of a drug which is an anti-depressant, hypnotic, sedative or tranquillizer.

5.5. The companies will maintain details, such as product name, doctor name Quantity of samples given, Date of supply of free samples distributed to Healthcare practitioners etc.

APPENDIX 3

Extract from Draft Uniform Code of Pharmaceuticals Marketing Practices (UCPMP) dated 16 March 2022 on distribution of free samples

5. Evaluation Samples

5.1. Free evaluation samples of Medical Devices shall not be supplied to any person other than HCPs or as per hospital protocol to reach the HCPs.

5.2. Where evaluation samples of products are distributed by a medical representative, the sample must be handed directly to a person qualified to use & prescribe such product or to a person authorized to receive the sample on their behalf.

5.3. The following conditions shall be observed in the provision of evaluation samples to a person qualified to prescribe such product:

i. *Such samples are provided for the purpose of acquiring experience in using such a product, hands on experience and evaluation.*

ii. *An adequate system of control and accountability must be maintained in respect of the supply of such samples by all Companies including maintaining proper documentation and rationale.;*

iii. *Each sample shall be accompanied by a copy of the most up-to-date version of the Product IFU/DFU/ e-IFU (link to the website/digital IFU), wherever applicable, relating to that product.*

iv. *The number of evaluation samples (single use products) provided at no charge should not exceed the quantity reasonably necessary for the adequate evaluation of the products.*

5.4. The Companies will maintain details, such as product name, HCP's name & contact information, Quantity of evaluation samples given, Date of supply of evaluation samples distributed to HCPs, relevant product traceability information.

5.5. Demonstration products: Company demonstration products are different from Evaluation Samples. Demonstration products can be either single use products, mockups, temporary software or equipment that are used for HCP and Patient awareness & education. Demonstration products are typically identified as not intended for patient use and demonstration equipment are taken back by Company after the demonstration period is over. However,

consumables used in live procedural demonstration usually cannot be taken back. Clause 5 of this code does not apply to demonstration products and is limited to Evaluation Samples only. Demonstration products shall be specifically identified and tracked by the Company.

5.6. The documents/records required to be maintained under this Clause shall be maintained by Company for a period, as per applicable laws specific to category of document/record and in absence of such applicable laws as per Company's record management policy.

APPENDIX 4

Extract of Drug and Cosmetics Rules, 1945 which provides the manner of labelling the free sample distributed to medical professionals

Rule 96 of Drug and Cosmetics Rules, 1945 :

(ix) Every drug intended for distribution to the medical profession as a free sample shall, while complying with the labelling provisions under clauses (i) to (viii), further bear on the label of the container the words Physician's Sample—Not to be sold' which shall be overprinted.

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IDMA representation to CBIC requesting for waiver of ITC reversal under Section 17 Sub-Section (5)(h) of CGST Act, 2017 for COVID related Raw Material (API) & Finished Goods (Medicines) - reg.

IDMA have submitted the following representation on 14th July 2022 to Shri Vivek Johri, Chairman, Central Board of Indirect Taxes and Customs, Ministry of Finance, New Delhi with the copies to Hon'ble Smt Nirmala Sitharaman ji, Minister of Finance & Chairman, GST Council, New Delhi and Shri Tarun Bajaj, Revenue Secretary & Ex-Officio Secretary to the GST Council, Ministry of Finance, New Delhi on the above subject:

Ref: Section 17 sub-Section (5)(h) of CGST Act, 2017

Greetings from Indian Drug Manufacturers' Association.

We wish to invite your kind attention towards a grave financial concern and GST related issue for Pharma Industry and which will impact the industry adversely in coming 3-6 months.

During the COVID pandemic, Government had advised all pharma manufacturers to ensure uninterrupted supply of COVID related medicines. Specially, Remdesivir, Liposomal amphotericin B injections, Posaconazole Tablets and injections, Baricitinib tablets, Molnupiravir tablets and Favipiravir tablets etc. and their APIs.

Pharma Industry on its part committed itself to the cause and did its best to ramp up the capacities and significantly increased the production of COVID related medicines. However, it was seen that after July 2021 the number of fresh COVID cases started declining and thereby the country witnessed reduced demand of such medicines.

In fact, since last several months now, there is virtually no demand of these drugs. A news item appearing in the Times of India on 6th June 2022 highlighted that around Rs.800-1000 crore worth medicines meant for use by Covid patients are about to expire soon.

It needs to be appreciated that the Pharma Industry manufacturing Covid related drugs not only had employed significant funds for Plant & Machinery to increase production capacity but also invested huge amounts and purchased Raw Materials (API) and other essential ingredients in bulk to ensure uninterrupted supply of medicine, if need arises. Now suddenly all these Medicines, Machines & Raw material remain unutilized / under-utilized due to extremely low demand. Hospitals/Institutions are also not accepting such Covid related Medicines due to short shelf-life. The Raw Material & Finished Goods both are going to expire soon due to this.

We are concerned that the huge amount of shortly expiring material is going to put significant financial burden on survival of small and medium industries upto the tune of Rs.100 crores as we have to reverse the ITC on Expired / Destructed Goods as well as per CGST Act 2017, Section 17 sub section 5(h).

If the unexpected and originally unplanned financial burden is not taken care of by government, the Pharma Industry which was tasked with ramping up production of Covid related medicines will be suffering a major financial loss as they are facing Blocked Working Capital, unutilized or under-utilized plant as well.

Since the matter is of considerable significance and has financial implication to be faced by vast section of the industry, it is earnestly requested to consider waiver of the reversal of ITC on COVID related drugs so that the impending losses to the related industries may be lowered.

We request your urgent indulgence and appropriate action in this matter.

Thanking you.

Yours sincerely,

For Indian Drug Manufacturers' Association,

Dr Viranchi Shah
National President

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Report on Schemes for Strengthening of Pharmaceutical Industries (SPI)

Dr. Mansukh Mandaviya, Minister for Chemicals & Fertilizers and Health & Family Welfare formally launched the schemeof **Strengthening of Pharmaceuticals Industries** at Dr Ambedkhar International Convention Centre, New Delhi on 21st July, 2022 in the presence of Minister of State for Chemicals & Fertilizers and New & Renewable Energy Shri Bhagwanth Khuba amidst the strong presence of pharma MSME industry players and representatives of major Pharma Associations. Dr Mandaviya said that the new scheme will help the

industry to enhance its quality, technology & infrastructure upgradation, & capacity building and encourage collaboration between various stakeholders for the overall development of the sector.

Dr Viranchi Shah, National President, IDMA being welcomed at the launch of Scheme. He said that it is an excellent scheme for MSMEs and complimented the Government's efforts. He further said that IDMA appreciates the initiative of Dr Mansukh Bhai, Madam S Aparna, Dr Yuvraj and all those who have helped to make this scheme.

Mr. S R Vaidya, Chairman – MSME Committee, IDMA was also present at the launch.

The approved guidelines of the schemes and corrigendum are available on DoP website at:

https://pharmaceuticals.gov.in/schemes.

This is an excellent initiative of the Government and an excellent opportunity for the Pharma Industry specially our IDMA Members. Please make the best of the opportunity and take full advantage of the schemes.

IDMA will shortly organise a webinar to discuss the nuances of the Schemes in greater detail.

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Shri Mehul Shah, Hon. General Secretary, IDMA exchanged pleasantries with Hon. Shri Piyush Goyal, Minister of Commerce & Industry during a meeting at Delhi on 18th July 2022 and handed over the IDMA Diamond Jubilee Coffee Table book as a token of our appreciation

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Report on Pharmac South- 7th Edition - held on 8th & 9th July 2022 at Chennai trade centre, Tamil Nadu

IDMA-TNPKSB in association with Orbit Exhibitions Pvt. Ltd., has once again delivered yet another successful edition of India's premier Pharma event - Pharmac South Exhibition and conference at Chennai Trade centre on 8th and 9th July 2022.

Pharmac South, an yearly B2B Exhibition cum Conference at Chennai, is one of the most sought after events for the Pharma and Nutraceutical sector.

Over the years, Pharmac South has actively facilitated leading contract manufacturing companies and the allied industries - Pharma Machinery and Packaging, Lab Analytical and Pharma ingredients segments across PAN India to showcase their unique products for the benefit of their prospective clients from various parts of the country.

The unique feature of Pharmac South is the conference organized with Senior Govt officials, leading Pharma stalwarts, Eminent speakers from Management, Marketing and Regulatory areas invited to provide comprehensive information to all the participants.

Pharmac South 2022 was conducted with great competence and professionalism attracting more than 100 Leading Exhibitors from across the country with Footfalls of about 3500 plus visitors.

The Inauguration of the Conference and the Trade Exhibition was made by the Chief Guest Shri. V. Arun Roy, Secretary to Govt, MSME Department, Govt of Tamil Nadu. He was one of the instrumental persons to bring the New Integrated Pharma Park into Tamil Nadu which has already been announced by Govt of Tamil Nadu with the investment of 180 crores, by which Pharma industry in Tamil Nadu will take a giant leap forward in the coming years.

In addition, Dr. Develena Chakraborty from Guidance cell of Tamil Nadu was one of the invited guests who have facilitated the announcement of Tamil Nadu Life Sciences and R&D policy guidelines.

The presence and expertise of chief mentor and IDMA past national president Mr. S. V. Veeraamani along with Pharmac South team headed by Mr. J. Jayaseelan, Chairman – IDMA (TNPKSB) led to the phenomenal success of Pharmac South 2022.

The CEO talk by Mr. Mehul Shah, Hon. General Secretary, IDMA, Mumbai and Managing Director, Encube Ethicals Pvt. Ltd., was a living example of how to rise up and be successful despite the different challenges in life.

Drawing from his experience, Guest Speaker, Mr. Kumaravel, Naturals salon and Spa narration of his drive to succeed was highly motivating.

Shri. Daara B. Patel, Secretary General, IDMA Mumbai, highlighted on the active role being played by IDMA for the growth and welfare of Pharma Industry.

The Chief regulators from both CDSCO and the State delivered in depth insights of the policies which provided valuable information to the audience.

In addition, the event witnessed business and Marketing Enclaves organized with leading Industry speakers.

Pharmexcil Director Mr. Murali Krishna, talk on various promotional schemes from Pharmexcil was well received.

The event was also supported with the active participation of fellow associations including The Indian Pharmaceutical Association, Tamilnadu Pharmaceutical Sciences Welfare Trust and The Pharmaceutical Manufacturer's Association of Tamil Nadu.

On the closing day, Mr. S. Sivanandhan, Hon. Secretary, IDMA (TNPKSB) announced Pharmac South 2023 to be held from 14th to 15th July 2023.

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OBITUARY

IDMA mourns the Sad demise of Shri Amarnath R Hegde Principal Consultant, Innova Pharma Consultants (IDMA Member)

A Tribute to Shri Amarnath R Hegde by Dr Dr Premnath Shenoy

DOB: 29.10.1941
DOD: 21.7.2022

It is an honor to write this tribute to Shri A.R. Hegde a senior colleague, mentor, friend and highly distinguished pharmacy professional who passed away on 21st July 2022. It was a privilege for me to have been a part of Shri Hegde's life. His, was a life well lived! He was a determined, visionary, collaborative, goal-oriented, caring person who loved life and all that it offered. His enthusiasm for that next big project was always infectious, and a huge component of his and his colleagues success. Shri Hegde's contributions were powerful and his work ethic more than remarkable, energy, commitment, integrity are all words that begin to capture my image of Shri Hegde. He was one of kind and will be sorely missed as a mentor, well-wisher and a friend. Shri Hegde a caring and beloved family man, a cherished colleague, will be missed by many, but never will he be forgotten by those who were fortunate enough to have known him!

Albert Einstein said, "The value of a man should be seen in what he gives and not in what he is able to receive." In one word, Shri Hegde was a man who gave. He gave much to his work, to the profession and colleagues. I would like to write in celebration of his life. Here was a life that, demand notice, a life that exemplified brilliance, a life that inspired emulation, a life that burned so that others' paths were lit.

I have known Shri Hegde since 1995 when he joined Astra IDL as a Managing Director. He was a strategic thinker, a visionary who was brilliant, innovative and creative. As such, he contributed much to the development of Astra IDL. He generously gave us his knowledge, his expertise, his skills. He was the first Pharmacy technical professional who became managing director of a multinational Pharmaceutical company in India. Prior to this role he worked in leadership roles in several organisations, such as Pfizer, Warner Hindustan, Ranbaxy, Max, Searl India. He also worked as Director and CEO of Orchid Healthcare. He was executive member of IDMA and OPPI. He was life member of IPA and joint secretary of IPC held at New Delhi in 1985. His contribution to the profession of Pharmacy will always be remembered.

Monkey Pox: ICMR invite for Collaboration

EOI No.ICMR/EOI/MPXV/2022 dated 27/07/2022

Expression of Interest (EOI)

Indian Council of Medical Research, New Delhi

invites EoI for

Collaboration for development of In-Vitro Diagnostic (IVD) Kits and Vaccine candidate against MonkeypoxVirus (MPXV)

Indian Council of Medical Research
(Department of Health Research, GoI)
V. Ramalingaswami Bhawan,
P.O. Box No. 4911, Ansari Nagar,
New Delhi - 110029, India

CONTENTS

Letter of Invitation

1. INVITATION OF EXPRESSION OF INTEREST

Indian Council of Medical Research, New Delhi, invites Expression of Interest (EOI) through email from the experienced vaccine manufacturer/ pharma companies/ R&D Institutions/In-vitro Diagnostic (IVD) kit manufacturers for joint collaboration in the following two categories–

I. Development of vaccine candidate against Monkeypox disease

II. Development of diagnostic kits for diagnosis of Monkeypox virusinfection.

The EOI Document containing the details of qualification criteria, submission details, brief objective & scope of work and evaluation criteria etc. the same can be downloaded from the ICMR website (https://www.icmr.gov.in). Due to the current COVID-19 pandemic situation, the EOI may be submitted through email to jitendra.narayan@gov.in . Shortlisted firm(s)/organization(s) shall only be contacted for the further process of finalization of agreement.

Schedule for the Proponents is as under:

EOI Document Number	ICMR/EOI/MPXV/2022 dated 27/07/2022
Date of Publication	Date: 27/07/2022
Last date of submission	Date: 10/08/2022

Note: EoI must be submitted separately for each category, whichever is selected by the interest of the firm.

ICMR reserves the right to cancel this EOI and/ or invite afresh with or without amendments, without liability or any obligation for such EOI and without assigning any reason. Information provided at this stage is indicative and ICMR reserves the right to amend/add any further details in the EOI, as may be desired by the competent authority at ICMR, which shall be duly notified on its website.

1. Background

The Indian Council of Medical Research (ICMR), New Delhi, the apex body in India for the formulation, coordination and promotion of biomedical research, is one of the oldest medical research bodies in the world. The ICMR has always attempted to address the growing demands of scientific advances in biomedical research on the one hand and to the need of finding practical solutions to the health problems of the country, on the other.

ICMR-National Institute of Virology (ICMR-NIV), Pune, one of the Institutes of the Indian Council of Medical Research (ICMR), New Delhi has isolated the Monkeypox virus, which is being propagated on specific cell lines under the biosafety laboratory conditions. These isolates were further purified and characterized. Tissue culture infective dose ($TCID_{50}$) has been estimated and bulk propagation of the virus stock has been achieved.

ICMR reserved all the Intellectual Property Rights and Commercialization rights on the Monkeypox virus isolates and its method/ protocols for purification, propagation and characterization. ICMR is lawfully entitled to enter into any form of non-exclusive agreements with experienced Drug/Pharma/Vaccine/IVD manufacturers through defined agreement for undertaking R&D as well as manufacturing activities using characterized Monkeypox virus isolates of ICMR for development of vaccine against Monkeypox disease or Diagnostic kit for diagnosis of Monkeypox virus, hereinafter referred to as the 'Product(s)'.

2. Objective

ICMR is willing to make available Monkeypox Virus strain/isolates for undertaking R&D, validation as well as manufacturing activities using characterized isolates of Monkeypox virus under the joint collaboration in the public-private partnership mode for the following two activities–

2.1 Development of vaccine candidate against Monkeypox disease.

2.2 Development of diagnostic kits for diagnosis of Monkeypox virus infection.

3. Broad Scope of Work

i. ICMR is in possession of characterized Monkeypox Virus isolates/strain and is thereby willing to collaborate with experienced vaccine manufacturer as well as the *in-vitro* diagnostics (IVD) manufacturers on **Royalty** basis on fixed term contract condition for undertaking R&D and manufacturing activities for Joint development and validation of

potential vaccine candidate against Monkeypox disease, development of diagnostic kit (IVD), for detection of the monkeypox virus leading to Product development.

ii. The firm(s)/organization(s) would be granted rights to undertake further R&D, manufacture, sell, and commercialize the end product(s) **'vaccine candidate/IVD'** against the Monkeypox disease under defined Agreement.

iii. The Agreement, following EoI will be executed on "Non-Exclusive" basis with single/multiple firms, due to the extensive demand of Monkeypox virus isolates which is being envisaged to develop vaccine candidates/IVD kits.

iv. ICMR-NIV has in its possession Monkeypox virus isolates envisaged to be useful for development of a vaccine against Monkeypox disease and development of IVD kits. ICMR-NIV has expertise in various techniques, methods and information relating to said virus strain/isolate. The scientific information available with ICMR experts could be utilized for development of vaccine, drug, IVD and other R&D activities etc.

v. ICMR-NIV will provide expert guidance & technical support on the R&D and product development, in all phases as per the terms of the Agreement to be executed with the firm. Such technical oversight by ICMR-NIV would accelerate the development of the Product.

vi. ICMR would provide technical support in development of IVD kits including serology assays and molecular kits and will also facilitate the validation of kit as per the terms & conditions under Agreement.

vii. The process/ Product developed by firm(s)/organization(s) during the course of development of the Product encompassing IP, shall be owned jointly by ICMR and firm(s)/organization(s). IP shall mean patents, rights to inventions, copyright and related rights, moral rights, rights in designs, rights in trademarks, rights to preserve the confidentiality of information (including know-how and trade secrets) and any other intellectual property rights, in each case whether registered or unregistered and including all applications (or rights to apply for and be granted), divisional, continuations, continuations-in-part, reissues, renewals or extensions of, and rights to claim priority from, such rights and all similar or equivalent rights or forms of protection which subsist or will subsist now or in the future in any part of the world regarding the Product(s) and shall include without limitation, the Technology (hereafter defined) Patents and

Trademarks, developed/ created for product(s) pursuant to this EOI through ICMR support;

4. Intellectual Property Rights

ICMR National Institute of Virology (NIV), Pune one of the constituent Institutes of the Indian Council of Medical Research (ICMR), New Delhi, has isolated Monkeypox virusisolates and is the owner of the said TECHNOLOGY including any underlying Intellectual Property(ies) and Commercialization rights. By virtue of financial support and research endeavor provided by ICMR, legally possess the rights and authority to retain full or part of the 'TECHNOLOGY' by itself or to assign at its discretion full or part of the 'TECHNOLOGY' including any patent(s) or intellectual property rights(s) on the invention(s) arising out of such endeavors, and/or ICMR is lawfully entitled to enter into any form of Agreement with selected vaccine/ diagnostic kits manufacturer(s) including transfer of the 'TECHNOLOGY'.

5. Royalty Payouts

Interested companies/manufacturers with demonstrated capabilities in vaccine manufacturing/ Diagnostic kit development are invited to join hands with ICMR for further development & validation of vaccine candidate and diagnostic kits (IVD).

The manufacturers/companies interested in this collaboration may quote **Royalty** not less than 5% (five percent) on **Net Sales** of the **END PRODUCT** on half yearly basis as entered in the books of account maintained by Company/Manufacturer, up to 30th September and up to 31st March respectively every year regularly and punctually and in any event not later than the last day of April and last day of October immediately following in every such year provided that the liability of the Company/Manufacturer to pay royalty shall accrue upon the commencement of the commercial sale of the '**Product'** manufactured at the plant, as per the terms of "**ICMR-Technology Transfer and Revenue Sharing Guidelines-2021"** and as per the amendments approved by the competent authority from time to time.

In the event of default in payment of royalty as above, interest @ 12% (twelve per cent) per annum on the **Royalty** due shall be charged for the first six months. If default persists for more than six months interest at similar rate will be charged on the accrued interest also from the due dates of payments till realization/recovery of such amounts by the ICMR. Taxes and levies, as made applicable by the Government, shall be charged at the time of payments made to ICMR over and above the payments that shall be applicable as per terms of specified license Agreement

to be executed with selected companies.

"NET SALES" shall mean Revenue from sales of goods or services by all ICMR grantees/Licensees/ Sub-licensee(s) base on the net sales realization from operations, net of discounts and indirect taxes as defined by cost Accounting Standards-24 and certified by the Chartered Accountant.

6. Validity of contract

i. An Agreement shall be executed with Company/Manufacturer to decide conditions for execution of this collaborative activity. The Agreement shall have a defined time line, which will be decided mutually by both the parties, considering the R&D requirements for product development.

ii. The Agreement shall be valid from the EFFECTIVE DATE and subject to covenants and conditions herein contained and shall remain in force for a specific period which shall not be less the twenty (20) years or shall be decided mutually with the approval of competent authority, commencing from the accrual of Company's obligation to pay **Royalty** to ICMR, after the commercialization of the Product (the "Term"). After the end of term of the Agreement, the Product(s) will be royalty free.

7. Details of documents to be furnished

Proponents are requested to go through all pre-qualification requirements, scope of work for execution & requirements with respect to technical / financial capabilities for acceptance and submission of documents for verification by ICMR.

Documents to be furnished are:

i. Authorization Letter (Format – 1)
ii. Declaration - Expression of Interest (Format – 2)
iii. Undertaking with regard to Blacklisting (Format-3)
iv. Undertaking with regard to laboratory facilities (Format – 4)
v. Undertaking with regard to Non-Litigation (Format – 5)
vi. Production Capacity Undertaking (Format-6)
vii. Royalty Offer (Format-7)
viii. EOI document with each page duly stamped and signed by the Authorized signatory.
ix. Supporting documents, as mentioned in Format-2

x. MSME Certificate (if applicable)

xi. Concept note on business plan

xii. Registration Certificate of Company/ organization etc.

xiii. Any other information which proponent may like to provide.

ICMR reserves the right to call for any clarifications confined in the broad scope, wherever such a clarification become necessary for proper judgment in evaluation.

8. Rejection Criteria

The application is liable to be rejected if:

i. The proposal is not submitted as per the requirements indicated in the EOI.

ii. Not in the prescribed format.

iii. Not properly stamped and signed as per requirements.

iv. Received after the expiry of due date and time.

v. All relevant supporting documents are not furnished with the Pre-Qualification criteria.

vi. The proposal shall be substantially responsive without any material deviation, failing which the proposal shall be summarily rejected.

9. Evaluation Methodology

Screening of EOIs shall be carried out as per Pre-Qualification criteria (Section 10) mentioned in the EOI document and based on verification of documents submitted. Only shortlisted proponents shall be contacted for execution of the Agreement.

10. Pre-Qualification Criteria (PQC)

The following will be the minimum Pre-Qualification Criteria (PQC). Responses not meeting the minimum PQC will be summarily rejected and will not be evaluated further:

Sl. No.	**Pre-Qualification Criteria**	**Supporting copy of documents required**(All documents must be self-attested by the authorized person of the proponent)
1	The proponent shall be a legal entity, registered as Institution/Company/ LLP/ Society/ partnership firm/ proprietorship firm under respective acts in India.	Registration of firm/organization/Company Incorporation Certificate from ROC/Partnership deed etc. whichever is applicable.

2	The proponent must be registered in India with taxation and other administrative authorities.	GST Registration or GST exemption certificate/ PAN Card.
3	The proponent should have prior experience in R&D and manufacturing of vaccine/ drug/ pharma product/IVD for any infectious disease and must have marketed such products in three (3) immediate preceding years.	Research paper/Pamphlet / brochure of the product/DCGI License for existing product.
4	The proponent must be profitable and should not have incurred overall loss in past three (3) years. (Applicable on commercial firms/organizations only)	Certificate from the Chartered Accountant of the Organization/ Audited Balance sheets for last three financial years or Income Tax return.
5	The proponent should have good track record and not black-listed by any Central / State Government / Public Sector Undertaking, Govt. of India, at least in three (3) immediate preceding Years. (Applicable on commercial firms/organizations only)	Undertaking on the Letter Head of the Proponent duly signed & Stamped by Authorized Signatory (As per format – 3).
6	The proponent should have a registered office and manufacturing unit in India	Registration copies of both.
7	The proponent should have functional laboratory to carryout R&D for the product development	Undertaking on Proponent's Letter Head, duly signed and stamped by the Authorized Signatory (As per format –
8	The proponent should not be involved in any major litigation that may have an impact of affecting or compromising the conditions required under this EOI and in the MoU.	Undertaking on Proponent's Letter Head, duly signed and stamped by the Authorized Signatory (As per format – 5)
9	GMP and ISO Certification (applicable on commercial firms/organizations only)	Registration copies of both.
10	Capacity to produce at least one lakh doses per week	Undertaking (As per format – 6).
11	Royalty offer	(As per format – 7)
12	Business Plan	A brief concept note on planning & execution, product development, clinical trials/ validation, regulatory affairs, production, marketing etc. (not more

11. Disclaimer

i. ICMR shall not be responsible for any late receipt of applications for any reasons whatsoever.

ii. ICMR reserves the right to cancel the EoI without assigning any reasons thereof.

iii. ICMR may relax or waive any of the conditions stipulated in this document as deemed necessary in the best interest of the ICMR, without assigning any reasons thereof.

iv. To include any other item in the Scope of work at any time after consultation with proponents or otherwise.

12. Contacts

In case of any clarification required, please contact:

For Scientific issues-
Dr. Pragya Yadav, Scientist-F, ICMR-NIV, Pune, Email: - hellopragya22@gmail.com;

For Administrative issues-
Dr. R. Lakshminarayanan, DDG (Admin), ICMR HQ, New Delhi
Email: - lakshminarayanan.r@icmr.gov.in

Format-1

Authorization Letter
(To be submitted on Agency's Letter Head)

To,

The Director General,
Indian Council of Medical Research,
Ansari Nagar, New Delhi.

Subject: Letter for Authorized Signatory

Ref: EOI No. ICMR/EOI/MPXV/2022 dated

Sir,

This has reference to your above-mentioned Expression of Interest (EOI) for Collaboration in R&D and manufacturing, commercialization of IVD Kits/Vaccine candidate *(only tick whichever is applicable)* against Monkeypox disease.

Mr./Ms./Mrs./Dr……..is hereby authorized to submit the EOI documents and participate in the processing on behalf of M/s……. (Company's Name)……., who's signature is below.

(Specimen Signature of Representative)

Date:
Place:

Yours faithfully,

(Signature of the Authorized signatory)
Name:……..
Designation:……..
Seal:……..

Format-2

Expression of Interest

(To be submitted on Agency's Letter Head)

To,

The Director General,
Indian Council of Medical Research,
Ansari Nagar, New Delhi.

Subject: Submission of Expression of Interest (EOI) for joint collaboration in R&D and manufacturing, commercialization of IVD Kits/Vaccine candidate *(only tick whichever is applicable)* against Monkeypox disease.

Ref: ICMR/EOI/MPXV/2022dated

Sir,

The undersigned having read and examined in detail all the EOI documents pertaining to your transfer of technology, and do hereby express the interest to undertake the research & development/ commercialization /manufacture/ sell of the product as mentioned in the EOI document. The details of the Company and contact person are given below:

Name of the Proponent	
Address	
Name, designation & address of the person (to whom all communications shall be made)	
Telephone No. (with STD code)	
Mobile No. of the contact person	
Email ID of the contact person	

The following documents are enclosed:

Sl. No.	Documents required	Type of document	Page
1	Company Incorporation Certificate from ROC/Partnership deed etc.		
2	GST Registration or GST exemption certificate/ PAN Card.		
3	DCGI/CDSCO license for the existing products available in the market		

4	Certificate from the Chartered Accountant of the Organization/ Audited Balance sheets for last three financial years, Income Tax return.		
5	Proof of registered office and manufacturing Unit in India.		
6	GMP and ISO Certification. Registration copies of both		
7	Authorization Letter	As per format – 1	
8	Undertaking on the Letter Head of the Proponent duly signed & Stamped by Authorized Signatory	As per format – 3	
9	Undertaking on Proponent's Letter Head, duly signed and stamped by the Authorized Signatory	As per format – 4	
10	Undertaking on Proponent's Letter Head, duly signed and stamped by the Authorized Signatory	As per format – 5	
11	Undertaking for declaring capacity to produce at least one lakh doses per week	As per format – 6	
12	Royalty Offer	As per format – 7	
13	MSME Certificate (if have any)		
14	Business Plan	A brief concept note on planning & execution, product development, clinical trials/ validation, regulatory affairs, production, marketing etc. (not more than 5 pages)	

I/we hereby declare that my/our EOI is made in good faith and the information contained is true and correct to the best of my/our knowledge and belief.

Thanking you,

Yours faithfully,

(Signature of the Authorized signatory)
Name:
Designation:
Seal:
Place:

Format-3

Undertaking with regard to blacklisting

(To be submitted on Agency's Letter Head)

To,

The Director General,
Indian Council of Medical Research,
Ansari Nagar, New Delhi.

Subject: Undertaking regarding Blacklisting / Non-Debarment.

Ref: ICMR/EOI/MPXV/2022dated

Sir,

It is hereby confirmed and declared that M/s……has not been blacklisted / debarred by any Government Department / Public Sector Undertaking / or any other agency for which works/assignments/services have been executed / undertaken.

Yours faithfully,

(Signature of the Authorized signatory)
Name:
Designation:
Seal:
Place:

Format-4

Undertaking with regard to laboratory facility

(To be submitted on Agency's Letter Head)

To,

The Director General,
Indian Council of Medical Research,
Ansari Nagar, New Delhi.

Subject: Undertaking regarding laboratory infrastructure.

Ref: ICMR/EOI/MPXV/2022dated

Sir,

It is hereby confirmed and declared that M/s…..... do have adequate laboratory infrastructure (equipped laboratory facility) and experienced staff/skilled manpower to undertake R&D and product development that is Vaccine candidate/IVD Kit *(only tick whichever is applicable)*.

Yours faithfully,

(Signature of the Authorized signatory)
Name:
Designation:
Seal:
Place:

Format-5

Undertaking with regard to Non-Litigation

(To be submitted on Agency's Letter Head)

To,

The Director General,
Indian Council of Medical Research,
Ansari Nagar, New Delhi.

Subject: Undertaking regarding Litigation.

Ref: ICMR/EOI/MPXV/2022dated:

Sir,

It is hereby confirmed and declared that M/s…..... and owner of the firm / Board of Directors, do not have any litigation / arbitration pending/under trial in court.

Yours faithfully,

(Signature of the Authorized signatory)
Name:
Designation:
Seal:
Place:

Format-6

Undertaking with regard to production capacity

(To be submitted on Agency's Letter Head)

To,

The Director General,
Indian Council of Medical Research,
Ansari Nagar, New Delhi.

Subject: Undertaking with regard to production capacity.
Ref: ICMR/EOI/MPXV/2022dated

Sir,

It is hereby confirmed and declared that M/s…… does have the capacity in all mean (including infrastructure, fund, material, staff etc.) for manufacturing of vaccine doses/IVD kits, min. 01 (one) lakh unit per week.

Yours faithfully,

(Signature of the Authorized signatory)
Name:
Designation:
Seal:
Place:

Format-7

Undertaking for Royalty

(To be submitted on Agency's Letter Head)

To,

The Director General,
Indian Council of Medical Research,
Ansari Nagar, New Delhi

Subject: Undertaking for Royalty.
Ref: ICMR/EOI/MPXV/2022dated

Sir,

It is hereby confirmed that M/s ……, agrees to pay a **Royalty** of ……. % (……. Percent) to the ICMR to be calculated against the **Net Sales** done with respect to the product developed under this collaboration.

(As per the terms of ICMR-Technology Transfer and Revenue Sharing Conditions, the **"NET SALES"** shall mean Revenue from sales of goods or services by all ICMR grantees/Licensees/ Sub-licensee(s) base on the net sales realization from operations, net of discounts and indirect taxes as defined by cost Accounting Standards-24 and certified by the Chartered Accountant.

Yours faithfully,

(Signature of the Authorized signatory)
Name:
Designation:
Seal:
Place:

SCHEDULE – (A)

Joint collaboration for development of vaccine against Monkeypox Disease

1. **About the Technology/Product/Process:**

The Monkeypox virus (MPXV), belonging to Orthopoxvirus genus and Poxviridae family, has been endemic in Central and West Africa since 1970, and now have shown the emergence in various non-endemic countries in 2022. It is a viral zoonotic infection, meaning that it can spread from animals to humans. It can also spread from person to person.There is no specific vaccine against Monkeypox but a smallpox vaccine was shown to be protective against Monkeypox in the past, current data on the effectiveness of newer smallpox/Monkeypox vaccines in the prevention of Monkeypox in clinical practice and in field settings are limited.

To overcome this problem, ICMR took the farsighted initiative for development of a new vaccine candidate which is intended to have higher efficacy and safety of the recipients. ICMR NIV Pune has isolated and characterized MPXV isolate during the current outbreaks of MPXV in India. The genomic analysis was carried out with the whole genomes of MPXV isolated was carried out which indicated West African lineage of virus that is current outbreak strain circulating globally in other WHO regions. Genome-wide sequence analysis of the recent outbreak strain of MPXV and other monkeypox viruses shows a very high conservation, with 97.9% (protein-based) and 97.8% (nucleotide-based) sequence identity.

Similarly, there are no indigenous enzymelinked immunosorbent assays (ELISA) IgM/IgG available to qualitatively analyze Human Monkeypox Virus (MPV) in Human serum, plasma. Very few ELISA kits are available which are costly and needs to be imported. To undertake serologic surveys in human population there is need for development of cost-effective ELISA kits specific for Monkeypox.

With the MPXV isolated from the current outbreak it'sprescient to develop variety of molecular assays with precise genetic targets for accurate diagnosis of Monkeypox virus infection. Using the recent isolate in development of IVD may have higher sensitivity and specificity in the outbreak patient.

2. **Need and utility of invention:**

Through several observational studies vaccination against smallpox was demonstrated to be about 85% effective in preventing Monkeypox. At the present time, the original (first-generation) smallpox vaccines are no longer available to the general public. While one vaccine (MVA-BN) and one specific treatment (tecovirimat) were approved for Monkeypox, in 2019 and 2022 respectively, these countermeasures are not yet widely available. A still newer vaccine based on a modified attenuated vaccinia virus (Ankara strain) was approved for the prevention of monkeypox in 2019. This is a two-dose vaccine for which availability remains limited. Scientific studies are now underway to assess the feasibility and appropriateness of vaccination for the prevention and control of Monkeypox. Some countries have, or are developing, policies to offer vaccine to persons who may be at risk such as laboratory personnel, rapid response teams and health workers.

Therefore, it may be appropriate to develop a new MPXV vaccine candidate using current circulating strains. With availability of fewer diagnostic kits for diagnosis of Monkeypox virus infection it's prudent to initiate the development of the cost effective diagnostic assays.

3. **Scope for collaboration:**

This collaboration will open up scope for development of new MPXV vaccine candidate and diagnostic kits for diagnosis of Monkeypox virus infection.

4. **Role of ICMR**

4.1 ICMR would provide technical support through team of experienced scientist in study planning, product development, development of clinical trial protocol, results/data analysis, outcome assessment, safety & efficacy assessment, product improvement, and other, if deemed fit upon the mutual understanding between ICMR and collaborative company.

4.2 ICMR through its Institutes would provide support and facilitation to conduct the clinical trial of new vaccine candidate in India through its Affiliates/ Institutes, in collaboration with company/institutions in a professional and mutually agreed-upon manner and timelines, which will be decided later under the Agreement.

4.3ICMR would provide technical support in development of IVD kits including serology assays and molecular kits and will also facilitate the validation of kit as per the terms & conditions under Agreement.

5. **Role of company**

5.1. The Company will undertake the research & development, manufacturing, and commercialization of Monkeypox vaccine/IVD Kit.

5.2. The partnering company should provide necessary infrastructure and depute experienced/skilled manpower.

5.3. The company will share the technical data with ICMR and participate in all discussions in a professional and mutually agreed-upon manner.

5.4. The company will allow authorized personnel/scientist/team of ICMR to participate in R&D activities and to carry out specific project activities as envisaged under this EoI and subsequent MoA.

5.5. The company shall be responsible for obtaining all the regulatory approvals required starting from R&D for product development to its commercialization.

6. **Methodology/process:**

ICMR-NIV Pune has isolated Monkeypox virus using Vero cells. Confirmation of the isolates was performed using next generation sequencing. These isolates were further purified and characterized using the complete genome sequencing. Bulk preparation of the virus stock was undertaken and Tissue culture infective dose ($TCID_{50}$) was estimated. This virus(inactivated)can be used for the development/validation of diagnostic assays for Monkeypox virus infection.

7. **Envisaged outcome:**

Development of a safe and effective Monkeypox vaccine for eliciting strong, durable, and broad immune responses towards robust clinical protection against Monkeypox virus infection as well as diagnostic kits for diagnosis of Monkeypox virus infection.

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In Rajya Sabha & In Lok Sabha

In Rajya Sabha

Steps taken to cap huge trade margins over medicines

Rajya Sabha Unstarred Question No. 186

Shri K.R. Suresh Reddy:

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

(a) whether Government agrees with the view that huge trade margins are on key medicines priced over ₹ 100 per unit, ranging from 50 per cent to 1000 per cent;

(b) if so, whether the National Pharmaceutical Pricing Authority (NPPA) has proposed/ is to propose steps to cap huge trade margins over medicines; and

(c) if not, the reasons therefor?

Answered on 19th July, 2022

A. (a) to (c): Drugs (Prices Control) Order, 2013 (DPCO, 2013) allows for 16% of the price to retailer as a margin to retailer in case of scheduled drugs. National Pharmaceutical Pricing Authority (NPPA) in February, 2019 has capped the Trade Margin of non-scheduled formulations of select 42 Anti-Cancer drugs as Pilot for Proof of Concept. Recently, during COVID-19, NPPA capped trade margins of Oxygen Concentrators, Pulse Oximeter, Blood Pressure Monitoring Machine, Nebulizer, Digital Thermometer and Glucometer.

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

Manufacture of faulty drugs

Rajya Sabha Unstarred Question No. 188

Shri Ayodhya Rami Reddy Alla:

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

(a) whether Government is taking any steps to combat the manufacture of faulty and adulterated drugs, which has caused many deaths in the country and brought us disrepute internationally, if so, the details thereof, and if not, the reasons therefor;

(b) the steps being undertaken by Government to improve manpower in the area of drug regulation, i.e. drug regulators, the details thereof; and

(c) whether Government has any data on the number of faulty drugs manufactured in the last five years and the action taken against the manufacturers in such cases?

Answered on 19th July, 2022

A. (a): As per the information received from Central Drugs Standard Control Organisation (CDSCO), CDSCO and Ministry of Health and Family Welfare have taken various regulatory measures to ensure the quality of medicines in the country. Major such reforms are as under:

i. The Drugs and Cosmetics Act, 1940 was amended under Drugs & Cosmetics (Amendment) Act, 2008 to provide stringent penalties for manufacture of spurious and adulterated drugs. Certain offences have also been made cognizable and non-bailable.

ii. The States / UTs were requested to set up special Courts for trial of offences under the Drugs and Cosmetics Act for speedy disposal. So far, 33 States have already set up designated special Courts.

iii. The number of sanctioned posts in Central Drugs Standard Control Organization (CDSCO) has been increased from 111 in 2008 to 478 till January 2022 and 220 posts have recently been created on 27-06-2022.

iv. The testing capacities of Central Drugs Testing Laboratories under CDSCO are being constantly strengthened to expedite testing of drug samples in the country.

v. On 3.4.2017, in order to ensure efficacy of drugs, the Drugs and Cosmetics Rules, 1945 have been amended providing that applicant shall submit the result of bioequivalence study along with the application for grant

of manufacturing license of oral dosage form of drugs falling under the Category II and Category IV of the Biopharmaceutical Classification System.

vi. On 27.10.2017, the Drugs and Cosmetics Rules, 1945 have been amended vide Gazette notification no. G.S.R. 1337 (E) making it mandatory that before the grant of manufacturing license, the manufacturing establishment is to be inspected jointly by the Drugs Inspectors of Central Government and State Government. The licensed manufacturing premises shall be inspected jointly by the Drugs Inspectors of Central Government and State Government to verify the compliance with the conditions of license and the provisions of the Drugs & Cosmetics Act and Rules for not less than once in three years or as needed as per risk-based approach.

vii. On 10.04.2018, the Drugs and Cosmetics Rules, 1945 have been amended vide Gazette notification no. G.S.R. 360 (E), making it mandatory for all drugs, that the applicants shall submit evidence of stability, safety of excipients etc. to the State Licensing Authority before grant of product manufacturing license by the Authority.

viii. Draft Rules have been published vide GSR 999 (E), dated 05.10.2018 to amend the Schedule-M of the Drugs and Cosmetics Rules, 1945 to make it more comprehensive at par with the WHO-GMP guidelines.

ix. The Government had approved a proposal for strengthening the drug regulatory system in the country, both at the level of Central and the State Governments at a total expenditure of Rs.1750 crores. Out of this, Rs. 900 crore was for strengthening the central drug regulatory structures and Rs.850 crore was for strengthening the drug regulatory system in the States. During the years 2016-17 and 17-18, Rs. 128.39 crore was released under the Central component whereas Rs. 87.90 crore was allocated during 2018-19 under this component. Rs. 82.90 crore was allocated during the year 2019-20. Under the State component, Rs. 81.36 crore was released during 2016-17 and 17-18 whereas Rs. 206 crore was allocated during 2018-19 under this component.

(b) : The Government vide letter No. A.11011/01/2015-DFQC dated 27-06-2022 has recently created 220 posts in various grade in CDSCO for strengthening of Drugs Regulatory system.

(c) : As per information received from various States/ UTs Drugs Controllers, No. of drug samples tested, no. of drug samples reported Not of Standard Quality /spurious /adulterated and enforcement action taken against the offenders during last five years is enclosed as **Annexure-I.** Similar information received from various zonal/Sub-zonal offices of CDSCO are enclosed as **Annexure-II**.

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

Annexure-I

Number of samples tested and enforcement actions taken, no. of drug samples reported Not of Standard Quality / spurious /adulterated and enforcement action taken by States/UTs Drugs Controller during last five years

Year	No. of drugs samples tested	No. of drugs samples declared not of standard quality	No. of drugs samples declared spurious/ adulterat ed	No. of prosecution launched for manufacturing, sale and distribution of spurious/ adulterated drugs	No. of cases (as mentioned in the earlier column) decided	No. of persons arrested	No. of Raids Conduc cted
2016-17	76,721	2,780	123	186	17	106	10,921
2017-18	82,599	2783	236	131	16	163	7067
2018-19	79,604	2,549	205	484	77	153	33,492
2019-20	81329	2497	199	421	61	220	15641
2020-21	84874	2652	263	236	17	164	20922

Annexure-II

Number of samples tested and enforcement actions taken, no. of drug samples reported Not of Standard Quality / spurious /adulterated and enforcement action taken by Zonal/Sub-zonal offices of CDSCO during last five years

Year	No. of drugs samples tested	No. of drugs sample s declared not of standard quality	No. of drugs samples declared spurious / adulterated	No. of prosecution launched for manufacturing, sale and distribution of spurious/ adulterated drugs	No. of cases (as mentioned in the earlier column) decided	No. of persons arrested	No. of Raids con-ducted
2016-17	5207	146	Nil	21	4	Nil	56
2017-18	7088	381	2	17	1	6	8
2018-19	10382	310	5	31	9	4	52
2019-20	9299	307	12	28	2	6	25
2020-21	5460	170	3	12	NIL	NIL	NIL

Pradhan Mantri Bhartiya Janaushadhi Kendra (PMBJK) generic drugs stores

Rajya Sabha Unstarred Question No. 191

Shri K.R.N. Rajeshkumar:

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

(a) whether Pradhan Mantri Bhartiya Janaushadhi Kendra (PMBJK) generic drugs stores are functional in all the States of the country;

(b) if so, the number of Janaushadhi Kendras set up/ functioning, State-wise;

(c) whether Government has conducted any review of the performance/functioning of PMBJK and if so, the outcome of the said review along with the action/ steps taken thereon; and

(d) the mechanism put in place to ensure availability of medicines at each of the said stores?

Answered on 19th July, 2022

A. (a) & (b): Pradhan Mantri Bhartiya Janaushadhi Kendras (PMBJKs) are functional in all the States of the country. Till 30.06.2022, about 8,742 PMBJKs have been opened across the country. State/ Union Territory-wise list of PMBJKs is enclosed as Annexure.

(c): A study for 'Improving Effectiveness of Jan Aushadhi Stores' was commissioned in January, 2019. Taking in consideration the recommendations made in the Study Report, the Scheme was revised and approved by the Standing Finance Committee (SFC).

(d): In order to ensure sufficient availability of medicines at all Kendras, the Pharmaceutical and Medical Devices Bureau of India (PMBI), the implementing agency of the scheme has set up a strong network of four warehouses and 39 distributors all over the country. All warehouses have SAP based inventory management system and the demand forecasting is done through the said system so as to place orders as per the desired inventory levels. Further, an Information Technology (IT) enabled End-to-End supply chain system with Point-of-Sale (POS) application for value added services has been implemented to ensure availability of medicines.

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

Annexure

Statement referred to in parts (a) & (b) of the Rajya Sabha Unstarred Q. No. 191 for answer on 19.07.2022 raised by Shri K.R.N. Rajeshkumar regarding Pradhan Mantri Bhartiya Janaushadhi Kendra (PMBJK) generic drugs stores

State/UT- wise list of PMBJKs opened across the country till 30.06.2022		
Sl. No.	Name of the State/UT	Number of PMBJK opened
1	Andaman & Nicobar	9
2	Andhra Pradesh	170
3	Arunachal Pradesh	28
4	Assam	96

5	Bihar	300
6	Chandigarh	7
7	Chhattisgarh	208
8	Delhi	382
9	Goa	10
10	Gujarat	511
11	Haryana	237
12	Himachal Pradesh	62
13	Jammu and Kashmir	212
14	Jharkhand	78
15	Karnataka	982
16	Kerala	990
17	Ladakh	2
18	Lakshadeep *	0
19	Madhya Pradesh	253
20	Maharashtra	635
21	Manipur	32
22	Meghalaya	15
23	Mizoram	12
24	Nagaland	19
25	Odisha	356
26	Puducherry	20
27	Punjab	307
28	Rajasthan	137
29	Sikkim	3
30	Tamil Nadu	845
31	Telangana	170
32	DNH & D&D	35
33	Tripura	24
34	Uttar Pradesh	1175
35	Uttarakhand	218
36	West Bengal	202
Grand Total		**8,742**

** Medicines are directly supplied to the administration of UT of Lakshwadeep.*

'Subsidy / Financial Assistance to MSME Sector'

Rajya Sabha Un-Starred Question No. 271

Ms. Saroj Pandey:

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

(a) the amount of subsidy / financial assistance provided by the Ministry to MSME sector during the last three years; and;

(b) the institutions which have benefitted directly or indirectly through such subsidy / financial assistance?

Answered on 19th July, 2022

A. (a) and (b): A series of steps have been taken during the last three years to provide financial assistance to the MSME sector which is summarised as under:

(i) Emergency Credit Line Guarantee Scheme (ECLGS) was launched in May, 2020 as part of Aatmanirbhar Bharat Abhiyaan to support eligible Micro, Small and Medium Enterprises (MSMEs) and business enterprises in meeting their operational liabilities and restarting their businesses. Under the scheme 100% credit guarantee was extended to the lending institutions by the Government. A sum of Rs 64,100 crore has been allocated towards the scheme till date. Further, an additional guarantee cover of Rs. 50,000 crore, earmarked exclusively for the hospitality and related enterprises, has been announced in Budget 2022-23, which will increase the admissible guarantee cover from Rs. 4.5 lakh crore to Rs. 5 lakh crore. The scheme has been extended till 31.3.2023.

(ii) Credit Guarantee Scheme for Micro Finance Institutions was launched in July 2021 wherein a guarantee was provided to the member lending institutions towards extending much needed liquidity to the NBFCs/MFIs for their on-lending support to eligible small borrowers. A sum of Rs 850 crore has been allocated towards the scheme.

(iii) Credit Guarantee Scheme for Subordinate Debt (CGSSD) was launched in June, 2020 by the Ministry of MSME for providing credit guarantee to credit facilities provided by eligible member lending institutions to the stressed or non-performing MSME accounts under the scheme. A sum of Rs 4,000 crore has been allocated towards the scheme.

(iv) Ministry of Housing and Urban Affairs (MoHUA) has implemented Credit Guarantee Fund for PM Street Vendor's AtmaNirbhar Nidhi (PM SVANidhi) in June, 2020 for facilitating credit to the street vendors. A sum of Rs 375 crore has been allocated towards the scheme.

Minister of State in the Ministry of Finance
(Dr. Bhagwat Karad)

Counterfeit Remdesivir Injections

Rajya Sabha Unstarred Question No.272

Shri Akhilesh Prasad Singh:

Q. Will the Minister of **HEALTH AND FAMILY WELFARE** be pleased to state:

(a) whether it is a fact that counterfeit Remdesivir injections have been found in the Central Drugs Laboratory(CDL), Kolkata;

(b) if so, whether Government has carried out any investigation in this regard; and

(c) if so, whether any action has been taken against the culprits post investigation?

Answered on 19th July, 2022

A. (a) to (c): As per information received from Food & Drug Administration, Punjab, recovery of injection (Remdesivir Vials, Cefoperazone vials & unlabelled vials) were made from a canal at Village Salempur, Tehsil Chamkaur Sahib, District Ropar and also from the canal at Village Balsandha, Tehsil Chamkaur Sahib, District Ropar and an FIR was registered at Police Station, Chamkaur Sahib, District Ropar. The Police Officials along with officers of Food & Drugs Administration, Punjab carried out the investigation and samples were drawn by the officers of CDSCO, which were sent for testing to Central Drugs Laboratory (CDL), Kolkata. The Govt. Analyst, CDL Kolkata based on test/analysis, has declared the sample of Remdesivir for injection 100 mg/vial as "Not of Standard Quality".

As per the information from Food & Drug Administration, Punjab, in the said case after investigation, Police has filed the challan/ report under Section 173 of CrPC in the Court of First Class Judicial Magistrate, District Court, Ropar and separate complaint/case under Drugs & Cosmetics Act / Rules has also been filed in the Court of Chief Judicial Magistrate, Ropar by Food & Drugs Administration, Punjab.

The Minister of State in the Ministry of Health and Family Welfare (Dr. Bharati Pravin Pawar)

Steps Taken to Maintain Quality of Medicinal Products

Rajya Sabha Unstarred Question No.276

Shri M. Mohamed Abdulla:

Q. Will the Minister of **HEALTH AND FAMILY WELFARE** be pleased to state:

(a) whether Government has taken any ambitious steps to maintain the standard quality of our medicinal products from the year 2019;

(b) if so, the details thereof, and if not, the reasons therefor; and

(c) whether Government has taken any steps from the year 2018 to make India the international capital for generic medicine, if so, the details thereof?

Answered on 19th July, 2022

A. (a) to (c): The Government has taken various regulatory measures since 2019 to ensure the quality of medicines in the country. The key measures are as under:

- The Drugs Rules, 1945 were amended providing that every Active Pharmaceutical Ingredient (bulk drug) manufactured or imported in India shall bear Quick Response Code on its label. The stored data or information shall include the minimum particulars including Unique product identification code, Batch No, Manufacturing date, Expiry Date.
- The Drugs Rules, 1945 were amended providing that any marketer who sells or distributes any drug shall be responsible for quality of that drug as well as other regulatory compliances along with the manufacturer under these rules.
- The Drugs Rules, 1945 were amended providing that *"in case the applicant intends to market the drug under a brand name or trade name, the applicant shall furnish an undertaking in Form 51 to the Licensing Authority to the effect that to the best of his knowledge based on search in trademarks registry, central data base for brand name or trade name of drugs maintained by Central Drugs Standard Control Organisation, literature and reference books on details of drug formulations in India, and internet, such or similar brand name or trade name is not already in existence with respect to any drug in the country and the proposed brand name or trade name shall not lead to any confusion or deception in the market".*
- The manufacture for sale, sale and distribution of 80 Fixed Dose Combinations (FDCs) drugs in India were prohibited in public interest after

consultation with the Drugs Technical Advisory Board.

- 220 additional posts of various levels have been created including Joint Drugs Controller, Deputy Drugs Controller, Asst. Drugs Controller and Drugs Inspector in the year 2022-23.

Department of Pharmaceuticals has launched a Scheme namely Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP). Under the Scheme, Generic Medicines are sold through dedicated outlets namely Pradhan Mantri Bhartiya Janaushadhi Kendras (PMBJKs). It is an initiative of Government of India towards making an impact on common masses to provide quality medicines at affordable prices. As on 30.06.2022, 8,742 Janaushadhi Kendras have been opened across the country. Product basket of PMBJP comprises 1,616 drugs and 250 surgical items.

The Minister of State in the Ministry of Health and Family Welfare (Dr. Bharati Pravin Pawar)

In Lok Sabha

Export of ITeS

Lok Sabha Unstarred Question No. 615

Shri S. Jagathrakshakan:

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

(a) whether the government concurs with the view that exports of Information Technology-Enabled Services (ITeS) along with professional services such as consultancy, legal, medicine, accounting, etc. should become the mainstay of India's export strategy instead of manufacturing;

(b) if so, the measures that are proposed to be taken by the Government in this regard; and

(c) if not, the reasons therefor?

Answered on 20th July, 2022

A. (a): The Merchandise and Services Exports of India for previous three years are as follows:

	2019-20	2020-21	2021-22
Merchandise Exports of India (in Billion USD) (Source: DGCIS)	313.36	291.81	421.89
Merchandise Export Share in India's Overall Exports (in %)	59.51	58.61	62.37
Services Export of India (in Billion USD) (Source: RBI)	213.19	206.09	254.53
Services Export Share in India's Overall Exports (in %)	40.49	41.39	37.63
Total Exports of India (in Billion USD)	526.55	497.90	676.42

Both Goods and Services Exports are among the key drivers of India's economic growth. The government will continue to promote both merchandise and services exports as part of its foreign trade policy.

(b) & (c): In order to promote trade in merchandise and services including Information Technology-Enabled Services (ITeS) and professional services such as consultancy, legal, medicine, accounting, Government follows a multi-pronged strategy which includes pursuing meaningful, predictable and transparent market access for Indian goods and service exporters through multilateral, regional and bilateral trade agreements. Further, Government has taken the following key steps to promote exports of merchandise goods and services:

1. Foreign Trade Policy (2015-20) has been extended upto 30-09-2022 to provide policy stability.
2. Interest Equalization Scheme on pre and post shipment rupee export credit has also been extended upto 31-3-2024.
3. A new Scheme, Remission of Duties and Taxes on Exported Products (RoDTEP), has been launched with effect from 01.01.2021.
4. Common Digital Platform for Certificate of Origin has been launched to facilitate trade and increase FTA utilization by exporters.
5. A comprehensive "Agriculture Export Policy" to provide an impetus to agricultural exports related to agriculture, horticulture, animal husbandry, fisheries and food processing sectors, is under implementation.
6. Promoting and diversifying services exports by pursuing specific action plans for the 12 Champion Services Sectors.
7. Promoting districts as export hubs by identifying

products with export potential in each district, addressing bottlenecks for exporting these products and supporting local exporters/manufacturers to generate employment in the district.

8. Active role of Indian missions abroad towards promoting India's trade, tourism, technology and investment goals has been enhanced.

9. Package announced in light of the covid pandemic to support domestic industry through various banking and financial sector relief measures, especially for MSMEs, which constitute a major share in exports.

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

Foreign Trade

Lok Sabha Unstarred Question No. 648

Shri E.T. Mohammed Basheer:

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

(a) whether the Government intends to have a policy framework with regard to foreign trade with any country in the future; and

(b) if so, the details thereof including the name of countries with which India has signed MoUs for trade in future in the recent Indian Delegates visit?

Answered on 20th July, 2022

A. (a) & (b): India has so far signed 13 Free Trade Agreements (FTAs) and 6 Preferential Trade Agreements (PTAs) with its partner countries for preferential access in those markets. These also include the recently signed FTAs with Mauritius, the UAE and Australia. As part of its endeavour to enlarge the scope of market access, India has entered into FTA negotiations with promising trading partners namely, the United Kingdom, Canada and the European Union. Apart from these FTAs/PTAs, India has also entered into MoUs for Trade and investment arrangements with its trading partner countries. Some of these are MoU between DP World FZE (DP World) of the UAE and National Investment Promotion and Facilitation Agency (Invest India), MOU between Invest India and Abu Dhabi investment office etc.

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

RCEP

Lok sabha Unstarred Question no. 657

Dr. Amar singh:

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

(a) whether the Government agrees with the view that for India, piecemeal agreements with many of the various component nations of the Regional Comprehensive Economic Partnership (RCEP) cannot and will not substitute for its failure to join the group;

(b) if so, the steps that are proposed to be taken by the Government to re-examine its attitude towards the RCEP; and

(c) if not, the reasons therefor?

Answered on 20th July, 2022

A. (a) to (c) The Government held extensive consultations with stakeholders such as the domestic industry, exporters, Export Promotion Councils, trade experts, various Ministries/Departments, academicians as well as the State Governments and received inputs, which were taken into consideration while formulating India's position in the Regional Comprehensive Economic Partnership (RCEP) negotiations. Based on such consultations, India's position in RCEP was formulated with an aim to achieve equitable outcomes, balanced ambitions and address domestic sensitivities of its stakeholders including small entrepreneurs. While RCEP was intended to provide mutually beneficial outcomes for RCEP countries, the structure of RCEP did not adequately address the ambitions and concerns of India's stakeholders. In light of these, India decided not to join the RCEP, in its current form. Accordingly, during the 3rd RCEP Leaders' Summit held on 4th November, 2019 in Bangkok, India conveyed its position that current structure of RCEP did not reflect the RCEP Guiding Principles or address the outstanding issues and concerns of India. However, India re-iterated that the Act East Policy has been the bedrock of India's economic policy and that India's engagement with the ASEAN countries and other trading partners would continue. There has been no change in India's position since then.

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

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PRESS RELEASE

Technology Transfer Association at ACHEMA 2022

Dear Member,

IDMA have received the communication from Mr.Y.H. Gharpure, President, Technology Transfer Association dated 27th July 2022 as reproduced below:

As you may be aware, I am the Founder President of Technology Transfer Association (TTA). ACHEMA 2022 is taking place at Frankfurt from 22nd to 26th of August and TTA has a Stand B15 in Hall No.3.1. We have been participated in ACHEMA for more than 2 decades regularly. It is held every 3 years and we participated in last ACHEMA held in 2018. Due to COVID, Achema is taking place after 4 years and there is a big rush. There are around 4500 stands including around 200 from India. Large number of Indian delegates visit ACHEMA. Our stand is made available to members for use at fraction of the cost of direct participation one would have to pay if one has to take separate stand. To avail the TTA Stand we have made a small press release and shall be grateful if the same is published in ensuing IDMA bulletin so that IDMA members can take advantage.

Technology Transfer Association at ACHEMA 2022

TTA members and others by becoming member can use the stand to display their brochure, display their posters , display small machines, have running electronic display and most importantly use the stand for meetings to take full advantage of this premier event for chemical process industry being held after a gap of 4 years. Normally, there are large number of Indian stands and visitors list is much much larger. Apparently, due to Covid as also problems in Getting Visa, higher fares etc, many who wanted to attend ACHEMA are unable to do so. Technology Transfer Association not only has a stand in ACHEMA but our representative can also help delegates who could not attend, send us your requirement, be it for equipment or technology or any other requirement on following email ID / mobile - technologytransfer0@gmail.com / 98200 26265

TTA will try to help

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ICMR's move to develop centres for phase-I clinical trial augurs well for pharma industry

The setting up of clinical trial centres across India will improve therapeutic regimens and ensure advancement in medical practice that is evidence based

ICMR's move to develop centres for phase-I clinical trial augurs well for pharma industry

The Indian Council of Medical Research (ICMR), the apex body in India for the formulation, coordination and promotion of biomedical research, will soon develop centres across the country for phase I clinical trials consisting of medical institutes across the country. The setting up of these centres will definitely improve therapeutic regimens and ensure advancement in medical practice that is evidence based. These clinical trial centres, for which the ICMR will provide technical, financial, and administrative support, will function as standalone facilities capable of effectively executing phase I clinical trials of the highest quality.

Last year, the ICMR had notified medical institutes selected for participation in the Indian Clinical Trial & Education Network (INTENT). The institutes were selected under Advanced Centre for Clinical Trial (ACCT), Regional Clinical Trial Unit (RCTU), ICMR-Centre for Clinical Trial (ICCT), Specialty Centre for Clinical Trial (SCCT) and Knowledge Partner for Clinical Trial (KPCT). For setting up the centres for phase-I clinical trial, ICMR will soon sign memorandum of understanding (MoU) with government and private medical colleges and universities to identify and evaluate investigational products and lead molecules through these centres for phase I clinical trials.

Setting up of country-wide centres for phase-I clinical trial by ICMR augurs well for the pharmaceutical industry in the country as phase-I studies of a new drug are usually the first that involve human beings. Phase-1 clinical trials typically focus on healthy participants in order to first determine whether medicines and vaccines are safe for use in patients and whether there are any side effects. The phase I study usually has 10 to 30 volunteers. Phase I studies are done to find the highest dose of the new treatment that can be given safely without causing severe side effects. The toxicity data (adverse effects) derived from these studies is used to characterize the safety profile of the new medicinal product.

ICMR has already sought expression of intent from medical institutions with the necessary facilities and capacity available to participate as its centres for phase-I clinical trials, which will enroll appropriate participants to successfully execute these trials. The medical institutes which have been selected as Advanced Centre for Clinical Trial (ACCT) include All India Institute of Medical Sciences, New Delhi; Post Graduate Institute of Medical Sciences and Education, Chandigarh; SMS Medical College and Attached Hospitals, Jaipur; Mahatma Gandhi Institute of Medical Sciences, Sevagram, Maharashtra; ICMR- National AIDS Research Institute (NARI), Pune; All India Institute of Medical Sciences, Bhubaneswar; ICMR- National Institute of Cholera and Enteric Diseases (NICED), Kolkata; North Eastern Indira Gandhi Regional Institute of Health and Medical Sciences (NEIGRIHMS), Shillong; King George Medical University, Lucknow; Jawaharlal Institute of Medical Education & Research (JIPMER), Puducherry; St Johns Medical College, Bengaluru; and Amrita Institute of Medical Sciences, Kochi. The George Institute of Public Health, Hyderabad, Telangana, Centre for Chronic Disease Control (CCDC), New Delhi and Centre for Public Health Kinetics, New Delhi have been selected as Knowledge Partners for Clinical Trials. All India Institute of Medical Sciences, Rishikesh, Uttarakhand, ICMR-National Institute For Research In Reproductive and Child Health, Mumbai (Dahanu), Maharashtra, ICMR-Regional Medical Research Centre, Bhubaneswar (Tigria), Odisha, Rajendra Institute of Medical Sciences, Ranchi, Jharkhand, Silchar Medical College & Hospital, Silchar, Assam and Gandhi Medical College, Secunderabad, Telangana have been selected as Regional Clinical Trial Unit.

This is not the first time the ICMR is setting up country-wide network of centres as it will soon establish hospital-based sexually transmitted infections (STIs) surveillance network across the country. This hospital-

based STIs surveillance network will study the frequency, clinical laboratory features, antimicrobial resistance (AMR) patterns and treatment outcome related to STIs in the Indian population. It will utilize the data to answer the research questions on STIs including disease spectrum, prognostic factors, risk factors, treatments, health systems, and current AMR patterns. Besides, it will serve as a platform for additional clinical research and advanced AI-based studies in selected sites as well as collect follow up data of the patients.

The network will provide prospective data collection from the dedicated hospitals and clinics in centres among six regions of the country - East, West, North, South, Central, and North East. The ICMR's initiative in this regard is of great significance as even though the STI cases are widely evidenced in India, systematic epidemiological studies to determine their exact prevalence are yet not available in the country. Under this background, the proposed STI surveillance network will go a long way in collecting data on clinical signs and symptoms of STIs and document the patterns of various etiologies of STIs, analyse the trends, and monitor AMR patterns among identified STIs in the country. All these efforts of the ICMR augur well for the pharmaceutical industry in the country. (The author is freelance journalist with varied experience in different fields)

Source: Sreeja Ramesh, Bizz Buzz, 26.07.2022

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Govt launches 3 schemes to strengthen MSMEs in pharmaceutical sector

The government on Thursday launched three schemes to strengthen Micro, Small and Medium Enterprises (MSMEs) in the pharmaceutical sector.

The Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS) would facilitate pharmaceutical MSMEs with proven track record to upgrade their technology

The government on Thursday launched three schemes to strengthen Micro, Small and Medium Enterprises (MSMEs) in the pharmaceutical sector.

Union minister Mansukh Mandaviya noted that the schemes envisage technology upgradation, setting up of common research centres and effluent treatment plants in clusters for the pharma MSMEs.

Small companies should be able to upgrade their facilities to global manufacturing standards, he said.

The chemicals and fertilisers ministry rolled out the schemes under the banner of 'Strengthening Pharmaceuticals Industry' (SPI).

"I believe the pharma MSME industry will greatly benefit from the schemes. The new schemes have many benefits that will go a long way in making the Indian pharmaceutical industry, Atma Nirbhar, more resilient and future-ready," Mandaviya, who heads both health as well as chemical and fertilisers ministries, said.

The schemes provide for credit linked capital and interest subsidy for technology upgradation of MSME units in pharmaceutical sector, as well as support of up to Rs 20 crore each for common facilities, including research centre, testing labs and ETPs, in pharma clusters.

SIDBI will be the project management consultant for implementing the scheme.

The Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS) would facilitate pharmaceutical MSMEs with proven track record to upgrade their technology.

The scheme has provisions for a capital subsidy of 10 per cent on loans up to a maximum limit of Rs 10 crore with a minimum repayment period of three years or interest subvention of up to 5 per cent (6 per cent in case of units owned by SC/ST) on reducing balance basis.

Similarly, Assistance to Pharma Industries for Common Facilities Scheme (API-CF) would strengthen the existing pharmaceutical clusters' capacity for sustained growth. It provides for an assistance of up to 70 per cent of the approved project cost or Rs 20 crore, whichever is less.

In case of Himalayan and north-east region, the grant-in-aid would be Rs 20 crore per cluster or 90 per cent of the project cost, whichever is less.

Pharmaceutical and Medical Devices Promotion and Development Scheme (PMPDS) would involve preparation of study reports on topics of importance for the Indian pharma and medical device industry.

The scheme is aimed at creating a database of pharma and medical device sectors. Mandaviya asked the industry to keep upgrading in order to cater to evolving requirements across global markets.

He stressed the importance of moving to 'value from volume'.

The minister also highlighted the various initiatives of the government towards the MSME sector and informed that 40 per cent of selected participants under the production-linked incentive scheme for pharmaceuticals belonged to the MSME category.

Mandaviya also emphasised the importance of demand-based research as the need of the hour and encouraged greater linkage of industry with academia.

He noted that the Prime Minister Narendra Modi-led government is working relentlessly towards strengthening the pharma industry.

"It (schemes) will increase investment, encourage research and innovation and enable the industry to develop futuristic products and ideas," the minister said, adding that the government is working to enhance ease of doing business and also reduce compliances to help the industry grow at a rapid pace.

(Only the headline and picture of this report may have been reworked by the Business Standard staff; the rest of the content is auto-generated from a syndicated feed.)

Source: Business Standard, 22.07.2022

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A Law Whose Date Has Expired



Dinesh Thakur & Prashant Reddy T

Earlier this month, the health ministry unveiled a new Bill to replace the Drugs and Cosmetics Act, 1940. The new Bill does nothing to replace existing regulatory structures with a modern legal structure required to regulate an increasingly complex pharmaceutical and medical device industry while protecting public health and patient rights.

Who should staff the new regulator? A parliamentary standing committee on health and family welfare first raised concerns about the people staffing India's drug regulator, the Central Drug Standard Control Organisation (CDSCO). It is run by a bureaucracy qualified mainly in pharmacy. Other drug regulators in developed countries are staffed with multi-disciplinary teams of professionals typically led by a doctor with experience in public health.

India is yet to move away from understanding drug regulation as purely a manufacturing issue to a public health one. Technically, the qualification criteria in the Drugs and Cosmetics Rules, 1945, for both entry level positions as drug inspectors and the top position of Drug Controller General of India (DCGI) allows for doctors to be appointed to these posts. However, that criterion is accompanied by a requirement to have 3 and 5 years of experience respectively in the manufacture or testing of drugs.

While doctors are employed by pharmaceutical companies, they are seldom involved in manufacture and laboratory testing of drugs, their role being in clinical research. This absurd qualification criterion continues despite a GoI expert committee agreeing with the parliamentary committee. At the state level, the situation is worse. In Telangana, the state drug controller has historically been an Indian Police Service (IPS) officer as the state views drug regulation as a `law and order' issue. In Andhra Pradesh, an officer from the Indian Revenue Service (IRS) dedicated to collecting taxes was once appointed as the state drug controller.

The new Bill does nothing to correct this situation. Instead, it delegates the power to state governments and GoI to decide the qualification criteria for their respective drug control officers. This is unlike the existing law where GoI laid down the qualification criteria for drug inspectors and licensing authorities across the country. The ministry must consider providing for the qualification criteria in the text of the Bill and ensure that a modern regulator is staffed with specialists from pharmacology, medicine, chemistry, and the biology regulatory sciences.

Creating an independent regulator: TheBill does nothing to upgrade the archaic status of CDSCO. In the pre-1990s, regulators did not have an independent legal existence. They fell within GoI's remit. This essentially meant:

- Regulators would be bound by all the cumbersome GoI rules ranging from recruitment to financial powers.
    - They would not have any 'rule-making' powers. All requests to create or amend rules would be made to the secretary of the ministry, generally an IAS officer who may or may not have expertise on the topic.
    - Regulators could be overruled by the ministry exercising oversight on certain issues. For example, the Drugs and Cosmetics Rules clearly provide for an appeal against the decision of drug

controllers to the central or state government, thereby allowing the minister acting on the advice of a non-specialist bureaucrat to overrule specialists making regulatory decisions.

Post-liberalisation, a new regulatory model was put in place with the creation of regulators like the Securities and Exchange Board of India (Sebi), Telecom Regulatory Authority of India (Trai), etc. Each of these regulators were 'independent,' not in the sense of judicial independence, but in that they were created with their own corporate existence separate from GoI.

This meant that although they were still answerable to a ministry and an elected minister, they could create their own recruitment and financial rules, allowing them the flexibility to operate with less red tape and hire better talent laterally from the private sector. More significantly, they were also given a limited degree of rule-making power so that they could respond to situations on the ground more rapidly.

The new Bill misses the bus on this issue, despite a 2013 legislation that was never voted upon in Parliament actually having proposed this model for a new drug regulator. As of today, CDSCO is an attached office to the Directorate General of Health Service (DGHS), itself a department of the health ministry answerable to the secretary. Simply put, CDSCO and DCGI who heads it are far away from the centre of power.

GoI also has a 'drug regulation section' under a joint secretary in charge of the rule-making powers under the Drugs and Cosmetics Act, 1940. It has the power to 'prohibit' drugs despite not really having any role in drug approvals. That the health ministry wants to continue with this outdated structure reflects poorly on the committee responsible for drafting this new law.

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