ISSUE No. 56

SILVER JUBILEE YEAR 2016

TAMILNADU PHARMACEUTICALS SCIENCES WELFARE TRUST

25 Years

Pharma Web

Newsletter of Tamilnadu Pharmaceutical Sciences Welfare Trust

Oct. - Nov. - Dec. 2022

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R & D and Manufacturing of Formulations

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Tamilnadu Pharmaceutical Sciences Welfare Trust

Pharma Web

Newsletter of Tamilnadu Pharmaceutical Sciences Welfare Trust

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TAMILNADU PHARMACEUTICAL SCIENCES WELFARE TRUST
No. 608A, 6th Floor, Phase I, Spencer Plaza, 768 / 769, Anna Salai, Chennai – 600002
Ph: 044 - 28491232
e-mail : pictrust@hotmail.com Website : www.pictrust.com

EDITORIAL

Dear Readers,

We are happy to publish the 56th issue of Pharma Web Newsletter for **Oct – Dec 2022**.

This 56th issue contains the program highlights as well as the following article published by eminent person in Pharma industry.

- **Laboratory Investigation, Compliance and Productivity**
  Dr. Subhash Pande, Principal Advisor – Pharmaceutical Regulatory Compliance (API & Dosage Form) & Skill Development, Ahmadabad.

We have also published the various Gazette Notifications pertaining to the amendment of Drugs & Cosmetics Act & Rules, important circulars issued by DCGI pertaining to Drugs & Pharmaceuticals.

Important news items connected to our Pharmacy profession appeared in various national news papers are published in this issue and also published the events of 61st national Pharmacy Week.

We are very much thankful to M/s. Delvin Formulations, M/s. Medopharm, M/s. Tablets (India) Ltd., for the continuous support by giving advertisement, in order to sustain the cost of publishing of this newsletter.

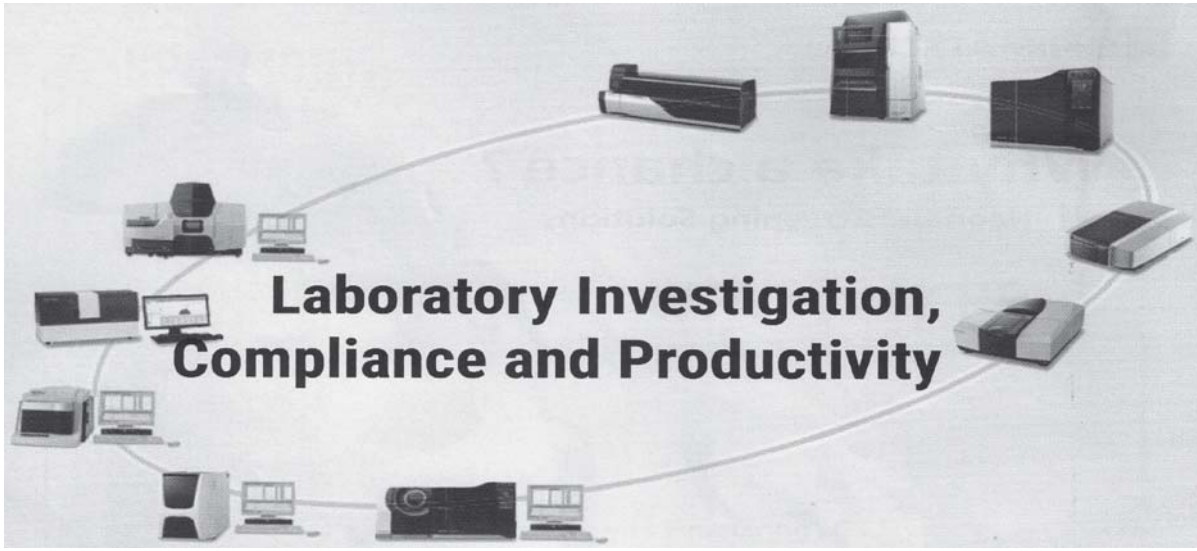
Our special thanks to M/s. Fourrts (India) Laboratories Pvt. Ltd., for supporting Pharma Web advertisement and also awarding meritorious award for B. Pharm Students of The Tamilnadu Dr. MGR Medical University, Guindy, Chennai.

Hope this Newsletter will benefit our Pharma professionals. Any suggestions to improve our news letter are welcome.

With Best Regards,

R. NARAYANASWAMY

Chief Editor



Manufacturing industries especially pharmaceutical units [API and Dosage form, both] are deeply focused on implementing cGMP practices for total regulatory compliance while striving to keep productivity levels high to meet market requirements, maintain quality and prevent complaints from the market. Regulatory inspections on such facilities covering quality assurance, quality control, manufacturing, data management etc., have enabled continuous improvement resulting in more safer products and systems.

Quite a number of 483s, warning letters, critical non conforming observations are pertaining to inconclusive or below standard investigation, without supporting date, logic or science based justifications for drawing conclusion.

Pharmaceutical industries have invested in automation or have taken initiative in their laboratories and also in manufacturing areas backed up with audit trail functions. With continuously evolving requirements and customization of software platforms to facilitate ease of working, there can be issues regarding traceability of the data, which regulators want to establish during audits. The key to success is planning, training, manpower extensively, providing adequate resources, periodic calibration, regular upgradation of instrumentation software/routine maintenance through AMC, documenting testing procedures along with critical steps and precautions etc.

Dr. Subhash Pande
Principal Advisor-Pharmaceutical Regulatory Compliance [API and Dosage forms] & Skill Development
Ahmedabad

Despite many steps being taken, still a number of events such as laboratory incidents, OOT, OOS, OOC are reported recurrently which are serious contributors to low productivity besides impacting product quality. Further, inadequate investigations of the events in laboratory lead to non-conformances and violations as per cGMP norms. Therefore, understanding the importance of investigation is a must and has to be practiced diligently.

What is meant by Laboratory Event?
An occurrence of incidents or even that interrupts normal procedure, which happens unexpectedly, Laboratory incidents may occur during handling sample, testing, data recording, data are review, batch release and /or after the batch approval/release. A laboratory incident shall be categorized as Non-Quality Impacting Laboratory Incidents and Quality Impacting Laboratory Incidents.

- Non-Quality impacting laboratory incident: any incident, which occurred before the analysis of test sample, is considered non-quality impacting.
- Quality Impacting Laboratory Incident: any incident, Which occurred during and/or after analysis of test sample, is considered quality impacting.

What Investigation should encompass?
A documented analysis conducted to determine the risk, root cause(s) impact assessment and corrective and preventive actions of a potential or existing non-conformity or trend.

Re-sampling
A new sample or specimen taken from original container(s) that represent originally submitted laboratory sample.

Additional sampling
Additional sampling involved sampling of additional units/quantities of same batch/lot as per approved sampling procedure.

Immediate action
An action taken to eliminate a detected non-conformity and / or a hold action to prevent further impact until investigation is completed.

Corrective Action
Action to eliminate the cause of the detected non-conformity or other undesirable situation.

Preventive Action
Action taken to eliminate the cause of the potential non-conformity or other undesirable potential situation.

CFT (Cross Functional Team)
A cross function team is a group of people that provide insight on investigations and evaluate possible impact with respect to observed discrepancy.

Out of Specification
Test results that fall outside the established approved specification limit.

Out of Trend
A result which is within the pre-defined limit (Specification Limit), but is found to be not fitting the normal distribution of results, once an appropriate amount of data has been generated. Any atypical/aberrant/anomalous result that does not fall in the purview of OOS result shall be considered as OOT.

Out of Calibration
Out-of-calibration result represents data that does not meet approved acceptance criteria.

Deviation
An unplanned/planned departure from an approved process, procedure, or established standard.

Analyst Error
An error attributable to the person performing the test such as sample or standard preparation error, calculation error, use of expired standards or reagents, incorrect settings of instrument parameters etc.

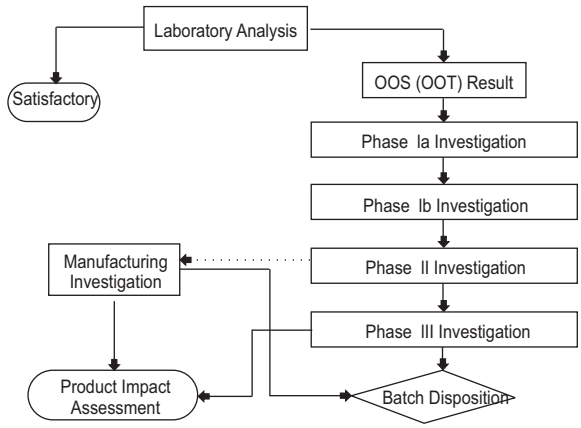
Instrument Related Error
An error which may arise due to malfunctioning or instrument or software.

Obvious error
An error that is identified readily as to be cause of procedural abnormality and can be considered to invalidate the original results.

Impact
Any non-conforming condition that has the potential to impact SISPPQ of an affected item i.e., product, raw material or component.

- Vertical impact assessment: Impact assessment to evaluate the impact of non-conformity on the same lot/process/equipment/system/area.
- Horizontal impact assessment: Impact assessment to evaluate the impact of non-conformity on the other lots of same product or other similar processes / equipment / system/area to avoid the same non-conformity in future by extending the scope of investigation.

Root cause
The underlying reason for the non-conformance, which is confirmed by evidence of a known sequence of events and observations.



Most Probable Cause
A most likely root cause that cannot be established as evident, but is adequately and substantially supported by data gathered and efforts demonstrated during the investigation with the application of scientific and logical approaches.

Major factors for laboratory non-compliance are ineffective handling of Laboratory Incidents, OOT, OOS results, shallow investigation, following shortcuts, inadequate maintenance of laboratory instruments and calibration. Laboratory testing, calibration of

equipment/instruments or any other activities are required to be performed in the laboratory strictly as per applicable procedures.

For example, an incident focusing on 'Investigation for Extraneous Peak, manual integration, deviation from STPs etc., is a good point for discussion here.

Lab Analyst/ Individual who discovered the incident
Should report the incidents to the supervisor after its discovery. Retain all the glassware used for analysis until results are reported and found to be satisfactory participate in the investigation, experimental analysis and/or repeat testing, as applicable.

Originator
Should log an even required details and submit the record with relevant details.

- plant name[In case of multiple facilities]
- Originating department.
- Section [Raw/packing/Finished Product/Stability/GLP]
- Description of the event [OOS/OOT/Lab Incident/Deviation]
- Analyst involved
- Investigation Assigned to with expected date of completion.

Review all relevant data. Record pertinent information of incident and submit to HOD for further Investigation & Review. Categorize the Laboratory incident.

Initiate immediate action, hold on the instruments/documents or any other items i.e. batch/material as required.

Participate in the experimental and investigational analysis, wherever needed.

Propose cancellation of Lab event record with scientific, logical justification.

Supervisor/ Investigator
Initiate review for adequacy and completeness of information regarding incident and perform investigation for identification of root cause reported incident.

Plan hypothesis study/experimental study to indentify root cause, or plan repeat testing, as required.

Initiate the re-sampling/additional sampling if sample collection and its stability is in question.

Perform impact assessment / risk assessment and propose corrective and preventive actions based on identified root cause.

Initiate Extension request, if further investigation is needed and cause and could not be ascertained.

If required a CFT (Cross Functional Team) may be constituted to take support for finding the cause.

Any laboratory incident/event reported during analysis or review should be investigated sequentially, thoroughly, timely in an unbiased manner with science-based approach with logic behind to identify the root cause and should be documented along with conclusion, immediate action/correction, corrective action and preventive action. There shall be no preconceived assumptions as cause of the reported event.

QMS number of observed incidents shall be generated immediately for the purpose of tracking.

Batch release shall be executed after ensuring closure of laboratory event. If investigation shows root cause is not impacting for the product quality, in such cases batches can be released and incident shall be closed after implementation of CAPA as proposed post investigation.

The examples for the different types of incidents (but not limited to) are Date of occurrence.

Quality Assurance shall verify the justification for cancellation thoroughly and if found satisfactory, approve the cancellation request and / or request more information.

In order to track the whole incident, a tracker should be maintained.

a) Date discovered
b) Serial number
c) Test parameter
d) Description of the event
e) Quality impacting incident (Yes/No)
f)Product / material related information
g) Product distributed in the countries
h) Analyst information / Investigator
I) Short description of the investigation
j) Instrument information, if applicable
k) Cause identifies
l) CAPA proposed
m)Date of completion of CAPA implementation
n) Whether CAPA was adequate

Non-Quality impacting laboratory incident

Any incident, which occurred before analysis of test sample, is considered non-quality quality impacting.

Quality impacting laboratory incident

Any incident, which occurred during and/or after analysis of test sample, is considered quality impacting.

Immediate Actions Examples

Hold of instrument / equipment, test procedure, glassware used, release of affected and impacted batches, testing of other test parameters of affected and impacted batches, relevant documents etc., on the immediate evaluation of the observed discrepancy.

a) In case observed incident are not associated with product/material then assigned to personnel shall select 'No' under field of 'Product / material information required?'.

Laboratory Investigation

In case of Non-Quality Impacting laboratory incident, evaluate the data along with the preliminary investigation. The cause of Non-Quality impacting laboratory incident shall be reported based on the findings and an appropriate action plan with suitable corrective actions shall be documented under them field of “investigation”. Analyst shall stamp affected / invalid chromatogram / Documents / Spectra / Histogram / Weight Print etc., as 'DISREGARDED' and mention the reason for disregard (citing incident no.), supporting documents i.e. analyst interview, investigation attachments etc.

Disregarded documents should be preserved for future reference. All results impacted of incident shall be reviewed and if found OOS/OOT or OOC, it shall be handled through OOS, OOT, OOC policies.

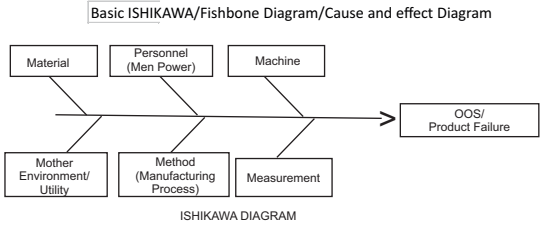
Preliminary investigation by evaluating below mentioned parameters (but not limited to) to identify assignable cause if any:

a) Instrument calibration
b) Standard used
c) Glassware
d) Analyst qualification
e) Chemical and reagent
f) System suitability
g) Test procedure
h) Calculation
I) Re-measurement of originally prepared solution, if required i.e., Re-injection, Re-Vialing, Re-dilution, Re-Sonication, Re-filters etc.
j) Analyst interview
k) Audit trails etc.

If assignable cause is identified from preliminary investigation, then investigation with applicable correction shall be submitted to QA for review. If cause is not identified from the preliminary investigation, then perform the following investigation but not limited to:

- Review previous laboratory events with the reported event for correlating error by same analyst / instrument / method / technique assisting investigation and trending.

- For stability samples, data from previous/similar intervals of same batch / other batch of the same product should be reviewed.



- Appropriate investigation tools like: Cause and Effect analysis (i.e. 6 M/ ISHIKAWA)/ 5 Whys may be employed to identify the cause.

5 Whys method is to determine a root cause of a defect or problem by repeating the question 'Why?' Each question forms the basis of the next question. Keep asking 'Why' till you reach root cause.

A hypothesis / experimental study may be planned to achieve the objective to identify the cause. Any hypothesis / experiment study requires prior approval for QA before its execution.

A request re sampling and additional sampling in case it is established that sample collection was faulty or sample has not been stable under given condition or exhausted.

QA head shall approve request of resampling / additional sample.

QA shall verify the correctness and completeness of submitted data and shall propose.

Cross Functional team assessment for evaluation of impact by this incident if any.

Root Cause Analysis / Action Item / CAPA

Upon completion of investigation, review following information under the state of root cause analysis / Action item / CAPA determination.

- Root cause identified – Yes / No
- Nature of Root cause and its category
- Justification if root cause not identified
- Impact assessment and specific impacted area (if any)
- Incident summary
- Action item required (Yes / No)
- CAPA plan CAPA description with target date of implementation.

Root cause
Identified root cause / Probable Cause should be documented and justified with scientific rational.

CAPA
For each identified root cause or most probable root cause, a CAPA are proposed

Impact Assessment
An impact evaluation shall be performed with respect to identified root cause / most probable root cause. Impact assessment should be both vertical and horizontal . it should be based on investigation findings. The impact assessment be done with respect to following: (but not limited to)

- containment of affected batches, impact of material lots, impact on preceding and succeeding batches (including compaign manufacturing)
- Impact on similar products(product group of other strength/market) and other products.
- Impact on regulatory / customer impact on vendor / supplier
- Impact on the batches which are under manufacturing at shop floor
- impact on market batches; impact on product / batch stability
- Impact on area/instruments
- Impact on validation status of applicable product, process, equipment, facility, method or system.
- Impact of quality system
- Impact on continued manufacturing of the product.

Conclusions
As regulations keep increasing and challenges confront teams responsible for manufacturing, quality pharmaceutical products, the supporting system and practices also need to continuously evolve so as to stay on course towards achieving the desired goals. Still many think that the following GMP norms and quality work culture reduces productivity, however it is other way round. A quality based mindset and routine quality work hobbits maximize the productivity with compliance many folds. Thus a culture of high quality and total compliance has to cascade across the entire organization. Human error reported as cause (easiest one) catches the attention of regulators, therefore further investigation needs to be conducted to understand why such error(s) have happened. All efforts should be made to determine the cause of an event. Even if the non-conformance has been traced a human error during analysis, the basic reason for such an error should be determined and trended to take effective steps to avoid such errors. CAPA should be implemented to in order to prevent repetition of the same or similar nature of non-conformance.

Keeping laboratory events minimum and ensuring a system for adequate investigation followed by effective CAPA is the way to achieving higher levels of compliance and productivity this affiliation should be followed in letter and spirit across the entire chain of functions in a pharmaceutical unit for success.

Some suggestions to achieve objectives

- Good development of Analytical Methods with identification of CPPs and CQAs
- Defining critical steps in the method/STPs and understanding of the specifications along with impact of the parameters and limits.
- Acquaintance of manufacturing process and critical manufacturing steps.
- Demonstration of the method in the receiving laboratory.
- Selecting good technical hands for critical analysis to achieve consistent performance.
- Continuous emphasis on skill development.
- Maintaining the instruments and calibrate the same as per defined frequency
- Keeping adequate inventory of spare parts.
- Minimum customization of software.
- Recurrent discussions with the doers to understand their practical issues and acting upon.
- Thoughtful and considerate handling for human errors, If found as possible reason for the noncompliance.
- Tracking and tracking productivity, noncompliance and quality of investigation (with cause identification) using statistical tools for addressing emerging trend on priority.
- Tracking CAPA effectiveness, post investigations.

Abbreviations

QC : Quality control

QA : Quality Assurance

OOS : Out of Specification

OOT : Out of Trend

OOC : Out of Calibration

CAPA : Corrective Action and Preventive Action

SISPQ : Safety, Identity, Strength, Purity and Quality

HOD : Head of Department

SOP : Standard Operating procedure

References:

US FDA and MHRA guidelines

Dr. Subhash Pande is a Ph.D (Pharmaceutics) and has about 32 years of experience in research, manufacturing of sterile oral solids, semisolids lyophilized Injections, DPIs and nasal sprays, biosimilars, pre-filled syringes, animal health care products, sterile and non-sterile APIs, quality control and quality assurance. He has served many pharmaceutical companies such as Cynamid India, Lupin, Glenmark Pharmaceuticals, Cadila Health Care (Zydus) and currently is principal advisor for new projects, quality management system, productivity enhancement, skill development, harmonization, regulatory inspections, gap assessment and is serving national and international consulting agencies. He has many years of exposure to audits by USFDA MHRA / EU GMP, ANVISA, ANVIMA, WHO, various other agencies including PIC/S and trained a large number of professionals in the pharmaceutical industry.

INFORMATION

G. Rangachari Memorial (PG Pharmacy Fellowship) Awards 2022

TNPSWT, a subsidiary of IPA (Tamilnadu Branch) started in 1989 and has been doing service to profession of Pharmacy in assisting the students as well as the industry. We have a small library and also provide abstracts and text articles to under graduate and post graduate students and help IPA Tamilnadu Branch for conducting seminars, conferences etc.

Apart from above, from year 1998, we initiated Research fellowship award to selected M.Pharm and latter Pharm D (2013) final year students from various colleges in Tamilnadu, for their ongoing project work. We receive applications on synopsesfor projectfrom students, codify the synopses and sent to an evaluator outside the state of Tamilnadu for evaluation. Based on the report we make cash awards for the first, second and third ranks.

This is 25th year of this project, we have received 290 (242+48) applications from 6 different branches of M. Pharm & Pharma D

This year we have received applications from 22 institutions. All synopses were sent to **Prof. Shailendra Saraf, Director- UGC-HRDC, Pt. Ravishankar Shukla University, Raipur 492010, Chhattisgarh** & his team for evaluation. Based on the ranking, 21 students have been selected for Awards as per the following details:

PHARMACEUTICS

Rank	Name	College	Prize Amount (Rs.)
I	Mr. Anuj Kumar Singh	JSS College of Pharmacy, Ooty	12,000
II	Ms. K. Priyadharshini	PSG College of Pharmacy, Coimbatore	10,000
III	Mr. A.M. Aswin Kumar	College of Pharmacy, Madras Medical College, Chennai	8,000

PHARMACEUTICAL CHEMISTRY

Rank	Name	College	Prize Amount (Rs.)
I	Ms. Jinu Mathew	JSS College of Pharmacy, Ooty	12,000
II	Ms. Ahamed Nisha. K	College of Pharmacy, Madras Medical College, Chennai	10,000
III	Mr. B. Jeeva	College of Pharmacy, Madras Medical College, Chennai	8,000

PHARMACEUTICAL ANALYSIS

Rank	Name	College	Prize Amount (Rs.)
I	Mr. Vignesh. S	KMCH College of Pharmacy, Coimbatore	12,000
II	Ms. Suriyapriya. K	KMCH College of Pharmacy, Coimbatore	10,000
III	Mr. Velmurugan. M	KMCH College of Pharmacy, Coimbatore	8,000

PHARMACOLOGY

Rank	Name	College	Prize Amount (Rs.)
I	Mr. Chandrasekar V	KMCH College of Pharmacy, Coimbatore	12,000
II	Mr. Mohankumar. R	College of Pharmacy, Madras Medical College, Chennai	10,000
III	Mr. Vinoth Kumar. R	KMCH College of Pharmacy, Coimbatore	8,000

PHARMACOGNOSY

Rank	Name	College	Prize Amount (Rs.)
I	Mr. R. Padmanaban	Mother Theresa Post Graduate and Research Institute of Health Sciences, Puducherry	12,000
II	Ms. S. Kirubavathi	College of Pharmacy, Madras Medical College, Chennai	10,000
III	Ms. K. Hamsaveni	College of Pharmacy, Madras Medical College, Chennai	8,000

PHARMACY PRACTICE

Rank	Name	College	Prize Amount (Rs.)
I	Ms. Yuvashri. K	KMCH College of Pharmacy, Coimbatore	12,000
II	Mr. Manikandan S	SRM College of Pharmacy, Chennai	10,000
III	Mr. U. Poli Reddy	SRM College of Pharmacy, Chennai	8,000

PHARM D

Rank	Name	College	Prize Amount (Rs.)
I	Mr. K. G. Sandeep, Mr. G. Ramanaprasanth, Ms. S. Tanushree	PSG College of Pharmacy, Coimbatore	15,000
II	Mr. Lokeshwaran. S, Ms. Saranya. S	College of Pharmacy, Sri Ramakrishna Institute of Paramedical Sciences, Coimbatore	12,000
III	Mr. S. Mukesh, Mr. B.T. UdhayaMoorthi, Mr. S.Vignesh, Mr.V. Siva Shankar	Vels Institute of Science, Technology and Advanced Studies, Chennai	10,000

Shri. G. Swaminthan Memorial Award - Essay Competition 2022 – Final Year B. Pharm Students

TNPSWT imitated a new activity from 2011 for Essay competition and this year subject being **"Pharmacy-Pharmacists: Always trusted for your Health".** This awarded is in the name of **"Shri. G. Swaminthan Memorial Award"** -- Sponsored by M/s. Pharm Product Pvt Ltd. Thanjavur.

This year we have received 81 applications from 19 colleges and this was evaluated by **Dr. B. Mahendran,** JSS College of Pharmacy, SS Nagar, Mysuru – 570015.

Based on the rating -- 3 students have been awarded as below

Rank	Name	College	Prize Amount (Rs.)
I	Ms. Nihala. M	SwamyVivekanandha College of Pharmacy, Tiruchengode	10,000/-
II	Ms. Pushmitha. M	Periyar College of Pharmaceutical Sciences, Tiruchirappalli	8,000/-
III	Ms. Keerthana. S	Saveetha College of Pharmacy, Chennai	7,000/-

We thank **Mr. T. Ravichandran M/s. Pharma Products Pvt Ltd**, Thanjavur for the above awards.

Fourrts (University) Merit Award 2021

From year 2015 M/s. Fourrts India ltd sponsored university merit award for topper candidates, who have secured high marks in B.Pharm examinations. passed during September 2021, examinations held in January 2022 of The Tamilnadu Dr. MGR Medical University, Guindy, Chennai

Rank	Name	College	Prize Amount (Rs.)
I	Mr. Karthikeyan. S	Sri Vijay Vidyalaya College of Pharmacy, Dharmapuri	10,000/-
II	Ms. Rupa. M	Senghundar College of Pharmacy, Tiruchengode	8,000/-
III	Ms. Anitha V	K.M. College of Pharmacy, Madurai	7,000/-

We thank to **Mr. S. V. Veerramnai,** Chairman & Managing Director,
M/s. Fourrts (India)LaboratoriesPvt Ltd, Chennai, for the above awards

EVENTS

61stNational Pharmacy Week (NPW) Celebration 2022

The 61st National Pharmacy Week (NPW) was celebrated from 20th to 26th November 2022

The theme selected for this year is: “Pharmacy of the World - India”.

The various activities carried out by various Associations, Pharmacy Colleges are highlighted.

Public Awareness / Rally by IPA TNSB & IPA Local Branches

As a part of National Pharmacy Week Celebrations, this year conducted the different activity, Public awareness Rally in various places of Tamilnadu are, Chennai, Coimbatore, Ooty, Salem, Komarapalyaam & Thanjavur.

Rally in Chennai

NPW Celebration by IPGA TN

IPGA, TN organized the various programs on the event of 61st National Pharmacy Week Celebration.

Issued the pamphlets about safe use of medicines, to the public and pharmacist in various places of Tamilndu.

Conducted the Blood Donation camp in Madras Medical College, Chennai and Dharmapuri.

Issue of Pamphlets to the public

Blood Donation Camp, MMC, Chennai

61st National Pharmacy Week Celebration function was organised on 26th November 2022 at 9.00 AM at Madras Medical college, Chennai. **Tmt. P. V. Vijayalakshi**, Director of Drugs Control, Tamilnadu Chief Guest of the function. The gust of Honors were Dr. B. Kumar, DDC, CDSCO, South Zone, Chennai, Mr. S. Ramkumar, MD, M/s. MM Pharma Group of Companies, and Mr. Udan Kumar Chordia, CEO, M/s. Medopharm. Dr. G. Selvarj, President, IPGA, TN welcomed the gathering. Mr. S. V. Veerramani, CMD, M/s. Fourrts India labs Pvt, Chennai, Vice-Chairman, Pharmexcil, was gave the key note address on the theme of **"Pharmacy of the World- India**"

During the event, the following pharmacists were awarded for their excellent contribution in the various divisions of Pharmacy such as Academic, Regulatory, Industry, Hospital and Community Pharmacy.

1) Mr. P. Ponrajan, Chairman of M/s Pharmafabrikon, Madurai was awarded for his excellence in setting up of Pharma Industry as a Pharmacy graduate.

2) Prof. V. Sankar , PSG College of Pharmacy , Coimbatore was awarded for best teacher.

3) Mrs R. Kalai Selvi, Drugs inspector, Govt of Tamilnadu for her excellence service in drug regulation.

4) Best meritorious rank in study by Ms. Charulatha, Sri Ramachandra Pharmacy College of Pharmacy, Porur, Chennai, tion camp in Madras Medical College, Chennai and Dharmapuri.

National Pharmacy Week Celebration – Valedictory by IPA TNSB

61stNational Pharmacy Week Celebration valedictory function was organised on 20th December 2022 at 3.00 PM at **IIT Madras Research Park,** Tharamani, Chennai. **Dr. Krishna M. Ella,** Founder and Chairman, M/s. Bharath Biotech Ltd, Hyderabad, Chief Guest of the function. The Guest of Honour is Mr. S. V. Veerramani, Chairman, TNPSW trust, Vice chairman, Pharmexcil, CMD, M/s. fourrts India Labs Pvt Ltd, Chennai Dr. S. Manivannan, DDC (I), CDSCO, New Delhi, welcomed the gathering. Mr. S. V. Veerramnai, addressed the gathering on "India – Pharmacy of the World". **Dr. Krishna M. Ella**, gave the address to the audience & students with recent developments and manufacture of vaccines particularly Covid vaccine .

Tamilnadu Pharmaceutical Sciences Welfare Trust, institutes various awards to the Pharmacy graduates as well to students and the same were distributed during the function. The awards were - M. Pharm / Pharm D Scholarship, B. Pharm Essay Competition, sponsored by M/s. Pharm Products Pvt. Ltd.,Thanjavur and University Merit award to B. Pharm students sponsored by M/s. Fourrts India Labs Pvt Ltd, Chennai.

During this function various awards were announced.1) Prof K. R. Arumugam , chairman of Ultra group of pharmacy college for academic excellence2) Mr. A. Sarangapani former director of drugs control Tamilnadu for excelent regulation 3) Mr. R. Srinivasan Chairman of Baid Metha college of pharmacy for his excellent work in Community pharmacy 4) Mr. V. Ravichandran , Chief operating officer of Apollo group of pharmacy 5) Mr. Pandian from Pharma Industries division and Mr. T Sathish as best pharmacist.


(Tamil Nadu State Br
61st National Pharmacy Week
IPA AWARD


Indian Pharmaceutical Association
(Tamil Nadu State Branch)
61st National Pharmacy Week
Theme :
"INDIA - Pharmacy of the World"
IPA AWARD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(Tamil Nadu State Branch)
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Theme :
"INDIA - Pharmacy of the World"

IRF Life time Achievement award

Every year IPA is giving the IRF Lifetime achievement award to members of IPA, and scrutinized by the selection committee. For the year 2022, the awardee from our trust Chairman, Mr. S. V. Veerramni.

IPA - State Branch of Excellence Award

For the year 2021 State branch excellence award received for Tamilnadu State Branch, IPA during the 72nd IPC held in Nagpur.

IPA - Local Branch of Excellence Award

For the year 2021 & 2022, IPA Local Branch of Excellence award received for South TN Local branch, IPA during the 72nd IPC held in Nagpur.

Pharma Knowledge and Training Institute (Finishing School)
9th Training
on
Industrial Orientation Training for Production and Quality Management Personnel

The 9th Training program for the fresh Pharmacy graduates by Pharma Knowledge and Training Institute (Finishing School) under the aegis of Tamilnadu Pharmaceutical Sciences Welfare Trust was held at Trust premises in Spencer Plaza, Anna Salai, Chennaifrom 28th Nov to 14th December 2023. The total 28trainees fromSri Vijay Vidyalaya College of Pharmacy, Dharmapuri, Periyar College of Pharmaceutical Sciences, Tiruchirappalli, Shree Venkateshwara College of Paramedical Sciences, Gobichettipalayam, ArulmiguKalasalingam College of Pharmacy, Krishnankoil,students were trained in this training program.

The 9th Training was inaugurated by Mr. A. Krishna Dev, vice Chairman of our Trust.

The students were given training both theoretically and practical on the subject of **"Industrial Orientation Training on Production and Quality management Personnel"**. The following subjects were taught as theory and practical during this training programme.

Theoretical Training Programme

- Overview of the Pharmaceutical Industry and job opportunities for the Pharmacy graduates
- Rules and Regulations of Import and Export, New Drug Approvals.
- Regulatory Requirements of Production and QC under Drugs & Cosmetics Act and Rules,. Role of Govt. Drug Testing Laboratories.
- Good Manufacturing Practices under Schedule "M" of Drugs & Cosmetics Act in respect of Production, Quality Control, Maintenance of record of Drugs & Pharmaceuticals".
- Plant Design & Site Master File
- cGMP's for manufacturing including entry & exit procedures.-
- ICH guidelines for production & Quality Control of Pharmaceuticals
- IQ, OQ, PQ and DQ of equipment of Production & QC, Validation, Qualification and calibration
- Market complaints, CAPA, OOS and OOT etc., What is containment? Essential steps to control contamination, handling of deviation, Risk Assessment
- Change control, Deviation control and theirimportance
- Documentation and records in Production and QC

- Standard Operating Procedures
- Sampling of Raw Materials, Packing materials, In- process Materials and Finished products
- Batch Manufacturing Records, Batch Packing Records and importance of online recording Basics of production planning & Inventory Control
- Ethics on Pharmaceutical Marketing.
- Testing of Pharmaceutical Analytical Instruments (TLC, HPLC, HPTLC, Spectrophotometer, GC, ect.)
- Dissolution & its Importance, Methods used in Dissolution Testing
- Microbiology - An Introduction, Microbiology for non-sterile preparations
- Ointments, Creams, Emulsions, Gargle solutions, Sanitizers, etc Different types of equipment used for their manufacture, Ingredients used and in-process tests to be carried during their production. Packing of the above
- Quality by Design (QbD)
- Tablets (Processes involved in the production of Tablets such as size reduction, sieving, granulation, compression, coating etc., Various components of a Tablet with examples of different materials used &, In process tests to be carried during production of Tablets)
- Types of tablets such as Plain Tablets, Press Coated Tablets, Tablet in Tablet, Film Coated Tablets, Enteric Coated tablets, Delayed Release tablets etc, their advantages , How to control and rectify (in case of failure) weight variation, Disintegration time, Hardness, Friability, Dissolution etc during production , Different types of Coating of Tablets, Materials used for coating & coating process
- Preventive maintenance, Predictive maintenance & Break down maintenance-
- Selection of Packing Materials like Bottle packing, Strip Packing, Blister Packing etc and selection of different materials according to stability of products Viz: tablets & Capsules, Powders etc.
- Stability Testing, Accelerated and Real Time Studies, Packaging Material Stability, Their Testing, Their Importance with Respect to the Product Stability
- Different types of Oral Liquid Dosage Forms such as Liquids, Syrups, Suspensions& Emulsions etc. Facilities required and their methods of manufacture, in process tests to be carried out during their manufacture.
- Powders for Dry Syrups: Main ingredients with examples of various materials used, equipment used for their manufacture, In process tests to be done, and their packaging Effervescent Powders their main ingredients their manufacture and packing
- Oral Rehydration Powders (ORS), Equipment used for their manufacture, WHO approved formula, Materials used for formulation of ORS, in process tests to be done and packing of ORS powders

- Air Systems, Water Systems, their sampling and testing
- Basic Calculations in Quality Control, Dilutions and Statistical Analysis, Qualitative Analysis, Quantitative Analysis & Elemental Analysis
- Analytical method validation
- Preparation and Standardization of Herbal Formulations

The above subjects were taught by well experienced senior level pharma industry manufacturing and quality assurance technical personnel through power point presentation.

Practical Training

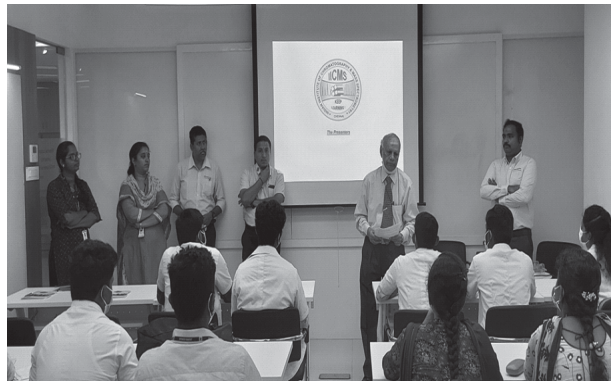
M/s. Fourrts (India) Laboratories Pvt. Ltd., Plant 1 & Plant 2, Chennai, M/s. Apex Laboratories Pvt. Ltd.,Alathur, Chennai, M/s. Medopharm, Guduvanchery, Chennai, M/s. Tablets (India) Ltd., T H Road, Chennai, M/s. SaiMirraInnopharm Pvt. Ltd., Ambattur, Chennai and M/s. The Madras Pharmaceuticals, OMR, Chennai, offered their facilities for practical training to the trainees for 6 days.

Evaluation

All the trainees were evaluated after each of the lecture programme as well as on the final date of completion of the programme on the basis of the evaluation these students were given 3merit awardsgiven during the valedictory function.

ValedictoryFunction

The Valedictory function was held on 14th December 2023.The Chief guest of the function was Mr. S. V. Veerramnai, Chairman of our Trust and M/s. Fourrts (India) Labs Pvt Ltd., Mr. R. Sabapathy, Mr. T. Sathish, Dr. R. Ilavarasan, Mrs. PratimaMathur, Mr. M. K. Pandiyan, were the guests of the valedictory. Mr. R. Narayanaswamy, Director, PKTI Welcomed the gathering and explained about the 8thtraining program. Certificates were distributed all the trainees.



NOTIFICATION

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, 8th the February, 2023

S.O. 627(E).—In exercise of the powers conferred by sub-section (2) of section 20 of the Drugs and Cosmetics Act, 1940 (23 of 1940) read with rule 44 of the Drugs Rules, 1945, and in supersession of the notification of the Government of India in the Ministry of Health and Family Welfare number S.O. 1520(E), dated the 7th April, 2021, except as respects things done or omitted to be done before such supersession, the Central Government hereby appoints—

i. Dr. Raghuram Reddy Adidala, Associate Pharmaceutical Chemist; and

ii. Shri. K. Nitin Kumar, Junior Scientific Assistant,

at the Central Drugs Testing Laboratory, Hyderabad, to be Government Analysts for the whole of India in respect of all classes of drugs, except the classes of drugs mentioned below, namely:—

1. Sera;
2. Solution of Serum Proteins intended for injection;
3. Vaccines (Parenteral and Oral);
4. Toxins;
5. Antigens;
6. Anti-toxins;
7. Sterilized Surgical Ligature and Sterilized Surgical Sutures;
8. Bacteriophages;
9. Anti-sera for veterinary use;
10. Vaccines for veterinary use;
11. Toxoids for veterinary use;
12. Diagnostic Antigens for veterinary use;
13. Venereal disease research laboratory (VDRL) Antigen;
14. Human Blood and Human Blood Products including components, to test for freedom for Human Immunodeficiency Virus (HIV) antibodies;
15. Blood Grouping reagents and diagnostics kits for Human Immunodeficiency Virus, Hepatitis B Surface Antigen and Hepatitis C Virus; and
16. Condoms.

[No. X.11014/11/2020-DR]
RAJIV WADHAWAN, Advisor (Cost)

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 17th November, 2022.

G.S.R. 823(E).—Whereas a draft of certain rules further to amend the Drugs Rules, 1945 was published, as required under sub-section (1) of section 12 and sub-section (1) of section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940) vide notification of the Government of India in the Ministry of Health and Family Welfare (Department of Health and Family Welfare) number G.S.R. 448(E), dated the 14th June, 2022, in the Gazette of India, Extraordinary, Part II, section 3, sub-section (i), inviting objections and suggestions from persons likely to be affected thereby, before the expiry of a period of thirty days from the date on which the copies of the Official Gazette containing the said notification were made available to the public;

And whereas, copies of the said Official Gazette were made available to the public on the 15th June, 2022;

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

Now, therefore, in exercise of the powers conferred by sections 12 and 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, after consultation with the Drugs Technical Advisory Board, hereby makes the following rules further to amend the Drugs Rules, 1945, namely:—

1. (1) These rules may be called the Drugs (Eighth Amendment) Rules, 2022.

(2) They shall come into force on the 1st day of August, 2023.

2. In the Drugs Rules, 1945 (hereinafter to be referred as the said rules), in rule 96, after sub-rule (5) and before the explanation, the following sub-rules shall be inserted, namely:—

"(6) The manufacturers of drug formulation products as specified in Schedule H2 shall print or affix Bar Code or Quick Response Code on its primary packaging label or, in 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.

(7) The stored data or information referred to in sub-rule (6) shall include the following 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; and

(viii) manufacturing licence number.".

"3. In the said rules, after Schedule H1, the following Schedule shall be inserted, namely:—

"SCHEDULE H2

[See sub-rules (6) and (7) of rule 96]

Serial Number	Brand name of drug formulation
1.	ACILOC 150 MG TABLET 30
2.	ACILOC 300 MG TABLET 20
3.	ACTEMRA 400 MG INJECTION 1
4.	ACTRAPID HUMAN 40 IU INJECTION 10 ML
5.	AEROCORT WITH DOSE COUNTER 50/50 MCG INHALER 200 MDI
6.	AJADUO 25/5 MG TABLET 10
7.	ALLEGRA 120 MG TABLET 10
8.	ALLEGRA 180 MG TABLET 10
9.	AMBISOME 50 MG INJECTION 20 ML
10.	AMICIN 500 MG INJECTION 2 ML
11.	AMLOKIND-AT 50/5 MG TABLET 10
12.	ASCORIL D PLUS NEW 5/2/10 MG SYRUP 100 ML
13.	ASCORIL LS 1/30/50 MG SYRUP 100 ML
14.	ASCORIL PLUS 50/1.25/2 MG EXPECTORANT 120 ML
15.	ASTHAKIND DX 5/2/15 MG SYRUP 100 ML
16.	ASTHALIN 100 MCG INHALER 200 MDI
17.	AUGMENTIN DUO 500/125 MG TABLET 10
18.	AVOMINE 25 MG TABLET 10
19.	AXCER 90 MG TABLET 14
20.	AZEE 500 MG TABLET 5
21.	AZITHRAL 500 MG TABLET 5

Serial Number	Brand name of drug formulation
22.	BECOSULES CAPSULE 20
23.	BECOSULES Z CAPSULE 20
24.	BETADINE 10 % OINTMENT 20 GM
25.	BETADINE 10 % SOLUTION 100 ML
26.	BETADINE MINT 2 % GARGLE 100 ML
27.	BETNESOL 0.5 MG TABLET 20
28.	BETNOVATE C 0.1/3 % CREAM 30 GM
29.	BETNOVATE N 0.1/0.5 % CREAM 20 GM
30.	BETNOVATE N 0.1/0.5 % CREAM 25 GM
31.	BETT 0.5 ML INJECTION 0.5 ML
32.	BEVON SYRUP 200 ML
33.	BIO D3 MAX 500 MG/0.25MCG/400MCG/120MG CAPSULE 15
34.	BRILINTA 90 MG TABLET 14
35.	BRO ZEDEX 50/1.25/4 MG SYRUP 100 ML
36.	BUDECORT 0.5 MG RESPULES 2 ML
37.	CALCIROL 60000 IU GRANULES 1 GM
38.	CALDIKIND PLUS 500 MG/0.25MCG/400MCG/60MG CAPSULE 10
39.	CALPOL 500 MG TABLET 15
40.	CALPOL 650 MG TABLET 15
41.	CALPOL PEAD 250 MG SUSPENSION 60 ML
42.	CANDIFORCE 200 MG CAPSULE 7
43.	CCM 250 MG TABLET 40
44.	CEFAKIND 500 MG TABLET 10

Serial Number	Brand name of drug formulation
45.	CEFTUM 500 MG TABLET 4
46.	CEPODEM 200 MG TABLET 10
47.	CHYMORAL FORTE 100000 IU TABLET 20
48.	CIDMUS 24/26 MG TABLET 14
49.	CILACAR 10 MG TABLET 15
50.	CIPREMI 100 MG INJECTION 1
51.	CLARIBID 500 MG TABLET 10
52.	CLAVAM 500/125 MG TABLET 10
53.	CLEXANE 40 MG INJECTION 0.4 ML
54.	CLEXANE 60 MG INJECTION 0.6 ML
55.	COBADEX CZS TABLET 15
56.	CODISTAR 4/10 MG SYRUP 100 ML
57.	COMBIFLAM 400/325 MG TABLET 20
58.	CONCOR 5 MG TABLET 10
59.	COREX DX 4/10 MG SYRUP 100 ML
60.	CREMAFFIN PLUS SF 1.25 ML/3.75ML/3.33MG LIQUID 225 ML
61.	CYPON 275/2 MG SYRUP 200 ML
62.	CYRA D 30/20 MG TABLET SR 10
63.	DALACIN C 300 MG CAPSULE 10
64.	DECA DURABOLIN 50 MG INJECTION 1
65.	DEFCORT 6 MG TABLET 10
66.	DERIPHYLLIN 25.3/84.7 MG INJECTION 2 ML
67.	DEROBIN 1.15/1.15/5.3 % OINTMENT 30 GM
68.	DEXONA (VIAL) 4 MG INJECTION 2 ML

Serial Number	Brand name of drug formulation
69.	DEXORANGE 160 MG/0.5MG/7.5MCG SYRUP 200 ML
70.	DOLO 650 MG TABLET 15
71.	DOLONEX 20 MG TABLET DT 15
72.	DOXINATE 10/10 MG TABLET 30
73.	DOXT SL 100 MG/5BIU CAPSULE 10
74.	DOXY 1 FORTE L DR 100 MG/5BIU CAPSULE 10
75.	DULCOFLEX 5 MG TABLET 10
76.	DUOLIN 3 1.25 MG/500MCG RESPULES 3 ML
77.	DUPHASTON 10 MG TABLET 10
78.	DYDROBOON 10 MG TABLET 10
79.	DYNAPAR AQ 75 MG INJECTION 1 ML
80.	EASY SIX PREFILLED SYRINGE 0.5 ML
81.	ECOSPRIN AV 10/75 MG CAPSULE 15
82.	ECOSPRIN GOLD 75/20/75 MG TABLET 15
83.	ELAXIM 40 MG INJECTION 1
84.	ELECTRAL SACHET 21.8 GM
85.	ELIQUIS 2.5 MG TABLET 10
86.	ELIQUIS 5 MG TABLET 10
87.	ELTROXIN 100 MCG TABLET 120
88.	ENTEROGERMINA 2 BIU ORAL SUSPENSION 5 ML
89.	EXHEP 40 MG PREFILLED SYRINGE 0.4 ML
90.	FABIFLU 200 MG TABLET 34
91.	FABIFLU 400 MG TABLET 17
92.	FABIFLU COPACK 800 MG TABLET 18

Serial Number	Brand name of drug formulation
93.	FARONEM 200 MG TABLET 10
94.	FARONEM 300 MG TABLET ER 10
95.	FORACORT 20/500 MCG RESPULES 2 ML
96.	FORACORT 6/200 MCG ROTACAP 30
97.	FORACORT 6/400 MCG ROTACAP 30
98.	FORXIGA 10 MG TABLET 14
99.	GABAPIN NT 400/10 MG TABLET 15
100.	GALVUS 50 MG TABLET 15
101.	GALVUS MET 50/1000 MG TABLET 15
102.	GALVUS MET 50/500 MG TABLET 15
103.	GEFTINAT 250 MG TABLET 30
104.	GELUSIL MPS 250/50/250 MG LIQUID 200 ML
105.	GEMCAL 500 MG/0.25MCG/7.5MG CAPSULE 15
106.	GEMER 2/500 MG TABLET 10
107.	GIBTULIO 25 MG TABLET 10
108.	GLUCONORM-G 2/500 MG TABLET 15
109.	GLYCOMET GP 1/500 MG TABLET 15
110.	GLYCOMET GP 2/500 MG TABLET SR 15
111.	GLYNASE MF 5/500 MG TABLET 10
112.	GLYXAMBI 25/5 MG TABLET 10
113.	GRILINCTUS 60/2.5/5/50 MG SYRUP 100 ML
114.	GUDCEF 200 MG TABLET 10
115.	GUDCEF CV 200/125 MG TABLET 10
116.	HCQS 200 MG TABLET 15

Serial Number	Brand name of drug formulation
117.	HEXAXIM INJECTION 0.5 ML
118.	HUCOG HP 5000 IU INJECTION 1 ML
119.	HUMINSULIN 30/70 100 IU CARTRIDGE 3 ML
120.	INFANRIX HEXA INJECTION 0.5 ML
121.	ISTAMET 50/500 MG TABLET 15
122.	IVABRAD 5 MG TABLET 15
123.	IVERMECTOL NEW 12 MG TABLET 2
124.	JALRA M 50/500 MG TABLET 15
125.	JANUMET 50/1000 MG TABLET 15
126.	JANUMET 50/500 MG TABLET 15
127.	JANUVIA 100 MG TABLET 7
128.	JARDIANCE 10 MG TABLET 10
129.	JARDIANCE 25 MG TABLET 10
130.	KABIMOL 1000 MG INFUSION 100 ML
131.	KARVOL PLUS CAPSULE 10
132.	KENACORT 40 MG INJECTION 1 ML
133.	KETOROL 10 MG TABLET DT 15
134.	KETOSTERIL TABLET 20
135.	LANTUS 100 IU CARTRIDGE 3 ML
136.	LANTUS SOLOSTAR 100 IU DISPOSABLE PEN 3 ML
137.	LEVERA 500 MG TABLET 15
138.	LEVIPIL 500 MG TABLET 10
139.	LIBRAX 2.5/5 MG TABLET 20
140.	LIMCEE CHEW ORANGE 500 MG TABLET 15

Serial Number	Brand name of drug formulation
141.	LIPAGLYN 4 MG TABLET 10
142.	LMWX 40 MG INJECTION 0.4 ML
143.	LOBATE GM NEO 0.05/0.5/2 % CREAM 15 GM
144.	LONOPIN 40 MG INJECTION 0.4 ML
145.	LOSAR 50 MG TABLET 15
146.	LOSAR H 50/12.5 MG TABLET 15
147.	MACBERY XT 50/1.25/4 MG SYRUP 100 ML
148.	MAGNEX FORTE 1000/500 MG INJECTION 1
149.	MANFORCE 100 MG TABLET 4
150.	MANFORCE 50 MG TABLET 9
151.	MAXTRA 5/2 MG SYRUP 60 ML
152.	MEFTAL SPAS 10/250 MG TABLET 10
153.	MEGALIS 20 MG TABLET 4
154.	MEGANEURON OD PLUS 1500 MCG CAPSULE 10
155.	MENACTRA INJECTION 0.5 ML
156.	MERO 1000 MG INJECTION 1
157.	MEROMAC 1000 MG INJECTION 1
158.	MERONEM 1000 MG INJECTION 1
159.	MEROZA 1000 MG INJECTION 1 ML
160.	MIFEGEST KIT 200 MG/200MCG TABLET 1
161.	MIKACIN 500 MG INJECTION 2 ML
162.	MINIPRESS XL 5 MG TABLET XL 30
163.	MIXTARD HM PENFILL 30/70 100 IU INJECTION 3 ML
164.	MIXTARD HUMAN 30/70 40 IU INJECTION 10 ML

Serial Number	Brand name of drug formulation
165.	MIXTARD HUMAN 50/50 40 IU INJECTION 10 ML
166.	MONOCEF 1000 MG INJECTION 5 ML
167.	MONOCEF O 200 MG TABLET 10
168.	MONOCEF SB 1000/500 MG INJECTION 1
169.	MONTAIR LC 10/5 MG TABLET 15
170.	MONTAZ 1000/125 MG INJECTION 1
171.	MONTEK-LC 10/5 MG TABLET 10
172.	MONTICOPE 10/5 MG TABLET 10
173.	MOX 500 MG CAPSULE 15
174.	MOX CV 500/125 MG TABLET 10
175.	MOXCLAV 500/125 MG TABLET 10
176.	MOXIKIND CV 500/125 MG TABLET 10
177.	MUCAINE MINT 10/291/98 MG GEL 200 ML
178.	MUCINAC SF ORANGE 600 MG TABLET 10
179.	NEBICARD 5 MG TABLET 10
180.	NEFROSAVE 150/500 MG TABLET 15
181.	NEUROBION FORTE TABLET 30
182.	NEXPRO 40 MG TABLET 15
183.	NEXPRO RD 30/40 MG CAPSULE 10
184.	NIKORAN 5 MG TABLET 20
185.	NISE 100 MG TABLET 15
186.	NITROCONTIN 2.6 MG TABLET CR 30
187.	NOVOMIX 100 IU CARTRIDGE 3 ML
188.	NOVOMIX 30/70 MG FLEXPEN 3 ML

Serial Number	Brand name of drug formulation
189.	NOVORAPID 100 IU CARTRIDGE 3 ML
190.	NUROKIND LC 500 MG/1.5MG/1500MCG TABLET 15
191.	NUROKIND PLUS RF 1500 MCG CAPSULE 10
192.	O2 200/500 MG TABLET 10
193.	OMEZ 20 MG CAPSULE 20
194.	OMEZ D 30/20 MG CAPSULE SR 15
195.	OMNIKACIN 500 MG INJECTION 2 ML
196.	ONDERO 5 MG TABLET 10
197.	ONDERO MET 2.5/500 MG TABLET 10
198.	OROFER FCM INJECTION 10 ML
199.	OROFER-XT 100/1.5 MG TABLET 10
200.	OROFER-XT PLUS 30 MG/500MCG/500MCG SUSPENSION 200 ML
201.	OTRIVIN OXY FAST RELIEF 0.05 % SPRAY 10 ML
202.	OVRAL L 0.03/0.15 MG TABLET 21
203.	OXRA 10 MG TABLET 14
204.	PAN 40 MG TABLET 15
205.	PAN D 30/40 MG CAPSULE 15
206.	PANDERM PLUS PLUS 0.05/0.5/2 % CREAM 15 GM
207.	PANTIN IV 40 MG INJECTION 10 ML
208.	PANTOCID 40 MG TABLET 15
209.	PANTOCID DSR 30/40 MG CAPSULE 15
210.	PANTODAC 40 MG TABLET 15
211.	PANTODAC DSR 30/40 MG CAPSULE 15
212.	PANTOP 40 MG INJECTION 10 ML

Serial Number	Brand name of drug formulation
213.	PANTOP 40 MG TABLET 15
214.	PANTOP D 10/20 MG CAPSULE 10
215.	PANTOP D SR 30/40 MG CAPSULE SR 10
216.	PHENSEDYL COUGH LINCTUS 4/10 MG SYRUP 100 ML
217.	PIPZO 4000/500 MG INJECTION 10 ML
218.	PRACTIN 4 MG TABLET 10
219.	PREGA NEWS KIT 6
220.	PREVENAR 13 INJECTION 0.5 ML
221.	R.B TONE SYRUP 200 ML
222.	RABLET-D 30/20 MG CAPSULE 10
223.	RANTAC 150 MG TABLET 30
224.	RAZO 20 MG TABLET 15
225.	RAZO D 30/20 MG TABLET 15
226.	REFRESH TEARS 0.5 % EYE DROPS 10 ML
227.	REJUNEX-CD3 TABLET 10
228.	REMDAC 100 MG INJECTION 1
229.	ROSUVAS 10 MG TABLET 15
230	ROSUVAS 20 MG TABLET 10
231.	RYZODEG 2.56/1.05 MG PENFILL 3 ML
232.	SARIDON 250/50/150 MG TABLET 10
233.	SEROFLO 50/250 MCG ROTACAP 30
234.	SHELCAL 500 MG/250IU TABLET 15
235.	SHELCAL XT 500 MG/2000IU/1500MCG/1MG/20MG TABLET 15
236.	SILODAL 8 MG TABLET 10

Serial Number	Brand name of drug formulation
237.	SILODAL D 8/0.5 MG TABLET 10
238.	SINAREST 125/5/1 MG SYRUP 60 ML
239.	SINAREST NEW 500/10/2 MG TABLET 10
240.	SINAREST NEW 500/10/2 MG TABLET 15
241.	SKINLITE 2/0.1/0.025 % CREAM 25 GM
242.	SOMPRAZ D 30/40 MG CAPSULE 15
243.	SPASMO PROXYVON PLUS 10/325/50 MG CAPSULE 8
244.	SPEGRA 50/200/25 MG TABLET 30
245.	STAMLO 5 MG TABLET 30
246.	STAMLO BETA 50/5 MG TABLET 15
247.	STEMETIL 5 MG TABLET MD 15
248.	SUCRAFIL O 1000/20 MG GEL 200 ML
249.	SUMO 100/325 MG TABLET 15
250.	SUMO L IV 1000 MG INFUSION 100 ML
251.	SUPRADYN TABLET 15
252.	SYNFLORIX INJECTION 1
253.	T BACT 2 % OINTMENT 15 GM
254.	T BACT 2 % OINTMENT 5 GM
255.	TARGOCID 400 MG INJECTION 1 ML
256.	TAXIM O 200 MG TABLET 10
257.	TAZOMAC 4000/500 MG INJECTION 2 ML
258.	TELEKAST-L 10/5 MG TABLET 15
259.	TELMA 40 MG TABLET 30
260	TELMA AM 40/5 MG TABLET 15

Serial Number	Brand name of drug formulation
261.	TELMA H 40/12.5 MG TABLET 15
262.	TELMIKIND 40 MG TABLET 10
263.	TELMIKIND AM 40/5 MG TABLET 10
264.	TELMIKIND H 40/12.5 MG TABLET 10
265.	THROMBOPHOB OINTMENT 20 GM
266.	THYRONORM 100 MCG TABLET 120
267.	THYRONORM 25 MCG TABLET 120
268.	THYRONORM 50 MCG TABLET 120
269.	TOSSEX NEW 4/10 MG SYRUP 100 ML
270.	TRAJENTA 5 MG TABLET 10
271.	TRESIBA FLEXTOUCH 100 IU DISPOSABLE PEN 3 ML
272.	TUSQ DX 5/2/15 MG SYRUP 100 ML
273.	UDILIV 150 MG TABLET 15
274.	UDILIV 300 MG TABLET 15
275.	ULTRACET 325/37.5 MG TABLET 15
276.	UNIENZYME TABLET 15
277.	UNWANTED 72 1.5 MG TABLET 1
278.	UNWANTED KIT 200 MG/200MCG TABLET 1
279.	UPRISE D3 60000 IU CAPSULE 8
280.	URIMAX 0.4 MG CAPSULE 20
281.	URIMAX D 0.4/0.5 MG TABLET 15
282.	URSOCOL 300 MG TABLET 15
283.	VARILRIX INJECTION 0.5 ML
284.	VELOZ D 30/20 MG CAPSULE SR 10

Serial Number	Brand name of drug formulation
285.	VELPANAT 400/100 MG TABLET 28
286.	VERTIN 16 MG TABLET 15
287.	VOLINI 1.16 % SPRAY 40 GM
288.	VORIER 200 MG TABLET 4
289.	VOVERAN SR 100 MG TABLET SR 15
290.	VYMADA 24/26 MG TABLET 14
291.	WYSOLONE 10 MG TABLET DT 15
292.	WYSOLONE 5 MG TABLET DT 15
293.	XONE 1000 MG INJECTION 5 ML
294.	ZAVICEFTA 2000/500 MG VIAL 10 ML
295.	ZEDEX 4/5/50 MG SYRUP 100 ML
296.	ZERODOL P 100/325 MG TABLET 10
297.	ZERODOL SP 100/325/15 MG TABLET 10
298.	ZIFI 200 MG TABLET 10
299.	ZORYL-M 2/500 MG TABLET 20
300.	ZOSTUM 1000/500 MG INJECTION 1

[No. X.11035/32/2019-DR]
Dr. MANDEEP K BHANDARI, Jt. Secy.

Note: The Drug Rules, 1945 were published in the Official Gazette vide notification number F. 28-10/45-H(1), dated 21st the December, 1945 and were last amended vide notification number G.S.R. 654(E), dated the 24th August, 2022.

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 2nd November, 2022

S.O. 5090(E).—In exercise of the powers conferred by sub-section (2) of section 20 of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government hereby makes the following amendment further to amend the notification of the Government of India in the Ministry of Health and Family Welfare (Department of Health and Family Welfare) vide number S.O. 2809(E), dated the 30th November, 2012, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (ii), dated the 30th November, 2012, namely,—

In the said notification, after item number (ii) and the entries relating thereto, the following shall be inserted, namely:—

"

(iii) Smt. G. Sasikala, Senior Scientific Assistant;

(iv) Shri Kishor Gembali, Junior Scientific Assistant;

(v) Smt. Rimjhim Kumari, Junior Scientific Assistant.".

[F. No. X.11014/5/2021-DR]
Dr. MANDEEP K BHANDARI, Jt. Secy.

Note : The principal notification was published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (ii) vide notification number S.O. 2809(E), dated the 30th November, 2012.

F. No. 29/Misc/03/2020-DC (301) Part I
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(Medical Device Division)
FDA Bhawan, Kotla Road
New Delhi-110002

Date 22 DEC 2022

NOTICE

Subject: Registration of Medical Device Testing Laboratory in Form MD-40 as per Medical Devices Rules (MDR) 2017 for Testing of Medical Devices on behalf of the manufacturer - Regarding

This is with reference to the notice published by this office vide F No 12-01-21-DC (Pt-306 –XXXVI-MDTL) dated 14.10.2021 on the subject cited above.

In accordance to above, this office is receiving the applications for registration under Medical Devices Rules 2017 from various laboratories, for testing of different medical devices and as on date more than 28 laboratories have been registered for this purpose. The list of MDTL registered by this office in published in website of CDSCO (www.cdsco.gov.in)

In order to enhance the testing capacity of medical device in the country identification registration & empanelment of government private testing laboratory for medical devices testing is under consideration as per MDR 2017.

In this regard, laboratories which have capacity for testing of medical device & are NABL accredited are requested to submit the application in Form MD-39 along with requisite fees and documents, through online portal www.cdscomdonline.gov.in., for taking further necessary action in the matter.

(Dr V. G. Somani)
Drugs Controller General (I)

To:
1. All Stakeholders through CDSCO website
2. All IITs (Delhi, Mumbai, Chennai, Kharagpur, Hyderabad, Guwahati etc).
3. All IISC (Bangalore, Pune, Bhopal, Thiruvananthapuram etc)
4. Director, DRDO. DRDO Bhawan, Rajaji Marg, New Delhi-110011
5. Director CSIR, Anusandhan Bhawan, 2 Rafi Ahmed Kidwai Marg, New Delhi - 110001
6. Director NIPER, Sector 67, S.A.S. Nagar - 160062, Punjab (INDIA).
7. Director, NIPER Sila Katamur (Halugurisuk), P.O.: Changsari, Dist: Kamrup, Assam, Pin: 781101, Assam, India
8. Director NIPER, Opposite Air force Station, Palaj, Gandhinagar-382355, Gujarat, India.

Copy to
1. PS to JS(R), MoHFW, Nirman Bhawan, New Delhi.

Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
Office of Drugs Controller General (India)
(PSUR/PV Cell), FDA Bhawan,
Indrajeet Gupta Road, New Delhi-110002
E-mail: psur.drugs@cdsco.nic.in, dci@nic.in

File No. PSUR/WHO/GBT/VIG/001/2022/8196358 **Dated:** 23/12/2022

NOTICE

Subject: Inspections/ Audits of Pharmacovigilance (PV) system of Importers and manufacturers of human Vaccine; -reg.

As per the 5th Schedule of NDCT Rules, 2019, the importer or Manufacturer of any new drug for sale and distribution shall have a Pharmacovigilance system in place for collecting, processing and forwarding the ADR reports to the Central Licensing Authority emerging from the use of the new drug imported or manufactured or marketed by the applicant in the country. The Pharmacovigilance system shall be managed by qualified and trained personnel and the Officer-In-Charge of collection and processing of data shall be a trained Pharmacist or Medical Officer in collection and analysis of Adverse Drug Reaction Reports (ADR).

Accordingly, you are required to maintain qualified trained personnel and Officer-In-Charge of collection, processing of data and furnishing of PSUR as per fifth schedule of NDCT Rules, 2019 as the same may be subject to inspection at any time for verification of compliance.

In this regard you are requested to furnish the following documents to this directorate at the earliest.

1. Summary of established pharmacovigilance system.
2. Name, email ID of Pharmacovigilance officer –in-charge (PvOI), Name address, contact, Email ID of the premises where PV system is established.
3. Self- Inspection report (if any)

(Dr. V. G. Somani)
Drugs Controller General (India)

To;

1. All the Manufacturers and importers of Human vaccines

Copy to;

1. QMS division, CDSCO(HQ)

PARLIAMENT QUESTION AND ANSWERS

GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE
DEPARTMENT OF HEALTH AND FAMILY WELFARE

LOK SABHA
STARRED QUESTION NO.54
TO BE ANSWERED ON 9th DECEMBER, 2022

SALE OF EXPIRED/UNCERTIFIED PROTEIN POWDER

***54. SHRIMATI SANGEETA AZAD:**

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

(a) whether the Food Safety and Standards Authority of India (FSSAI) or any other agency is conducting regular checks and raids on the manufacturers of branded protein powder across the country to ascertain/check the sale of expired/uncertified/unlicensed products which also violate the established manufacturing and safety protocols;

(b) if so, the details thereof;

(c) whether the Government is aware of the diseases and deaths due to use/consumption of these protein powders/anabolic steroids; and

(d) if so, the details thereof during the last five years along with the number of cases filed/solved/penalty imposed and the other corrective steps taken/being taken in this regard?

ANSWER

THE MINISTER OF HEALTH AND FAMILY WELFARE
(DR. MANSUKH MANDAVIYA)

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

STATEMENT REFERRED TO IN REPLY TO THE LOK SABHA STARRED QUESTION NO. 54 FOR 9TH DECEMBER, 2022.

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(a) to (d): Food Safety and Standards Authority of India (FSSAI) is mandated to lay down science based standards for articles of food and to regulate their manufacture, storage, distribution, sale and import to ensure availability of safe and wholesome food for human consumption. Section 31(1) of Food Safety and Standards (FSS) Act, 2006 provides that no person shall commence or carry on any Food Business except under a license.

Surveillance of Food Business Operators including manufacturers of health supplements like protein powders is conducted regularly through intensive surveillance drives by the States/UTs. The responsibility for implementation and enforcement of FSS Act 2006, Rules and Regulations made thereunder primarily lies with State/UT Governments. Penal action is initiated against the defaulting Food Business Operators (FBOs) by the Food Safety Officers of States/UTs as per the provisions of FSS Act, 2006, Rules and Regulations.

FSSAI has notified FSS (Food or Health Supplements, Nutraceuticals, Foods Special Dietary Use, Foods for Special Medical Purpose, Functional Foods and Novel Foods) Regulations, 2016, which specify provisions for regulation of these products in the country.

The articles of food covered under these regulations are required to comply with the general labelling requirements under the FSS (Packaging and Labelling) Regulations, 2011. Further, since these products are intended for specific physiological conditions or general maintenance of health and are required to be taken as per the regulated usage levels by the specific targeted group, labelling provisions for specific food product categories have also been specified under the said regulations. These regulations state that the label on such articles of food shall specify the purpose, the target consumer group and the physiological or disease conditions which they address and recommended duration of use. The label, accompanying leaflet or other labelling and advertisement of each type of article of food shall also provide sufficient information on the nature and purpose of the article of food and detailed instructions and precautions for its use, and the format of information given shall be appropriate for the intended consumer.

Based on information made available by the States/UTs, details of food samples analyzed, found adulterated/sub-standard/misbranded and action taken thereon during the last three years i.e. 2019-2020, 2020-2021and 2021-22 is Annexed.

Annexure

Annual Public Laboratory Testing Report/Data for last three years												
S. No.	Year	No. of Samples Analysed	No. of Samples found non-conforming	Non Confirming Samples			Civil Cases			Criminal Cases		
				Unsafe	Sub Standard	Labelling defects /Misleading/ Miscellaneous	No. of Cases Launched	No. of Convictions	Penalties Raised (Cr.)	No. of Cases Launched	No. of Convictions	Penalties Raised (Cr.)
1	2	3	4	5	6	7	8	9	10	11	12	13
2	**2019-20**	118775	29589	4526	15671	8995	27412	17345	56.38	4681	780	1.61
3	**2020-21**	107829	28347	5220	13394	9733	24195	14817	49.92	3869	506	0.83
4	**2021-22**	144345	32934	4890	16582	11482	28906	19437	53.39	4946	671	1.38

GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE
DEPARTMENT OF HEALTH AND FAMILY WELFARE

RAJYA SABHA
STARRED QUESTION NO. *146
TO BE ANSWERED ON 20th DECEMBER, 2022

PERFORMANCE OF AYUSHMAN BHARAT PRADHAN MANTRI JAN AROGYA YOJANA

***146 DR. SASMIT PATRA:**

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

(a) The total number of beneficiaries treated under the Ayushman Bharat-Pradhan Mantri Jan Arogya Yojana since its inception, year-wise and State-wise;

(b) the reasons for the increase or decrease in expenditure incurred towards this programme for the beneficiaries;

(c) the total insurance claimed from the Hospitals or Health care institutions for this programme; and

(d) the total insurance collected by the Hospitals or Health care institutions for this Programme?

ANSWER

THE MINISTER OF HEALTH AND FAMILY WELFARE
(DR. MANSUKH MANDAVIYA)

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

STATEMENT REFERRED TO IN REPLY TO RAJYA SABHA
STARRED QUESTION NO. 146 FOR 20TH DECEMBER, 2022
*****

(a) to (d): State/UT-wise and Year-wise details of total number of authorized hospital admissions under Ayushman Bharat- Pradhan Mantri Jan Arogya Yojana (AB-PMJAY) since its inception are at Annexure.

As of 15th December 2022, a total amount of Rs. 14,810.08 crore has been released to the States/UTs as Central share for the implementation of the scheme, since the inception of the scheme on 23rd September 2018. Increase in expenditure is due to

is due to uptake of the scheme on account of increase in the number of empanelled hospitals, hospital admissions, elective surgeries which were impacted during COVID-19 pandemic and the launch of rationalized Health Benefit Packages.

As of 15th December 2022, approximately 4.07 crore claims worth Rs. 51,444 crore have been submitted by the empanelled hospitals for the treatment provided under the scheme and approximately 3.5 crore claims worth Rs. 40,549.5 crore have been paid.

Annexure

State/UT-wise & year-wise details of authorized hospital admissions under AB-PMJAY

State/UT	2018-19	2019-20	2020-21	2021-22	2022-23
Andaman And Nicobar Islands	14	151	342	838	495
Andhra Pradesh	139,931	654,946	692,364	975,502	316,333
Arunachal Pradesh	375	1,345	84	189	928
Assam	32,702	90,173	92,761	175,949	160,771
Bihar	18,503	155,023	88,776	116,423	127,204
Chandigarh	273	3,228	5,375	8,349	6,569
Chhattisgarh	230,982	636,102	497,229	897,690	894,084
Dadra And Nagar Haveli	5,917	24,094	14,821	16,113	11,698
Daman And Diu	1,758	7,438	4,123	4,509	3,239
Goa	9,723	374	139	167	282
Gujarat	314,087	1,140,221	825,702	566,816	602,429
Haryana	10,427	95,598	138,792	185,271	161,166
Himachal Pradesh	8,290	46,851	29,228	47,498	43,795
Jammu And Kashmir	6,278	67,152	68,207	251,413	267,916
Jharkhand	107,125	407,541	298,084	326,699	266,196
Karnataka	116,134	566,707	654,601	1,092,856	1,096,584
Kerala	-	974,864	1,043,792	1,698,861	888,952
Ladakh	-	-	-	599	5,110
Lakshadweep	-	1	-	67	243
Madhya Pradesh	42,533	268,875	381,554	708,248	850,485
Maharashtra	108,067	214,343	150,023	136,646	89,427
Manipur	1,482	12,615	16,361	24,064	26,995
Meghalaya	1,122	124,434	123,734	145,307	138,067
Mizoram	7,067	27,621	16,986	13,866	16,341
Nagaland	262	10,122	7,357	5,654	7,972
Puducherry	-	1,368	2,587	11,926	15,762
Punjab	-	196,594	422,815	536,032	199,009
Rajasthan	-	925,684	410,464	1,226,774	1,366,790
Sikkim	9	1,213	2,022	2,872	2,981
Tamil Nadu	380,070	815,779	1,894,993	4,494,393	896,691
Telangana	-	-	-	272,588	316,283
Tripura	7,763	50,967	30,130	46,173	53,882
Uttar Pradesh	65,920	283,505	318,776	501,825	530,897
Uttarakhand	20,321	129,950	121,628	182,240	172,929

Note: Above list does not include the State/UT of West Bengal, Odisha and NCT of Delhi as they are not implementing the scheme.

GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE
DEPARTMENT OF HEALTH AND FAMILY WELFARE

LOK SABHA
UNSTARRED QUESTION NO. †528
TO BE ANSWERED ON 09TH DECEMBER, 2022

FIXATION OF PRICES OF ESSENTIAL DRUGS

†528: SHRI DILESHWAR KAMAIT:

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

(a) the details of the criteria/guidelines for fixing of prices of Essential Drugs including those used for the treatment of Cancer, Diabetes, HIV, Cardiovascular and Kidney diseases;

(b) whether the prices of Essential Drugs have come down;

(c) if so, the details thereof; and

(d) the details of Jan Aushadhi Kendras established in each district of Bihar including Supaul for sale of generic drugs at cheaper prices under the Pradhan Mantri Jan Aushadhi Yojana?

ANSWER

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (DR. BHARATI PRAVIN PAWAR)

(a): As informed by Department of Pharmaceuticals, the National List of Essential Medicines (NLEM) is adopted as the primary basis for determining essentiality and is incorporated in the First Schedule of Drugs (Prices Control) Order (DPCO), 2013, which constitutes the list of scheduled medicines, including the medicines used for the treatment of cancer, diabetes, HIV and Heart and kidney diseases for the purpose of price control. The key principles for regulation of prices in the National Pharmaceuticals Pricing Policy, 2012 are essentiality of drugs; control of formulations prices only; and Market Based Pricing.

National Pharmaceutical Pricing Authority (NPPA), fixes the ceiling price of scheduled medicines specified in the first schedule of the DPCO, 2013. All manufacturers of

scheduled medicines have to sell their products within the ceiling price (plus applicable Goods and Service Tax) fixed by the NPPA. DPCO, 2013 allows an annual price rise for scheduled formulations based on Wholesale Price Index (WPI). NPPA also fixes retail price of a new drug under DPCO, 2013 for existing manufacturers of scheduled formulation. Hence, the annual increase allowed in the case of Scheduled formulations is upto the level of annual revision in WPI. Further, in case of non-scheduled formulation, no manufacturers can increase MRP by more than 10% of MRP during preceding 12 months. Instances of overcharging are dealt with by NPPA under the relevant provisions of DPCO 2013.

(b) & (c): The details of drugs brought under price control/ regulation by NPPA are given below:

i. Ceiling prices of 890 scheduled formulations across various therapeutic categories under NLEM 2015 which includes four scheduled medical devices i.e. Intra Uterine Devices (Hormone releasing IUD, IUD containing Copper), Condom and Coronary Stents (bare metal stent and drug eluting stent) have been fixed by NPPA.

ii. Retail price of approx. 2185 new drugs under DPCO, 2013 till 18.11.2022 have been fixed.

iii. In 2014, NPPA capped the MRP of 106 non-scheduled drug formulations under Para 19 of DPCO 2013 which includes 22 diabetic and 84 cardiovascular drugs.

iv. Ceiling price of Orthopaedic Knee Implants fixed under Para 19 of DPCO, 2013 since 16th August 2017 in public interest.

v. Trade Margin of non-scheduled formulations of 42 select Anti-cancer medicines capped under "Trade Margin Rationalization" approach as a pilot for proof of concept, wherein price of above 500 brands of medicines were reduced upto 90%. This is in addition to 86 anticancer drugs which are scheduled drugs and whose ceiling prices have been fixed by NPPA (the figures are included in the 890 drugs in Para (I) above.

vi. NPPA invoked Paragraph 19 of the DPCO, 2013 to regulate the price of Oxygen Concentrators, Pulse Oximeter, Blood Pressure Monitoring Machine, Nebulizer, Digital Thermometer and Glucometer under "Trade Margin Rationalisation" Approach in June/July 2021.

The fixation of prices has resulted in a notional savings of about Rs 12,447 Cr. per annum to the public after implementation of DPCO, 2013.

(d): Under Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP), till 30.11.2022, 8916 Pradhan Mantri Bhartiya Janaushadhi Kendras (PMBJKs) have been opened across the country, of which, 341 PMBJKs have been opened in Bihar, the details of which are as under:

Sl. No.	Name of the District of Bihar State	No. of PMBJKs
1.	Araria	1
2.	Arwal	2
3.	Aurangabad	5
4.	Banka	2
5.	Begusarai	12
6.	Bhagalpur	7
7.	Bhojpur	10
8.	Buxar	4
9.	Darbhanga	9
10.	Gaya	17
11.	Gopalganj	2
12.	Jamui	2
13.	Jehanabad	2
14.	Kaimur (Bhabua)	5
15.	Katihar	3
16.	Khagaria	1
17.	Kishanganj	1
18.	Lakhisarai	2
19.	Madhepura	3
20.	Madhubani	26
21.	Munger	4
22.	Muzaffarpur	38
23.	Nalanda	4
24.	Nawada	9
25.	Pashchim Champaran	9
26.	Patna	46
27.	Purbi Champaran	32
28.	Purnia	3
29.	Rohtas	13
30.	Saharsa	6
31.	Samastipur	13
32.	Saran	6
33.	Sheikhpura	4
34.	Sheohar	5
35.	Sitamarhi	9
36.	Siwan	4
37.	Supaul	7
38.	Vaishali	13

GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA
UNSTARRED QUESTION NO. 604
TO BE ANSWERED ON 09th December, 2022

Medicines added under National List of Essential Medicines

604. SHRI THIRUNAVUKKARASAR SU:
SHRI P. RAVINDHRANATH:

Will the Minister of **CHEMICALS AND FERTILIZERS** be pleased to state:

(a) whether the Department of Pharmaceuticals has revised the National List of Essential Medicines and included several medicines under NLEM with price control;

(b) whether the Government has constituted any monitoring mechanism to ensure the controlled price of such essential medicines, if so, the details thereof;

(c) the number of medicines added so far under essential medicines - National List of Essential Medicines (NLEM);

(d) whether the Government has recently added more drugs including four major anti-cancer drugs under the NLEM, if so, the details thereof;

(e) whether some drugs were dropped from the NLEM and the steps taken/proposed to be taken to ensure affordable and quality medicines to all citizens in the country; and

(f) if so, the details thereof and if not, the reasons therefor?

ANSWER

MINISTER OF STATE IN THE MINISTRY OF CHEMICALS & FERTILIZERS
(SHRI BHAGWANTH KHUBA)

(a): National List of Essential Medicines, 2022 (NLEM, 2022) was notified on 13.09.2022 by Ministry of Health and Family Welfare. Accordingly, Department of Pharmaceuticals (DoP) revised Schedule-I of the Drugs (Prices Control) Order, 2013 (DPCO, 2013) vide S.O. 5249 (E) dated 11.11.2022. The National Pharmaceutical Pricing Authority (NPPA) under the DoP is mandated to fix the ceiling prices for the medicines included in revised schedule-I of DPCO 2013 within sixty days from the date of notification issued by the DoP.

(b): The NPPA under the DoP fixes the ceiling price for all scheduled drugs notified under Schedule-I of DPCO, 2013. No manufacturer of a scheduled formulation can sell a such formulation at a price higher than the ceiling price (plus local taxes as applicable) fixed and notified by the Government, failing which such

manufacturers shall be liable to deposit the overcharged amount along with interest thereon, from the date of such overcharging. A manufacturer is at liberty to fix the maximum retail price of a non-scheduled formulation (branded or generic) launched by it. However, as per the DPCO, the manufacturers of non-scheduled formulations are not allowed to increase the maximum retail price of such formulations by more than 10% per annum.

(c): NLEM 2022 consists of 388 medicines (including 2 animal vaccines and 2 stents for heart)

(d): A total of thirty-four (34) new medicines comprising of 4 anti-cancer drugs have been included in NLEM 2022. These are lenalidomide, leuprolide acetate, Irinotecan HCI Trihydrate and Bendamustine Hydrochloride.

(e) and (f): Twenty-six medicines have been dropped in NLEM 2022. NPPA is mandated to fix ceiling prices of the essential medicines contained in Schedule-I of DPCO, 2013 and monitors price trends so that drugs remain affordable to all citizens in the Country.

GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA
UNSTARRED QUESTION No. 678
TO BE ANSWERED ON THE 9TH DECEMBER, 2022

Indian Pharma Industry

678. DR. AMAR SINGH:

Will the Minister of **CHEMICALS AND FERTILIZERS** be pleased to state:

(a) whether the Government has chalked out any action plan to ensure that the Indian pharma industry breaks into the top-10 countries in terms of value by 2030, and enter the top-5 club by 2047;

(b) if so, the details thereof; and

(c) if not, the reasons therefor?

ANSWER

MINISTER OF STATE IN THE MINISTRY OF CHEMICALS & FERTILIZERS
(SHRI BHAGWANTH KHUBA)

(a) to (c): The Government has taken several measures to encourage domestic manufacturing of Pharmaceutical drugs, including bulk drugs and medical devices to reduce import dependence and to establish a dominant position in the global market.

Various Programmatic interventions to support Pharma and Medical Devices Industries are as follows;

(i) Under the Production Linked Incentive (PLI) Scheme for promotion of domestic manufacturing of critical Key Starting Materials (KSMs)/ Drug Intermediates (DIs) and Active Pharmaceutical Ingredients (APIs) in India, with a financial outlay of Rs. 6,940 crores and the tenure from FY 2020-2021 to FY 2029-30, the financial incentive is planned to be provided for 41 identified products. A total of 51 applications have been selected under the scheme. Out of these, 21 projects have already been commissioned with the installed capacity of 33,895 MT.

(ii) Production Linked Incentive Scheme for Pharmaceuticals, with a financial outlay Rs. 15,000 crores and the tenure from FY 2020- 2021 to FY 2028-29, provides for financial incentive to 55 selected applicants for manufacturing of identified products under three categories for a period of six years.

(iii) Scheme for Promotion of Bulk Drug Parks, with a financial outlay of Rs. 3,000 crores and the tenure from FY 2020-2021 to FY 2024-25, provides for financial assistance to three States for establishing Bulk Drug Parks. After evaluation of the proposals received from 13 States, the proposals of the states of Gujarat, Himachal Pradesh and Andhra Pradesh have been finally approved for providing grants-in-aid for creation of common infrastructure facilities in the proposed Bulk Drug Parks.

(iv) The Department is implementing the scheme of Strengthening of Pharmaceutical Industry (SPI), with a financial outlay of Rs. 500 crores and the tenure from FY 2021-2022 to FY 2025-26 to provide infrastructure support for pharma MSMEs in clusters and to address the issues of technology upgradation of individual pharma MSMEs.

(v) Under the scheme for Promotion of Medical Devices Parks, final approval for financial assistance of Rs. 100 crore each, has been given to the States of Uttar Pradesh, Tamil Nadu, Madhya Pradesh and Himachal Pradesh for establishment of common facilities in their Medical Device Parks.

(vi) Under the Production Linked Incentive (PLI) Scheme for Promoting Domestic Manufacturing of Medical Devices, with a financial outlay of Rs. 3,420 Cr and with the tenure from FY 2020-21 to FY 2027-28, financial incentives is to be given to selected companies at the rate of 5% of incremental sales of medical devices manufactured in India and covered under the four Target segments of the scheme, for a period of five (5) years. A total of 21 applications/projects have been selected under the scheme. Out of these, 13 projects have been commissioned for 31 products.

The non-schematic interventions are as follows-

i. In order to attract investments in this sector, the Government has allowed 100% foreign direct investments (FDI) in medical devices sector. Similarly, the Government has allowed 100% FDI in pharma sector for greenfield projects under automatic route. For the brownfield projects, upto 74%, FDI investments are allowed under automatic route and beyond 74% to 100%, FDI investments are allowed under government approval route.

ii. In order to redress the specific challenges of the MedTech Industry, in view of the diversity and multi-disciplinary nature of the sector, the institutional mechanism of Standing Forum of Medical Devices Associations, has been set up to deliberate on various issues with all the stakeholders including regulators.

GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA
UNSTARRED QUESTION No. 623
TO BE ANSWERED ON THE 9TH DECEMBER, 2022

Self Reliance in Manufacturing of Pharmaceuticals

623. SHRI S. JAGATHRAKSHAKAN:

Will the Minister of **CHEMICALS AND FERTILIZERS** be pleased to state:

(a) whether the Government has taken any steps to make India self-reliant in Active Pharmaceutical Ingredients (APIs), Drug Intermediates (DIs) and Key Starting Materials (KSMs);

(b) if so, the details thereof; and

(c) if not, the reasons therefor?

ANSWER

MINISTER OF STATE IN THE MINISTRY OF CHEMICALS & FERTILIZERS
(SHRI BHAGWANTH KHUBA)

(a) to (c): Yes, Sir. In order to make the country self-reliant and to reduce import dependence in Active Pharmaceutical Ingredients (APIs), Drug Intermediates (DIs) and Key Starting Materials (KSMs), the Department of Pharmaceuticals, amongst other, is implementing the following three schemes:

(i) Production Linked Incentive (PLI) Scheme for promotion of domestic manufacturing of critical Key Starting Materials (KSMs)/ Drug Intermediates (DIs) and Active Pharmaceutical Ingredients (APIs) in India, with a financial outlay of Rs. 6,940 crores and the tenure from FY 2020-2021 to FY 2029-30, provides for financial incentive for 41 identified products. A total of 51 applications have been selected under the scheme. Out of these, 21 projects have already been commissioned with the installed capacity of 33,895 MT.

(ii) Production Linked Incentive Scheme for Pharmaceuticals, with a financial outlay Rs. 15,000 crores and the tenure from FY 2020- 2021 to FY 2028-29, provides for financial incentive to 55 selected applicants for manufacturing of identified products under three categories for a period of six years. The eligible drugs under this scheme include APIs among other categories of pharmaceutical products. A total of about 1,666 products have been approved for the selected 55 applicants under the scheme.

(iii)Scheme for Promotion of Bulk Drug Parks, with a financial outlay of Rs. 3,000 crores and the tenure from FY 2020-2021 to FY 2024-25, provides for financial assistance to three States for establishing Bulk Drug Parks. After evaluation of the proposals received from 13 States, the proposals of the states of Gujarat, Himachal Pradesh and Andhra Pradesh have been finally approved for providing grants-in-aid for creation of common infrastructure facilities in the proposed Bulk Drug Parks.

GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

RAJYA SABHA
UNSTARRED QUESTION No. 662
TO BE ANSWERED ON THE 13TH DECEMBER, 2022

Uniform Code of Pharmaceutical Marketing Practices (UCPMP)

662 Shri Mohammed Nadimul Haque:

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

(a) whether it is a fact that pharmaceutical companies are promoting specific drugs by incentivising doctors;

(b) the steps taken by Government to stop the over-use of such drugs which jeopardize the health of patients;

(c) the steps taken by Government to ensure mechanisms of transparency and accountability in the implementation of the Uniform Code of Pharmaceutical Marketing Practices;

(d) whether Government has taken any steps to prohibit the excessive flow of such irrational and high-priced drugs in the market; and

(e) if so, the details thereof and if not, the reasons therefor?

ANSWER

MINISTER OF STATE IN THE MINISTRY OF CHEMICALS & FERTILIZERS
(SHRI BHAGWANTH KHUBA)

(a) to (c): The Government has put in place a Uniform Code for Pharmaceutical Marketing Practices (UCPMP) for Pharmaceutical companies, which is in operation since 01.01.2015, to prevent unethical practices by the pharmaceutical companies. This code governs the conduct of pharmaceutical companies in their marketing practices, duly covering the various aspects such as medical representatives, textual and audio-visual promotional materials, samples, gifts, etc. Further, the code establishes relationship with healthcare professionals, wherein the provisions related to travel facilities, hospitality and cash or monetary grants to physicians or their families have been elaborated. The code also details the mode of operation of the code, responsibilities of the Pharmaceutical Associations in constituting the Ethics Committee for Pharmaceutical Marketing Practices (ECPMP) for handling the complaints and Apex Ethics Committee for Pharmaceutical Marketing Practices (AECPMP) for review, procedure of lodging a complaint, procedure of handling of complaints by the Pharmaceutical Associations and various penalty provisions.

The code has been adopted by the all the major associations of pharmaceutical companies and the Department on various instances has reviewed implementation of the code by the Pharmaceuticals associations. The complaints of violation of the voluntary UCPMP by pharma companies, as received by the Department, are forwarded to the concerned pharmaceutical associations for taking necessary action.

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

(d) to (e): As per information received from Central Drugs Standard Control Organisation (CDSCO) under the Ministry of Health & Family Welfare that the manufacture, sale and distribution of drugs in the country are regulated under the provisions of Drugs & Cosmetics Act, 1940 and Rules thereunder through a system of licensing and inspection. Licenses for manufacture, sale and distribution of drugs are granted by the State Licensing Authorities (SLAs) appointed by respective State Governments. Under the said Rules, Fixed Dose Combinations (FDC) is a New Drug. For the manufacture of any FDC falling under the definition of New Drug, permission is required from Central Drugs Standard Control Organisation (CDSCO) before obtaining manufacturing license for the New Drug from the concerned State Licensing Authority. Under the aforesaid Act, manufacture/sale/distribution of any banned drug is a punishable offence. State Licensing Authorities are empowered to take action in this regard.

Some cases of grant of manufacturing license of new drugs including Fixed Dose Combinations (FDCs) by some of the State Licensing Authorities (SLAs) without due approval of the Drugs Controller General (India) [DCG (I)] came to the notice of the Government. Apart from issuing repeated statutory directions under Section 33P of the Drugs & Cosmetics Act, 1940 to the State Governments not to issue such licenses to FDCs falling under definition of new Drugs without approval of DCG(I), the Central Government constituted an Expert Committee under the chairmanship of Prof C.K. Kokate to examine the safety and efficacy of such FDCs.

Based on the recommendations of the Prof. C. K. Kokate Expert Committee, the Central Government prohibited 344 FDCs vide notification dated 10.03.2016. Further, the Central Government also prohibited 5 FDCs vide notification dated 08.06.2017.

However, with respect to prohibition of the said 344 FDCs, several writ petitions were filed in different High Courts across the country challenging the ban of the FDCs. After that, the Hon'ble High Court of Delhi vide its order dated 01.12.2016 quashed the said notification. The Union of India challenged the said order of Hon'ble Delhi High Court before the Hon'ble Supreme Court by way of filing Special Leave Petition (SLP). Further, about 20 cases against 5 FDCs prohibited on 08.06.2017 which were pending before various High Courts across the country, were also transferred to Supreme Court. Hon'ble Supreme Court, vide its order dated 15.12.2017, directed that an analysis be made in greater depth and these cases of (344+5) FDCs should go to the Drugs Technical Advisory Board (DTAB) and/or a Sub-Committee formed by the DTAB for the purpose of having a relook into these cases.

Accordingly, a Sub-Committee of DTAB was constituted which after providing hearing to all the petitioners/appellants, submitted its report to DTAB which was accepted by DTAB. Based on the recommendations of DTAB, the Central Government, vide notifications dated 07.09.2018, prohibited 328

FDCs for manufacture, sale or distribution. The Government also restricted 06 FDCs for manufacture, sale or distribution with certain conditions vide notifications issued on the same date. However, various firms/stakeholders have filed writpetitions in various High Courts across the country including the Hon'ble Supreme Court against the said notifications dated 07.09.2018.

Earlier, in 2007, CDSCO had received complaints from consumer association regarding rationality of certain Fixed Dose Combinations (FDC) marketed in the country. As follow up action, CDSCO prepared a list of 294 FDCs and communicated to State Drugs Controllers vide letter dated 14.08.2007. A writ petition was filed in the Hon'ble High Court of Madras and the Hon'ble Court granted stay order. However, DTAB in its meeting held on 16.1.2008 constituted a sub-committee to examine these FDCs. The recommendation of the subcommittee was referred to Hon'ble Supreme Court. The Hon'ble Supreme Court in its judgment, dated 15.12.2017, accepted the recommendations of DTAB and ordered for disposal of these petitions. Accordingly, Central Government vide notifications S.O. 180(E) to S.O.259 (E), dated 11.01.2019, prohibited 80 FDCs for manufacture, sale or distribution.

GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE
DEPARTMENT OF HEALTH AND FAMILY WELFARE

RAJYA SABHA
UNSTARRED QUESTION NO.751
TO BE ANSWERED ON 13th DECEMBER, 2022

MANUFACTURING OF BANNED DRUGS

751: SHRI HARBHAJAN SINGH:

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

(a) whether certain cases of manufacturing and marketing of banned or unapproved drugs have been reported in the country;

(b) if so, the details thereof indicating the number of such cases reported during each of the last three years and the current year, State/UT-wise;

(c) the action taken against the offenders during the said period, State/UT-wise;

(d) whether Government proposes to put in place a comprehensive mechanism to stop the manufacturing and marketing of banned or unapproved drugs across the country; and

(e) if so, the details thereof?

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE
(DR. BHARATI PRAVIN PAWAR)

(a) to (c): A few cases of grant of manufacturing license of new drugs including Fixed Dose Combinations (FDCs) by some of the State Licensing Authorities (SLAs) without due approval of the Drugs Controller General (India) [DCG (I)] came to the notice of the Government.

36 cases of unapproved FDCs licensed by State Licensing Authorities (SLAs) considered as New Drugs, have been reported during the year 2020 to 2022 (till date). In all such cases, the office of DCGI took up the matter with respective SLAs for necessary action. Further, the State Drugs Controllers have also been requested in the Drug Consultative Committee meetings to ensure that new drugs and FDCs are not permitted without approval from the office of DCGI. The State/UT-wise details of these 36 cases is as below:

Uttarakhand (10), Maharashtra (02), Daman & Diu (01), Himachal Pradesh (09), Karnataka (02), Gujarat (04), Sikkim (05), Uttar Pradesh (02), Telangana (01)

(d) & (e): Manufacture, sale and distribution of prohibited/banned drugs is a punishable offence under section 18 of the Drugs and Cosmetics Act. State Licensing Authorities are empowered to take action in this regard.

GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

RAJYA SABHA
UNSTARRED QUESTION No. 1457
TO BE ANSWERED ON 20th December, 2022

Supply of medicines at affordable rates

1457 # Shri Narhari Amin:

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

(a) whether there is any special scheme to provide medicines at affordable rates to the common people living in rural areas;

(b) if so, the total amount of medicines made available in the rural areas during the last two years under this scheme; and

(c) the total consignment of medicines made available in rural areas of Gujarat in the last two years and the details thereof?

ANSWER
MINISTER OF STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS
(SHRI BHAGWANTH KHUBA)

(a): With an objective of making quality generic medicines available at affordable prices to all, especially the poor and the deprived ones, Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) was launched by the government in the year 2008. Under the scheme, dedicated outlets known as Pradhan Mantri Bhartiya Janaushadhi Kendras (PMBJKs) are opened all over the country to provide generic medicines to the masses. Till 30.11.2022, about 8,916 PMBJKs have been opened all across the country.

(b) & (c): Pharmaceutical and Medical Devices Bureau of India (PMBI), the implementing agency of the Scheme has opened four warehouses at Gurugram, Chennai, Guwahati and Surat, which are backed by SAP based inventory management system. In addition, there is a strong network of 36 distributors across the country. Medicines are supplied to the Kendras all across the country, including in rural areas, through this wide network wherein Kendra owners have an option to procure either from distributors or PMBI warehouse directly. During the financial year 2020-21, medicines and surgical devices worth about Rs. 665.83 Crore and in financial year 2021-22 worth about Rs. 893.56 Crore have been sold in the entire country.

About 1,759 medicines and 280 surgical devices have been included in the product basket covering all major therapeutic groups, viz., Analgesic & Antipyretic / Anti-inflammatory, Antidiabetic, Anti-biotic and Anti-Fungal, Cardiovascular System (CVS), Central Nerve System (CNS), Dermatology/Topical / External, Supplements / Vitamins & Minerals, Eye / Ear drops, Gastrointestinal (GIT), Respiratory, Anti-cancer, Steroids & Hormones, etc. Further, Jan Aushadhi Suvidha Oxo-biodegradable Sanitary Napkins are also being made available for sale @ Rs.1/ per pad only.

As per information provided by PMBI, during the Financial Year 2021-22 sale of about Rs. 27.10 crore was made in the state of Gujarat which has led to estimated savings of about Rs. 160 crore to the citizens as compared to the branded medicines. In the current financial year up to 30.11.2022, PMBI has made a sale of Rs. 24.12 crore in the State.

GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

RAJYA SABHA
UNSTARRED QUESTION No. 1458
TO BE ANSWERED ON 20th December, 2022

Differing quality standards in drugs manufacture

1458 Shri Ayodhya Rami Reddy Alla:

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

(a) whether differing standards are followed by pharmaceutical manufacturers in the quality of drugs being exported to developed and undeveloped countries or being used domestically; and

(b) whether it is a fact that the Indian pharmaceutical industry is more likely to sell substandard drugs in the poorly regulated markets of Africa than in the slightly better-regulated markets of middle-income and emerging economies as per an international study; and

© if so, whether Government plans to standardize the quality of generic medicine for all exports and domestic use?

ANSWER
MINISTER OF STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS
(SHRI BHAGWANTH KHUBA)

(a) to (c): The subject of quality of the drugs is handled by the Ministry of Health and Family Welfare and the Central Drugs Standard Control Organization (CDSCO) under the Ministry of Health & Family Welfare has informed that for the drugs meant for export, the manufacturer is required to meet the requirements of the importing country.

Further, for manufacturing drugs for export, the manufacturers are required to obtain license from the concerned State Licensing Authority (SLA) and the drugs are required to be manufactured in accordance to the conditions of license under the provisions of the Drugs and Cosmetics Act, 1940 and Rules made thereunder.

Ministry of Health and Family Welfare has taken various measures to ensure the quality of medicines manufactured in the country. A list of such measures is given in the Annexure to this reply.

Annexure

List of such measures to ensure Quality of Drugs.

(i) On 17-11-2022, the Drugs Rules, 1945 were amended vide G.S.R.823(E) which would come into force on 1st of August, 2023 providing that the manufacturers of drug formulation products as specified in Schedule H2 shall print or affix Bar Code or Quick Response Code on its primary packaging label or, in 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 stored data or information referred to in sub-rule (6) shall include the following particulars, namely:

(a) unique product identification code;
(b) proper and generic name of the drug;
(c) brand name;
(d) name and address of the manufacturer;
(e) batch number;
(f) date of manufacturing;
(g) date of expiry; and
(h) Manufacturing licence number.

(ii) On 18.01.2022, the Drugs Rules, 1945 were amended vide G.S.R. 20 (E) providing that every Active Pharmaceutical Ingredient (bulk drug) manufactured or imported in India shall bear Quick Response Code on its label at each level of packaging that store data or information readable with software application to facilitate tracking and tracing. The stored data or information shall include the minimum particulars including Unique product identification code, Batch No, MFG date, expiry date, etc.

(iii) The number of sanctioned posts in 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) On 11.02.2020, the Drugs Rules, 1945 were amended vide G.S.R. 101 (E), providing that w.e.f. 01.03.2021 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.

(v) On 6.11.2019, the Drugs Rules, 1945 were amended vide Gazette notification no. G.S.R.828(E), 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 with effective from 06.11.2019.

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

(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) 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.

(x) 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.

(xi) 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.

(xii) 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.

(xiii) 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.

GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

RAJYA SABHA
STARRED QUESTION No. 1464
TO BE ANSWERED ON 20th December, 2022

Medical devices sector

1464 Dr. Dharmasthala Veerendra Heggade:

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

(a) current market size of medical devices sector and number of domestic medical device manufacturers in the country;

(b) steps taken to build an ecosystem for innovation in medical devices and drugs, thereby enhancing the industry-academia linkages;

(c) whether India's import of medical devices is staggering at almost 80 per cent and if so, steps taken to reduce import dependence on medical devices;

(d) present status of Production Linked Incentive Scheme in manufacturing of medical devices; and

(e) whether all devices required for critical care are categorized as 'Scheduled Medical Devices' and brought under the National List of Essential Medicines?

ANSWER
MINISTER OF STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS
(SHRI BHAGWANTH KHUBA)

(a): Indian medical devices' market stood at USD 11 billion in 2020 as per Industry sources. The number of domestic medical device manufacturers is not available right now with the Department. As per the provisions of Medical Devices Rules, 2017 of Ministry of Health and Family Welfare, the medical devices are being brought under regulations (class A and B Medical Devices w.e.f 1.10.2022 and class C and D Medical Devices w.e.f 1.10.2023).

(b): There are seven National Institutes of Pharmaceutical Education and Research (NIPERs) under the Department. Besides conducting academic courses for the pharma and medtech sector, these institutes facilitate strong industry-academia linkages to build an ecosystem for innovation and research.

(c) and (d): The Government has taken several measures to encourage domestic manufacturing of medical devices and reduce import dependence and the programmatic interventions are as follows:

I. Under the scheme "Assistance to Medical Device Industry for Common Facility Centres", assistance was provided for establishment of common facility of Super conducting magnetic coil testing and research facility at Andhra Pradesh Medtech Zone Ltd. (AMTZ), Andhra Pradesh with a project cost of Rs.25 Cr.

ii. Under the scheme "Promotion of Medical Devices Parks", final approval has been given to the States of Uttar Pradesh, Tamil Nadu, Madhya Pradesh and Himachal Pradesh for establishment of common facilities in the Medical Device Parks being developed by these 4 States.

iii. Under the Production Linked Incentive (PLI) Scheme for Promoting Domestic Manufacturing of Medical Devices, with a financial outlay of Rs. 3,420 Cr and with the tenure from FY 2020-21 to FY 2027-28, financial incentives will be given to selected companies for manufacturing of medical devices covered under the four Target segments of the scheme, for a period of five (5) years. Under the scheme, a total of 42 applications have been received. So far, 21 applicants (including 10 MSME) have been approved and out of this, 13 applicants have commissioned their projects.

iv. Under the Production Linked Incentive (PLI) scheme for Pharmaceuticals, with the tenure from FY 2020-2021 to 2028-29 and incentives for a period of six years, five (5) industry applicants have been selected for manufacturing In-vitro diagnostic medical devices.

v. under the Pradhan Mantri Bharatiya Jan Aushadhi Pariyojana, efforts are made to make available 240 types of surgical supplies in over 8900 Jan Aushadhi Kendras at highly affordable prices.

(e): The mandate of revision of National List of Essential Medicines (NLEM) is with Ministry of Health and Family Welfare (MoHFW). Four 4 devices (Bare metal stents, drug eluting stents, condoms and intra uterine devices) have been included in the National List of Essential Medicines 2022 issued by MoHFW. Accordingly, NPPA under the Department of Pharmaceuticals, notified these 4 devices in revised Schedule-I of the DPCO, 2013 vide S.O. No. 5249(E) dated 11th November 2022.

GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE
DEPARTMENT OF HEALTH AND FAMILY WELFARE

LOK SABHA
UNSTARRED QUESTION NO.†1784
TO BE ANSWERED ON 16th DECEMBER, 2022

COMBINATION OF UNSCIENTIFIC MEDICINES

†1784: SHRI AJAY NISHAD:

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

(a) whether the Government is aware of the fact that the several unscientific combinations of medicines are being sold as a prescribed quantity of fixed dose combination;

(b) if so, the details thereof;

(c) whether the Government is aware of the fact that lax regulatory framework has led to such a situation across the country; and

(d) if so, the response of the Government thereto?

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE
(DR. BHARATI PRAVIN PAWAR)

(a) to (d): A few cases of grant of manufacturing license of new drugs including Fixed Dose Combinations (FDCs) by some of the State Licensing Authorities (SLAs) without due approval of the Drugs Controller General (India) [DCG (I)] came to the notice of the Government.

In all cases, where unapproved FDCs have been licensed by SLAs, CDSCO took up the matter with respective SLAs for necessary action. Further, the State Drugs Controllers have also been requested in the Drug Consultative Committee meetings to ensure that new drugs and FDCs are not permitted without approval of DCG(I).

Manufacture, sale and distribution of prohibited/banned drugs is a punishable offence under section 18 of the Drugs and Cosmetics Act. State Licensing Authorities are empowered to take action in this regard.

GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE
DEPARTMENT OF HEALTH AND FAMILY WELFARE

LOK SABHA
UNSTARRED QUESTION NO.1807
TO BE ANSWERED ON 16th DECEMBER, 2022

CONTAMINATED COUGH SYRUP

1807: SHRI ANUBHAV MOHANTY:

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

(a) whether the Government is aware that many children/infants have lost their lives after consuming contaminated cough syrup;

(b) whether the Government has taken/proposed to be taken steps to ensure that Indian pharmaceutical products are not of sub-standard quality or contaminated, if so, the details thereof;

(c) the details of the action taken by the Government against pharmaceutical companies that are habitual offenders;

(d) whether there is a lack of coordination between State and Central drug regulators, if so, the details thereof;

(e) whether the Government has any plans to centralise all licensing functions with the Central regulator, if not, the reasons therefor;

(f) whether the Government has any plans to establish a statutory regulator for pharmaceuticals and medical devices thereby revamping the Central Drugs Standard Organisation (CDSO); and

(g) if so, the details thereof and if not, the reasons therefor?

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE
(DR. BHARATI PRAVIN PAWAR)

(a) to (g): There is a regulatory framework under the provisions of Drugs and Cosmetics Act and Rules to regulate drugs, medical devices and cosmetics. Manufacture, sale and distribution of Drugs is primarily regulated by the State Licensing Authorities (appointed by respective State Governments) through a system of licensing and inspection while the Central Licensing Authority is responsible for approval of New Drugs, Clinical Trials in the country, laying down the standards for Drugs, control over the quality of imported Drugs etc. Isolated cases of allegedly contaminated cough syrup leading to death in Children have been reported in the past.

For regulation of Medical Device, comprehensive Medical Device Rules 2017 have been published which came into force with effect from 1st day of January, 2018.

The cases concerning quality or safety of drugs when reported, the matter is taken up with the concerned State Licensing Authority (SLA) in order to take necessary action under the provisions of Drugs and Cosmetics Act 1940 and its Rules. The State Licensing Authorities are empowered to take action on violation of any conditions of such licenses including prosecution in appropriate Court of law.

Central regulator coordinates activities of State Drug Control Organisations and provides expert advice through the Drugs Consultative Committee (DCC) meetings held with State Drugs Controllers for uniformity in administration of the Drugs and Cosmetics Act.

NEWS

Tamil Nadu: 4 ESI Staffers held in Rs 27 Crore Medicine Scam

Four employees of the Employees State Insurance (ESI) Corporation have been booked for submitting fake documents and causing 27 crore loss to the government while placing orders for lifesaving drugs during the tenure of the previous government.

Directorate of Vigilance and Anti-corruption (DV&AC), in its first information report (FIR), named Dr Enbasekaran, former director of Medical and Rural Health Service, Dr John Andrew, the former regional administrative medical officer (RAMO) of ESI in Madurai, Amarnath, former superintendent of the office of director of Medical and Rural Health Service in ESI, Chennai and Ashok Kumar, former superintendent, RAMO, ESI, Chennai as suspects.

The DVAC said these officials tried to obtain pecuniary advantage from private Pharma companies by placing bulk orders worth about 41 crore, instead of buying medicines for 13.1 crore as per the instructions of the medical store officer. The FIR stated that the procurement list of medicine was prepared by the medical store officer Kalyani for ESI's Madurai region for the year 2017-18 under the central medical store, ESI scheme. The purchase order was to be placed for medicines worth 13.12 crore.

The FIR mentioned that the purchase proposal was initiated by the medical store officer without informing the medical officer of Madurai. The accused named in the FIR had forged the indent for the procurement of medicines with the ulterior motive to obtain pecuniary advantage for themselves from private medicine manufacturing units with the purchase of bulk orders. Further inquiries revealed that the audit officer in the office of the principal accountant general had conducted inspections from January 22, 2018, to February 6, 2018 at the office of the RAMO.

The worst part of the suspected scam is the fact that the accused officials even transferred another officer who refused to toe their line, prompting the latter had to approach the high court to overturn the transfer.

Source: *The Times of India,* 20th November 2022

A Week on, Drugmakers Grapple with QR/Bar Code Logistics

Industry players could seek more time from Government to roll-out

Faced with supply-chain and price issues, drugmakers are looking to seek more time from the Government to sport QR or barcodes on their medicines.

A week ago, the Centre had mandated that the country's 300 top brands sport QR/barcodes by August 2023, in an effort to weed out fake and counterfeit products.

Pharma industry representatives agree the writing is on the wall when it comes to improving the traceability of their products and the authenticity of the medicine for consumers. But they are still evaluating the logistics involved in its roll-out, said

representatives, speaking for drugmakers of all hues.

While they were aligned with the concept, Vivek Sehgal, Director General of the Organisation of Pharmaceutical Producers of India (OPPI) said, they would seek more time, as they were grappling with the backend logistics of the supply chain and of medicines that are imported in the country. OPPI is a platform largely representing multinational drugmakers in India and has 26 companies on board.

Speaking for large domestic drugmakers, Sudarshan Jain with the Indian Pharmaceutical Alliance, said they were evaluating the details of the roll-out and the logistics involved across the different manufacturing plants, formulations and so on. In fact, speaking for mid and small-sized companies, the Indian Drug Manufacturers Association's Daara Patel said, they too were evaluating the cost and logistic implications involving packaging.

Though the bar and QR codes are for the top 300 brands, for now, industry watchers say, the planning should keep in mind that there are 10,000 production facilities in the country and 60,000 formulations, sold across eight lakh retailers.

One-time investment

Meanwhile, service providers of track and trace technologies say, the process involves a minimal, one-time investment and possible "retooling" of systems, that drugmakers will have to undertake in the interest of their products and consumer safety, especially against the backdrop of the Gambia incident, where deaths of over 60 children are being investigated for potential links to adulterated syrups from a company in India. While the quality of the product is itself being called into question, having complete traceability on the product's supply chain would have helped investigation, says a technology provider.

Pharmaceuticals are among the top industry segments faced with the problem of fakes and counterfeits, says Lokesh Harjani, Founder and CEO, OnSpot Solutions, and this was witnessed particularly during the pandemic. OnSpot offers cloud-based anti-counterfeiting, brand protection and product authentication services. Explaining the technology they provide, he said, it involved simple tools that aligned with a company's systems. Stressing its importance, he said, it was significant given the brand-sales erosion it could prevent, besides the safety it could ensure a consumer armed with a mobile phone.

Source: *The Hindu Businessline,* 25th November 2022

Top Novartis Cardiac Drug to go off Patent

Cardiology, one of the fastest growing therapies after diabetes, is all set to witness intense action in the Pharma retail market as a blockbuster drug is going off patent. Major companies including Natco, Cipla, Torrent, Lupin, Sun Pharma and USV are readying plans to enter the Rs 24,000-crore space to get a slice of the opportunity, with Swiss major Novartis's blockbuster cardiology drug losing patent protection in January.

Industry experts expect cut-throat competition in the heart failure therapy, with over 50 companies launching generic versions of Swiss firm Novartis's heart failure drug, Vymada (Sacubitril and Valsartan) at a fraction of the innovator's price. People suffering from cardiac problems can therefore look forward to substantial savings in their healthcare budget.
The drug enjoys a near 40% compound annual growth rate (CAGR). It is one of the fastest growing molecules in the cardiology segment. The combination Sacubitril and Valsartan, currently under patent from Novartis, is indicated for heart failure patients with 'reduced ejection fraction'. The Swiss firm markets the heart failure drug as Entresto, estimated to have $4 billion annual sales worldwide.

Affordable versions of the blockbuster drug are expected to hit retail chemists in January, reducing the cost of the therapy by nearly half. A similar trend was witnessed in another chronic therapy when cheaper versions of US Merck's diabetes blockbuster drug Januvia (Sitagliptin) hit the market in July, slashing patients' bill by nearly a third.

Cardiovascular diseases (CVDs) are the leading cause of death globally. The World Health Organization estimates that CVDs will account for over 35% of all deaths in India by 2030, up from 25% as of 2016.

Besides Novartis's Vymada, Dr Reddy's, JB Chemicals and Mankind are the other players who are marketing it under their own brands at present. The Swiss firm had launched its brand in India in February 2017, and in-licensed it to Cipla and Lupin.
"No single drug in the Pharma space has reached a size of Rs 550 crore over five years. With several companies entering the space with the innovator brand going off patent, volumes are expected to triple. There will also be a reduction of prices (from the innovator's price) by 50-75% over the next few months," an industry expert told TOI.

Keeping in mind its potential, companies including Mumbai-based JB Chemicals and Hyderabad-based Dr Reddy's, armed their portfolio through the acquisition of brands Azmarda and Cidmus, respectively, from Novartis, earlier this year. Most companies whom TOI contacted declined to comment on the matter due to the confidentiality involved around launch. However, some of them confirmed plans separately on condition of anonymity.

Heart failure is a progressive chronic

syndrome characterised by a decrease in functional status and quality of life. The burden of heart failure is experienced by an estimated 23 million people worldwide. In India, the prevalence is estimated to be about 1% of the population.

Source: *The Times of India,* 3rd December 2022

Pharma Industry to Grow to $130 billion by 2030: Pharmexcil

The Indian pharmaceutical industry is expected to grow at a compound annual rate (CAGR) of 12% and reach $130 billion by 2030, industry executives said at an industry event.

"There is a strong push from the government towards creating an ecosystem for innovation so that India can become a leader in discovery of drugs and medical technology," said S.V. Veeramani, Vice-chairman, Pharmexcil.

"Currently, the Indian pharmaceutical market is valued at around $50 billion, out of which almost $25 billion constitutes the export market. The domestic market will touch $130 billion by 2030 out of which over 60% will only be exports,' he added.

Industry executives said the government should set up a separate Ministry for the Pharma sector to encourage domestic producers and help bring down Chinese imports.

They also mulled the idea of having a single industry organisation to put across the grievances of the Pharma industry before the government, to help expand it to its true potential.

They were speaking at the 15th edition of CPHI & PMEC India.

Vivek Singhal, director general of The Organisation of Pharmaceutical Producers of India said: "The industry needs to collaborate and co-work and unite for a collective voice on IPR related issues."

Ravi Uday Bhaskar, director general, Pharmexcil said: "Indian Pharmaceutical exports have recorded an impressive growth of around 5% in the current financial year. Despite having global challenges, we have exported over $25 billion in the biggest market, which means about 30% of our exports are going to the US."

Addressing the opportunities in this sector, Yogesh Mudras, managing director, Informa Markets in India, the organisers of the event, said, "India's Pharmaceutical sector has emerged as a life sciences leader within the post-pandemic order."

"India's Pharmaceutical sector is a $50 billion industry and is anticipated to grow to at least $150 billion in less than a decade. The government is also developing new strategies to strengthen the sector which has led to the creation of innovation hubs making India an ideal testing ground for innovations in digital health" he added.

Source: *The Hindu,* 3rd December 2022

Indian Pharma Cos Turn Bullish on M&A Route

SNAP UP MNCs' BRANDS TOO THIS YR

Target	Acquirer	Top 10 deals by value (in $mn)
Panacea	Mankind	253
Curatio Health	Torrent	250
Sanzyme	JB Chem	85
Oaknet	Eris Life	83
Novartis	Dr Reddy's	62
Anglo French	Lupin	44
Razel	JB Chem	39
Novartis	JB Chem	33
Boehringer Ingelheim	Lupin	26
J&J unit (Telangana)	Hetero	16

(Source: Industry)

Mergers and acquisitions (M&As) are not new in the recession-proof domestic Pharmaceuticals sector. But this year has been unique.

The industry saw 16 deals during 2022 — the largest perhaps in a decade, worth nearly a billion dollars in value. Industry experts estimate the volume could be more. Interestingly, it's not foreign companies that have backed these acquisitions. It's the local firms that have become aggressive acquirers, snapping up brands of even MNCs. In the past, foreign firms such as Abbott, Daiichi Sankyo and Sanofi made headlines with sizeable buyouts of domestic players like Piramal Healthcare, Ranbaxy and Shantha Biotech respectively. There were only a few where domestic firms-led M&As. Significantly, a majority of the M&A deals in the Pharma sector have been backed by private equity (PE) investors.

Among the largest deals this year are Torrent Pharma's buyout of dermatology firm Curatio Healthcare for Rs 2,000 crore, and Mankind Pharma's acquisition of Panacea's domestic formulation brands for Rs 1,872 crore (see graphic). Among companies, Mumbai-based JB Pharma announced four deals this year, the highest number in the industry with the latest being the acquisition of Glenmark's cardiac brand Razel (Rosuvastatin and combinations) in India and Nepal, for Rs 314 crore. Ahmedabad based Torrent Pharma has been aggressive on the deal front too.

"Deal activity has been very lively in the domestic Pharma market. Large Indian players are doubling down on the country as an attractive diversification from a US generics market that's beaten up heavily by price erosion. As a consequence, we saw several deals where Indian companies snapped up brands from local sellers. Brands have been supported by attractive valuations and active interest. Looking ahead to 2023, we see more of the same, given slow growth elsewhere in the world," said Sujay Shetty, global health industries advisory leader at PwC India.

The Indian Pharmaceutical sector is expected to log a growth of 8-10% this fiscal, buoyed by robust expansion in the domestic Pharma market, and exports to semi-regulated markets. The Rs 1,91,887-crore organised Pharma retail market registered a growth of 6% moving annual total as of November. The market grew 14% in November year-on-year, according to data from market research firm IQVIA.

"Most M&As have been done by Indian strategics, including ones backed by Indian PEs. Foreign-branded formulation companies,

on the other hand, have been net sellers in the branded generic space. This is an outcome of their global portfolio rationalisation strategy, which is directing them to shed their branded generic portfolio in emerging markets," noted Sunil Thakur, partner at PE firm Quadria Capital.

Overall, deal activity has been heightened with India Inc becoming aggressive on overseas acquisitions. "The YTD (year-to-date) 2022 deal volumes are on par with YTD 2021, which should be taken as a positive response, considering the black swan events at the start of the year. This was due to higher activity witnessed in the first six months, thereby making YTD22 much better than YTD21. On the other hand, values saw a 47% increase due to a couple of multi-million-dollar deals executed during the year, driven by a significant 135% increase in M&A values," a recent deal tracker analysis by Grant Thornton Bharat said.

Source: *The Times of India,* 19th December 2022

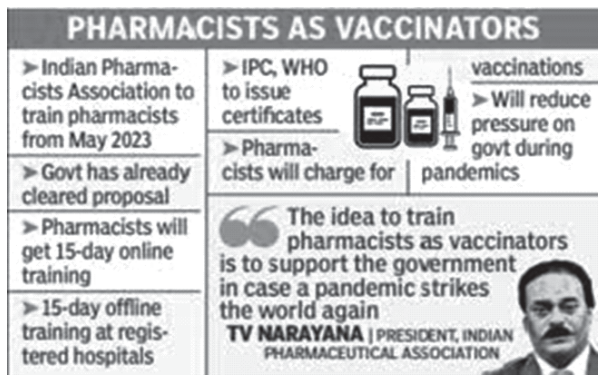
Pharmacists to Soon Start Administering Vaccine Jabs

Worried about who will administer vaccines in the absence of doctors and nurses, particularly in rural areas? Now, pharmaceutical shop owners could come to your help.

The Indian Pharmaceutical Association (IPA) has started an ambitious programme to turn Pharmacist's into 'vaccinators' by providing training. The IPA has set a target to train all 12.5 lakh registered pharmacists in India to take up the role of vaccinators by 2025, which it feels would save at least 25% lives in a global crisis like Covid-19 pandemic.

The training would commence from May 2023, where pharmacists would be provided online training for 15 days followed by 15 days offline training at registered hospitals. They would also be provided a certificate by IPA, and World Health Organisation (WHO).

3/03/2023, 15:04 Pharmacists to soon start administering vaccine jabs | Nagpur News-TimesofIndia https://timesofindia.indiatimes.com/city/nagpur/pharmacists-to-soon-start-administering-vaccine-jabs/articleshow/97233591.cms 1/1 Speaking to TOI on the sidelines of the 72nd Indian Pharmaceutical Congress (IPC) valedictory function, IPA president Prof TV Narayana said the government had already approved their proposal in this regard. The practice is prevalent in developed countries like the United States and the United Kingdom.



"The initial training would be provided by the International Pharmaceutical Federation (FIP), a global body representing pharmacy and pharmaceutical sciences. IPA is also associated with them. Their experienced members from various countries would initially train a few pharmacists, who will then act as trainers. The objective is to support the government in future if such a pandemic strikes the world again."

Asked why pharmacists would come forward for this, Narayana, who is also IPC Association general secretary, said a revenue model was designed where they could charge commercial rates from patients. "However, during a pandemic, they would provide free services. In the last two years, the government has provided over two crore doses to citizens across the country to fight the Covid-19 pandemic. It had raised a big workforce for the mammoth task and trained many. We realised pharmacists would be of big help in this sector. In many remote villages, you will not find dispensaries or nurses, but medicine shops are always available in every nook and corner of India," he said.

Explaining the system in western countries, Narayana said pharmacists were trained in inoculation there, but here it was not possible as it was not part of their syllabus. "It would not only reduce a big burden on government machinery and doctors, nurses and paramedical staff, but also help pharmacists earn additional revenue. Moreover, they can also act as counsellors to patients on immunization and work as frontline workers in the battle against pandemics, which may be never ending," he said.

Source: *The Times of India,* 23rd January 2023

Serum Institute of India launches First Made-in-India HPV Vaccine for Cervical Cancer

The indigenously developed vaccine, "CERVAVAC" launch took place in the presence of Home Minister Amit Shah, Adar Poonawalla, and the Director of Government & Regulatory Affairs at Serum Institute of India, Prakash K Singh. 'CERVAVAC' is an outcome of a partnership of DBT and BIRAC with the Bill and Melinda Gates Foundation, supported by Serum Institute of India Private Limited for the indigenous development of quadrivalent vaccine through its partnership programme 'Grand Challenges India'.

Chief Executive Officer of Serum Institute of India (SII), Adar Poonawalla, announced the launch of the first made-in-India Human Papillomavirus (HPV) "CERVAVAC" vaccine, for the prevention of cervical cancer. The launch took place in the presence of Home Minister Amit Shah, Adar Poonawalla, and the Director of Government & Regulatory Affairs at Serum Institute of India, Prakash K Singh. "On the occasion of India's National Girl Child Day and Cervical Cancer Awareness Month, @SerumInstIndia is pleased to launch the first made-in-India HPV vaccine by the hands of our Hon'ble Home Minister Shri @AmitShah Ji.@Prakash Ksingh7," tweeted Adar Poonawalla.

'CERVAVAC' is an outcome of a partnership of DBT and BIRAC with the Bill and Melinda Gates Foundation, supported by Serum Institute of India Private Limited for the indigenous development of quadrivalent vaccine through its partnership programme 'Grand Challenges India'.

Earlier in December last, Dr NK Arora, Chairman of the COVID working group, National Technical Advisory Group on Immunisation (NTAGI) had said that it is expected India to get the HPV vaccine, by April at one-tenth cost. Speaking to ANI, Dr Arora said, "There are two or three companies which are in the process (of manufacturing the vaccine in India) but the Serum Institute of India (SII) has already got the regulators' clearance and the vaccine should be available for our patients by April or May 2023."

"The vaccine should be available soon. I don't know the exact cost yet but am given to understand that the cost of the vaccine will be one-tenth of the internationally-branded vaccine currently available," he added. Dr Arora further informed that almost 80,000 cases of cervical cancer occur in India every year. "During the last 24 hours, our country lost 95-100 women due to cervical cancer.

India accounts for the bulk of deaths from cervical cancer in the world. Almost 80,000 cases are reportedly worldwide every year. What is important to note here is that cervical cancer is entirely preventable through vaccination. The Human Papilloma Virus or HPV causes cervical cancer and a vaccine is available which can prevent it," he added. He said the Union government will be able to roll out the HPV vaccine as part of its national health programme for girls aged between 9 and 14 years. (ANI)

Source: *ET Healthworld,* 25th January 2023

DCA in Telangana Should Create Industry-Friendly Atmosphere for Pharma Industry: Dr PV Appaji

The top level officers in the health department and the senior officers at the drugs control administration (DCA) under the Government of Telangana should create conducive operational atmosphere for the Pharma manufacturing industry, especially for the small-scale and medium level formulation units, to operate freely in compliance with all the norms of the Act and the Rules.

Stringent norms and rigid enforcement activities will discourage the entrepreneurs from jumping forward and often put them into trouble. The formulation industry of Telangana enjoys a reputation for quality products and services and there is no distinction between products of larger units and of small-scale industries working in Telangana, says Dr PV Appaji, former director general of the Pharmaceuticals Export Promotion Council of India (Pharmexcil).

“As far as the medicinal products manufactured by the big players and the MSMEs in Telangana are concerned, the quality of the products of both the sectors is the

same and no complaint is coming from any part of the world. All the MSME units and the corporate sector manufacturers follow the same principles. Hence Telangana's Pharma industry has very less defects in their production process and in quality aspects when compared with those of other states. The number of NSQs declared by the regulatory bodies is also less in Telangana," he told Pharmabiz in a telephonic interview.

Concerned over the pathetic status of the MSMEs, Dr Appaji opined that the industry association itself can build a conducive atmosphere for growth provided they hold regular interaction with the Department of Pharmaceuticals (DoP) under the central government as well as go side by side with the state government. The DoP has several plans to boost up the industry and it funds under various schemes to the MSME units. The association should utilize such schemes for the benefit of their member units. In the same way, the government of Telangana is providing all support to the Pharma sector. Fortunately, the ministers of the industry and the health departments are experienced persons with good vision for the future. The present secretaries of the departments are also experts in their areas. So, this is the best time for the Pharma sector in Telengana to prosper, he said in response to a question from Pharmabiz.

Sharing further information, Dr Appaji, who is now advisor to several industry associations including Indian bulk drugs manufacturing industry, said the MSME sector has to become proactive in their vision and in the dealings with government officials. The association should apprise the government and the officers of the necessity of an industry-friendly approach by the regulatory officials. Currently, the regulatory officers are reportedly behaving in an arrogant and hostile manner. The association should inform the chief minister, the health minister and the industry minister about the way the enforcement agency is acting and want ministerial level intervention in the matter to solve the issues. At the same time, the association should make all attempts for regular interaction with the top bureaucrats and the ministers under central and state governments.

Further, Dr Appaji suggested that there are senior industry experts, policy experts and Pharma ideologues in Hyderabad. The drug manufacturers should seek their advice and suggestions for the industry's development. He said everybody in Telangana and in Andhra Pradesh knows that the Pharma MSME units are in trouble and in struggles due to the rigid enforcement activities of the drug control department.

An industry person in Hyderabad, in anonymity, told Pharmabiz that the department of drug control in Telangana and also in Andhra Pradesh is headed by senior civil service officers who always stick to rules and regulations specified in the book. They do not want to know the problems of the industry or the exertions taken by the entrepreneurs.

He said because of this strict method of enforcement of drug rules, no new entrepreneur is coming forward to start a Pharma unit.

Source: *Pharmabiz,* 6th February 2023

Government to Clamp Down on e-pharmacies

The government will take strict action against companies which will sell online drugs without license, a top official told the New Indian Express. Nearly two dozens of companies have received show cause notice from the Ministry of Health. Companies including Practo, Tata1mg, Amazon, Flipkart, Zeelabs, Netmeds, Apollo, ParmEasy and Healthcart have to submit their response to the Central Drugs Standard Control Organisation (CDSCO) within two days.

"We have asked more than 20 companies to show cause within two days from the issue of our notice, why action shall not be taken against them for online sale of such drugs. In case we don't receive any reply, we will take strict action against these companies without any further notice," the official cited above who didn't want to be quoted.

"The government has received various representations raising concerns regarding sale of drugs via online platforms in contravention to the Drugs and Cosmetics Act, 1940 & Rules there under. Some drugs are also being sold online which are only allowed for sale by retail under a valid prescription of a registered medical practitioner and supplied under the supervision of a Pharmacist," the official added.

The CDSCO has also forwarded the Delhi High Court order of 2018 giving injunction on online sale of drugs to all the States/UTs drugs controllers. There are cases in various courts in this regard requesting to prohibit the online sale of drugs, the official said.

He further stated that the sale or exhibit or offer for sale or distribution of drugs through online, internet or other electronic platforms including various mobile applications without a license have potential impact on quality of drugs and pose risk to the public health due to potential misuse of drugs through self-medication, indiscriminate use of the drugs etc.

Several firms get show cause notice

Nearly two dozen firms have received show cause notice from health ministry. Firms including Practo, Tata1mg, Amazon, Flipkart, Zeelabs, among others, have to submit their response to CDSCO within two days.

Source: *The Indian Express,* 10th February 2023

Pharma Exports to Top 10 Destinations Decline 4.2% in FY 22

Pharma exports to the top 10 destinations for the industry have seen a decline of 4.2 per cent during the last fiscal year ended March, 2022, led by a decline in exports to countries including South Africa and United States of America, according to the Ministry of Commerce and Industry.

Exports to the top 10 destinations have come down to $12.15 billion during the year 2021-22, as compared to $12.69 billion in 2020-21, even though the exports to some of these destinations have seen a growth, according to the data. However, compared to the $10.83 billion exports to these countries in 2019-20, the financial year 2021-22 has reported a 12.18 per cent growth.

The top 10 destinations that India exports pharmaceutical products in terms of value are the USA, United Kingdom, South Africa, Russia, Nigeria, Brazil, Germany, France, Netherlands and Belgium, respectively. These destinations contributed around 50 per cent of the total pharma exports from the country in the last three years. The total exports for the year 2019-20 was $20.703 billion, which has seen a growth to $24.44 billion in 2020-21 with a significant momentum, while losing it to have only a 0.6 per cent growth in the fiscal year 2021-22 at $24.59 billion, which not in tandem with the government's target.

The exports to South Africa, which is the third largest export destination for Indian pharma in terms of value, has seen a decline of 26.5 per cent decline to $612.68 million in 2021-22, as against $ 833.53 million in the year of 2020-21, during the peaks of Covid-19 across the world.

Exports to USA, the largest destination in terms of value, has declined to $7.1 billion in 2021-22, as against $7.71 billion during the previous fiscal year, while exports to UK, which is the second largest destination in 2021-22, declined to $706 million as against $716.52 million in the previous fiscal year.

Similarly, pharma exports to Germany have also seen a decline to $529.28 million in FY 22, as compared to $575.47 million registered in the previous year.

Exports to Russia, Nigeria, Brazil, France, Netherland and Belgium, however, reported a growth. Pharma exports to Russia have registered a marginal growth to $598.24 million in FY 22, as compared to $590.69 million, while exports to Nigeria registered a growth to $588.34 million as compared to $573.17 million during the comparable period.

Exports to Brazil grew to $583.75 million compared to $525.28 million, France to $513.69 million from $412.81 million, Netherland to $460.58 million compared to $375.18 million, and Belgium to $449.06 million as against $370.19 million during the comparable fiscal years, according to data from the Ministry.

Union minister of state in the ministry of commerce and industry, Anupriya Patel has recently said in the Parliament that the recent trade agreements signed by India along with various other initiatives by the Centre has given wider market access for Indian pharmaceutical products and medical devices.

Some of the major initiatives taken by the government to utilise the potential market for export of drugs and medical devices include the financial assistance provided under the Market Access Initiative (MAI)

scheme of Department of Commerce to develop new markets, to promote new products and new exporters as well as to consolidate the existing Indian exports markets.

The activities supported under the MAI scheme include organising/participating in fairs, exhibitions and buyer seller meets abroad and reimbursement of expenditure incurred by exporters on statutory compliances such as product registration charges, plant inspection charges etc.

"The recent trade agreements signed by India, namely, India-UAE Comprehensive Partnership Agreement and India-Australia Economic Cooperation and Trade Agreement have given wider market access for Indian pharmaceutical products and medical devices," said the Minister in response to a question in the Parliament.

Pharmaceutical products and medical devices have been covered under RoDTEP Scheme (Remission of Duties and Taxes on Exported Products) with effect from December 15, 2022 under which the duties/ taxes/ levies paid by the exporters at the Central, state and local levels, that were not being rebated/refunded so far, will be refunded/rebated thus enhancing the export competitiveness of pharmaceutical industry.

The market access issues highlighted by Indian pharma exporters are regularly taken up with concerned trade partners through Indian Missions as well as through bilateral institutional mechanisms with these countries. In case of Russia, the meeting of India-Russia Sub-Group on elimination of barriers and restrictions in trade, economic and investment spheres was held on December 22, 2022 wherein trade issues of the pharmaceutical sector were raised, she added.

Source: *Pharmabiz,* 15th February 2023

Government Steps up Efforts to Drive Innovation in Pharmaceutical Sector

The government has begun stakeholder consultations to identify 'moonshot' projects and role of industry as it plans to roll out its latest budget proposal to promote research and innovation in the pharmaceutical sector to be taken up through centres of excellence. "We are in the process of identifying seven centres of excellence (CoE) which will undertake research in moonshot areas," N Yuvaraj, joint secretary, department of pharmaceuticals, to ET

Yuvaraj said the CoEs will be government institutions like National Institute of Pharmaceutical Education and Research (NIPERs), India Institute of Technologies (IITs), and other public universities.

"We will finalise the moonshot projects, and the quantum of investment required by March end in consultation with the stakeholders; the programme will be rolled out two-three months thereafter," Yuvaraj said.

"The government will be investing in these projects, along with the private sector participation," he added.

Yuvaraj said the industry response has been encouraging so far. An industry person said some of the moonshot research projects will be specific to India requirements like precision medicine, infectious diseases, chronic disease management, artificial intelligence, among others.

Finance minister Nirmal Sitharaman in her latest budget announced a new programme to promote research and innovation in pharmaceuticals, which will be taken up through centers of excellence. "We shall also encourage industry to invest in research and development in specific priority areas," Sitharaman said.

In addition to CoE, the government also made proposals in the budget to support faculty from medical colleges and R&D teams from the industry; access is being granted to facilities at select laboratories that are run by the Indian Council of Medical Research where they can undertake research activities

The Indian Pharmaceutical industry, which is a powerhouse of generic pharmaceuticals, is still to establish itself as an innovator. The industry, especially large Indian pharmaceutical companies, are trying to move up the value chain from copycat drugs to innovation driven products, but that transition hasn't been easy, due to lack of drug discovery ecosystem in the country that includes strong academic research, risk funding, robust intellectual property regime, and lack of success stories, among others.

Meanwhile, China, which has started late, has made a huge headway, by investing in research, reforming its regulatory systems, establishing bioclusters and tapping the talent returning from overseas. Indian industry has been asking for tax rebates on investments in R&D, and urging the government to take steps to actively foster innovation through strengthening research in the public academic institutions.

Source: *The Economic Times,* 14th February 2023.

IDMA Urges DoP to Delete Para 18 (i) of DPCO-2013 as it Leads to Lower Prices of Pharma Products

The Indian Drug Manufacturers' Association (IDMA) has urged the Department of Pharmaceuticals (DoP) to revisit their long pending recommendation of deleting Para 18 (i) of Drug Prices Control Order (DPCO-2013) as it leads to lower prices of Pharma products and will also lead to increase in cases of overcharging.

According to the industry, the new National List of Essential Medicines (NLEM) will see further reduction in prices for the formulations which will be covered in the Scheduled category going forward. Para 18 (i) of DPCO-2013 averages the prices of scheduled formulations every 5 years.

As a part of the representation made by the IDMA, DoP has also suggested to make use of Integrated Pharmaceutical Database Management System (IPDMS 2.0) for the impact to be minimized for scheduled

formulations.

IPDMS 2.0 envisages creating an authentic database of information on products, prices, production and sale of scheduled, non-scheduled formulations and active pharmaceutical ingredients (APIs). It also aims to optimize synergies in operations by providing a single window for submissions of various forms as mandated under the Drug Prices Control Order (DPCO) - 2013.

The NPPA on February 6 this year revised and fixed the ceiling price of 400 scheduled formulations with an average reduction of 15.39 per cent in ceiling prices, according to the ministry of chemicals and fertilisers.

The Ministry said that the Department of Pharmaceuticals (DoP) notified Revised Schedule-I of Drugs (Prices Control) Order (DPCO) on November 11, 2022 incorporating the National List of Essential Medicines (NLEM), 2022 notified by the ministry of health and family welfare on September 13, 2022.

There are 388 medicines (including 2 animal vaccines and 2 stents) consisting of approximately 954 formulations in the Revised Schedule-I of the DPCO, 2013.

Ceiling prices of total 890 scheduled formulations have been fixed under the NLEM-2015, out of which ceiling prices of 174 formulations have been fixed during the last five years.

Retail prices of 2,262 new drugs have been fixed under DPCO, 2013 till February 3, 2023, out of which retail prices of 1,821 new drugs have been fixed in the last five years.

NPPA capped trade margin of non-scheduled formulations of 42 select Anti-cancer medicines under “Trade Margin Rationalization” approach in February, 2019, whereby the price of around 500 brands of anti-cancer medicines were reduced by up to 90%. This is in addition to 86 scheduled anti-cancer drugs whose ceiling prices have been fixed by NPPA.

A total of 5,178 cases alleging overcharging were received in NPPA during the period April, 2018 to January, 2023. NPPA examines such cases and if sufficient information indicating overcharging is found, overcharging proceedings are initiated as per the provisions under DPCO- 2013.

Source: *Pharmabiz,* 15th February 2023

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