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SILVER JUBILEE YEAR 2016

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25 Years

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Newsletter of Tamilnadu Pharmaceutical Sciences Welfare Trust

Jan. - Feb. - Mar. 2022

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Pharma Web

Newsletter of Tamilnadu Pharmaceutical Sciences Welfare Trust

ISSUE : 53 Jan. - Feb. - Mar. 2022

CONTENTS **Page No.**

TAMILNADU PHARMACEUTICAL SCIENCES WELFARE TRUST
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EDITORIAL

Dear Readers,

We are happy to publish the 53rd issue of Pharma Web Newsletter for Jan – Mar 2022.

This 53rd issue contain the program highlights as well as the following article published by eminent persons in Pharma industry.

- **Quality Control Compliance in Pharmaceutical Laboratory**

  Mr. Harinath. A, Associate - Quality Assurance, Hibrow Healthcare Private Limited, Chennai

  Dr. Sumathi. V, Director – Quality, Hibrow Healthcare Private Limited, Chennai

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

Important news items connected to our Pharmacy profession appeared in various national news papers are published in this issue.

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

ARTICLES

Quality Control Compliance in Pharmaceutical Laboratory

Mr. Harinath. A,
Associate, Quality Assurance, Hibrow Healthcare Private Limited, Chennai

Dr. Sumathi. V,
Director – Quality, Hibrow Healthcare Private Limited, Chennai

Introduction:

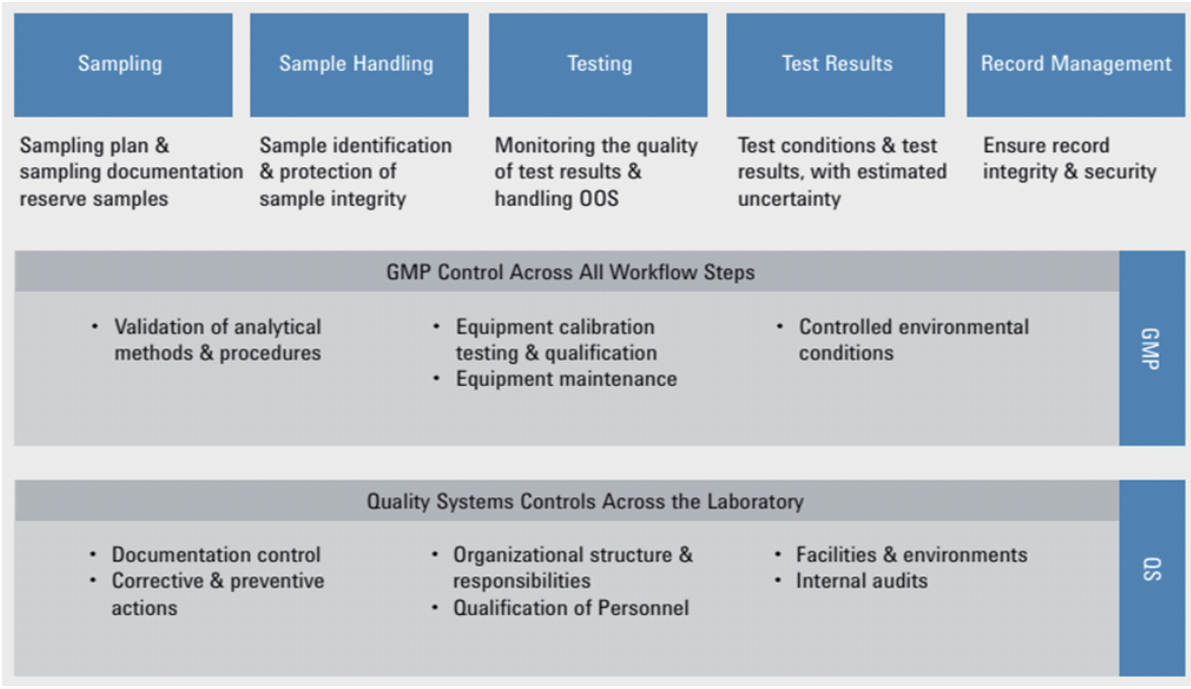
The pharmaceutical quality control laboratory serves one of the most important functions in pharmaceutical production and control. A significant portion of the CGMP regulations (21 CFR 211) pertain to the quality control laboratory and product testing.

The pharmaceutical laboratories carry out tests and assays for the confirmation of active pharmaceutical ingredients, pharmaceutical finished product and excipients to meet predefined specifications. Pharmaceutical regulation is heavily dependent on the analytical results generated by pharmaceutical testing laboratories to describe accurately about the quality of each drug. For these reasons, the results produced by pharmaceutical laboratories must be as accurate as possible, all aspects of the laboratory operations must be reliable and reporting must be timely in order to be useful.

Compliance Overview:

The overall impact of regulations on a pharmaceutical laboratory can be illustrated by looking at the whole workflow (Figure 1). The upper part shows a typical laboratory workflow of samples and test data, together with key requirements underneath. The middle part shows GMP compliance requirements that are applicable to the entire sample. The lower part shows general quality assurance requirements that are applicable not only to regulated laboratories.

Figure 1:



Regulatory Requirements:

- 21 CFR 211.160 (b) : General Requirements (Laboratory Control)
- 21 CFR 211.165 (e) : Testing and release for distribution
- ICH Q 9 Quality Risk Management
- FDA Guidance for industry, 2006, Investigation OOS Test results for Pharmaceutical Production.

Sampling:

Sampling of Drug Substance, Materials, Finished Products for subsequent testing should follow a well-documented procedure. A sampling plan with a description of the sampling system, how sampling is performed, and by whom, should be in place. Sampling data should be recorded, such as sampling procedure used, location, the identification of the person who took the sample and equipment used for sampling and environmental conditions if relevant.

Sample Handling:

Quality control laboratories should ensure proper identification and protection of samples from the time the sample is taken until the time of its disposal. Receipt, protection, storage, processing, retention and disposal should be described in a procedure. The procedure should include provisions for protection against deterioration, loss or damage during transportation, handling and storage.

Testing:

Procedures for testing should ensure that only validated methods are used, that the equipment is qualified and that sufficient system suitability test runs are conducted. Specifications and acceptance criteria should be defined for the sample to be tested. Procedures and parameters for testing should be documented. CGMP require that an investigation be conducted whenever a test result is observed that falls outside the previously specified acceptance criteria. This includes laboratory testing during the manufacture of API, Raw material and testing Finished products to the extent that CGMP regulations apply.

Test Results:

Test results should be signed by the analyst and reviewed, approved by a second person.

Record Management:

All records associated with testing should be archived. Such records include certificates of analysis (COA), instrument and method parameters, supporting information such as chromatograms and spectra, and equipment qualification records. The archiving period is defined by individual regulations and can rang form 6 to 15 years, and even beyond. Controls should be in place to ensure security, integrity and availability of the records. They should have the ALCOA attributable: Who generate them, Legible (are they readable), Contemporaneous (are they recorded in real time), Original (are you sure they have not been changed), and are they Accurate?

Validation of Analytical methods and procedures:

GMPs require analytical methods and procedures to be validated to demonstrate suitability for their intended use. The ultimate objective of the method validation process is to provide evidence that the method does what it is intended to do – accurately, reliably and reproducibly. Typical method characteristics to be validated are: precision of amounts, reproducibility, specificity, linearity, accuracy, robustness, limit of quantitation and limit of detection.

Equipment / Instrument Calibration and Qualification:

All equipment that impacts regulated activities should be qualified and computer systems should be validated. The objective it to provide evidence that the equipment and computer systems are suitable for intended use.

Equipment / Instrument Maintenance:

Equipment should be well maintained to ensure proper ongoing performance. Procedure should be in place for regular preventive maintenance of hardware to detect and fix problems before they can have a negative impact on analytical data.

Controlled Environmental Conditions:

Environmental conditions such as temperature and humidity should be controlled and monitored to ensure that they do not adversely affect the performance of equipment and material. Environmental requirements are typically provided by suppliers of equipment and material.

Documentation Control:

CGMP require that regulated documents be controlled from creation and approval through to distribution, archiving and disposal. Typical documentation includes (but not limited to): policies, quality plans, master plans, standard operating procedures and records such as analytical test records and training records.

Corrective and Preventive actions:

Corrective and preventive actions are initiated when nonconformity is observed. The root cause of non-confirming work should be identified and adequate corrective actions are implemented, documented and monitored to eliminate the specific problem and prevent recurrence of the same problem. Preventive action should be initiated when potential sources of non-conformities have been identified. The objective is to reduce the likelihood of important to monitor the results of any corrective and preventive action taken and results of such action are submitted for laboratory management reviews.

Organizational Structure and Responsibilities:

Organizational arrangements should be such that departments with conflicting interests do not adversely influence quality and compliance of data. For example, QA department should operate independently from laboratory activities. Task and responsibilities should be defined for each job.

Qualification of Personnel:

Personnel should be qualified for the assigned task. Qualification is based on education, experience in the job, and from training. The effectiveness of trainings should be verified and documented.

Facilities and environments:

The laboratory should ensure that its facilities and environmental conditions do not adversely affect or invalidate sample handling, instrumentation, instrument calibration and qualification and analytical testing.

Internal Audits:

Internal audits are a key element for any quality system. Their objective is to evaluate activities and existing documentation to confirm that these meet predetermined internal and external standards / regulations / customer requirements have been satisfied.

Reviewing Recent Inspection Findings:

FDA warning letters can provide insight into the FDA's current and specific thinking on the interpretation of regulations and offer valuable information for developing, improving, and implementing a compliance program.

This list of citations from warning letters,

- Quality System
- Documentation / Procedures
- Qualification of Personnel
- Standard Material
- Validation of Analytical Procedure
- Laboratory Equipment Qualification
- Validation of Laboratory Computer systems
- Sampling and Sampling Handling
- Testing and reporting of test results
- Handling of Out-of-Specification / Out-of-Trend
- Data Integrity

Quality Risk Management:

Protection of patient by managing risk in the quality systems and manufacturing process is being given importance in the pharmaceutical industry. Every product and every process associated with risks. It is important that product quality should be maintained throughout the product lifecycle.

In earlier days risk in the product quality and process had been assessed in the following informal ways.

- Trend review
- Check lists
- Flow charts
- Observations compilation (Complaints, deviations etc.)
- Changes review

Now the risk management approach initiated by regulatory agencies with recognized management tools along with support of statistical tools in combination, which make easy for application of quality risk management principles across the industry.

A risk management program starts with identifying the possible risks associated with a product or with process used to develop, manufacture and distribute the product. An effective quality risk management ensures the high quality of drug product to the patient. In-addition quality risk management improves decision making if a quality problem arises. It should include systemic processes designated to co-ordinate, facilitate and improve science based decision making with respect to risk.

Risk Management Approach:

The FDA defines a risk Management as “a strategic safety program designed to decrease product risk by using one or more interventions or tool. Risk Management planning generally encompasses all efforts by a sponsor to minimize the risk from its product's use and may include product labelling, risk assessment, pharmacovigilance and special studies or interventions.

The FDA expects the Risk Management to follow a basic process of:

1. Learning about the interpreting a product's benefits and risks.
2. Designing and implementing interventions to minimize a product's risks.
3. Evaluating interventions in light of new knowledge that is acquired over time.
4. Revising interventions when appropriate.

Four Major Components:

The risk management program consists of four major components:

1. Risk Assessment
2. Risk Control
3. Risk Review
4. Risk Communication

All four components are essential. All the above methods should address the mentioned four basic components.

Team selection and method selection are also plays a vital role in the risk management process, so care should be taken while selection of risk management team and method.

Risk Management Methods and Tools:

1. Basic Risk Management Facilitation Methods (Flowcharts, check list, process mapping, Fishbone Diagram)
2. Failure Mode Effects Analysis (FMEA)
3. Failure Mode, Effects and Critically Analysis (FMECA)
4. Fault Tree Analysis (FTA)
5. Hazard Analysis and Critical Control Points (HACCP)
6. Hazard Operability Analysis (HAZOP)
7. Preliminary Hazard Analysis (PHA)
8. Risk Ranking and filtering
9. Supporting Statistical Tools

Potential Areas for Risk Management Application in Quality Control:

- Documentation (SOP, Analytical Records, Calibration Documents, etc.)
- Training (Schedules and effectiveness)
- Quality defects (Complaints, deviation, OOS, etc.)
- Audits (Compliance)
- Periodic reviews (Revalidation assessment)
- Change Controls
- Instrument / Equipment and Utilities (components, maintenance etc.)
- Material Management (Receipt, Storage, testing)

Laboratory Management and Continual Improvement:

Overall management of the laboratory work, its staff, and the evaluation of the results of analysis are important elements in the evaluation of a control laboratory. Supervisory, control, personnel qualifications, scope of the laboratory's responsibility are important issues to examine when determining the quality of overall management and supervision of work. Individually or collectively, these factors are the basis for an objection only when they are shown to result in inadequate performance of responsibilities required by the CGMPs.

Review laboratory logs for the sequence of analysis and the sequence of manufacturing dates. Examine laboratory records and logs for vital information about the technical competence of the staff and the quality control procedures used in the laboratory.

Observe analysts performing the operations described in the application. There is no substitute for actually seeing the work performed and nothing whether good technique is used. You should not stand over the analysts, but watch from a distance and evaluate their actions.

Sometimes the company's employees have insufficient training or time to recognize situations that require further investigation and explain and explanation. Instead they accept unexplained peaks in chromatograms with no effort to identify them. They may accept stability test results showing an apparent increase in the assay of the drug with the passage of time with no apparent question about the result. Also, diminishing reproducibility in HPLC chromatograms appearing several hours after system suitability is established is accepted without question.

Quality Control (QC) in terms of A to Z:

A	**Aprons / Analyst / Audit**	**N**	**Note Books / Nose Mask**
B	**Balances**	**O**	**Observation / OOS / OOT**
C	**Calibration / Chemicals / Cleaning**	**P**	**Procedures**
D	**Documentation**	**Q**	**Qualification**
E	**Entry / Exit / Equipment**	**R**	**Reagents**
F	**Fume Hood**	**S**	**Safety / Solutions**
G	**Glassware**	**T**	**Training / Testing**
H	**Health / Hygiene**	**U**	**Upkeep of Document**
I	**Instrument / Incident**	**V**	**Validation**
J	**Justification**	**W**	**Weighing**
K	**Knowledge**	**X**	**X-ray diffraction**
L	**Laboratory / Logbooks**	**Y**	**Your Lab**
M	**Methods**	**Z**	**Zero Error**

Key words:

Laboratory quality management system, laboratory quality, laboratory quality systems, laboratory documents and records, quality control laboratory facilities, equipment, sample management, process improvement, Quality risk Management

Abbreviations:

FDA : Food and Drug Administration

CGMP: Current Good Manufacturing Practices

API : Active Pharmaceutical Ingredients

COA : Certificate of Analysis

QA : Quality Assurance

QC : Quality Control

CFR : Code of Federal Regulation

OOS : Out of Specification

HPLC : High Performance Liquid Chromatography

SOP : Standard Operating Procedure

Reference:

1. Laboratory Quality Management System Handbook, WHO, 2011.
2. Quality management System in Testing Laboratory, IPC/GC/07, 2021.
3. Compliance by Design for Pharmaceutical Quality Control Laboratories, Insight from FDA warning letters, The measure confidence, 2015.
4. Guide to inspections of pharmaceutical quality control laboratories, (7/93), FDA.
5. A Review of Quality Management System in Drug Industry, 2018.
6. Guidance for industry "Q 9 Quality Risk Management" by US department of Health and Human services, Food and Drug Administration, Center for Drug and Evaluation Research June 2006.

INFORMATION

M.PHARM & PHARM D SCHOLARSHIPS 2021-22 AWARDED BY TNPSW TRUST

Profile of 1st Rank

PHARMACEUTICS

Name: Ms. Sanskruti Shrenik Patil

Project Title: Production of monoclonal antibodies (MAbs) against oral carcinoma and its Bioconjugation with liposomes for drug delivery

College: JSS College of Pharmacy, Ooty

Guide's Name: Dr. Vasanth Raj. P.

PHARMACEUTICAL CHEMISTRY

Name: Mr. Dhinesh Kumar. M

Project Title: Design, Synthesis of Pyrazole Substituted 9-Anilinoacridine Derivatives and Evaluation of Breast Cancer Activity. .

College: JSS College of Pharmacy, Ooty

Guide's Name: Dr. R. Kalirajan

PHARMACEUTICAL ANALYSIS

Name: Mr. Vinothkumar. P

Project Title: Molecular Docking Studies to Validate the Efficacy of Phytochemicals against SARS-CoV-2 Proteins and Development of Validated Novel Chromatographic Methods for the Simultaneous Determination of Selected Biomarkers and its Application to Standardization of Siddha Formulation – Kabasura Kudineer.

College: COP, SRIPMS, Coimbatore

Guide's Name: Dr. A. Suganthi

PHARMACOLOGY

Name: Ms. Neha Roy

Project Title: 5 – Amino Salicylic Acid promotes Angiogenesis via MAPK/ Erk Pathway by Vascular Endothelial Growth Factor Receptor in Doxorubicin-Induced Myocardial Infarction model.

College: JSS College of Pharmacy, Ooty

Guide's Name: Mr. B. Shivaramakrishnan

PHARMACOGNOSY

Name: Ms. D. Susmitha

Project Title: Formulation, Chracterization and Evaluation of Resveratrol Loaded Nanosponges for the Treatment of Breast Cancer.

College: College of Pharmacy, Madras Medical College, Chennai

Guide's Name: Dr. R. Vadivu

PHARMACY PRACTICE

Name: Mr. Santhosh Kumar M

Project Title: Effectiveness of Patient Education for the Improvement of Patient Adherence and Reducing the Severity of Adverse Drug Reaction in Anti-tubercular Theraphy

College: JSS College of Pharmacy, Ooty

Guide's Name: Dr. Deepalakshmi. M

PHARM D

Name: Mr. Arun. G.R, Ms. Swetha. B, Ms. Anuba. P.A

Project Title: Comparative effectiveness of rivaroxaban plus aspirin versus ticagrelor plus aspirin as a dual antiplatelet theraphy after percutaneous coronary intervention(PCI) with drug eluting stents – A prospective observational study.

College: SRM College of Pharmacy, SRMIST, Chennai

Guide's Name: Mrs. S. P. Ahalya

Our Chairman,
Shri S V Veeramani was presented
with **'Chief Mentor Award'**
for his outstanding contribution to
IDMA & Indian Pharmaceutical Industry,
during Diamond Jubilee celebrations of
IDMA on 14th April at Mumbai

NOTIFICATION

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 13th January, 2022

G.S.R. 14(E).—Whereas a draft of certain rules further to amend the New Drugs and Clinical Trials Rules, 2019, was published as required by sub-section (1) of section 12 read with 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. 767(E), dated the 27th October, 2021, in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), inviting objections and suggestions from persons likely to be affected thereby, before the expiry of a period of forty-five days from the date on which the copies of the Official Gazette containing the said notification were made available to the public;

And whereas, copies of the Gazette were made available to the public on 27th October, 2021;

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 under section 12 and section 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 New Drugs and Clinical Trials Rules, 2019, namely:—

1. (1) These rules may be called the New Drugs and Clinical Trials (Amendment) Rules, 2022.

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

2. In the New Drugs and Clinical Trials Rules, 2019, in rule 2, in sub-rule (1), in clause (w), in sub-clause (v), for the words “stem cell derived product”, the words “cell or stem cell derived product” shall be substituted.

[F. No. X.11014/12/2021-DR]
Dr. MANDEEP K. BHANDARI, Jt. Secy.

Note: The principal rules were published in the Gazette of India vide notification number G.S.R. 227(E), dated the 19th March, 2019 and last amended vide notification number G.S.R. 605(E), dated the 31st August, 2021.

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi the 18th January, 2022

G.S.R. 19(E).—Whereas a draft of certain rules further to amend the Medical Devices Rules, 2017, was published as required under sub-section (1) of section 12 and sub-section (1) of section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), vide notification of the Government of India in the Ministry of Health and Family Welfare (Department of Health and Family Welfare) number G.S.R. 729(E), dated the 12th October, 2021, 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 seven 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 12th October, 2021;

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), with consideration that consultation with Drugs Technical Advisory Board shall be held as per the provisions, the Central Government hereby makes the following rules further to amend the Medical Devices Rules, 2017, namely:—

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

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

2. In the Medical Devices Rules, 2017(hereinafter to be referred as said rules), in rule 19B, in sub-rule (2), in item (iii), at the end, the following Proviso and Explanation thereto shall be inserted, namely:—

"Provided that in case the applicant submits, on or before the 28th February, 2022, an undertaking that applicant shall obtain the ISO 13485 certificate on or before the 31st May, 2022 in lieu of certificate of compliance as referred in clause (iii) of sub-rule (2) of rule 19B, a provisional registration number shall be generated which will remain valid up to the 31st May, 2022 or the date on which the applicant obtained such ISO certificate whichever is earlier. The said generated provisional registration number shall be valid for all purposes.

Explanation.— For the removal of doubt, it is hereby declared that in case of such ISO 13485 certificate not obtained before the 31st May, 2022 as per undertaking referred in the Proviso by the applicant the provisional registration shall be deemed to have been cancelled for all purposes without any notice."

3. In the said rules, in rule 19C, for the words “shall mention the registration number” the following words, letters and figures shall be substituted, namely:—

“may, if so desired, mention the registration number or provisional registration number, as the case may be, for a period up to the 31st May, 2022, thereafter it shall be mandatory for all registration holders”.

4. In the said rules, in rule 19D, in sub-rule (2), in item (iii), at the end, the following Proviso and Explanation thereto shall be inserted, namely:—

“Provided that in case the applicant submits, on or before the 28th February, 2022, an undertaking that applicant shall obtain the ISO 13485 certificate on or before the 31st May, 2022 in lieu of certificate of compliance as referred in clause (iii) of sub-rule (2) of rule 19D, a provisional registration number shall be generated which will remain valid up to the 31st May, 2022 or the date on which the applicant obtained such ISO certificate whichever is earlier. The said generated provisional registration number shall be valid for all purposes.

Explanation.—For the removal of doubt, it is hereby declared that in case of such ISO 13485 certificate not obtained before the 31st May, 2022 as per undertaking referred in the Proviso by the applicant the provisional registration shall be deemed to have been cancelled for all purposes without any notice.”

5. In the said rules, in rule 19E, for the words “shall mention the registration number” the following words, letters and figures shall be substituted, namely:—

“may, if so desired, mention the registration number or provisional registration number, as the case may be, for a period up to the 31st May, 2022, thereafter it shall be mandatory for all registration holders”.

[F. No. X.11014/12/2018-DR]
Dr. MANDEEP K BHANDARI, Jt. Secy.

Note : The Medical Devices Rules, 2017 was published in the Official Gazette vide notification number G.S.R. 78(E), dated the 31st January, 2017 and last amended vide notification number G.S.R. 918(E), dated the 31st, December, 2021.

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 18th January, 2022

G.S.R. 20(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. 567(E), dated the 8th August, 2019, 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 10th August, 2019;

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

Now, therefore, in exercise of the powers conferred under 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 (Amendment) Rules, 2022.

(2) They shall come into force on the first day of January, 2023.

2. In the Drugs Rules, 1945, in rule 96, after sub-rule (4), following sub-rule shall be inserted, namely:—

"(5) Every active pharmaceutical ingredient (bulk drug) manufactured or imported in India shall bear Quick Response code on its label at each level packaging that store data or information readable with software application to facilitate tracking and tracing. The stored data or information shall include the following minimum particulars, namely:—

(i) Unique product identification code,
(ii) Name of the API,
(iii) Brand name (if any),
(iv) Name and address of the manufacturer,
(v) Batch no.,
(vi) Batch size,
(vii) Date of manufacturing,
(viii) Date of expiry or retesting,
(ix) Serial shipping container code,
(x) Manufacturing licence no. or import licence no.
(xi) Special storage conditions required (if any).".

[F.No.X.11014/17/2019 -DR]
Dr. MANDEEP K BHANDARI, Jt. Secy.

Note : The principal rules were published in the Official Gazette vide notification number F.28-10/45-H (1) dated 21st December, 1945 and last amended vide notification number G.S.R.848(E), dated the 9th December, 2021.

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 18th January, 2022

G.S.R.21(E).—Whereas a draft of certain rules further to amend the New Drugs and Clinical Trials Rules, 2019, was published as required by sub-section(1) of section 12 read with 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. 524(E), dated the 2nd August, 2021, in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (I), inviting objections and suggestions from persons likely to be affected thereby, before the expiry of a period of forty-five days from the date on which the copies of the Official Gazette containing the said notification were made available to the public;

And whereas copies of the Gazette were made available to the public on 2nd August, 2021;

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

Now, therefore, in exercise of the powers conferred by section 12 and section 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 New Drugs and Clinical Trials Rules, 2019, namely:—

1. (1) These rules may be called the New Drugs and Clinical Trials (2nd Amendment) Rules, 2022.

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

2. In the New Drugs and Clinical Trials Rules, 2019 (hereafter referred to as the principal rules), in rule 2, in sub-rule(1), after clause (l), the following clause shall be inserted, namely:—

   (la) "Designated Registration Authority" means the authority designated under sub-rule (1) of rule 17;"

3. In the principal rules, in Eighth Schedule, in Form CT-03,—
   (a) In para1,—
      (i) for the words, "The designated authority", the words "The Designated Registration Authority" shall be substituted;

      (ii) the words, "Regulation of", shall be omitted;

   (b) For the words, "Central Licensing Authority", the words "Designated Registration Authority" shall be substituted.

[F.No. X.11014/13/2021-DR]
DR. MANDEEP K BHANDARI, Jt. Secy.

Note: The principal rules were published in the Gazette of India vide notification number G.S.R. 227(E), dated the 19th March, 2019 and last amended vide notification No. G.S.R. 14(E), dated the 13th January, 2022.

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 20th January, 2022

G.S.R. 30(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. 628(E), dated the 13th September, 2021, 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 13th September, 2021;

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 (2nd Amendment) Rules, 2022.
(2) They shall come into force on the date of their publication in the Official Gazette.

2. In the Drugs Rules, 1945, in Schedule K, in the table, after serial number 38 and the entries relating thereto, the following serial number and entries shall be inserted, namely:—

Class of Drugs	**Extent and Conditions of Exemption**
"39. Liquid Antiseptics for household use	The provisions of Chapter IV of the Act and rules made thereunder, which require them to be covered with a sale license in Form 20 or Form 20A, subject to the following conditions, namely:— (a) The drugs are manufactured by licensed manufacturers; (b) the drugs do not contain any substance specified in Schedule G, H, H1 or X; (c) the drugs are sold in the original unopened containers of the licensed manufacturer; (d) the drugs are purchased from a licensed wholesaler or a licensed manufacturer."

[F.No. X.11014/10/2021-DR]
Dr. MANDEEP K BHANDARI, Jt. Secy.

Note: The principal rules were published in the Gazette of India vide notification number F.28-10/45-H (1), dated the 21st December, 1945 and last amended vide notification number G.S.R. 20(E), dated the 18th January, 2022.

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 9th February, 2022

S.O. 553(E).—Whereas, there is an outbreak of COVID-19 pandemic throughout India, resulting into dangerous and opportunist infections, disease like Mucormycosis, etc., due to which emergency has arisen to make available new drugs for treatment or management of COVID-19 and related diseases;

Whereas, the Central Government is satisfied that making available suitable new drugs is essential to meet the requirements of emergency arising due to pandemic COVID-19, and in public interest it is necessary and expedient to regulate the manufacture and stock for sale or distribution of such new drugs for prevention and treatment of COVID-19 and associated infection;

Now, therefore, notwithstanding anything contained in the Drugs Rules, 1945 and New Drugs and Clinical Trials Rules, 2019, for the purposes of making available suitable drugs to meet the requirements of emergency arising due to COVID-19, in exercise of the powers conferred by section 26B of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, hereby notifies the following, namely:—

(a) In case a person intends to manufacture and stock a new drug for COVID-19, which is under clinical trial for marketing authorisation for sale or distribution, then, such person shall have to obtain permission in Form CT-06 to conduct clinical trial of such drug and on successful completion of the clinical trial and after obtaining permission in Form CT-23 from the Central Licensing Authority under the New Drugs and Clinical Trials Rules, 2019, he shall make an application under rule 69 or rule 70A or rule 75 or rule 75A of the Drugs Rules, 1945, as the case may be, to the concerned Licensing Authority appointed by the State Government along with the permission obtained for conducting clinical trial in Form CT-06 under the New Drugs and Clinical Trials Rules, 2019, for grant of license to manufacture and stock the drug for sale or distribution under the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) (hereinafter referred to as the said Act) and the rules made thereunder:

Provided that the requirement of prior permission from the Central Licensing Authority under rule 81 of the New Drugs and Clinical Trials Rules, 2019 to manufacture the new drug as required under rule 83 of the said rules shall be deferred in public interest to meet the emergent situation arisen out of COVID-19 and such person shall obtain the said permission after successful completion of the clinical trial and submission of application along with fees, data and particulars in accordance with the provisions of the New Drugs and Clinical Trials Rules, 2019.

(b) The Central License Approving Authority or the State Licensing Authority, as the case may be, if satisfied that requirements under the provisions of the said Act and the Drugs Rules, 1945 and the New Drugs and Clinical Trials Rules, 2019 have been complied with, grant License in accordance with the provisions of the Drugs Rules, 1945 to manufacture and stock the new drug subject to the condition that the licensee shall sell or distribute the new drug only after obtaining permission for such new drug in Form CT-23 from the Central Licensing Authority under the New Drugs and Clinical Trials Rules, 2019.

2. In case of any inconsistency between this notification and any rule made under the said Act, the provisions of this notification shall prevail over such rule in public interest so as to meet the emergency which has arisen due to COVID-19 pandemic.

3. This order shall come into force on the date of its publication in the Official Gazette.

[F. No. X.11014/02/2020-DRS]
Dr. MANDEEP K BHANDARI, Jt. Secy.

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 4th March, 2022

G.S.R. 174(E).—Whereas a draft of certain rules further to amend the Medical Devices Rules, 2017, was published as required under sub-section (1) of section 12 and sub-section (1) of section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940) vide notification of the Government of India in the Ministry of Health and Family Welfare (Department of Health and Family Welfare) number G.S.R. 850(E), dated the 10th December, 2021, in the Gazette of India, Extraordinary, Part II, section 3, sub-section (I), inviting objections and suggestions from persons likely to be affected thereby before the expiry of a period of forty five days from the date on which the copies of the Official Gazette containing the said notification were made available to the public;

And whereas copies of the said Official Gazette were made available to the public on 10th December, 2021;

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

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

1. (1) These rules may be called the Medical Devices (2nd Amendment) Rules, 2022.

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

2. In the Medical Devices Rules, 2017, in rule 36, in sub-rule (3), for the words “or the United States of America” the words “United Kingdom or the United States of America” shall be substituted.

[F. No. X.11014/7/2021-DR]
Dr. MANDEEP K. BHANDARI, Jt. Secy.

Note : The Medical Devices Rules, 2017 was published in the Gazette of India, Extraordinary, Part II, section 3, sub-section(i) vide notification number G.S.R. 78 (E), dated the 31st January, 2017 and last amended vide notification number G.S.R.19(E), dated the 18th January 2022.

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 24th February, 2022

G.S.R. 158(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. 840(E), dated the 29th November, 2021, 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 29th November, 2021;

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 (3rd Amendment) Rules, 2022.

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

2. In the Drugs Rules, 1945, in rule127, in sub-rule (1), under the heading (3) relating to „Coal Tar Colours", after the entry „Carmoisine" and before the entry „BLUE Indigo Carmine", the following entry shall be inserted, namely:—

Common Name of the Colour	Colour Index Number	Chemical Name
1	2	3
"Allura Red	16035	Disodium 6-hydroxy-5-[(2-methoxy-5-methyl-4-sulfophenyl)azo]-2-Naphthalenesulfonic acid"

[F.No. X.11014/22/2021-DR]
DR. MANDEEP K BHANDARI, Jt. Secy.

Note: The principal rules were published in the Gazette of India vide notification number F.28-10/45-H (1), dated the 21st December, 1945 and last amended vide notification number G.S.R. 30(E), dated the 20.01.2022.

PARLIAMENT QUESTION AND ANSWERS

GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

RAJYA SABHA
UNSTARRED QUESTION NO. 1466
TO BE ANSWERED ON 15th March, 2022

Research and development in pharma sector

1466 Shri Iranna Kadadi:

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

(a) the details regarding Research and Development (R&D) expenditure of Indian pharmaceutical companies/Public Sector Undertakings (PSUs) across various segments during the last five years, year-wise;

(b) the steps taken by Government to enhance the expenditure on R&D activities for development of new drugs;

(c) the details of the new drug molecules developed in the country;

(d) steps taken to promote the production and use of nano fertilizer; and

(e) the steps taken by Government to facilitate the development of new drug molecules in the country?

ANSWER

MINISTER IN THE MINISTRY OF CHEMICALS & FERTILIZERS
(DR. MANSUKH MANDAVIYA)

(a): Biotechnology Industry Research Assistance Council (BIRAC), a PSU under the Department of Biotechnology (DBT) supports Research and Development (R&D) of drugs, through its various schemes and programmes. The year-wise details of fund disbursements to various companies/institutes for R&D by BIRAC are as under:

2016-17	2017-18	2018-19	2019-20	2020-21
120.61 cr.	142.21 cr.	149.56 cr.	150.67 cr.	137.73 cr.

All the five pharma PSUs under the Department of Pharmaceuticals have been identified for closure/ strategic sale. The details of R&D expenditure of three functional PSUs under the Department of Pharmaceuticals are as under:

2016-17	2017-18	2018-19	2019-20	2020-21
2.21 cr.	2.64 cr.	2.33 cr.	2.65 cr.	1.12 cr.

The information regarding R&D expenditure by private pharmaceutical companies is not maintained by the department.

(b): R&D and innovation in pharma sector is done by number of institutions and organizations under various scientific ministries/ departments, which have their own budgetary provisions. Department of Pharmaceuticals has set up seven National Institutes of Pharmaceutical Education & Research (NIPERs) as institutes of national importance, which besides imparting postgraduate and doctorate education, conduct high end research in various pharma specializations. The Department has already incurred an expenditure of more than Rs. 1,600 cr for setting up of these institutes. Further, Expenditure Finance Committee (EFC) has approved Rs. 1500 cr. for up-gradation of campuses of these existing seven NIPERs for the period 2021-22 to 2025-26.

(c): Various laboratories of Council of Scientific and Industrial Research (CSIR) are working for repurposing and clinical trial for drugs used for COVID-19, as well as working on various drug candidates/ lead compounds. Similar efforts are being undertaken by various institutes/ laboratories functioning under other departments.

(d): In order to boost indigenous production of Nano Urea in the country, two Central Public Sector Undertaking (CPSUs), viz., National Fertilizers Limited (NFL) and Rashtriya Chemicals and Fertilizers Limited (RCF) under administrative control of Department of Fertilizers, have signed Memorandum of Understanding (MoU) with Indian Farmers Fertilizer Cooperative (IFFCO) to transfer technology of Nano Urea production from IFFCO.

(e): NIPERs, after detailed inter departmental consultations have formulated a programme on Drug Discovery for Affordable Healthcare in mission mode. Further, various institutes of CSIR have also developed various mission mode projects for focussed efforts on new drug development. CSIR-CDRI has built a unique model for drug research in India – having everything under one roof, from synthesis, screening, development studies, process up-scaling to clinical studies for the development of drugs. BIRAC also supports the development of new drug molecules in the country through its various schemes.

GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

RAJYA SABHA
UNSTARRED QUESTION No. 2901
TO BE ANSWERED ON THE 29th MARCH, 2022

PLI scheme for Bulk Drugs

2901 Shri K.R.N. Rajeshkumar:

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

(a) the details of applications received and selected under Production Linked Incentive (PLI) Scheme for Bulk Drugs, per State since the commencement of the scheme till date;

(b) the details of the measures taken by Government to promote the scheme;

(c) whether steps have been taken to establish backward linkages with Micro, Small and Medium Enterprises (MSMEs); and

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

ANSWER

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

(a): In total 239 applications have been received for the 36 products spread across the 4 Target Segments for the PLI schemes for Bulk Drugs from all over the country in two rounds of applications. Out of these, 49 applications have been approved by the Government till date.

(b): The Government promoted the Scheme by holding meetings with the Industry associations, manufacturers & investors. It also held interactions with number of state governments as well as foreign embassies. The Guidelines of the Scheme were also uploaded on the Department's website for wider dissemination. The Scheme was also promoted through print and electronic media as well as social media handles.

(c) & (d): The selected 49 applications are from 33 companies, Out of these 33 companies, 13 are Micro, Small and Medium Enterprises (MSMEs) besides some newly incorporated entities. The scheme provides for minimum domestic value addition to be achieved by each approved applicant. Thus, these large number of projects approved under the Scheme will also accelerate domestic procurement, which will further strengthen the eco system and marketplace for MSME sector.

GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

RAJYA SABHA
UNSTARRED QUESTION NO. 3697
TO BE ANSWERED ON 05th April, 2022

Medical devices notified as drugs under the Drugs (Price Control) Order, 2013

3697 Shri K.C. Ramamurthy:

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

(a) whether it is a fact that Medical devices/equipments have been notified as Drugs and are governed under the provisions of the Drugs (Price Control) Order, 2013;

(b) if so, the reasons and objective for which the medical devices/equipments have been included in the Legal Metrology (Packaged Commodities) (Amendment) Rules, 2017; and

(c) the steps taken by Government to address this anomaly?

ANSWER

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

(a): As per the Gazette notification S.O. 648(E) dated 11.02.2020 issued by the Ministry of Health & Family Welfare, all medical devices have been notified as Drugs under sub-clause (iv) of clause (b) of section 3 of the Drugs and Cosmetics Act, 1940 (23 of 1940) w.e.f. 01.04.2020. Pursuant thereto, National Pharmaceutical Pricing Authority (NPPA) vide notification dated 31.03.2020 has ordered that all medical devices shall be governed under the provisions of the Drugs (Prices Control) Order, 2013.

(b) & (c): Prior to declaration of all medical devices as drugs, the Department of Pharmaceuticals had requested the Department of Consumer Affairs in the Legal Metrology (Packaged Commodities) (Amendment) Rules, 2017 to have Maximum Retail Price (MRP) as part of fixed sticker on medical device packaging and to make the unit of packaging match the unit of prescription /use to avoid any ambiguity of unit costs to the end user/patient.

Subsequent to the notification of Medical Devices as Drugs and notification of Medical Devices Rules, 2017, wherein elaborate rules are available for labelling requirements of Medical Devices and based on the representation from the Industries, the Department of Pharmaceuticals has since prepared the proposal to Department of Consumer Affairs to exempt the licensed Medical Devices from the Legal Metrology (Packaged Commodities) Rules 2011 in February 2022.

GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

RAJYA SABHA
UNSTARRED QUESTION NO. 3699
TO BE ANSWERED ON THE 05th April, 2022

Production of Active Pharmaceutical Ingredients (API) in the country

3699 Dr. Fauzia Khan:

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

(a) the details of the works done for production of Active Pharmaceutical Ingredients in the past three years, State-wise;

(b) the details of the funds allocated, released and spent for increasing production of the APIs in the past three years, State-wise;

(c) whether there has been any delay in the release of the allocated funds;

(d) if so, the reasons therefor; (e) the details of proposed/in progress projects for the construction of production facilities for the APIs, State-wise especially in Maharashtra; and

(f) the details of the quantity of API being imported and the total quantity necessary to meet the national demand?

ANSWER

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

(a) to (f): The Indian Pharmaceutical industry is 3rd largest in the world by volume. India exported pharmaceuticals worth Rs. 1,80,551 crore in the financial year 2020-21. India exported Bulk Drugs/ Drug Intermediates worth Rs. 32,857 crore in financial year 2020-21. However, the country also imports various Bulk Drugs/ Active Pharmaceutical Ingredients (APIs) for producing medicines from various countries including China. The details of export and import of Bulk Drugs and Drug Intermediates of the country is given below;

Export and Import of Bulk Drugs and Drug Intermediates				
Year	Export		Import	
	Quantity (MT)	Value (In Rs Cr)	Quantity (MT)	Value (In Rs Cr)
2018-19	3,66,616	27,346	3,45,944	24,850
2019-20	2,71,544	27,533	3,64,433	24,172
2020-21	3,24,331	32,857	3,90,476	28,529
2021-22 (April to December 2021)	3,35,627	24,107	3,02,745	26,490

Source: DGCIS, Ministry of Commerce and Industry.

The Government strives to minimize country's dependence on imports and to give fillip to indigenous manufacturing.

• In order to make the country Atmanirbhar in pharmaceuticals, the Department of Pharmaceuticals has launched 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. The total financial outlay of the scheme is Rs. 6,940 crore and the tenure from FY 2020-2021 to FY 2029-30. Under the scheme, Total 49 projects have been approved for 33 critical APIs with a committed investment of ₹ 3,685 crore. Twenty projects are commissioned so far and remaining projects are in investment phase getting commissioned gradually. Incentive shall be eligible on the sales of eligible products from FY 2022-23 onwards. Under the scheme, Consultancy fee of Rs.1.55 Cr and Rs.2.18 Cr has been released to M/s IFCI Ltd., the Project Management Agency (PMA), for the last two financial years 2020-21 & 2021-22 respectively.

• Another Production Linked Incentive Scheme for Pharmaceuticals has been launched with total financial outlay of Rs. 15,000 crore and tenure from FY 2020-2021 to FY 2028-29. The scheme intends to enhance India's manufacturing capabilities by increasing investment and production in the sector and contributing to product diversification to high value goods in the pharmaceutical sector. The eligible drugs under this scheme include APIs among other categories of pharmaceutical products and total of 55 projects have been approved under the scheme. The projects shall be eligible for incentives from FY 2022-23 on incremental sales.

• Department has launched the scheme "Promotion of Bulk Drug Parks" that provides for grant-in-aid support (Rs.1000 Cr per State) for creation of Common Infrastructure Facilities to 3 bulk drug parks and the tenure is of the scheme from FY 2020-2021 to FY 2024-25. Under this scheme, Department of Pharmaceuticals has received proposals from 13 states including Maharashtra, which are under evaluation.

• Further, Department provides support to the pharma clusters for creating common infrastructure facilities under Assistance to Pharmaceutical Industry for Common Facilities (API-CF).

• Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS) has been approved to support SME units in pharmaceutical sector, including for APIs, for quality and technology upgradation.

GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

RAJYA SABHA
UNSTARRED QUESTION No. 3708#
TO BE ANSWERED ON THE 5th APRIL, 2022

Unethical practices being adopted by Pharma companies

3708 # Shri Brijlal:

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

(a) whether Government is aware of the nexus such as adopting unethical modes of marketing and luring doctors to increase the sale of medicines by the Pharma companies;

(b) if so, the details thereof, along with the steps taken by Government to stop such unethical practices and nexus; and

(c) whether Government is also considering to make any law in this regard and if so, the time by which it is likely to be implemented?

ANSWER

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

(a) & (b): The Department has formulated the Uniform Code of Pharmaceutical Marketing Practices (UCPMP), w.e.f 1.1.2015, which is a voluntary code to be adopted by the pharmaceutical companies. Under this, all the associations of pharmaceutical and medical devices companies shall constitute committees viz, Ethics Committee for Pharma Marketing Practices (ECPMP) and Apex Ethics Committee for Pharma Marketing Practices (AECPMP) to enquire complaints received against a pharmaceutical company and have to host the actions taken on such complaints in their websites, besides sending the quarterly reports in this regard to National Pharmaceutical Pricing Authority (NPPA) under the department.

NPPA prepared a proforma for furnishing quarterly return as per para 8 of the UCPMP; the same has been circulated on 24.07.2021 to associations for submission to NPPA within 30 days at the end of each quarter via email. Further, Department and NPPA on various instances have reviewed implementation of the voluntary code.

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

(c): The Department is not considering to make any law in this regard.

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

LOK SABHA
UNSTARRED QUESTION NO. 1822
TO BE ANSWERED ON THE 11th FEBRUARY, 2022

GENERIC NAMES OF MEDICINE IN MEDICAL PRESCRIPTIONS

1822 SHRIMATI GEETA KORA:
SHRI HIBI EDEN:
SHRI DILESHWAR KAMAIT:
SHRI JYOTIRMAY SINGH MAHATO:
SHRI JUGAL KISHORE SHARMA:

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

(a) whether the Government has taken note that many doctors do not prescribe the generic name of the medicine;

(b) if so, the details thereof; and

(c) the steps proposed to be taken by the Government in this regard?

ANSWER

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

(a) to (c): Clause 1.5 of the Medical Council of India (Professional Conduct, Etiquette and Ethics) Regulations, 2002 provides that every physician should as far as possible prescribe drugs with generic names. Further, the erstwhile Medical Council of India (MCI) had issued Circulars in which all the Registered Medical Practitioners were directed to comply with the aforesaid provisions.

The National Medical Commission (NMC) Act, 2019 empowers Ethics and Medical Registration Board (EMRB) of NMC and the appropriate State Medical Councils to take disciplinary action against a doctor for violation of provisions of the aforesaid Regulations.

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

LOK SABHA
UNSTARRED QUESTION NO.†3874
TO BE ANSWERED ON 25th MARCH, 2022

MISLEADING ADVERTISEMENT BY PHARMA COMPANIES

†3874: SHRI NIHAL CHAND:

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

(a) whether the Government has taken into cognizance the misleading advertisements of pharmaceutical companies on television, if so, the details thereof;

(b) the norms formulated by the Government for the drug sellers in relation to the sale of medicines;

(c) the measures taken by the Government for ensuring compliance of the above norms by the drug sellers;

(d) whether the Government has received complaints against the drug sellers in this regard; and

(e) if so, the details thereof along with the action taken thereon?

ANSWER

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

(a) to (e): Advertisements concerning drugs are regulated under the provision of Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954, which is administered by the State Governments. The Drugs & Cosmetics Rules, 1945 were amended in 2015 and a provision was made to the effect that no advertisement of drugs specified in Schedule H, Schedule H1 and Schedule X (i.e. Prescription drugs) shall be made except with the previous sanction of the Central Government. State Licensing Authorities are empowered to take action in case of non-compliance.

Ministry of Information & Broadcasting, on the basis of information provided by Ministry of AYUSH, in order to protect the citizens from misleading advertisement and health risk, issued an advisory on 12.07.2017 in which all TV channels were advised to advertise only products that have valid licence issued by Ministry of AYUSH or State Drug Licensing Authorities.

The sale and distribution of drugs in the country are regulated by the State Licensing Authority (SLAs) through a system of inspection and licensing under the provisions of the Drugs and Cosmetics Act, 1940 and Drugs and Cosmetics Rules, 1945. The said Rules prescribe conditions to be satisfied before grant of licence for sale of drugs. These include adequacy of the premises, proper storage facilities for preserving the properties of drug, requirement of competent person to supervise and control the sale of drugs, etc. SLAs are legally empowered to take action in case violation of the condition of license.

GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA
STARRED QUESTION No. *336
TO BE ANSWERED ON THE 25th March, 2022

Establishment of Pharma Parks

***336. SHRI RAJIV RANJAN SINGH ALIAS LALAN SINGH:**
SHRI SATYADEV PACHAURI:

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

(a) whether the Government has announced to establish a number of pharma parks in the country;

(b) if so, the details thereof;

(c) the details of such pharma parks established, so far, State/UT-wise; and

(d) the details of investment made in all those pharma parks, so far, park-wise?

ANSWER

MINISTER IN THE MINISTRY OF CHEMICALS & FERTILIZERS
(Dr. MANSUKH MANDAVIYA)

(a) to (d): A statement is laid on the table of the house.

STATEMENT REFFERED TO IN REPLY TO PARTS (a) TO (d) OF STARRED QUESTION NO. *336 FOR REPLY ON 25.03.2022

(a) to (d): The Department of Pharmaceuticals is implementing a scheme namely "Promotion of Bulk Drug Parks" which provides for grant-in-aid towards creation of Common Infrastructure Facilities (CIF) in the bulk drug parks to be developed by the States. The total financial outlay of the Scheme is Rs. 3,000 Crore with maximum grant-in-aid for one bulk drug park limited to Rs 1,000 crore or 70% of the project cost of CIF, whichever is less. In case of North Eastern states and Hilly States (Himachal Pradesh, Uttarakhand, Union Territory of Jammu & Kashmir and Union Territory of Ladakh), the maximum limit of financial assistance is Rs 1,000 crore or 90% of the project cost of CIF, whichever is less. The Guidelines of the scheme are available on the website of the Department of Pharmaceuticals, i.e., http://pharmaceuticals.gov.in.

Department has received proposals from 13 States, viz., Uttar Pradesh, Tamil Nadu, Telangana, Karnataka, Maharashtra, Gujarat, Madhya Pradesh, Rajasthan, Punjab, Haryana, Himachal Pradesh, Andhra Pradesh and Odisha under the scheme.

GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA
UNSTARRED QUESTION No. 1766
TO BE ANSWERED ON THE 11th February, 2022

Sale of Fake Cosmetic Products

1766. SHRI JAGDAMBIKA PAL:

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

(a) the steps taken by the Government to control the sales of fake cosmetic products;

(b) the data depicting the estimates of market captured by the sales of fake cosmetic products along with the market share of cosmetics, separately for both imported and make in India Products;

(c) whether the cosmetics market size is expected to grow in the coming years and if so, the details thereof;

(d) whether the Government is planning to bring a policy for Make in India Cosmetic Products to ensure that the Indian Cosmetic Companies grow under the Atmanirbhar Bharat Mission; and

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

ANSWER

MINISTER IN THE MINISTRY OF CHEMICALS & FERTILIZERS
(Dr. MANSUKH MANDAVIYA)

(a) to (e): Cosmetics are regulated under the provisions of the Drugs and Cosmetics Act, 1940 and Cosmetics Rules, 2020. The State Licensing Authorities appointed by the respective State Governments under the said Act are empowered to take action on sale and distribution of Spurious cosmetics, Adulterated cosmetics etc. under the provision of Drugs & Cosmetics Act, 1940 and Cosmetics Rules, 2020. For isolated complaints on quality of cosmetics, as and when received the matter is referred to the concerned state licensing authority for taking necessary action as per Drugs & Cosmetics Act, 1940 and Rules made thereunder.

In December 2020, the Ministry of Health and Family Welfare (MoHFW) announced the New Cosmetic Rules 2020 which demarcates cosmetics from drugs, both of which were regulated by the Drugs and Cosmetics Act of 1940. The rules relate to the import, manufacturing, labelling, distribution and sales of cosmetics in India and have been separately updated and codified.

Department does not maintain the data relating to market size of cosmetics. As per available industry sources, currently, the cosmetics market size ranges between USD 6.5 billion and USD 13.2 Billion and is estimated to reach USD 35 billion by 2035.

GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA
UNSTARRED QUESTION No. 3724
TO BE ANSWERED ON THE 25th March, 2022

Audits of Cosmetic Products

3724. SHRI SRIDHAR KOTAGIRI:
SHRI P.V. MIDHUN REDDY:

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

(a) whether the Government conducts any audit of claims made by cosmetic companies after acquiring a license to sell their products in the Indian market;
(b) if so, the details thereof and if not, the reasons therefor;
(c) whether the Government has conducted any study to check levels of prohibited substances of lead and arsenic mixed in cosmetics;
(d) if so, the details thereof and if not, the reasons therefor; (e) whether any studies have also been conducted by some prominent think tanks and the other research organisations in this regard and if so, the details thereof;
(e) if so, whether the regulatory body has sanctioned any study to follow-up on the findings; 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) & (b): As per information provided by the Central Drugs Standard Control Organisation (CDSCO) under the Ministry of Health & Family Welfare, no cosmetic may purport or claim to purport or convey any idea which is false or misleading to the intending user as per Rule 36 of the Cosmetics Rules, 2020 notified under the Drugs & Cosmetics Act, 1940. In case of any concern or complaint regarding the claims, Licensing Authorities are empowered to take action including conduct of inspection as per the Cosmetics Rules, 2020.

(c) & (d): As per information provided by CDSCO, no such study has been conducted. However, as per Rule 39 of the Cosmetics Rules, 2020, the limit of arsenic and lead in cosmetics have been prescribed as under:

(i) Not more than 2 parts per million of Arsenic calculated as Arsenic Trioxide.
(ii) Not more than 20 parts per million of lead calculated as lead.
(iii) Not more than 100 parts per million of Heavy Metals other than lead calculated as the total of the respective metals.

Further, as per Rule 39(6) of the Cosmetics Rules, 2020, the use of lead and arsenic compounds for the purpose of colouring cosmetics is prohibited.

(e) to (f): CDSCO has not received any list of such studies. However, earlier in 2014 a study titled 'Heavy Metals in Cosmetics' was conducted by the Centre for Science and Environment (CSE), which is available in public domain. CDSCO had taken up the matter and forwarded the same to the concerned State for necessary action as per provisions of the Drugs and Cosmetics Act, 1940 and rules made thereunder. CDSCO has not sanctioned any study to follow-up on the findings.

GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA
UNSTARRED QUESTION No. 3769
TO BE ANSWERED ON THE 25TH MARCH, 2022

Promotion of Domestic Medical Devices

3769. SHRI N. REDDEPPA:
DR. SANJEEV KUMAR SINGARI:
SHRI KURUVA GORANTLA MADHAV:
SHRI ADALA PRABHAKARA REDDY:

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

(a) the steps undertaken by the Government to reduce dependence on imports of medical devices; and

(b) the current status of implementation of Production Linked Incentive (PLI) Scheme for Promoting Domestic Manufacturing of Medical Devices?

ANSWER

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

(a) and (b): Department of Pharmaceuticals has launched a 'Production Linked Incentive (PLI) Scheme for Promoting Domestic Manufacturing of Medical Devices' with total financial outlay of Rs. 3,420 crore. In total 21 applicants with committed investment of Rs 1058.97 cr have been approved under the scheme.

Further, the Department has launched another Scheme for 'Promotion of Medical Devices Parks' with a total financial outlay of Rs. 400 crore for setting up common infrastructural facilities in medical devices parks to be set up in four States/ UTs. The proposals from the states of Uttar Pradesh, Tamil Nadu, Madhya Pradesh and Himachal Pradesh have been approved under the scheme.

GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA
UNSTARRED QUESTION NO. †4881
TO BE ANSWERED ON 01st April, 2022

Regulation of Drug Prices

†4881. DR. MANOJ RAJORIA:
SHRI SUMEDHANAND SARASWATI:
SHRIMATI RANJEETA KOLI:

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

(a) the percentage increase in the prices of drugs during the last five years, drug-wise;

(b) the details of the drugs of which prices have come down during the said period, drug-wise;

(c) whether the manufacturers of drugs have sought permission from the Government to increase the prices of certain drugs;

(d) if so, the details thereof and the reaction of the Government thereto; and

(e) whether there are any rules and regulations regarding controlling of increase in prices of drugs and if so, the details thereof?

ANSWER

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

(a) and (b): As per the extant provisions of Drugs Prices Control Order, 2013 (DPCO, 2013), the ceiling price of all scheduled formulations figuring in the National List of Essential Medicines (NLEM) issued by the Ministry of Health & Family Welfare (M/o H&FW) are fixed by the National Pharmaceutical Pricing Authority (NPPA) under the Department of Pharmaceuticals. The ceiling prices of scheduled medicines are revised annually on the basis of Wholesale Price Index (WPI) for preceding calendar year on or before 1st April of every year, which is notified by the Government on the 1st day of April every year. The WPI revision notified by NPPA during the last five years is as under:

Year	WPI Increase/Decrease (%)
2021	0.53638 %
2020	1.884668 %
2019	4.2662 %
2018	3.43812 %
2017	1.97186 %

The details of retail/ceiling prices fixed/revised by NPPA are available on its website at www.nppaindia.nic.in.

(c) & (d): Representations from manufacturers of drugs are received from time to time by NPPA for upward revision of prices of the drugs on account of increase in raw material, transportation and other input costs, etc. These representations are examined and considered by NPPA after scrutiny. NPPA has invoked extraordinary powers in public interest under para 19 of DPCO, 2013 for upward revision of the ceiling prices of 30 scheduled formulations of 15 drugs by giving one time increase of 50% from the extant ceiling price in December 2019 and July 2021 respectively. Details of the same are available on NPPA's website at www.nppaindia.nic.in.

(e): As per the extant provisions of DPCO, 2013, the ceiling price of all scheduled formulations figuring in NLEM are fixed by NPPA. All manufacturers of these scheduled drugs are required to sell their products at a price equal to or lower than the ceiling price. Further, NPPA monitors the prices of non-scheduled drugs so as to ensure that increase in their Maximum Retail Price (MRP) is not more than 10% of what was prevalent during the preceding twelve months. The details of various medicines under price control are available on the website of NPPA at www.nppaindia.nic.in.

GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA
UNSTARRED QUESTION No. 5045
TO BE ANSWERED ON THE 1st APRIL, 2022

Pharmaceutical Industry

5045. DR. PRITAM GOPINATHRAO MUNDE:
SHRI GIRISH BHALCHANDRA BAPAT:
SHRI CHANDRA SEKHAR SAHU:
SHRI RAHUL RAMESH SHEWALE:

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

(a) whether the Government has recently issued any guidelines for the scheme for strengthening of Pharmaceutical Industry in the country;

(b) if so, the details thereof along with the details of funds allocated for the said scheme;

(c) whether the Government also proposes to improve the existing infrastructural facilities of the pharma sector in the country;

(d) if so, the details thereof along with the targets fixed by the Government under the said scheme; and

(e) the steps taken to establish India a global leader in the pharma sector?

ANSWER

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

(a) & (b): The Department has recently issued the guidelines of the scheme "Strengthening of Pharmaceutical Industry (SPI) in 11th March 2022 with the following objectives:

- To strengthen the existing infrastructure facilities in order to make India a global leader in the Pharma Sector by providing Financial assistance to pharma clusters for creation of Common Facilities.
- To upgrade the production facilities of SMEs and MSMEs, to meet national and international regulatory standards, by providing interest subvention or capital subsidy on their capital loans.
- To promote knowledge and awareness about the Pharmaceutical and Medical Devices Industry by taking up studies, building databases and brining industry leaders, academia and policy makers together to share their knowledge and experience.

The total financial outlay of the scheme is Rs. 500 crore for a period of five years from 2021-22 to 2025-26.

(c) to (e): Department of Pharmaceuticals strives to improve the infrastructural facilities of the pharma sector in the country towards making India, a global leader in the sector.

- In order to make the country Atmanirbhar in pharmaceuticals, the Department of Pharmaceuticals has launched the Production Linked Incentives (PLI) Scheme for promotion of domestic manufacturing of critical Key Starting Materials (KSMs)/Drug Intermediates (DIs), and Active Pharmaceuticals Ingredients (APIs) in India. The Total financial outlay of the scheme is Rs. 6,940 crore and the tenure from FY 2020-2021 to FY-2029-30.
- Another 'Production Link Incentive (PLI) scheme for Pharmaceuticals has been launched with total financial outlay of Rs. 15,000 crore and tenure from FY 2020-2021 to FY 2028-29. The scheme intends to enhance India's manufacturing capabilities by increasing investment and production in the sector and contributing to product diversification to high value goods in pharmaceuticals sector. The eligible drugs under this scheme include APIs among other categories of pharmaceuticals products.
- The Department has launched a scheme to provide further support to API pharma companies through providing, financial assistance to the States for establishing three Bulk Drug Parks.
- Further, Department provides support to the pharma clusters for creating common infrastructure facilities under Assistance to Pharmaceuticals Industry for Common Facilities (API-CF).
- Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS) has also been approved to support SME units in pharmaceutical sector for quality & technology upgradation.

Details of all the above schemes can be accessed at https://pharmaceuticals.gov.in/schemes .

NEWS

Health Ministry to Direct PCI to Implement DPEE Regulations to Weed out Fake Diploma Certificates

The Union health ministry is learnt to have taken a decision to implement the D Pharm Exit Examination (DPEE) Regulations 2018 across the country in order to weed out fake diploma certificates from getting registered with state pharmacy councils.

The government is now ruminating on implementing the regulations followed by a proposal in this regard submitted by the Delhi State Pharmacy Council (DSPC). According to sources, the Pharmacy Council of India (PCI) will soon receive a direction in connection with this from the central government very soon.

News about the government deliberation was informed to the Delhi State Pharmacy Council by the Union health ministry in its reply to the letter written to the health minister by the DSPC.

According to the ministry's letter, which has been reviewed by Pharmabiz, the government has become aware of the need of conducting the exit examination for the D Pharm pass outs, and the PCI will be given the approval to implement the regulations shortly. Further, it is learnt that PCI is also seriously considering the implementation of the regulations from this academic year.

Sharing information with Pharmabiz, Ajay Sharma, the acting president of the DSPC said the union health ministry is planning to completely revamp the country's pharmacy education as several fake colleges and universities conduct various courses in pharmacy and issue certificates to people who pay money for them. Such anomalies were brought to the attention of the union government by the DSPC, resultantly the government has perceived the necessity to conduct a professional test to be qualified for registering the certificate with a council. He said many of the students passing out from institutions lack basic knowledge of the subject because they do not attend the theory and practical classes regularly. The institutions collect huge money from them towards course fees and issue pass certificates.

Five years ago, on receiving complaints from various corners about this malpractice by certain institutions, when the education visionary Dr. B. Suresh was the president of the PCI, he called a special meeting of the PCI and after prolonged deliberations the council introduced the DPEE Regulations 2018. But, so far it could not be implemented in the country because of resistance from institutions conducting diploma course. The institution management argues that there is zero necessity for the exit exam as universities or government boards conduct theory and practical examinations as per the syllabus designed by the PCI to evaluate the knowledge and the skill of the students who have completed two years study in class rooms. Ajay Sharma, president of the Delhi pharmacy council justifies his part by saying that a lot of fake certificates are submitted to the state pharmacy councils for registration, and it is necessary to assess the

knowledge and skill of the students as pharmacy course is a technical course.

Meanwhile, some academic experts have commented that exit exams should be conducted for the degree (B Pharm) and for the Pharm D pass outs and not for the D Pharm holders as the course is not a basic educational program for dispensing drugs. Although it is approved in India as the basic qualification for pharmacists, it is a technical course and it should be stopped immediately.

As per the DPEE Regulations, a student of D Pharm, after passing his two year course, must take the exit exam to become eligible for registration of his certificate with a state pharmacy council. The exam will be conducted by the PCI by assigning some agencies as the authority to hold the professional test which comprises three papers covering topics from pharmaceutics, pharmaceutical chemistry, pharmacology, pharmacognosy, forensic pharmacy, bio-chemistry and physiology. A candidate has to obtain 50% marks in each paper separately.

The president of the DSPC said he will soon write to the PCI to expedite the process for the implementation of the regulations. He said gradually state pharmacy councils will undertake the responsibility to conduct the examination in each state.

Source: *Pharmabiz,* 16th February 2022

Indian Companies Stay Put in Russia But Pharma Exports Could be Hit

Pharmaceutical major Dr Reddy's Laboratories said, it was focused on business continuity in and around Russia, as Indian drug exporters brace for temporary disruptions to sales due to the Ukraine crisis.

No Indian company has publicly withdrawn from Russia and New Delhi has declined to condemn Moscow's invasion of Ukraine, despite pressure from the United States to do so.

Western companies such as McDonald's, PepsiCo, Coca-Cola and Starbucks have stopped sales of their best-known products in Russia.

"We have had a presence in the region for over three decades," a Dr Reddy's spokesperson said in an email.

"Ensuring the well-being of our staff is our first and foremost priority, along with measures to meet patient needs and business continuity. Overall, we are monitoring evolving developments closely and preparing accordingly."

It declined to say if it would raise or scale back investments in Russia, which accounted for more than 8% of its total sales of Rs 18,970 crore ($2.47 billion) in the last fiscal year that ended on March 31.

Dr Reddy's, India's fourth-biggest pharmaceutical company by market value, sells pain killers and other medicines in Russia. It is the main distributor in India for Russia's Sputnik Covid-19 vaccines.

Executives at Indian pharma companies Torrent Pharmaceuticals and Zydus Lifesciences said they saw little or no impact on sales due to the Ukraine conflict.

But the Indian Drug Manufacturers' Association (IDMA) told Reuters that prices of raw materials derived from benzene or other petroleum products would rise due to the war, and pharmaceutical exporters would have to seek buyers elsewhere.

"Overall demand for medicines will not go down, but there may be a temporary disruption," said IDMA president Viranchi Shah.

"The problematic thing is managing payments from Russia" because of Western sanctions. "It will take some time to be addressed as an alternate mechanism will be required to be put in place," he said.

An Indian government official, who declined to be named, said the country was confident of finding alternative markets for its pharmaceutical industry if needed.

At $173.7 million, pharmaceuticals accounted for 30% of India's total exports to Ukraine between April and December last year. Sales to Russia during the period reached $386 million, or 15% of the total shipments to the country.

The Indian embassy says there are an estimated 300, most of them involved in trading tea, coffee, tobacco, pharmaceuticals, rice, spices, leather footwear, granite, IT services and garments.

Source: *The Times of India,* 9th March 2022

Make Pharma Companies Liable for Bribing Doctors: PIL

The Supreme Court sought the Centre's view on a PIL seeking to make Pharma companies criminally liable for bribing doctors through freebies to the tune of over Rs 4,000 crore every year to get their drugs over-prescribed, which adversely impact public health.

A bench of Justices D Y Chandrachud and Surya Kant issued notice to the Union government on the PIL filed by the Federation of Medical and Sales Representatives Association of India, which alleged that showering of freebies on doctors influences them to prescribe the overpriced and potent drugs leading to lowering of inherent immunity system of patients and future complications.

Appearing for the petitioner, senior advocate Sanjay Parikh said that a prime example of it was the mindless prescription of costly Remdesivir injections for Covid patients during the pandemic even when its efficacy against coronavirus was not scientifically proved. Such a practice violated the general public's right to life and health, he said.

Parikh said, at present only doctors are criminally liable for receiving bribes instead of prescribing a particular medicine, though the SC has time and again ruled that both the bribe givers (in this case the parma companies) and the bribe-takers (doctors) are equally liable.

He requested the court to intervene in laying down a guideline to hold Pharma companies liable for giving freebies to doctors. The petition filed through advocate Aparna Bhat informed the court that "pharmaceutical companies in India spend enormous amounts of money in sales promotion to influence doctors to generate maximum prescriptions thereby increasing drug sales."

The SC had upheld 2012 circular issued by the Central Board of Direct Taxes clarifying that such expenses incurred by pharmaceutical and allied health sector industries for distribution of incentives to medical practitioners are ineligible for the benefit of Section 37(1) of the Income Tax Act about business deduction.

Source: *The Times of India,* 12th March 2022

Bitter Pill: Paracetamols, Pain Killers, Antibiotics to Pinch Pockets from Apr

The National Pharmaceutical Pricing Authority's (NPPA) announcement of a price rise for 800 drugs from April 1 is likely to hit consumers in Kolkata soon. Prices of over the counter (OTC) medicines, often used for fever or gastrointestinal disorders, are likely to see a steep rise. The pharmacy retailers in the city said it would take 20-30 days for the new batch of drugs to arrive and the new prices to become effective.

After the government allowed an increase of over 10% for scheduled drugs, including pain killers, antibiotics and anti-infective, the prices are set to go up from April 1. For the scheduled drugs, which are under price control, the increase is 10.7%. “For the non-controlled drugs the increase might be as high as 20%. The medicines which are sold as OTC products will come under the 20% bracket,” said Sajal Ganguly, secretary of the Bengal Chemists and Druggists Association (BCDA).

Based on Wholesale Price Index data, ministry of commerce and industry worked out the wholesale price index at 10.7% during calendar year 2021 over the corresponding period of 2020. Accordingly, NPPA allowed price rise for 800 drugs under the National List of Essential Medicines. “For the buyers, it will be a steady rise in price for medicines ranging from paracetamol to amoxicillin,” Ganguly said.

Bengal, which has the highest consumption of medicines in the eastern India, is likely to be hit hard

According to Rajendra Khandelwal of Dhanwantary Pharma, medicines for diabetes, blood pressure or cardiac disorders are under the price control. “But new medicines, especially some of those which we have seen usage during Covid, will not fall under the price controlled category,” he said. “Anti-viral drugs like Remdisivir, used in Covid treatment, were brought under NPPA. But there are other patented drugs under non-scheduled category. Price rise for these drugs will depend on price of active pharmaceutical ingredients used in manufacturing them,” said Rajiv

Singhal, general secretary of All India Organisation of Chemists and Druggists (AIOCD).

"There is a chance that people will start buying in bulk to avail the old price," felt Somnath Ghosh of Metro Pharma.

Source: *ET Healthworld,* 28th March 2022

DGGI Acts on Pharma Companies for GST Evasion: These Companies Come Under Hammer

Directorate General of GST Intelligence (DGGI) which works under the aegis of the Ministry of Finance has taken action against many big pharma companies in the country for not filing **Goods and Services Tax** (GST).

The pharma giants included are Dr. Reddys Laboratories, Glenmark, Aurobindo Pharma, Mylan and Cipla, as reported by Zee Business's Tarun Sharma.

The aforementioned pharma companies did not pay tax in violation of the rules of section 25 of GST, on which this action has been taken, he added.

DGGI, the investigation branch of the Central Board of Indirect Taxes & Custome (CBIC), conducted a survey on taxation in pharma sector companies, in which it was revealed that these companies had not paid tax since the implementation of GST.

Pharma companies did not pay by misinterpreting section 25, Sharma said.

Which companies owed how much tax?

Investigation revealed that Dr. Reddys had not paid tax of about Rs 130 crore. Apart from this, Glenmark did not pay a tax of Rs 125 crore, Aurobindo Pharma Rs 60 crore, Mylan Rs 20 crore and Cipla Rs 18 crore, he explained.

Companies admit mistake

After the **DGGI** survey came to the fore about the non-filing of GST, these pharma companies accepted their mistake and paid the outstanding GST. However, after this, the GST department is not only checking section 25.

The department is also keeping an eye on many other things, such as some companies sending their medicines abroad, which were rejected by the **USFDA.** But companies took ITC (Input Tax Credit) on it in the country, which was not refunded, according to Sharma.

What is section 25

According to section 25 of GST, if a company makes any payment from its head office to the branch office, then it has to pay GST on the transfer of more than 20 lakhs. But these companies did not pay tax on transactions above 20 lakhs, Sharma explained.

Companies will remain on the radar of GST even further

After this action of **DGGI,** these pharma companies are going to be on the

radar of GST even further. GST department is now going to see not only their section 25, but other transactions as well, he added.

Market expert Siddharth Sedani said that despite this news, the pharma sector has already hit its bottom, which gives scope for improvement. And in such cases, Cipla has proven to be a good stock.

Source: *The Health Master,* 31st March 2022

First Case of Infection from Diabetes Medication in India

State drug controllers told to include warning for patients using SGLT2 inhibitors

After the U.S. and Canada, India too has admitted incidence of a rare but serious infection of the genitals and area around the genitals among Type-2 diabetes patients using sodium-glucose cotransporter-2 (SGLT2) inhibitors .

This serious rare infection, called necrotizing fasciitis of the perineum, is also referred to as Fournier's gangrene.

As a precautionary measure the Central Drugs Standard Control Organization (CDSCO) has requested all State Drug Controllers to direct the manufacturers of SGLT2 inhibitor class drugs named Canagliflozin, Dapagliflozin, Empagliflozin, under their jurisdiction to include warnings in the package insert and promotional literature of these drugs.

The Health Ministry, responding to a question on the adverse reaction to the anti-diabetes medicine by MP P. Velusamy, submitted the information recently.

Sodium-glucose cotransporter-2 (SGLT2) inhibitors and dipeptidyl peptidase IV (DPP-IV) inhibitors are recommended as preferred add-on oral anti-diabetic drugs (OADs) after metformin among type-2 diabetes mellitus (T2DM) patients with atherosclerotic cardiovascular disease (ASCVD), heart failure (HF), and chronic kidney disease (CKD). They are generally many times costlier than other OADs, note experts.

The Ministry submitted in Parliament that CDSCO was notified about a Health Canada communication to all those authorised to market sodium-glucose co-transporter-2 (SGLT2) inhibitors regarding a summary safety review (SSR) on the potential risk of pancreas inflammation (acute and chronic).

United States Food and Drug Administration (USFDA) in its drug safety communications (DSC) has cautioned about cases of rare but serious infection of the genitals and area around the genitals bring reported with use of SGLT2 inhibitors.

“This serious rare infection, called necrotizing fasciitis of the perineum, is also referred to as Fournier's gangrene. USFDA has revised the labels of SGLT 2 inhibitors to include new warnings about the risk to patients,'' noted the Ministry.

It added that the issue was examined in consultation with Subject Expert Committee (SEC) of CDSCO and information available under the Pharmacovigilance Programme of India (PvPI) has also been obtained.

Diabetes is a chronic, metabolic disease characterized by elevated levels of blood glucose (or blood sugar), which leads over time to serious damage to the heart, blood vessels, eyes, kidneys and nerves. The most common is type-2 diabetes, usually in adults, which occurs when the body becomes resistant to insulin or doesn't make enough insulin. In the past three decades the prevalence of type-2 diabetes has risen dramatically in countries of all income levels, according to the World Health Organisation.

Union Health Minister Dr. Mansukh Mandaviya had stated in Parliament that while the exact number of patients suffering from diabetes in India is not known, however, as per 10th edition of Diabetes Atlas 2021 of International Diabetes Federation (IDF), the estimated number of patients with diabetes between the age group of 20-79 years is 74.2 millions in year 2021 and it is estimated to be increased to 124.8 millions in year 2045.

Source: *The Hindu,* 4th April 2022

Govt. wants to Reduce Compliance Burden on Pharma Sector: Mandaviya

Union Minister for Chemicals and Fertilizers Mansukh Mandaviya on Thursday said that the government wants to reduce the compliance-burden on the Pharma industry for ease of doing business.

Speaking as the chief guest at an Indian Drug Manufacturers' Association (IDMA) event here, Mandivya, who is also the Minister for Health and Family Welfare, said that the Narendra Modi-led government at the Centre is not only "pro-poor" and "pro-farmer" but "industry-friendly" as well.

"We want the ease of doing business for the industry and lessen the compliance burden on it. This is why we always carry out consultations with all stakeholders prior to the formulation of any policy or regulation (governing the pharma industry)," Mandaviya said.

The government is helping the industry by amending the Drugs and Cosmetics Act, 1940 and promoting Ease of Doing Business, he said, adding, "We are involving the industry in decision-making processes".

Also, through a series of webinars, the government has tried to reach out and consult industry and other stakeholders on the implementation of Union Budget provisions, the minister stated.

"Our government is pro-poor, pro-farmer and industry-friendly government. It is dedicated to the poor and farmers but at the same time it is an industry-friendly government as well," he emphasized.

Stating that the industry plays an important role in nation-building and also in achieving self-reliance, the Minister said that today the Indian pharma industry is known in the world which is due to the efforts of both the Government and the industry.

He said that the government is working to make the pharma industry self-reliant and also enhancing and the introduction of the Rs 15,000 crore Productivity-Linked Incentive (PLI) scheme is a step in this direction.

Through the Production Linked Incentive Scheme, the government has tried to reduce imports by encouraging domestic manufacturing of pharmaceuticals, he said.

Manufacturing of 35 Active Pharma Ingredients (API), which used to be imported earlier, has started in the country now under the PLI Scheme for the pharma sector, Mandaviya said.

The Minister urged the pharmaceutical sector to prepare a plan for the next 25 years

"Government does not view the health sector as a profit-making industry. When we export medicines, we do it with an attitude of 'Vasudhaiva Kutumbakam'. During the first wave of COVID-19 pandemic, India supplied medicines to 125 countries," he added.

Source: *ET Healthworld,* 15th April 202

Govt Likely to Set Export Target of $800 Billion for FY23

India is likely to set an ambitious export target of around $800 billion for goods and services for 2022-23, almost 19.5% higher than $670 billion clocked in 2021-22. The targets - of $450-480 billion for merchandise and $350 billion for services - were discussed in a series of meetings that commerce and industry minister Piyush Goyal had with exporters.

India's goods exports touched a record $420 billion in 2021-22, exceeding the government's target by about 5% and up 40% on-year while services exports touched $250 billion.

"These are consultative meetings and the targets are yet to be fixed," said an official. Exporters raised the issue of high prices of inputs as buyers are now reluctant to raise prices proportionately due to sufficient inventory and lack of demand.

Restoration of the Market Access Initiative scheme for opening of warehouses overseas, easing of visa requirements for inbound tourism and a revised Transport and Marketing Assistance scheme for certain agricultural products in view of the opportunity in farm exports from the Russia-Ukraine crisis were also taken up, according to sources.

"Despite a rise in Covid cases globally, there is an expectation that travel and tourism will grow this year," said an industry representative.

Source: *The Economic Times,* 21st April 2022

DCGI Claims India on Course to Become Global Drugs Hub

Claiming that India is on course to become a 'global hub for medicines', Dr VG Somani, Drug Controller General of India (DCGI), said that there has been a fourfold increase in applications of the investigational new drugs in the country.

Speaking at the Indian Drug Manufacturers' Association (IDMA) Annual Conclave, Somsaid, "We are getting the applications of the investigational new drugs. Earlier, there used to be hardly 5-10 applications. At present, there are 23 applications in the pipeline for the investigational new drug and this is a great achievement of our country."

He said that the "Made in India" drugs will make a difference and hit the world in the coming years.

The DCGI official also explained how drug controllers work while taking decisions about vaccines and drugs.

"We have been in regular contact with the WHO and all regulators of the world through ICMR, ICH platform etc. There are various platforms for the approval of vaccines and drugs including trials. That's what we have done with remdesivir. There is no single platform for decisions to be taken," he added.

He further said that India has been recognised as a "Pharmacy of the world" and added "we want to become the well-managed pharmacy of the entire world so that our potential can be recognised".

Source: *ET Healthworld,* 15th April 202

Pharma Industry Must Focus on Generic, Better Link Between Input and Output: Goyal

Union Commerce and Industry Minister Piyush Goyal, asked the domestic pharmaceutical industry to strengthen its generic medicine sector and ensure better linkage between input and output of products to become self-reliant. Speaking at an event hosted by the Indian Drug Manufacturers' Association to commemorate its Golden Jubilee celebrations here, Goyal also asked the industry to plan for a long-term to tackle challenged related to global supply chain.

"The phenomenal growth that we have seen in the last ten years should be carried forward to ensure that we become self sufficient. Global supply chains are becoming more and more difficult to predict. The challenges are getting unimaginably serious," he said.

In this situation, the minister said, "it's extremely important that we focus not only on our strengths in the generic sector but also ensure our backward and forward linkages."

"We should plan for the long term to become more and more self-sufficient and with that we will go to the world with the confidence of a powerful nation, engaging with the world on

equal terms for a better future for our industry," Goyal said, adding that India's aim should be to become the healthcare custodian of the world.

Stressing on the need for mutual support within the industry, the minister said, "Every country does protect its core industry and I feel our core industry is the Pharma industry.

Goyal also mentioned government measures like the production-linked incentive scheme for the manufacturing of active pharmaceutical ingredient and medical devices and said, "I do hope that many of the manufacturers in the Pharma industry are taking advantage of the scheme."

It is important that the industry tries product development and break new grounds in medical research, he said.

"Our international competitiveness should be very important to keep us abreast of the new developments and good manufacturing practices," he added.

He also said that the government's efforts towards having free-trade agreements with different countries will create pathways for easier approvals of Indian Pharma products across the globe.

Source: *ET Healthworld,* 16th April 2022

How Indian Pharma can Actually Save the World:

Domestic Firms Need to Produce Basic Inputs for Medicines that China Now Dominates

More than 15 blockbuster drugs with annual global sales exceeding $100 billion will go off-patent by 2030. Is India ready to make and export these? Its pharma value chain needs urgent strengthening to take advantage of such opportunities.

Here is the core issue. Making medicines is an 8-10 stage process. We are not competitive in making most medicines from the initial or intermediate stages. We import penultimate stage products to make medicines. The example of the fever-reducing tablet Crocin will make this clear.

Crocin's illustrative story

The base material for making Crocin is crude petroleum oil. Petroleum refining produces Naphtha, which leads to new chemicals, Benzene and Propylene. These two produce Phenol, the key starting material (KSM) for making Crocin. Phenol produces Paracetamol, the chemical that reduces fever. We call it the active pharma ingredient (API) or bulk drug. Mix Paracetamol with some binder, and Crocin is ready. Keywords here are APIs and KSMs, which are penultimate products.

For the making of most medicines, we import APIs and KSMs. Worse, we buy about 70% of such inputs from a single supplier – China. For specific APIs, over 90% of imports come from China. In cases where we make APIs or KSMs, we use intermediates imported from China.

India last year exported $28 billion worth of medicines and related products to over 200 countries. So pharma sector is growing well, and using imported inputs for enhancing competitiveness is good for business. But critical dependence on a single supplier may lead to a hostage situation. We have seen

how the Covid-led shutdown of a few Chinese pharma units last year created panic world over. China moving up the value chain, may also decide to restrict the supply of inputs.

Old-timers find critical dependence on imported inputs strange. India was nearly self-sufficient in pharma inputs in the 1990s.

Brief history of our turn to dependency

Two government actions in the 1970s set Indian pharma on a growth path. Indian Patent Act 1970, by not recognising product patents, allowed Indian firms to use their reverse engineering skills to make generic versions of medicines. And drug policy in 1975 nudged the firms to make bulk drugs from the primary stages. The rules also forced them to spend on R&D to innovate new molecules and cut costs. By 1990 local firms were making 70% of the API and intermediates needed in the country. India became the largest maker of antibiotics, anti-malarial, anti-TB drugs, Paracetamol etc
Source: *Business Line,* 20th April 2022

Rules changed in 1995 with the founding of WTO. India agreed to recognise both process and product patents as a WTO member. Around the same time, many drugs became free from patent protection in the US. Indian pharma lapped up this opportunity to make reverse-engineered generic versions of these drugs. Contrary to apprehensions, this was a period of heady growth.

But making APIs needed significant investment and it was a low-returns (10-15%) game while making medicines from APIs generated 40-60% value addition. Most Indian firms opted for imported APIs to maximise profits.

By the turn of the century, China, with large capacity plants, investment in R&D, and subsidies, started selling intermediates and APIs at discounted prices. By 2005, India stopped making fermentation-based APIs. India also stopped producing many chemical-based APIs, raw materials, intermediates, solvents and catalysts.

Action plan for a different future

We must go deeper into the pharma value chain for key frontline drugs for global and domestic health security. For this we must make inputs and intermediates for chemical- and fermentation-based APIs. This means going below the API and KSM stages. A four-step plan will help:

- Create 50 large pharma parks with pre-approved environment clearances. Here incentivise plants with continuous processing, making of solvents, reagents and fluorinating agents. Install common centres for solvent recovery, distillation and effluent treatment.

- Invest in creating a global standards strain for developing fermentation-based APIs. Poor quality strains were one of the reasons for the closure of most fermentation-based units in the past 20 years. Consider reviving PSUs for making fermentation-based products. These are capital-intensive and need a longer incubation period.

- Mandate similar standards for medicines for the domestic market and exports. This may not be very difficult as we already have over 600 USFDA-approved medicine-making units, the largest outside the US.

- Finally, strengthen R&D at all levels to support small firms and expand the patent portfolio. Strengthen regulatory oversight to check the menace of spurious medicines.

- The world loves buying medicines from India and it is looking for a China+1 strategy for diversifying the sourcing of medicines. With a large pool of researchers, biotechnologists, pharmacists and entrepreneurs, India is in the best position to become a self-reliant supplier of affordable medicines.

- Source: *The Times of India,* 26th April 2022

DCGI Claims India on Course to Become Global Drugs Hub

Claiming that India is on course to become a 'global hub for medicines', Dr VG Somani, Drug Controller General of India (DCGI), said that there has been a fourfold increase in applications of the investigational new drugs in the country.

Speaking at the Indian Drug Manufacturers' Association (IDMA) Annual Conclave, Somsaid, "We are getting the applications of the investigational new drugs. Earlier, there used to be hardly 5-10 applications. At present, there are 23 applications in the pipeline for the investigational new drug and this is a great achievement of our country."

He said that the "Made in India" drugs will make a difference and hit the world in the coming years.

The DCGI official also explained how drug controllers work while taking decisions about vaccines and drugs.

"We have been in regular contact with the WHO and all regulators of the world through ICMR, ICH platform etc. There are various platforms for the approval of vaccines and drugs including trials. That's what we have done with remdesivir. There is no single platform for decisions to be taken," he added.

He further said that India has been recognised as a "Pharmacy of the world" and added "we want to become the well-managed pharmacy of the entire world so that our potential can be recognised".

Source: *ET Healthworld,* 15th April 202

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Union Commerce and Industry Minister Piyush Goyal, asked the domestic pharmaceutical industry to strengthen its generic medicine sector and ensure better linkage between input and output of products to become self-reliant. Speaking at an event hosted by the Indian Drug Manufacturers' Association to commemorate its Golden Jubilee celebrations here, Goyal also asked the industry to plan for a long-term to tackle challenged related to global supply chain.

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அதிர்ச்சியூட்டும் மருந்து விலை உயர்வு!

கடந்த சில நாட்களாகவே குடும்ப பட்ஜெட்டில் பெரிய துண்டு விழுந்து கொண்டிருக்கிறது. அன்றாடம் பெட்ரோல்-டீசல் விலை உயர்ந்து கொண்டே போகிறது. 'இது எங்களுக்கு அத்தியாவசியம். ஆனால், இவ்வளவு விலை உயர்வை தாங்கிக்கொண்டு, எங்களுடைய மொபட்டில், ஸ்கூட்டரில் பெட்ரோல் போட்டு பயன்படுத்த முடியாது' என்ற நோக்கில், பலர் வீட்டில் வைத்திருந்த சைக்கிளை துடைத்து, ரிப்பேர் செய்து பயன்படுத்த தொடங்கிவிட்டனர். மேலும் சிலர் மோட்டார் வாகன பயன்பாட்டை குறைத்துக்கொண்டனர். விவசாயிகள் டிராக்டரை பயன்படுத்தித்தான் ஆக வேண்டும். ஆனால், இந்த டீசல் விலை உயர்வை எங்களால் தாங்க முடியவில்லை என்று மனம் நொந்து கூறுகிறார்கள்.

இது மட்டுமல்லாமல், மற்ற பொருட்களின் விலையும் உயர்ந்துவிட்டது. விலைவாசி உயர்வுக்கு பெட்ரோல்-டீசல் விலை உயர்வும் எரிகிற தீயில் எண்ணெய் விடுவதுபோல் காரணமாகிவிட்டது. ஆனால், விலைவாசி உயர்வுக்கு ஏற்ற வகையில், மக்களின் வருமானம் உயரவில்லை. குறிப்பிட்ட நிலையான வருமானத்தை வைத்துக்கொண்டு, பெருகிவரும் விலைவாசி உயர்வை சமாளிக்க முடியாமல், குடும்ப பட்ஜெட்டில் துண்டு விழுவது அதிகமாகிக்கொண்டே இருக்கிறது. மற்ற பொருட்கள் விலை உயர்ந்தால், ஒரு பொருளுக்கு பதிலாக மாற்றுப்பொருளை பயன்படுத்த முடியும் அல்லது பயன்பாட்டை குறைத்துக்கொள்ள முடியும். ஆனால், மருந்து விலை அப்படி அல்ல. நோய்வாய்ப்பட்டவர்கள் தொடர்ந்து உயிர்வாழ வேண்டும் என்றால், நாள்தோறும் உட்கொள்ளும் மருந்து, மாத்திரைகளை சாப்பிட்டுத்தான் ஆகவேண்டும். போடவேண்டிய ஊசியை போட்டுத்தான் ஆகவேண்டும். அதற்கு ஒரேயொரு எடுத்துக்காட்டு, நீரிழிவு நோய்க்காக சாப்பிடும் மாத்திரைகள், போட்டுக்கொள்ளும் இன்சுலின் மருந்து.

இந்த நிலையில், இப்போது அத்தியாவசிய மருந்துகளின் விலையையெல்லாம் 10.70 சதவீதம் உயர்த்திக்கொள்ள இந்திய மருந்து விலை நிர்ணய ஆணையம் அனுமதித்துள்ளது. அட்டவணையில் உள்ள 872 மருந்துகள், தேசிய அத்தியாவசிய மருந்து பட்டியலில் இருக்கிறது. அந்த மருந்துகள் எல்லாம் விலை உயரப்போகின்றன. இதுவரையில் இல்லாத விலை உயர்வாக இந்த மருந்து விலை உயர்வு இருக்கிறது. சாதாரண வலிநிவாரணி மருந்துகள், ஆன்டிபயாடிக்குகள், தொற்று எதிர்ப்பு மருந்துகள், குறிப்பாக பாரசிட்டமால், அசித்ரோமைசின் போன்ற ஆன்டிபயாடிக்குகள், அனீமியா எதிர்ப்பு மருந்துகள், வைட்டமின்கள், காய்ச்சல், சரும நோய்கள், இதயநோய்கள், ரத்த அழுத்தம், ஏன், கொரோனா சிகிச்சைக்குப் பயன்படும் மருந்துகள்கூட விலை உயருகிறது.

ஆண்டுதோறுமே இவ்வாறு விலை உயர்ந்தாலும், கொரோனா பாதிப்பால் மக்கள் தங்கள் வருவாயில் பெரும் பாதிப்பை அடைந்துள்ள நிலையில், இந்த மருந்து விலை உயர்வை நிச்சயமாக தாங்க முடியாது. இந்த வலியை தாங்க வேண்டுமென்றால், விலை

குறைவான ஜெனரிக் மருந்துகளை மக்கள் பயன்படுத்த தொடங்கலாம். ஜெனரிக் மருந்து என்பது, தயாரிக்கும் கம்பெனி பெயர் குறிப்பிடாமல், ஊசி மற்றும் மருந்து, மாத்திரைகளை அதன் ரசாயன கூறு அடிப்படையிலான பெயரில் விற்கும் மருந்துகளாகும்.

எடுத்துக்காட்டாக, மெட்டாசின், டோலோ- 6 5 0 என்ற பெயரில் இல்லாமல், பாரசிட்டமால் என்ற பெயரில் இந்த மாத்திரைகள் இருக்கும். மத்திய அரசாங்கத்தின் மலிவுவிலை மருந்து கடைகளில் இந்த ஜெனரிக் மருந்துகளே விற்பனை செய்யப்படுகின்றன. ஆனால், ஜெனரிக் மருந்துகளில் தரமிருக்காது என்ற பயம் மக்களிடம் இருக்கிறது. அந்தப் பயத்தை நீக்க மத்திய அரசாங்கம் முயற்சி செய்ய வேண்டும்.

இங்கிலாந்தில் 60 வயதுக்கு மேற்பட்டவர்களுக்கும், 16 வயதுக்கு குறைந்தவர்களுக்கும் மருந்து கடைகளில் இலவசமாக மருந்துகள் வழங்கப்படுகின்றன. அதுபோன்ற சலுகைகளை வழங்க மத்திய அரசாங்கம் பரிசீலிக்க வேண்டும்.

இப்போதைய சூழ்நிலையில், அத்தியாவசிய மருந்துகளை தயாரிக்கும் மருந்து கம்பெனிகளுக்கு அரசு வேறு ஏதாவது மானியம், சலுகைகள் கொடுத்து, மருந்து விலை உயராமல் தடுக்க முடியுமா என்பது மருந்தில்லாமல் உயிர் வாழ முடியாத மக்களின் மன்றாட்டு கோரிக்கையாக இருக்கிறது.

Source: *Daily Thanthi,* 6th April 2022

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