ISSUE No. 54

SILVER JUBILEE YEAR 2016

TAMILNADU PHARMACEUTICALS SCIENCES WELFARE TRUST

25 Years

Pharma Web

Newsletter of Tamilnadu Pharmaceutical Sciences Welfare Trust

Apr. - May. - Jun. 2022

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Tamilnadu Pharmaceutical Sciences Welfare Trust

Pharma Web

Newsletter of Tamilnadu Pharmaceutical Sciences Welfare Trust

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

EDITORIAL

Dear Readers,

We are happy to publish the 54th issue of Pharma Web Newsletter for Apr – Jun 2022.

This 54th issue contains the program highlights as well as the following article published by eminent person in Pharma industry.

- **Current thinking and FDA expectations from recent OOS Guidance by Dr. BM Rao**, VP & Head– CQC, ASAT and EMQA, Dr. Reddy's Laboratories Limited, Hyderabad, India

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

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

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

Current thinking and FDA expectations from recent OOS Guidance

Dr. BM Rao,
VP & Head– CQC, ASAT and EMQA, Dr. Reddy's Laboratories Limited, Hyderabad, India

Abstract:

On 16th May 2022, FDA announced revisions to the 2006 guidance "Investigating Out-of-Specification (OOS) Test Results for Pharmaceutical Production." Specifically, this revision updates terminology for consistency with current FDA guidance, e.g., quality control unit is changed to quality unit, as well as clarifies concepts related to addressing outlier results, and practices related to the averaging of OOS results. This guidance provides FDA's current thinking on how to evaluate OOS test results. The investigation of out of specification (OOS) results is a regulatory requirement in a GMP laboratory, and these investigations are intensively scrutinized by health authority inspectors. The reason for most of 483 observations/warning letters was inadequate investigation of Laboratory Non-Conformances. The inadequate investigation because of unawareness of regulatory guidance requirements while performing the investigation.This article covers thesummary of changes provided in the new updated OOS guidance.

Keywords: Out of specification results, Quality unit, Good Manufacturing Practices, Batch rejection, Re-testing, Re-sampling, Averaging, Outlier tests.

Background & Introduction:

Laboratory testing, is required by the cGMP regulations, is necessary to confirm that components, containers and closures, In-process materials, and finished products conform to specifications, including stability specifications [1]. The OOS process is not applicable for In-process testing while trying to achieve a manufacturing process endpoint i.e. adjustment of the manufacturing process. (e.g. pH, viscosity), and for studies conducted at variable parameters to check the impact of drift (e.g. process validation at variable parameters) [2].Both finished pharmaceuticals and active

pharmaceutical ingredients (APIs) are to be manufactured in accordance with current GMPs [3,4]. Current good manufacturing practice for APIs includes the performance of scientifically sound raw material testing, in-process monitoring, release and stability testing, process validation, and adequate investigations of any OOS result obtained from such testing.FDA regulations require that an investigation be conducted whenever an OOS test result is obtained. The purpose of the investigation is to determine the cause of the OOS result. The source of the OOS result should be identified either as an aberration of the measurement process or an aberration of the manufacturing process [5]. An initial OOS result does not necessarily mean the subject batch fails and must be rejected. The OOS result should be investigated, and the findings of the investigation, including retest results, should be interpreted to evaluate the batch and reach a decision regarding release or rejection which should be fully documented [2].The investigation should be thorough, timely, unbiased, well-documented, and scientifically sound [5]. Even if a batch is rejected based on an OOS result, the investigation is necessary to determine if the result is associated with other batches of the same drug product or other products. The investigation shall extend to other batches of the same drug product and other drug products that may have been associated with the specific failure or discrepancy. Batch rejection does not negate the need to perform the investigation. The regulations require that a written record of the investigation be made, including the conclusions and follow-up (§ 211.192) [6,7].

Changes in the FDA OOS guidance issued in May 2022:

The following are the changes in 'Investigating Out-of-Specification (OOS) Test Results for Pharmaceutical Production' (Revision 1)

The update contains minor editorial changes from the 2006 version, replaces the term 'Quality control unit' to 'Quality unit', some updates with more information in phase I laboratory investigation and clarifies concepts on outlier results, and provides additional information on averaging results from the same final sample preparation.

Updates related to Phase I laboratory investigation:

If this initial assessment indicates that **no causative errors** (change from meaningful error) were made in the analytical method used to arrive at the data, a full-scale OOS investigation should be conducted. The manufacturing firm's **QU** (change from QCU) should initiate the Phase 2 (full-scale) OOS investigation, **whenever no clearly causative laboratory error** was identified. Under the section responsibilities of laboratory supervisor, updated the statement as 'OOS test results should not be attributed to analytical error **without completing** (change from without performing and documenting) investigation **that clearly establishes a laboratory root cause'.**

Under the section B Additional laboratory testing, provides the clarity 'A full-scale OOS investigation may include additional laboratory testing **beyond the testing performed in Phase I.** These include (1) retesting a portion of the original sample and (2) resampling'.

Under the section 'Outlier Tests', modified the statement as 'occasionally, an outlier test may be of some value in understanding how discordant from a data set a result is, but can be used solely in an informational capacity in the course of an investigation to determine the distance of a result from the mean'. Also provides a clarification as **'Outlier testing should not be used to invalidate chemical assays'.**

Under the section 'Cautions', a new subsection of the guidance on averaging results from same final sample preparations explains that 'there may be cases where the test method specifies appropriate acceptance criteria for variability and a pre-defined number of replicates from the final diluted sample solution to arrive at a result. For example, an HPLC test method may specify both acceptance criteria for variability and that a single reportable result be determined by averaging the peak response from a number of consecutive, replicate injections from the same test vial. In these cases, and given the acceptance criteria for variability are met, the result of any individual replicate in and of itself should not cause the reportable result to be OOS'.

Summary of key learnings from the new FDA OOS guidance:

The points which are updated in recent guidelines do not have major impact in current practices. These changes were providing with more clarity on below:

1. Quality Control Unit replaced with Quality unit
2. Detailed information provided on handling of outlier test results for chemical tests
3. Detailed sub sections were described under cautions with more clarity on
   a. *Averaging results from multiple sample preparations from the original sample*
   b. *Averaging results from same final sample preparation*
   c. *Borderline results that are within specification*

Recommended OOS Investigation flow:

OOS Test result	
Phase I laboratory investigation	**Phase II laboratory investigation**
1. Preliminary assessment to identify any obvious error 2. Detailed investigation to identify any assignable cause 3. Examination of retained solutions, to identify any dilution error, instrument malfunction. 4. If laboratory error exists invalidate the test result and provide appropriate CAPA 5. If no causative laboratory error identified, initiate Phase II (Full-scale) OOS investigation	A. Manufacturing investigation - Investigation confirms OOS, root cause identified, terminate investigation and product rejected B. Additional laboratory testing - Retesting of original sample and resampling - In case of clearly identified laboratory error, the retest results would substitute for the original test result. - If no laboratory or calculation errors are identified in the first test, there is no scientific basis for invalidating initial OOS results in favour of passing retest results. All test results, both passing and suspect, should be reported and considered in batch release decisions.

Phase I laboratory investigation:

The Phase I laboratory investigation involves the preliminary assessment of laboratory data and verifications of initial preparation(s). These activities performed by analyst and supervisor.The supervisor's assessment should be objective and timely, and there should be no preconceived assumptions as to the cause of the OOS result.

If laboratory errors are obvious, such as the spilling of a sample solution or the incomplete transfer of a sample composite, the analyst should immediately document and correct invalid result. No further investigation required.

If no error was identified, proceed for detailed investigation such as,

1. Discuss the test method with the analyst; confirm analyst knowledge of and performance of the correct procedure.
2. Examine the raw data obtained in the analysis, including chromatograms and spectra, and identify anomalous or suspect information.
3. Verify that the calculations used to convert raw data values into a final test result are scientifically sound, appropriate, and correct; also determine if unauthorized or unvalidated changes have been made to automated calculation methods.
4. Confirm the performance of the instruments.
5. Determine that appropriate reference standards, solvents, reagents, and other solutions were used and that they met quality control specifications.
6. Evaluate the performance of the test method to ensure that it is performing according to the standard expected based on method validation data and historical data.

7. Fully document and preserve records of this laboratory assessment.

The assignment of a cause for OOS results will be greatly facilitated if the retained sample preparations are examined promptly. Hypotheses regarding what might have happened (e.g., dilution error, instrument malfunction) should be tested. Examination of the retained solutions should be performed as part of the laboratory investigation.When the initial laboratory assessment does not determine that laboratory error caused the OOS result and testing results appear to be accurate, a full-scale OOS investigation using a predefined procedure should be conducted.

Phase II Full scale investigation:

Phase II investigation involves:

- Production process review/ Manufacturing Investigation
- Hypothesis testing/Experimentation
- Additional laboratory testing

The objective of such an investigation should be to identify the root cause of the OOS result and take appropriate corrective and preventative action. A full-scale investigation should include a review of production and sampling procedures, and will often include additional laboratory testing. These include Re-sampling and Retesting a portion of the original sample. If the investigation determines that the initial sampling method was inherently inadequate, a new accurate sampling method must be developed, documented, and reviewed and approved by the Quality Unit (QU). The decision to retest should be based on sound scientific judgment. The test plan must be approved before re testing occurs. Retesting Performed on Original sample[8].A full-scale OOS investigation should consist of a timely, thorough, and well-documented review. If this part of the OOS investigation confirms the OOS resultand is successful in identifying its root cause, the OOS investigation may be terminated and the product rejected. However, a failure

investigation that extends to other batches or products that may have been associated with the specific failure must be completed. To conclude the investigation, the results should be evaluated, the batch quality should be determined, and a release decision should be made by the QU. The relevant SOPs should be followed in arriving at this point. Once a batch has been rejected, there is no limit to further testing to determine the cause of the failure so that a corrective action can be taken.

Summary and conclusion:

Scientifically sound OOS laboratory investigations are an essential part of ensuring data integrity and cGMPs. Outlined here are the key requirements for an OOS investigation to find and assignable or root cause so that a result could be invalidated. Note that the FDA and other regulatory authorities take a very keen interest in invalidated OOS results, especially where analyst error is cited continually as the cause of the OOS. Your laboratory should know the OOS rate as well as the percentage of OOS results invalidated. The frequent occurrence of OOS results indicates that the manufacturing and analytical procedures are not in control, so the formation of good corrective and preventative actions is of great importance. By setting appropriate CAPA then the possibility of an OOS resurfacing can be reduced. An example of a means to limit out-of-specification results is proper qualification of equipment and analysts. A second area is around training; a third around technology transfer, and there are many others. The importance is with development robust CAPA.

The updated guidance provides the detailed information on how to conduct investigation for the OOS test result. It is also stating that the investigation should be 'Thorough, timely, unbiased, scientifically sound and well documented'. Especially the changes updated in current guidance provided clarity on 'averaging of test results from final sample preparation' and 'Outlier test also specified about the borderline results that are within the specification results'.

Reference:

1.Guidance for Industry Investigating Out-Of-Specification (OOS) Test Results for Pharmaceutical Production U.S. Department of Health and Human Services, Food and Drug Administration Center for Drug Evaluation and Research (CDER) October 2006

2.MHRA (Regulating Medicines and Medical Devices), Guideline on Out of Specification investigations. 2013.

3.Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients (September 2016) (ICH Q7)

4.21 CFR 211 Current Good Manufacturing Practice for Finished Pharmaceutical Products (Food and Drug Administration, Silver Spring, Maryland, 2008).

5. Investigating Out-of-Specification (OOS) Test Results for Pharmaceutical Production Guidance for Industry,U.S. Department of Health and Human Services, Food and Drug Administration Center for Drug Evaluation and Research (CDER) May 2022

6. Current Good Manufacturing Practice for Finished Pharmaceuticals 21 CFR 211.192, Subpart J Records and Reports.

7. USP General Chapter <1010> Outlier Testing (United States Pharmacopoeia Convention Inc., Rockville, Maryland, 2012).

8. Mote NN. Reference for Investigation of Out of Specification Results in Pharmaceutical Industry. Austin Pharmacol Pharm. 2021; 6(1): 1023

Acknowledgements: Author would like to thank Mr. BNV Ganapati Rao and Dr. M Veena Prasanna CQC Dr. Reddy's Laborator2s Limited for their support during the preparation of the article.

PHARMACY - PHARMACISTS: ALWAYS TRUSTED FOR YOUR HEALTH

by

Mr. Nirmal. P,
C. L. Baid Metha College of Pharmacy, Chennai

Note: This article was awarded 1st prize in the Essay Competition conducted by our Trust

"To be trusted is a greater compliment than being loved." World Pharmacist Day is observed each year on 25th September to honor Pharmacists for their contributions to global health. This year's World Pharmacist Day theme is "Pharmacy: Always trusted for your health". Trust is essential for a person, because it provides a sense of safety. A Pharmacist's professional duty includes a variety of responsibilities, depending on the field of Pharmacy in which they work; although, the fundamental role of a Pharmacist is to assist patients in getting better. Pharmacists do this by distributing medicine correctly with good quality, safety, and efficacy; delivering the proper dosage; providing patients with adequate counseling on how to take the drug effectively; and assuring the best possible outcome for the patient following its usage. As well as answering any queries patients have regarding their medication's mechanism of action in a way that the patient understands. When patients seek general health advice, Pharmacists have a role to play in promoting good public health and equipping patients with the knowledge they need to conduct self-care, especially in the event of mild illnesses. They also do quality testing; formulating and re-formulating dosage forms; and monitoring and reporting drug safety. A Pharmacist can assist other healthcare professionals, such as physicians and nurses, in devising the optimal way to cure a patient.

In the midst of the pandemic, pharmacists around the world are offering services such as triage services, visiting patients, and relieving the demand of patients on health-care facilities such as hospitals and GP practices, and also continuing to care for patients with chronic diseases, working in hospital pharmacies and providing pharmaceutical care to corona virus patients..

Pharmacists are also working to provide home delivery in addition to coping with the growing number of people visiting pharmacies with various conditions. In multiple countries, people united to 'flatten the curve. With a near-global shutdown, pharmacists appear to be an even more important initial point of contact for meeting the public's healthcare demands. Pharmacies are one of the few facilities available for public service even under tight lockdowns across the world. As a result, various problems have developed, and pharmacists are employing novel techniques to handle them

"You are entitled to the service of your trusted neighbors."

A pharmacist gives care to patients by gathering and integrating information about the patient's drug history, ensuring that the patient understands the intended dosage regimen and method of administration, informing the patient of drug-related precautions, and monitoring and evaluating the therapeutic response. They make the relationship strong, friendly and sincere in order to express that they understand their concern. A pharmacist will always go the extra mile for people, make that extra effort for people, and always be an integral part of the health care team.

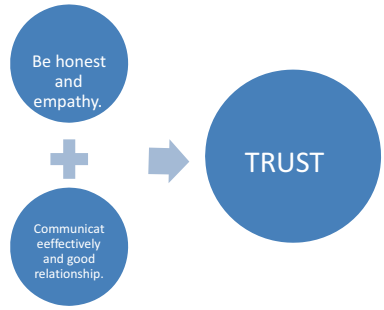
Traditional remedies are supported and supplied by pharmacists, who also administer homoeopathic prescriptions. Provide a non-prescription medication with the recommendation to seek medical assistance for self-limiting mild illnesses. Give basic counsel rather than prescribing medication.

"We are as delighted with your pet as you are."

The pharmacist also provides veterinary medicines and medicated veterinary feed. A veterinary pharmacist prepares medications, calculates doses, and assists in the administration of medications to animals. Communication with the owner of a pet or livestock animal so that they understand how to administer medicine is one of their duties in this field.

"The Pharmacist is THE DOCTOR OF MEDICINE"

"Your health is our number one priority, "quotes a pharmacist."I would like to recall an incident where a pharmacologist saved the day. It happened in Germany on November 16th, 1961, when it was a period that thalidomide was used for morning sickness. But it had some life-threatening side effects. Pregnant women who consumed thalidomide led to birth defects in their babies like very short or missing arms and legs, missing parts of the ears, and deafness, as well as defects in the heart, kidney, and genitals (sex organs). Mrs. Frances Kathleen Oldham Kelsey was a Canadian-American pharmacologist and physician who declined to approve thalidomide for usage in the United States due to a lack of data concerning the drug's safety and withheld approval for the drug and requested further studies. Researchers discovered that thalidomide caused serious birth defects. She saved many pregnant women and was honored by the president.



Many pharmacists also serve as members of non-governmental organizations (NGOs) that give information, raise awareness, and organize campaigns for the needy. Especially during this COVID crisis, when the globe is experiencing a period of widespread distrust and the transmission of false, fear-inducing information, public trust in pharmacies is at an all-time high.

"Pharmacist care beyond what your doctors have prescribed"

In conclusion, pharmacists remain one of the most trusted healthcare professionals in the world. They have been working brilliantly and continuously to keep the trust of millions of patients to improve and maintain healthy living. They are professionals who can offer advice and set goals that affect a patient's quality of life. These pharmacists respect the oath and follow it, saying "I shall follow the system which I consider best for pharmaceutical care and counseling of patients."

"Pharmacy: Always trusted for your health"

PHARMACY - PHARMACISTS: ALWAYS TRUSTED FOR YOUR HEALTH

by

Mr. G. E. Thillai Govindarajan,
Faculty of Pharmacy, Dr MGR Educational and Research Institute, Chennai

Note: This article was awarded 2nd prize in the Essay Competition conducted by our Trust

Introduction:

Pharmacy an incredible and vital part of healthcare system which deals the manufacturing, compounding, preserving and dispensing drugs. It is one of the top five leading professions of all time and plays major part in producing the healthier environment. As per the Gallup reports 2019, pharmacy is ranked as the fourth most honesty and ethical standard profession. Honesty and ethical standards is the key to gain trust. Trust is connecting bridge between the people and professionals, it enables profession to develop and broaden the futuristic scope. Pharmacy-Pharmacist proven as the saviour when the world needs them most. The scientist, academician and druggist of pharmacy profession work hard to develop it and to prosper. Pharmacy provided the immense support to other healthcare workers like doctors, nurses, etc,.

Objective:

The main objective of the Pharma field is to focus on the health and wellbeing of the people. Pharmacy proven them in many instance. In this present COVID-19 situation, the world suffered a lot, Pharmacy-pharmacist involved directly and indirectly to control this situation. Indian pharmaceutical industries is one the largest supplier of medicine to the world, more than 133 countries received drug from India. At early stage, Hydroxychloroquine is suggested for the treatment of COVID-19 by US FDA. This lead to increased world demand for Hydroxychloroquine drug, Indian pharmaceutical companies made a strenuous effort to supply Hydroxychloroquine drug and controlled the demand. Pharmacy research scholar dedicatedly engaged in development of new drug for treating COVID-19. India is one of the leading producers of vaccine to the world. Retail pharmacist works day and night to dispense the drug on appropriate time.On tackling these situation Indian pharmaceutical companies created huge attention of world and proven themself as “trusty worthy profession”.Not only in COVID-19 situation, Pharmacists had provided aggressive support and care in many infectious instance like Zika, Ebola, HIV, SARS, etc.

Knowledge:

"Knowledge is power"

Knowledge is another key factor to gain trust. World Pharmacy Council, International Pharmaceutical Federation, Pharmacy Council of India and other Pharma association made arduous effect to make this proficiency profession. The rules, regulations, guidelines and eventsthese council helps to produce the skill full, adroit and knowledge candidates to the world. On other hand communication helps to build the trust between the Pharmacists and people. The Pharmacy profession maintains good relation and co-ordination with other healthcare workers to provide safest support to people. The Pharmacist involves direct contact with peoples, it leads Pharmacists to involve in verbal and non-verbal conversation. Communication allows building confidence in the patient to follow the medication and creating awareness about the medication. Counselling for the drug therapy is considerably important step to eradicate the disease or disorder, hospital and community pharmacist provides better service in counselling than other health care system.

Pharmacist as the rescuer:

Medication errors, a major problem in prescribing drug to the patient and it's been a hidden problem not known to the most people. Pharmacist plays imminent role in overcoming this problem. Unintentional error made by physicians on reaching to the patient could cause hazardous effect to the patient, but pharmacist as the rescuerclears out medication error dispensing the safe medicine and maintains profession's integrity. The respect and the reputation gained by pharmacy is gift for their honesty to the people. If the Pharmacist loses their honesty, it would affect the patient's confidence on the pharmacist. Ultimately it affects the spirituality and respect of the profession. Pharmacy also ensured the privacy and dignity of the peoples, it also paved the way to earn their respect. Care and support in every hard situation given by the pharmacist to the patient paid back as patient's respect, confidence, love and trust. Pharmaceutical Industries helped all scale of peoples and gained their trust. Here the scale refers to the economic status of people. Every country includes poor, middle class and rich people. Pharmaceutical industries extend their support to all states of people. They provided drugs with in

affordable price for the poor and middle class without compensating in the quality. Many pharmaceutical industries like pifzer, BioNTech, Sun Pharma, Johnson & Johnson donated more than million dollar worth medical support to the government and economically poor people. World runs mainly because of the trust.

Conclusion:

Trust is unseen communicable device which holds the people and professionals together. Pharmacy profession which started before 150 years ago earned the trust of the people and it used to keep trust without losing it. It never mislead the people's trust, and maintained their loyalty to the peoples. Many profession couldn't tackle changes in modern era but pharmacy profession held their ethical standard extended better care to the needed people. The Pharmacy committees, Academician, industries, druggist and research scholar made full commitment to the profession all time to build this unbreakable trust. This unbreakable trust isn't built in a year, it took more than a century and all together hard efforts of pharmacist. Peoples trust could lead profession to its best of standards and enlightens the future prospects. Pharmacy-pharmacist shown their best when the world needs them most and earned the people support & love, being a future pharmacist we pledge to follow the same standard and maintain people's trust.

INFORMATION

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

Profile of 2nd Rank

PHARMACEUTICS

Name: Ms. Sweety Kuriakose

Project Title: Photoluminescent Theranostic Graphene Quantum Dots as a Smart Nanovector for Targeted Drug Delivery

College: College of Pharmacy, Sri Ramakrishna Institute of Paramedical Sciences, Coimbatore

Guide's Name: Dr. M. A. Amutha Gnana Arasi

PHARMACEUTICAL CHEMISTRY

Name: Mr. Benin Thanka Solomon

Project Title: Design and Synthesis of Pyrazole derivatives as a possible anti-Parkinson agent targeting SIRT-3 enzyme.

College: JSS College of Pharmacy, Ooty

Guide's Name: Dr. S. Gomathy

Name: Ms. G. Sathya Pooja

Project Title: Synthesis, Computational studies and biological evaluation of pyrimidine linked coumarin derivatives for invitro anti-breast cancer activity.

College: College of Pharmacy, Sri Ramakrishna Institute of Paramedical Sciences, Coimbatore

Guide's Name: Dr. K. P. Beena

PHARMACEUTICAL ANALYSIS

Name: Ms. Vani. S

Project Title: Development and validation of Analytical method for Quantification of Synthetic Vanilin in Adulterated Natural Vanilla Extracts Viz., Impurity Profiling.

College: JSS College of Pharmacy, Ooty

Guide's Name: Dr. N. Krishnaveni

PHARMACOLOGY

Name: Ms. Vanitha. N

Project Title: Ameliorative Potential of 3-Acetyl-11-Keto-B-Boswellic Acid in L-NAME Induced Nephrogenic Systemic Fibrosis through the Upregulation of PPAR γ Receptor.

College: KMCH College of Pharmacy, Coimbatore

Guide's Name: Dr. G. Venkatesh

PHARMACOGNOSY

Name: Ms. K. Robina Rahmath Aara

Project Title: Phylogenetic Analysis of COVID-19, Resulting in Developing a Computational Simulation of the Active Constituents of Visha Sura Kudineer – A Siddha Anti-SARS-COV-2 Formulation and Modernizing the Traditional Dosage form into the Herbal dip bag with its Stability Determination.

College: College of Pharmacy, Mother Theresa Post Graduate and Research Institute of Health Sciences, Puducherry

Guide's Name: Prof. Dr. V. Gopal

PHARMACY PRACTICE

Name: Ms. Ranjitha. K. R

Project Title: A Prospective Observational Study on Antibiotic Usage in Sepsis Management in a Teritary Care Hospital

College: College of Pharmacy, Sri Ramakrishna Institute of Paramedical Sciences, Coimbatore

Guide's Name: Dr. G. Andhuvan

PHARM D

Name: Ms. Jerlin Michelle. I, Mr. Dhivakaran. K, Mr. Nidhish Raj. V, Mr. Ajithkumar. A

Project Title: Comparision of the effectiveness of Obeticholic acid and Pioglitazone on non Alcoholic Fatty Liver Disease in Type-2 Diabetic Patients: A Randomized, Controlled Open-Label, Pilot Study.

College: SRM College of Pharmacy, SRMIST, Chennai

Guide's Name: Dr. N. A. Rajesh

Congratulations to Smt. P. V. Vijayalakshmi

We congratulate Smt. P.V. Vijayalakshmi, Joint Director of Drugs Control, placed to hold in-charge of the post of Director of Drugs Control Tamilnadu, wide G.O. (Rt) No. 662 dated 30th June 2022.

She is a Pharmacy graduate from, Madras Medical College, Chennai. She joined as a Drug Inspector in the year 1987 and elevated to various positions such as, Senior Drug Inspector, Assistance Director of Drugs Control, Deputy Director of Drugs Control and Joint Director of Drugs Control in the year 2021.

Her Contribution in the Drugs Control Department as follows

i. She has initiated various numbers of cases relating to the misuse of Psychotropic / Habit forming medicines.

ii. She has detected and investigated the many number of Spurious cases.

iii. She has contributed her efficient work in handling of cases relating to expiry drugs Honable High Court of Madras.

iv. She is specially recognized by her nature of “Honesty and Straight Forward”

ACHIEVEMENTS:

I. She has got first mark in Chemistry Subject in Higher Secondary examination in Chennai District.

II. She has completed B. Pharmacy in Madras Medical College during 1980-1984 as a meritorious student.

III. She was second Woman Drugs Inspector 35 years ago in Drugs Control Department, Tamil Nadu.

IV. She has been awarded as best Drugs Inspector in India.

V. She was the First Woman Deputy Director of Drugs Control, Tamil Nadu.

VI. She was the First Woman Joint Director of Drugs Control, Tamil Nadu

VII. She is the First Woman Director of Drugs Control in Tamil Nadu.

VIII. She is conducting a free tuition Centre for Govt. school students in the name of Galam Tuition Centre.

IX. She has contributed Rs. 1 Lakh amount to the Tamil Nadu Government as a Covid 19 contributory fund.

X. She has also helped to the affected people during many Natural Calamities including flood in 2015 and Gaja Storm in 2017.

AWARDS:

i. In the year 2021, when she was working as Joint Director of Drugs Control she has been awarded with Women Achievers' Award by IPGA.

ii. An article was published about her in “Vanigamani” / April-2021 Edition, in the topic of Woman Pharmacist achievers.

We wish her success in achieving the growth pharmacy profession and pharmaceutical industries in Tamilnadu

EVENTS

29th Convocation, College of Pharmacy, SRIPMS, Coimbatore

29th Convocation of College of Pharmacy, Sri Ramakrishna Institute of Paramedical Sciences, Coimbatore, was held on 11th June 2022 at S.N.R. Kalaiarangam.

Thiru. D. Lakshmi Narayanasamy, Managing Trustee, SNR Sons Charitable Trust, presided over the event and delivered the keynote address. Shri. J. Jayaseelan, President, Tamil Nadu Pharmacy Council and Managing Director M/s. Delvin Formulation group of companies, as a special guest. More than 250 students received their degrees at the event.

Tanamani (2020), Sangeetha and Jagannath (2021) who studied at the college received their Ph.D. Students Keerthi, B.Pharm (2015-19) and Nithiya Ramdas, B.Pharm (2016-20) won the gold medal of the college.

Students Nimita Dresa, Pharm.D (2013-19) Kesia An Babu, Pharm.D (2014-2020), Ebin C.P., Pharm.D (PB) (2016-19), Trisl M. Babu, Pharm.D (PB)) (2017-20) Tresa Thomas, M.Pharm (2017-19) and Vishnuja Vishwanath, M.Pharm secured the first overall rank in their respective fields during the academic year.

The Alumni Association of the college presented the 'Best Outgoing Student' award to deserving students. Principal of the college Dr. T. K. Ravi delivered the welcome address and Vice Principal of the college Dr. Gopal Rao gave the vote of thanks.

SPSS Statistical Workshop Organised by KK College of Pharmacy

A biostatistics workshop on SPSS statistical package for the social sciences was organised by KK college of Pharmacy on 7& 8th July 2022. The resource person for the workshop was Mr. P. Janakiraman, M.Sc, [Ph.D] from PES institute of medical sciences and research. He explained the basics of SPSS, along with data management, handling and inferential statistics. He also had a group discussion on related exercises with pharm D students and clarified their queries. The workshop was hands-on training which focused on key concepts and demonstration of methods on applying statistical methods. ISO approved participation certificate was provided for the participants. Principal Dr. A. Meena was the convener, Vice Principal Dr. A. Shanthy was the co convenor, Head of Department Dr. S. Ramlakshmi coordinated the programme with the help of organizing committee members Dr. N. Vani, Prof. S. Vedha pal Jeyamani, Dr .A. Niventhi, Dr. Aswathi Elizabeth philip, Dr. Santhosh, Mr. Yuvaraj.

Pharmac South 2022

The Indian Drug Manufacturers Association, Tamilnadu, Puduchery & Kerala State Board organised a exhibition at Chennai Trade Centre, Tamilnadu on 8th & 9th July 2022 on the theme of "Discover Innovative & Cost Effective Technology".

Pharmac South 2022 Exhibition was inaugurated by Shri. V. Arun Roy, IAS., Secretary to Govt, MSME Department, Govt of Tamilnadu, and the guest of Honours were Shri. S. V. Veerramnai, Vice-Chairman, Pharmexcil, Shri. Mehul M. Shan, Hon. Gen. Secretary, IDMA, Shri, Dara B. Patel, Secretary General, IDMA, Tmt. P. V. Vijayalakshmi, Director of Drugs control (In-charge), Tamilnadu, and Shri. B. Kumar, Deputy Director, CDSCO, South Zone, Chennai.

In this exhibition, parallel sessions of seminars also arranged by IDMA as follows

- CEO Talk – Success story of Encube Ethicals by Shri. Mehul M. Shah, Managing Director, Encube Ethicals

- Growth: A 360 Degree Perspective (Secrets to 10x Business Growth for Pharma MSME) by Shri. Prakash Seshadri, Founder and Management Consultant: S ee Change Consulting

- CEO Talk – Scaling of Business Strategics for Startups by Shri. C. K. Kumaravel, Co-Founder & CEO– M/s Naturals Salon & Spa

- Pharma Market Insights & Opportunities by Dr. Hari Natarajan, Founder & Managing Director, Pronto Consult

- Emotional Intelligence @ work – Pharma Marketing by Shri. Sivakumar Bellan, Director – Marketing, Simple and Smart Solutions

- Export Opportunities for Pharma MSME by Shri. S Murali Krishna, Director, Pharmexcil

Around 2200 visitors are visited the exhibition on both days.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ACES

NOTIFICATION

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 30th June, 2022

G.S.R. 502(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. 383(E), dated the 23rd May, 2022, in the Gazette of India, Extraordinary, Part II, section 3, sub-section (I), inviting objections and suggestions from persons likely to be affected thereby, before the expiry of a period of 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 the 23rd May, 2022;

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

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

1. (1) These rules may be called the Drugs (Fifth 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 serial number 39, in the column under the heading "Extent and Conditions of Exemptions", at the end, the following proviso shall be inserted, namely:—

"Provided that the condition specified in clause (d) shall not be applicable for the drugs manufactured on or before the 30th November, 2022.".

[F. No. X.11014/10/2021-DR]
RAJIV WADHAWAN, Advisor

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. 357(E), dated the 18th May, 2022.

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 15th June, 2022.

G.S.R. 450(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. 228(E), dated the 29th March, 2022, in the Gazette of India, Extraordinary, Part II, section 3, sub-section (i), inviting objections and suggestions from persons likely to be affected thereby before the expiry of a period of forty-five days from the date on which the copies of the Official Gazette containing the said notification were made available to the public;

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

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

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

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

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

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

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

[F.No. X.11014/25/2021-DR]
Dr. MANDEEP K BHANDARI, Jt. Secy.

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

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 18th May, 2022

G.S.R. 357(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. 75(E), dated the 1st February, 2022, in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (I), inviting objections and suggestions from persons likely to be affected thereby, before the expiry of a period of thirty days from the date on which the copies of the Official Gazette containing the said notification were made available to the public;

And whereas, copies of the said Official Gazette were made available to the public on the 2nd February, 2022;

And whereas, objections and suggestions received from the public on the said draft rules have beenconsidered 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 (Fourth Amendment) Rules, 2022.

(2) They shall come into force with effect from the 1st day of November, 2022.

2. In the Drugs Rules, 1945, in Schedule H, after serial number 551 and the entries relating thereto, the following serial number and entry shall be inserted, namely:—

"552. Acitretin".

[F. No. X.11014/11/2021-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. 158(E), dated the 24th February, 2022.

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 18th May, 2022

G.S.R. 356(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. 23(E), dated the 18th January, 2022, in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (I), inviting objections and suggestions from persons likely to be affected thereby, before the expiry of a period of fortyfive 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 19th January, 2022;

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

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

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

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

2. In the Medical Devices Rules, 2017, after rule 43, the following rule shall be inserted, namely:—

"43A. Suspension and cancellation of licence.— (1) If the manufacturer or licensee fails to comply with any of the conditions of an import license, or any provisions of the Act and these rules, the Central Licensing Authority may after giving the manufacturer or licensee an opportunity to show cause why such an order should not be passed, by an order in writing stating the reasons therefor, cancel a license issued under rules, or suspend it for such period as it may thinks fit either wholly or in respect of any of the part of medical device to which it relates or direct the licensee to stop import, sale or distribution of the said medical device and, thereupon, order the destruction of medical device and the stock thereof in the presence of an officer authorised by the Central Licensing Authority, if in its opinion, the licensee has failed to comply with any of the conditions of the licence or with any provisions of the Act or the rules made thereunder:

Provided that a person who is aggrieved by the order passed by the Central Licensing Authority under this rule may, within thirty days of the serving of the order, file an appeal to the Central Government, and the Central Government may, after such enquiry into the matter, as it considers necessary and after giving the said appellant an opportunity of being heard, pass such order as it thinks fit.".

F. No. X.11014/4/2019-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. 174(E), dated the 4th March, 2022.

NEWS

Pfizer Opens Global Drug Development Centre on IIT-M Research Park Campus

Pfizer, the leading pharmaceutical company, inaugurated a global drug development centre on IIT Madras Research Park campus. This is the company's first such facility in Asia.

The centre, which is one of the company's 12 such centres in the world, will develop and support products in its global markets and manufacturing centres. The centre, set up at a cost of over Rs.150 Crore, is spread over 61,000 square feet and has ten laboratories with cutting edge equipment.

The centre will develop small molecules, innovative formulations and active pharmaceutical ingredients for global markets, a release by the company said. “The centre's capabilities will include the development of both, APIs and finished dosage forms (FDFs) of differentiated products such as complex/value-added formulations, controlled-release dosage forms, device-combination products, lyophilized injections, powder-fill products, and ready-to-use formulations.”

Stating that India was hailed as the “pharmacy of the world” because of its capabilities to produce generic versions of various drugs, S. Sridhar, country manager, Pfizer India, expressed hope that the centre would be an opportunity to showcase the potential of research and development in the country. He said the centre will do “research in India for the world.”

“The world-class scientific technology and innovation-driven research park campus provides an ideal setting for our work. We are hopeful that the proximity to IIT Madras and other technology research park start-ups will improve academia and industry partnerships, and encourage greater collaboration to drive innovation,” he added.

Apart from manufacturing, done through third parties, Pfizer has three manufacturing centres in India in Visakhapatnam, Goa and Ahmedabad. The research and development centre, now opened in Chennai, will employ more than 250 scientists and other professionals.

Tamil Nadu Health and Family Welfare department Principal Secretary J. Radhakrishnan said the centre will offer Indian scientists the opportunity to establish a global footprint in medical research and development.

Ashok Jhunjhunwala, president, IIT Madras Research Park, said the proximity of Pfizer to IIT Madras, scientists and students, the tech corridor and other leading industry start-ups will foster greater collaboration between industry and academia.

Source: *The Hindu,* 5th May 2022

Ministry to Meet Industry on Import Substitution

The commerce and industry ministry is likely to discuss with exporters and industry representatives next week import substitution of 100-odd products whose imports are high and have a significant share in the country's overall inbound shipments. The meeting is likely on May 10, according to sources.

The meeting follows the identification of 102 priority items such as integrated circuits, personal computers, insulin injections, cameras, antibiotics, turbojets, lithium-ion accumulators and machines, whose imports are high and need immediate interventions for domestic production opportunities.

"The idea is to deliberate ways to enhance the domestic capacity expansion of these products and reduce the import bill," said an official.

The government had in 2020 zeroed in on 12 priority sectors with potential for import substitution and boosting exports including food processing, organic farming, iron & steel, aluminium & copper, agrochem, electronics, industrial machinery, furniture, leather & footwear, auto parts, textiles and marine products.

In FY22, India's imports were a record $611.89 billion.

In a recent analysis of India's imports, the commerce department said that of the 102 products, emphasis may be given to 18 items which have been consistently growing and have a significant share consistently across the long, medium and short terms.

Source: *The Economic Times,* 6th May 2022

Pharma Sales Dip 9% in April, 1st Drop in 2 Years

For the first time in nearly two years, the domestic pharma retail market dipped into negative territory in April with a 9% decline, indicating a slowdown in the overall industry growth. The market had last posted a negative growth during May and August 2020, due to poor sales during the lockdown triggered by the pandemic.

What is of a bigger concern is that sales of chronic therapies — usually more resilient — are also sluggish, with cardiac drugs even registering a decline of 4% month-on-month. The negative growth is attributed to the base effect, an industry expert said — the base of higher sales of Covid-related portfolio in the corresponding period of the previous year. Amid the Delta wave, sales of anti-respiratory, painkillers, antibiotics and anti-virals had spiralled.

Significantly, excluding Covid-related medication drugs, the market was flat in April, showing a negative growth of 0.5%, the latest figures by market research IQVIA firm said.

Overall, the pharma retail market was valued at Rs 1,44,486 crore with a 13% growth

at MAT (moving annual total), or the 12-month period ended April. For the month alone, it was around Rs 13,502 crore.

Sluggish sales at this stage reaffirm fears of an impact on earnings, with the industry already facing headwinds from rising input, logistics costs, and shutdowns and supply disruptions from China over the last few months.

The market registered tepid sales among most therapies, excluding Covid-related medicines, during most of 2020 due to the absence of prescriptions and lower OPD (outpatient department) visits. In 2021, the market slowly bounced back with lockdowns and restrictions removed across the country.

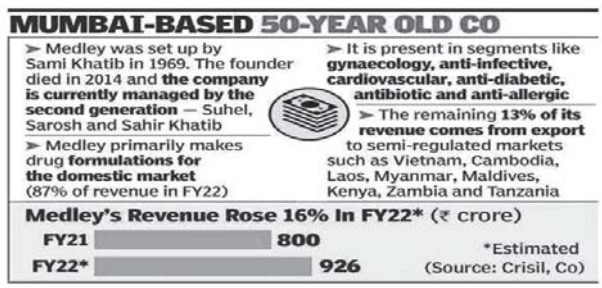
Source: *The Times of India,* 14th May 2022

Medley Pharma Likely to be Sold in Deal Worth Rs 5,000 Crore

Medley the privately held Mumbai-based company, is on the block. majors like , Dr Reddy's, KKR-backed JB Chemicals, and Torrent, along with marquee private equity investors Advent, Carlyle and Blackstone are seen as potential buyers for its Rs 1,000-crore business. The deal size is expected to be in the range of Rs 4,000-5,000 crore, sources close to the development told TOI.

A mid-sized player, Pharma — founded by Sami in 1969 as 'Medley Laboratories' — is among the top 40 pharmaceutical companies in India, according to healthcare market research firm IQVIA. Khatib's second generation — Suhel, Sarosh and Sahir — manage the company now.

It has manufacturing plants in the domestic formulations market, primarily in the hematinic, anti-diarrhoea, cardiovascular, anti-diabetes, analgesic and anti-ulcer segments. Gastroenterology, anti-diabetes and gynaecology drugs contribute two-thirds of revenues, with top brands like Telmed, RB Tone, Vogli, O2 and Dompan. Certain brands launched first in India include Dompan (Domperidone & Pantoprazole), O2 (Ornidazole & Ofloxacin), Tazocef (Tazobactum & ceftriaxone) and Ostium k2 (first brand of vitamin K27 combination in India).



According to a recent report from credit rating agency Crisil, the company's revenue is estimated to have grown by 16% to Rs 926 crore for fiscal 2022, from Rs 800 crore in the previous year, backed by increased contribution from the acute segment (about 53% of the overall sales) and rest from chronic therapies. It is expected to maintain growth of over 8- 10% over the medium term, driven by its established position in the domestic formulations market and increasing focus on the chronic segment (which now accounts for 47% of sales, as compared to 30%, a few years ago).

Two of its products, RB Tone and O2 (to treat hematinic deficiency and diarrhoea, respectively) feature among the top 300 brands, according to market research data. In fiscal 2022, about 53% of revenues came from acute therapies, and the rest from the chronic segment. The company's product profile is moderately diversified with the top five brands accounting for 57% of revenue.

Sources said that the promoters are looking at a strategic sellout, including all assets, with Cipla possibly being a frontrunner. The company did not comment till the time of going to the press.

Medley's operating margins improved to 21% in fiscal 2022 and should sustain at 19-21% levels, aided by an improvement in scale and better fixed cost absorption. Additionally, there's a focus on increasing supplies to regulated markets, which fetch higher realisations. The share of exports reduced to 13% of revenue in fiscal 2022, from 15-18% earlier, owing to logistic challenges and discontinuation of sales to certain African countries such as Uganda and Sudan, where certain earlier payments are still stuck.

The company will continue to export to the UK and Europe and focus on increasing contributions from these markets. It has also started supplying to the US from fiscal 2022. Though there is a subsidiary in Russia, the business scale is negligible (revenue of Rs 2-4 crore).

Armed with a modest loan of Rs 200,000 under the technician-entrepreneurs scheme of The Maharashtra State Finance Corporation and driven by a determination to succeed, Sami Khatib managed to get a toehold in a tough industry. The company's first formulation plant was set up at Aurangabad in 1976 for tablets, capsules and liquid orals, followed by units at Daman and Jammu. The company exports to 26 countries in southeast Asia, Africa, the Middle East, Russia and the CIS.

Source: *The Times of India,* 25th May 2022

Uttarakhand STF Busts Counterfeit Drugs Manufacturing Racket, Conducts Raids in Haridwar and Saharanpur

A special task force (STF) of Uttarakhand police claimed to have exposed a counterfeit drugs manufacturing racket on Sunday. The development came following overnight raids at counterfeit drug manufacturing factories in Haridwar and Saharanpur districts.

The STF action came after police received input about fake drugs being sold in the market. Based on the tip-off, the agency was working covertly for the past two months to identify the factories where illegal drugs were being manufactured. Till the time of filing this report, the STF investigation was going on with the help of Haridwar and Saharanpur police units.

Ajay Singh, senior superintendent of police, Uttarakhand STF told TOI,

"The raids were planned after two

people -- identified as Rashid Khan and Nitin Prajapati --were arrested a couple of months ago with fake drugs worth Rs 4 lakh. During interrogation, they disclosed the locations of factories in Haridwar and Saharanpur where fake drugs were being manufactured. These drugs were packaged in wrappers of major pharmaceutical companies to avoid any suspicion," said Singh.

He added, "A factory named "Innova Drugs and Pharmaceutical Company" in Bhagwanpur (Haridwar) was shut down for the same crime earlier as well. However, their owners Vishal and Pankaj Kumar re-started the illegal activity. Besides the Bhagwanpur unit, a factory each at Laksar (Haridwar) and Saharanpur was also busted."

The STF head further said that during raids, police recovered fake drugs worth Rs 15 lakh along with raw materials to manufacture more fake drugs worth about Rs 1 crore. "A majority of the fake drugs being manufactured were antibiotics. The accused were supplying them across the country with the help of courier companies and private transporters," added Singh.

Source: *The Times of India,* 6th June 2022

Pharma Packaging Industry Urged to Develop Elder Friendly, Child Safety Solutions

The Indian pharma packaging industry has been urged to come up with effective solutions towards child safety and elder friendly packaging of pharmaceutical products to safeguard their interest and to aid the growth of the pharma industry.

"Pharma packaging is one of the important stakeholders of pharma industry," said H. G. Koshia, Commissioner, Food & Drugs Control Administration, Government of Gujarat. "Besides packing, it also protects the product from environment, it carries lot of information, maintains the integrity of the product," he said. "I have asked packaging solution providers to focus more on child resistant packaging (CRP) so that children should not consume the drugs by mistake," Mr. Koshia added.

"Packaging should be elder friendly considering their illness, weakness and difficulty in opening bottles. Going forward the geriatric number will grow and appropriate packaging must be developed through proper R&D," he said, while speaking on the sidelines of the InnoPack Pharma Confex here.

Stating that the pharma industry had to ensure safety, H.G. Ananthakrishnan, director general, Organisation of Pharmaceutical Producers of India (OPPI) emphasised on child-safe packaging so as to not fall in the wrong hands.

He said innovation and sustainability would drive growth in the future. "Innovation is important because very sophisticated treatment will require sophisticated packaging, which will help sustain these medicines, maintain their integrity, and make it available to patients," Mr. Ananthakrishnan said.

He said emphasis has to be given on developing eco-friendly packaging. "The question is how to make the packaging materials sustainable without compromising on the quality of the product. Not every material can store the medicine and can retain its integrity. There should not be any interaction of the medicine with the material," he said.

Stating that government reforms and surge in demand had kept the pharmaceutical packaging industry on a strong growth trajectory, Yogesh Mudras, managing director, Informa Markets in India said, "The pharmaceutical packaging market valued at $1.4 billion is expected to grow at a rate of 8.10% CAGR during 2022-2027 and 7.54% CAGR till 2030 and a reach market size of $3 billion."

According to Chakravarthi AVPS, global ambassador, World Packaging Organisation, the future of pharma packaging would be driven by user centricity and sustainability at large.

Source: *The Hindu,* 12th June 2022

After Covid Vaccine, India Seeks Drug Patent Waiver

As trade negotiators got down to working out a package, India on Monday called for talks for a TRIPS waiver on Covid therapeutics and devices after working out a plan on patent waiver for vaccines. India had originally proposed a waiver of patent and other intellectual property rights for Covid vaccines, medicines and devices but the US, the EU, the UK and Switzerland, among others, were not agreeable to the plan and limited the discussions so far only to vaccines

"It is of immense interest to us to commence negotiations on therapeutics and diagnostics. We cannot have a pandemic response which does not deliver an effective and workable outcome on TRIPS," commerce and industry minister Piyush Goyalsaid at the WTO ministerial meeting. Pointing to the easier availability of vaccines now, the minister said blocking some of the clauses may send a wrong message. "

If it's only vaccines that we are looking at providing, I think it's too late in the day for that, the pandemic has run its initial course, currently vaccines are not in short supply. And if you're not even able to look at the near-term future and the requirements of that period, then I think it's pretty much clear that rather than concern for humanity for the hundreds of thousands of lives lost or the millions affected, it is sad that the super profits of a few pharmaceutical companies prevail over global good," he said. India said to reach this stage of discussion on response to the pandemic amid strong opposition from some of the developed countries has meant making several sacrifices and concessions, and trashing the draft proposal will mean that the efforts of negotiators go waste. "I hope that the flexibility that we have shown will pave the way for its acceptance and also be replicated in other tracks for a successful 12th ministerial conference," Goyal said. He also said that given the principles of WTO, there should not be any attempt to treat developing countries differently.

Source: *The Times of India,* 14th June 2022

Govt Planning Trade Margin Rationalisation for Widely Used Drugs

In a move to bring down prices of all widely used medicines, the government is planning to fix trade margins of drugs of specific therapeutic categories and classes of medicines such as anti-infectives, and those used to treat cancer and chronic kidney diseases, top official sources said.

Margins earned by wholesalers, distributors and retailers will be capped in a phased manner. The Department of Pharmaceuticals and drug price regulator National Pharmaceutical Pricing Authority (NPPA) are finalising a proposal in this regard following consultations with the Prime Minister's Office (PMO) and multiple stakeholders.

Trade margin is the difference between the price at which a manufacturer sells the device or product to a distributor or stockist and the price paid by the end consumer (MRP).

While prices of over 355 medicine formulations that are part of the National List of Essential Medicines are capped directly by the government, the idea behind trade margin rationalisation is to bring under the scanner other drugs that are not part of NLEM but are commonly used and are expensive, contributing substantially to health expenditure.

"There is need to maintain required balance between interest of patients, manufacturers, innovators and distribution supply chain. Our objective is to make medicines affordable for patients, while also ensuring that it remains viable for other stakeholders," a senior official said.

In February 2019, the NPPA capped trade margins of 41 anti-cancer medicines at up to 30% on a pilot basis. This was done using extraordinary powers under the Drugs Price Control Order (DPCO) in public interest. Besides, it also fixed prices of coronary stents and knee implants.

During Covid-19, the government capped trade margins of several commonly used medical devices such as pulse Oximeter, Glucometer, Oxygen concentrators and digital thermometer. This lowered prices of most of the brands by up to 89%, the Economic Survey 2022 said.

The NPPA is now conducting an elaborate study to assess the impact of trade margin rationalisation on such drugs and other pharmaceutical products. Findings of the study will be assessed before arriving at a final decision, the official said.

Source: *The Times of India,* 15th June 2022

Stop Indiscriminate Prescription of Vitamins, Says Senior Pharmacologists

India needs evidence-based guidelines for the use of vitamins or mineral supplements, pharmacologists from Delhi's Maulana Azad Medical College (MAMC) and Ram Manohar Lohia Hospital say.

In an article published in the Indian Journal of Medical Research, Dr Proteesh Rana, who was with RML earlier and is currently working at the University College of Medical Sciences (UCMS), and Dr Vandana Roy, who heads the pharmacology department of MAMC, state that vitamins must be prescribed for specific indications as per the scientific evidence and their indiscriminate use for health promotion or prevention of chronic diseases should be stopped.

Their call for action comes against the backdrop of an increasing trend of prescribing multivitamins. Many people also purchase it over the counter, often without any specific indication, doctors say.

'Focus on healthy diet instead of just popping pills'

Evidence-based guidelines for the use of vitamin/mineral supplements must be developed by building consensus among experts from the fields of nutrition, pharmacology and clinicians across various specialties. These guidelines should be formulated considering the dietary needs of the Indian population and must also clarify the role of nutritional supplements in individuals otherwise taking a regular diet," the IJMR article says. "This holds true even more so for B-vitamins, a much-misused vitamin complex," it adds.

B-vitamins are a class of water-soluble vitamins that are commonly used as a dietary supplement. These are a diverse group of chemical substances comprising of thiamine (B1); riboflavin (B2); niacin (B3); pantothenic acid (B5); pyridoxine (B6); biotin (B7); folic acid (B9) and cyanocobalamin (B12), which are collectively referred to as "vitamin B complex". Dr Neeraj Nischal, additional professor in the department of medicine at AIIMS, said instead of popping pills to meet nutritional requirements people should focus on having a healthy diet. "Supplements should be prescribed after due diligence on medical needs and not otherwise," he said.

The article says B-vitamins are often used in conditions not characterised with a vitamin B deficiency for which evidence for efficacy is lacking. "For example, the use of B-vitamins like folic acid has been found harmful in those with high baseline homocysteine levels. Similarly, the use of MVM (multi-vitamin) supplements containing beta carotene increases the risk for lung cancer and those with high-dose vitamin E increases overall mortality among users," it adds.

Vitamins are the largest selling segment of the global dietary supplement market registering a revenue of $37.64 billion in 2018

According to the IJMR article, studies assessing the prescribing behaviour of doctors in various parts of India reveal that vitamins

constitute about 24-25% of all prescribed drugs.

In the US, National Health and Nutrition Examination Survey data shows that 52% of adults reported using at least one dietary supplement in the prior 30 days and 31% reported using a multivitamin-mineral supplement. The most commonly cited reason for using supplements is for overall health and wellness and to fill nutrient gaps in the diet.

Last week, the US Preventive Services Task Force released its updated guidelines on the use of vitamins, minerals and multivitamin supplements to prevent cardiovascular diseases and cancer. It recommends against the use of beta carotene or vitamin E supplements for the prevention of cardiovascular disease or cancer. The USPSTF also concludes that the current evidence is insufficient to assess the balance of benefits and harms of the use of multivitamin supplements for the prevention of cardiovascular disease or cancer, according to a report published in the Journal of American Medical Association.

Source: *The Times of India,* 28th June 2022

Indian-Origin Woman Gets Cancer-Free Following Drug Trial in UK

Miracles happen when science progresses! Jasmin David, a 51-year-old Indian-origin woman from Manchester, was given just months to live a few years ago due to breast cancer. Now, doctors have declared that she is showing no evidence of cancer, after undergoing a clinical trial at a UK hospital. She was diagnosed with an aggressive form of breast cancer in 2017 when she found a lump above the nipple, and now she feels "reborn" after scans showed no cancer evidence.

David had previously undergone six months of chemotherapy and a mastectomy in 2018. This was followed by 15 cycles of radiotherapy which had cleared her body of cancer. But the worse was not yet over and in October 2019, the cancer returned and scans showed multiple lesions throughout her body. The cancer had spread to the lungs, lymph nodes and chest bone. David was given the heartbreaking news that she had only less than a year left to live.

Two months later, David was given the opportunity to be part of research by participating in a Phase I clinical trial. She agreed to be a part of it for the benefit of the next generation, even if it worked out for her or not.

"When I was offered the trial, I didn't know if it would work for me, but I thought that at least I could do something to help others and use my body for the next generation. At first, I had many horrible side effects including headaches and spiking temperatures, so I was in hospital over Christmas and quite poorly. Then thankfully I started to respond well to the treatment," she said.

David's two-year trial at the National Institute for Health and Care Research (NIHR)

Manchester Clinical Research Facility (CRF) at Christie NHS Foundation Trust involved an experimental medicine combined with Atezolizumab, an immunotherapy drug administered intravenously which she continues to have every three weeks.

"I celebrated my 50th birthday in February 2020 while still in the middle of treatment and not knowing what the future held. Two and a half years ago I thought it was the end and I now feel like I've been reborn," David said.

By June 2021, scans showed no cancer in her body and she was declared cancer free. David told BBC Radio Manchester that it was emotional returning to India with the good news, after having gone two years before to say her goodbyes. She will remain on treatment until December 2023 but still has no evidence of the cancer.

David is now excitedly looking forward to celebrating her 25th wedding anniversary in September, after the successful National Health Service (NHS) trial.

Source: *The Times of India,* 5th July 2022

Chennai: Research And Development, Lifesciences Policies Unveiled

Tamil Nadu chief minister M K Stalin unveiled two new policies to define the growth of life sciences and research & development in the state.

The emphasis on life sciences has increased manifold in recent years due to ever-changing geopolitics and the state is aiming to achieve self-reliance in the post Covid-19 world. Hence, a sector-specific policy to promote and develop industries in life sciences has been the need of the hour, said a note on the Life Sciences Policy 2022 unveiled at the Investors' Conclave in Chennai.

Tamil Nadu has been a pioneer in life sciences with more than 300 NABL labs, the second largest health sciences university in India and the establishment of TICEL Bio-Park to support and amplify the life sciences research ecosystem. This policy aims to strengthen the industrial ecosystem for life sciences by investing in infrastructure and skill development for four broad segments – biotechnology and bioservices, pharmaceutical and nutraceutical industry, medical devices and medical textiles, the note added.

In the case of R&D Policy 2022, the note from the state government said Tamil Nadu is among the top three states in India in fostering innovation and it ranks first in human capital in the India Innovation Index. Tamil Nadu being a manufacturing hub, R&D is mostly driven by industries. To boost this sector, a sector-specific policy has been drafted with a goal to double the R&D expenditure from the government, higher education and private sector by 2030.

The policy aims to increase the inputs to R&D including the number of researchers and scientists in both government and private sectors, besides improving innovation outputs such as patents and publications. It also seeks to develop a synergetic innovation ecosystem of research parks, research centres, centres of excellence and innovation hubs, besides promoting R&D in private sector by targeting new indigenous R&D performing firms in both manufacturing and service sectors, the note said.

Source: *The Times of India,* 5th July 2022

Medicated Sunscreen Sales are A Scorcher

Blame it on the severe summer: Consumers are smearing medicated sunscreens like never before to shield themselves from harmful rays. Sales of prescription sunblocks jumped nearly 55% in May over 2020, latest data culled from research firm IMS said.

Medicated sunscreens are made by pharma companies, while other normal ones are cosmetic in nature and made without any chemical formulation.

After March 2020, once the coronavirus struck the country, sales of medicated sunscreens became sluggish as people reduced usage since they were mostly home-bound due to the pandemic. Overall, the market - valued at around Rs 300 crore (12-year period ended May 2022) - is growing at a robust 10-15% with Sun Pharma, Hegde & Hegde, IPCA and Glenmark among the major players. Most companies have either doubled or tripled sales this year.

The growth is being attributed to increasing awareness among consumers, and easy availability of prescription products. Interestingly, prescription sunscreens seem to be popular despite the fact that they are priced two to three times their cosmetic counterparts. Further, there is a blurring of products available over-the-counter with those that have a medical prescription, categorised under 'cosmoceuticals', experts pointed out. Though most medicated sunscreens need to be dispensed only with a prescription, they are available freely over the counter.

Patients are also prescribed certain medicated sunblocks as these could be combination products, with a formulation to treat skin issues like acne. In May, sunscreens posted the highest growth among derma drugs, of over 150% year-on-year. It may be pointed out that this is over the low base of last year when the country was reeling under the second Covid wave.

"There are two primary reasons for the high growth we are seeing in the sunscreen market. First, last year's base is low as Covid significantly impacted patient flow to dermatologists.

With almost all skin clinics now open, patients are returning to dermatologists. Second, most of the offices have opened and travel is picking up. We are also seeing increased awareness about sunscreens in India," says Sun Pharma CEO (India business) Kirti Ganorkar.

Sun Pharma leads in the prescription sunscreen market with around 18% share (IMS MAT May 2022), represented by two brands - Photostable and Suncros, followed by 'SunBan' of Hegde & Hegde. Companies say growth had been similar in the pre-Covid era too.

"Compared with FY19-20 base, we have seen 'La Shield' grow three times in value," a Glenmark executive said. "We have seen searches for sunscreen reaching unexpected highs during Q1 of this year and this has also reflected on the online and offline sales of various sunscreen brands, including the LaShield range," he added. Industry experts say sales in the first quarter (April to June) usually peak each year, due to the harsh summer.

Source: *The Times of India*, 6th July 2022

Drugs, Medical Devices & Cosmetics Bill 2022: A Law Whose Date has Expired

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

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

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

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

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

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

*Regulators would be bound by all the cumbersome GoI rules ranging from recruitment to financial powers.

*They would not have any 'rule-making' powers. All requests to create or amend rules would be made to the secretary of the ministry, generally an IAS officer who may or may not have expertise on the topic.

*Regulators could be overruled by the ministry exercising oversight on certain issues.

For example, the Drugs and Cosmetics Rules clearly provide for an appeal against the decision of drug controllers to the central or state government, thereby allowing the minister acting on the advice of a non-specialist bureaucrat to overrule specialists making regulatory decisions.

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

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

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

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

Source: *The Economic Times,* 5th July 2022

Exports of Ayush and Herbal Products in Volume Grew 42% in Five Years

Exports of Ayush and herbal products in the last five years till the fiscal year 2021-22 has registered a growth of 41.5 per cent growth in terms of volume, while imports has registered a three-fold growth during the same period. The Ministry of Ayush has said that the government is taking various initiatives including support to meet the international regulatory requirements, to grow exports of Ayush and herbal products from the country.

According to data from the Directorate General of Commercial Intelligence and Statistics (DGCIS), the exports of Ayush and herbal products in the year 2017-18 was 8.91 crore kilograms, which has grown to 12.61 crore kilograms during the year 2021-22, a year when globally industries faced supply chain constraints

The exports crossed 10 crore kilogram first time in the last five years in the year 2018-19, at 10.81 crore kilograms before falling to 9.22 crore kilograms in the following year. However, the exports bounced back to 12.06 crore kilogram in the following year, according to the data.

Imports have registered a steady growth till 2020-21, when it touched 7.63 crore kilogram, though the following year of 2021-22 has seen a decline. The exports for the five years have grown from 1.36 crore kilogram

in 2017-18 to 5.37 crore kilogram during the year 2021-22.

Exports for the first two months of the current fiscal year of 2022-23 was at 2.15 crore kilogram, while imports crossed 1.07 crore kilogram during the two months of April and May, this year.

In context to International regulatory requirements, the Ministry of Ayush has taken the steps including encouraging the Certification of Pharmaceutical Products (CoPP) as per World Health Organisation guidelines for herbal products. The Ministry, in cooperation with the Quality Council of India has developed a Quality Certification programme, that is Premium mark to increase reliability of standards of ASU&H Products, said Sarbananda Sonowal, Minister of Ayush, in Lok Sabha.

In order to ensure Quality Standards of Ayush products, the Ministry has collaborated with the Bureau of Indian Standards to develop the International (ISO) Standards. A Memorandum of Understanding (MoU) between the Pharmacopoeia Commission for Indian Medicine & Homoeopathy (PCIM&H), Ministry of Ayush and American Herbal Pharmacopoeia, USA was signed on September 13, 2021 for strengthening, promotion, and development of standards in the field of Ayurveda and other Indian Traditional systems of medicine between the two countries on the basis of equality and mutual benefit.

The Ministry has also established an India-EU Technical Working Group (TWG) on Ayurveda. The Technical Working Group has the representation of technical experts from the Ministry of Ayush, Government of India, the European Commission, the European Medicines Agency (EMA) and its Committee on Herbal Medicinal Products (HMPC).

As a part of the policy for the development and export of Ayush products & services across the world, the Ministry of Ayush has taken various steps including signing 25 Country to Country MoUs for cooperation in the field of traditional medicine and homoeopathy with foreign nations. Another 37 MoUs have been signed with international institutes for undertaking collaborative research/academic collaboration. Besides, 15 MoUs have been signed with international institutes for the setting up of Ayush Academic Chairs in foreign nations.

The Ministry has provided support for the establishment of 38 Ayush Information Cells in 34 foreign nations. The Ministry, under its International Fellowship/Scholarship Programme offers scholarships to foreign nationals for undertaking Ayush courses in recognized Ayush institutions in India. The setting up of Ayush Export Promotion Council (AEPC) will also help to promote Ayush products overseas, it said.

Source: *Pharmabiz,* 26th July 2022

India has not Imposed any Country Specific Ban on Imports, Minister Piyush Goyal Informs Parliament

India has not imposed any country-speci c ban on imports, Union Minister of Commerce and Industry Piyush Goyal informed Parliament in reply to a question on whether the central government has taken or proposed to take any steps to impose a ban on Chinese products.

"India and China, are both members of the WTO, and any trade restriction imposed must be TO compliant. Government has from time to time reviewed and taken WTO compliant measures to address the concerns raised by various stakeholders to have a holistic global trade strategy," he said further
in his reply.

However, as per the import policy of the government, all goods imported into India are subject to domestic laws, rules, orders, regulations, technical specifications, environment, and safety norms.

Government takes appropriate action including a ban on goods if these are found to violate these regulations or have implications for national security," Goyal added.

There had been several calls to shun Chinese products after a border clash with China in 2020 in which 20 Indian soldiers and several PLA soldiers were killed. Following the event, India imposed a ban on 59 apps including Tik Tok, UC Browser, and other apps. Almost all the apps banned have some preferential Chinese interest and the majority have parent Chinese companies.

The Centre regulates imports on the grounds of public morals, protection of human, animal, or plant life and health, protection of patents and copyrights, and protection of national treasures of artistic, historical, and archaeological value, among others.

The Directorate General of Trade Remedies (DGTR) is empowered to recommend restrictions on imports.

Further in his reply, he said in order to support and expand domestic capacities, the government has implemented policies to promote domestic manufacturing like the Production Linked Incentive (PLI) Schemes for various key sectors in line with the Atmanirbhar Bharat policy to reduce dependence on imports, with an estimated outlay of Rs 197,000 crore.

In addition, to promote the semi-conductor industry, the Government has formulated a scheme amounting to Rs 76,000 crore.

Source: *The Economic Times,* 27th July 2022

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