ISSUE No. 52

SILVER JUBILEE YEAR 2016

TAMILNADU PHARMACEUTICALS SCIENCES WELFARE TRUST

25 Years

e-NewsLetter

*Happy New Year 2022*

# Pharma Web

## Newsletter of Tamilnadu Pharmaceutical Sciences Welfare Trust

Oct. - Nov. - Dec. 2021

Delvin Formulations

*Destiny for Innovation*

# MOVING GLOBALLY

**R & D and Manufacturing of API**

**R & D and Manufacturing of Formulations**

**International Marketing**

**Domestic Marketing**

**Medical Devices**

**Surgical**

## Pharmaceuticals

| NURAY CHEMICALS PVT. LTD. | HIBROW | Sai Mirra Innopharm | Numen Healthcare | Delvin Formulations | Inventz Lifesciences | Dr. KALAM COLLEGE OF PHARMACY |
|---|---|---|---|---|---|---|
| API (Bulk Drug) | Formulation R & D - Manufacturing | Formulation R & D - Manufacturing | International Marketing - Based at Singapore | Domestic Formulation Marketing | OTC with Spring Board Ventures | Educational Institution |

## Healthcare

| i2H SOLUTIONS | LIFE SPAN DIABETES CLINICS | SCITUS |
|---|---|---|
| Diagnostic Care @ Home | Chain of Diabetic Clinics | Clinical Research Organisation |

www.delvin.in

info@delvin.in

Tamilnadu Pharmaceutical Sciences Welfare Trust

# Pharma Web

## Newsletter of Tamilnadu Pharmaceutical Sciences Welfare Trust

ISSUE : 52 Oct. - Nov. - Dec. 2021



**CONTENTS** **Page No.**



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 wish all our readers a very **HAPPY NEW YEAR 2022**

We are happy to publish the 52nd issue of Pharma Web Newsletter for **Oct – Dec 2021.**

We are publishing this issue as e-newsletter. There is a delay in publishing this news letter due to various reasons like COVID pandemic and non-availability of suitable articles and other information. We are sending this issue to all our Pharma professionals through email and What's app. This news letter will also be available in our website.

This 52nd issue contains the program highlights as well as the following article was published by eminent resource persons.

- **Dissolution Tester: Trends in Automation**, Shri. Hrudayanath Vinayak Jadhav, Assistant General Manager – AR&D, Micro Labs Ltd, Mumbai
- **Nitrosamine Impurities – Current Regulatory Status**, Dr. BM Rao, VP & Head – EMQA, ASAT & CQC, Dr. Reddy's Laboratories Limited

We have 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

## DISSOLUTION TESTER: TRENDS IN AUTOMATION

by

**Hrudayanath Jadhav**
GM-R&D(Analytical), Micro Labs Limited, Mumbai

### Dissolution Tester: Trends in Automation

Dissolution testing plays many important roles throughout the pharmaceutical industry, from the research and development of drug products to the control and evaluation of drug quality. However, it is a challenging task to perform both high-efficient separation and high-temporal detection to accomplish precise dissolution profile of each active ingredient dissolved from a drug tablet. The accuracy of drug dissolution testing is ensured by the excellent repeatability of the sequential analysis, as well as the similarity of the evaluation of dissolution testing. Historically, the assessment of drug release from oral solid dosage forms was based on tablet disintegration time. It was not until the 1960s that dissolution testing was introduced to assess drug release from dosage forms as a function of time. Dissolution testing is one of the most labor-intensive and time-consuming quality testing procedures involving a number of unit operations. In addition, to the duration of the dissolution testing, there are numerous additional steps such as sample withdrawal, sample analysis, temperature measurements, media filling, media change, pH change, and vessel cleaning, often consuming twice the time of the testing procedure. As a result, pharmaceutical companies are now investing in more automated laboratory procedures, and a number of automated dissolution devices have been developed to increase the capacity while improving accuracy and reducing variability. Furthermore, the increase in the number of modified and sustained-release drug formulations, which require much longer dissolution testing times (anywhere from 3–24 h), adds to quality control testing burden. Manual dissolution testing of modified-release products usually requires additional personnel, and often, a single dissolution test would be conducted by different individuals, resulting in higher variability and leading to repeated analysis in a number of cases. An out-of-specification result does require investigation and documentation, a major concern for the regulator and the industry in general.

**Overview of Dissolution Test**

Basically, the dissolution test mimics the first few stages of this process under very controlled laboratory conditions (in vitro).

- For immediate release products:
  - Wetting in the stomach
  - Disintegration in the stomach
  - De-aggregation in the stomach
  - Dissolution in the stomach and intestine
  - Permeation through the intestinal wall
  - Absorption into the blood stream
  - Transit to the therapeutic site (via liver)
  - Decomposition and elimination

**Dissolution is an important tool for characterizing the biopharmaceutical properties of a pharmaceutical product at different stages throughout its life cycle.**

- Product Development
  - API characterization, Formulation evaluation, Stability testing
- Bioavailability / Bioequivalence
  - In Vitro / In Vivo Relationships
- Quality Control
  - Pass / Fail product release
- Scale-Up and Post-Approval Changes
  - Raw materials, Formulation, Process, Manufacturing site

**Dissolution is one the three primary tests used to release a finished drug product:**

- **Assay** – determines the overall potency of the batch and ensures the accuracy of the finished drug product.

- **Dose Uniformity** – determines the consistency among the individual dosage units and ensures the precision of the manufacturing process.

- **Dissolution** – ensures that the performance of the finished drug product is consistent with the release rates of the API as determined in bioavailability studies during the clinical trials.

**Why Automate Dissolution testing?**

**Increase Productivity**

Fully automated dissolution improves the productivity in the lab by automating the routine tasks of filling and cleaning vessels.

**Improve Data Reliability**

With the introduction of automation in the lab, you can significantly improve the quality of your data. Each dis- solution test is performed the same way, every time, for more precise datasets. Every step is recorded in a secure database reducing instances of data entry errors. Test results are no longer operator-dependent.

**Reduce Time-to-Market**

The strategic implementation of laboratory automation is helping many companies to remain competitive. By placing automation in both R&D and Quality departments, some companies have created a seamless method transfer process, helping reduce the time-to- market for new products.

**Enhance Safety**

Automation improves safety by reducing exposure to hazardous compounds used in testing. In addition, automation reduces ergonomic stress by eliminating com- mon repetitive tasks, such as sampling and filtering.

**Return on Investment**

Go beyond the auto-sampler and automate the tedious filling and cleaning of vessels. Time can now be reallocated towards mission critical activities helping to reduce process cycle times by > 80 %.

The use of automated dissolution testing devices is an added advantage to pharmaceutical companies, particularly with the increased number of required dissolution tests and the added requirements to narrow quality control specifications. Automated systems achieve high productivity and perform test runs continuously and automatically.

Automation offers not only benefits, but also challenges, which the manufacturer has to overcome:

- Easy validation of hardware and software;
- Robust systems that can be used 24 h a day in routine;
- Efficient sampling system;
- Efficient cleaning system;
- Choice of media change procedures;
- High accuracy and reproducibility;
- Flexible concepts allowing customized solutions; and high throughput for maximal productivity increase for the customers.

**Dissolution automation levels**

Choosing the level of automation that best fits the throughput requirements, process steps, and laboratory operating procedures, can help to ensure reproducibility and standardization of your dissolution test. Individual process steps for automation of dissolution tester was shown in Figure 1. The sequence of individual process steps before (pre-test), during (dissolution test), and after (post-test) the dissolution test include:

The following are the main criteria for choosing the level of automation needed:

- Quantity of test per year
- Duration of dissolution test
- Number of time points
- Number of additional process steps / options

Statistical data of lots or time with respect to manual, semi-automated, and fully automated dissolution tester are presented in Figure 2.

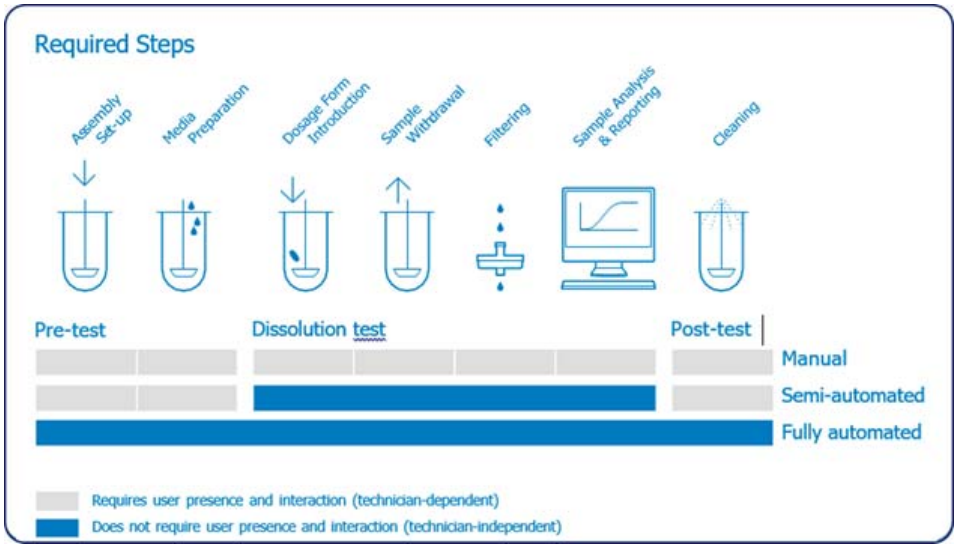



Figure 1: Individual process steps for automation of dissolution tester

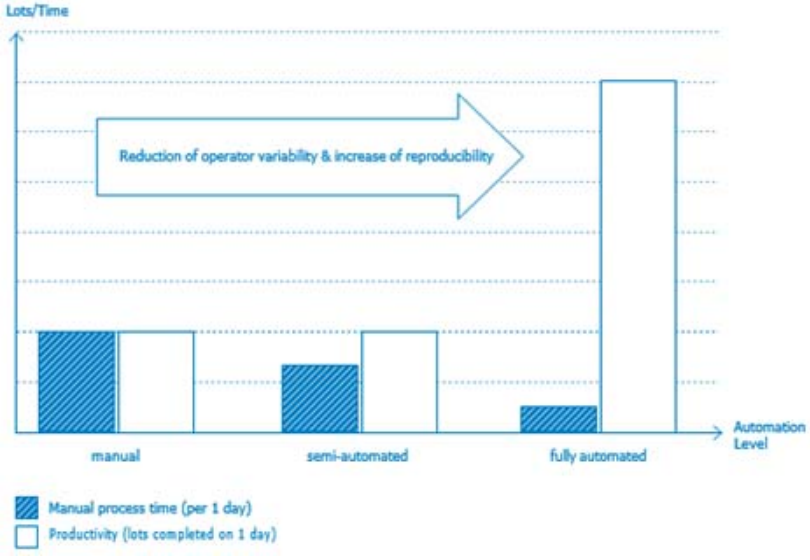



Figure 2: Statistical data of the manual, semi-automated and fully automated dissolution tester

## Manual steps in dissolution tester

When dissolution is performed manually, every single process step before, during, and after the test is executed manually by the user. This is the most technician-dependent way of testing.

For a high number of samples per year, a fully automated test instrument is the most promising solution as 2000 batches or more per year can be tested with a limited number of personnel. Otherwise, semi-automated solutions are of great importance when only single tests have to be automated. Semi-automated systems are based on a modular concept and can be customized. There are off- and online solutions or a combination of these types available. Figure 3 shows the manual online dissolution tester.

Figure 3: manual online dissolution tester

## The important features of the manual dissolution tester

Complies with USP, IP, Ph. Eur. and JP specifications, Larger LCD of 40 characters and 4 lines for user friendly operation. Automatic stirrer height positioning for USP 1, 2, 5, 6, intrinsic test methods and also allows user specified height, Easy Snap-Fit TM shaft locking mechanism for positive engagement and wobble free operation. Clear water bath with composite top-plate, Precise individual vessel cantering system, Adjustable levelling of instrument and Vibration free smooth motorized lift movement. Isolated water circulating pump for precise temperature control of the water bath 20 programmable protocols 24 programmable sampling intervals Easy to empty and clean water bath with bottom drainage Instrument accessories like paddles, baskets, jars etc. are laser marked with serial numbers designed to minimize routine validation report for online validation of test, monograph, error log during the test and physical validation Programmable wake-up for temperature control Programmable sample volume from 1 ml to 99 ml Audio-visual indicators for system status Power failure detection facility.

## Semi-automated dissolution tester systems

Semi-automated systems ensure that all the sequential steps done during the dissolution run are reproducibly executed without need for user interaction until the post-run activity. The semi-automated system for dissolution testing with automated sampling and subsequent sample storage for later analysis. The Figure 4 shows semi-automated dissolution tester with the Fraction Collector.

The important features of the semi-automated dissolution tester

- Performs key operations like diluting and mixing samples up to 1:25, filtering, storing and replacing withdrawn samples with fresh media.
- The glass/Teflon syringes eliminate adsorption and offer a high accuracy of dosing (better than +/- 1%).
- The high suction capability enables efficient use of fine inline disk type syringe filters (0.45 microns) eliminating manual filtration process.
- Special sensor detects the alignment and type of tray used to prevent any human errors.

Figure 4: Semi-automated dissolution tester

## Fully Automated Dissolution System

This may be used for multicomponent drugs where one active substance is measured by means of UV and the other by HPLC. In addition, in UV measurement a collection of samples is popular as this retainer sample can be tested in case of an unexpected result. In this case, only the collected sample is retested and for investigation the test does not have to be repeated. Modular detection and automation components can easily be integrated to accomplish a UV analytical finish during dissolution technique. These systems come with online UV dissolution capabilities with UV-Vis spectrophotometer with multicell and fiber optic configurations. Figure 5 shows Multicell UV Dissolution System. With this system type, laboratories achieve the highest productivity gain as the system is loaded with multiple batches of samples and performs test after test with all necessary steps being automated.

The configuration depends very much on the applied analytical method. We distinguish between the following types:

- UV online systems with a spectrophotometer;
- UV online systems with fibre-optic probes;
- HPLC online systems; and
- combined system on-/offline.

UV online systems with a spectrophotometer are very widely used and are reliable semi-automated solutions. UV online systems are widely used as they represent the highest security and comfort level for laboratories.

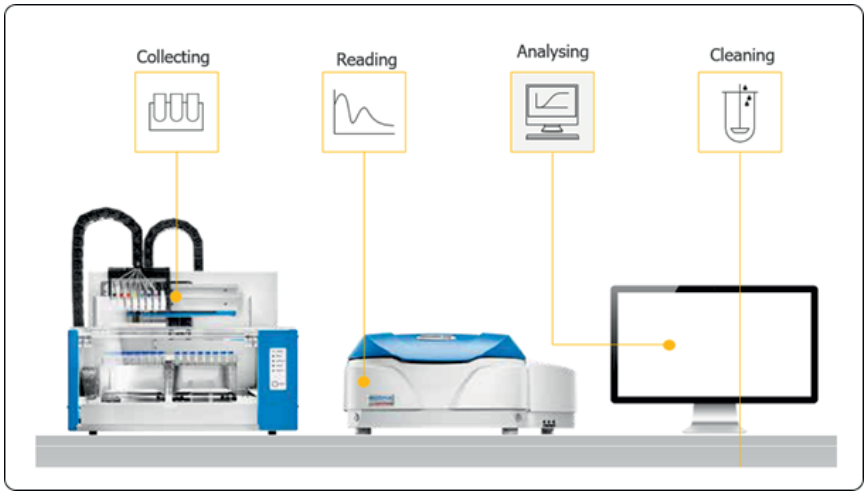



Figure 5. Fully automated dissolution tester equipped with UV-Visible spectrophotometer

In addition, systems allowing pH changes with a media selector for up to three media are possible. This allows one to perform in-vitro/invivo studies or tests for extended release forms. Additional options like solvent replacement after sampling and solvent addition for pH change are available. In addition, the on-/offline option is very popular as it gives the laboratory flexibility either to measure online or to collect a sample, or both. Figure 6 shows fully-automated dissolution tester.

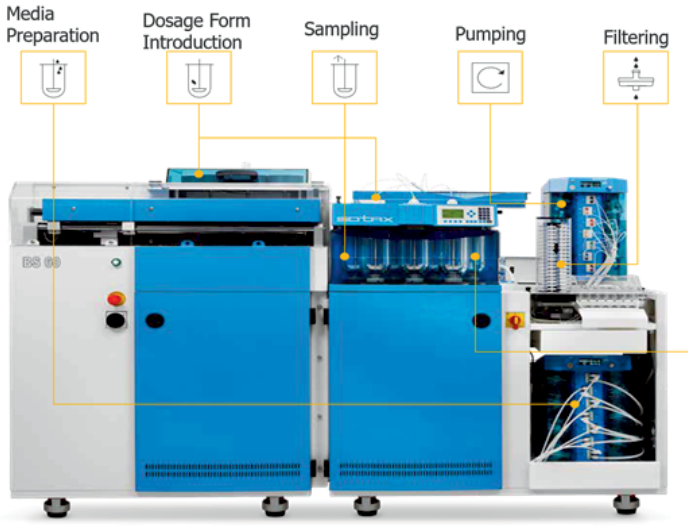



Figure 6: Fully-automated dissolution tester

This system is equipped with a very efficient cleaning system, with two rotating cleaning heads that spray cleaning solution at 4 bar in all angles of the system. This efficiently prevents any carry over and cross-contamination from test to test. The cleaning consists of the following steps.

1. Emptying of the vessels after each test run through the bottom valve system allowing one to remove capsule residues and even small sinkers or the pellet device.
2. Multiple rinsing of the vessels and tubing with 4-bar jet cleaning. This is done before the test with the selected media and after the test with de-ionized water. A final purge with air to remove any remaining liquid. After this stage, the whole system is practically liquid free and new tests can be started.

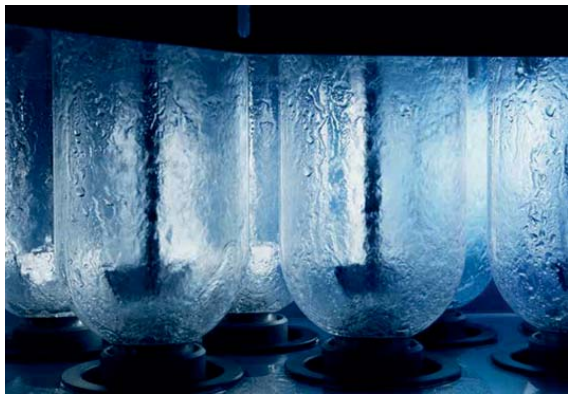


Figure 7: Self-cleaning process in the fully automated dissolution system

Cleaning is essential for fully automated systems as it prevents carry-over and cross-contamination between individual dissolution runs

## Conclusion

The development and use of automated dissolution test systems helps one to cope with the increased number of tests. The required documentation has grown even faster and occupies a very high amount of work time for laboratory staff. Automation enables laboratories to be more efficient and improve the accuracy of their data. Some available automation concepts are very flexible, easy to validate and can be used during 24 h non-stop. Finally, the high gain in productivity gives a very short return on investment. Therefore, automation is expected to gain a higher share while manual systems are replaced or used only for long tests or for minor products.

**References:**

1. Food and Drug Administration. Guidance for Industry Protocols for the Conduct of Method Transfer Studies for Type C Medicated Feed Assay Methods; Center for Drug Evaluation and Research (CDER), U.S. Department of Health and Human Services: Rockville, MD, 2006.

2. Cohen, J. L.; Hubert, B.; Leeson, L.; et al. The Development of USP Dissolution and Drug Release Standards. Pharm. Res. 1990, 7, 983–987.

3. Fontenay, G. Analytical Method Transfer: New Descriptive Approach for Acceptance Criteria Definition. J. Pharm. Biomed. Anal. 2008, 46, 104–112.

4. United States Pharmacopeia (USP); United States Pharmacopeial Convention: Rockville, MD, 2009.

5. Steinman, T. A. Qualification of a Multidose Automated Dissolution Workstation for Dissolution Testing of Fexofenadine HCl Capsules. J. Lab. Autom. 2000, 5, 81–86.

# Nitrosamine Impurities
## - Current Regulatory Status

**Dr. BM Rao, Ph.D.**
VP & Head – EMQA, ASAT (Analytical Science & Technology) & CQC (Corp. Quality Control)
Dr. Reddy's Laboratories Limited

Sensitivity and reliability of analytical methods for detection and quantitation of nitrosamines in pharmaceuticals is crucial due to the extremely low levels of these impurities determined acceptable by regulatory agencies

Medicine Regulatory Authorities first became aware of the presence of the nitrosamine impurity, N-Nitrosodiethylamine (NDMA), in products containing valsartan in July 2018. Nitrosamine impurities were already recognized as environmental contaminants, having been found in water and food, but their presence in an API was unexpected. Valsartan is an Angiotensin II Receptor Blocker (ARB) and belongs to a family of analogue compounds commonly referred to as the sartans. These initial reports by the European Medicines Agency (EMA), U.S. Federal Drug Administration (FDA) and Health Canada noted that NDMA has been detected in the Valsartan API. This was soon followed by the discovery of another nitrosamine impurity, N-Nitrosodiethylamine (NDEA). Since then, Nitroso-N-methyl-4-aminobutyric acid (NMBA) has also been identified as an impurity in drug products (DP). The presence of NDMA, NDEA and NMBA in DP is a cause for concern because they are all recognized probable human carcinogens. Even at low levels, these genotoxic impurities pose a significant threat to human health.

**What are nitrosamines?**

Nitrosamines, or more correctly N-nitrosamines, refer to any molecule containing the nitroso functional group. These molecules are of concern because nitrosamine impurities are probable human carcinogens. Although they are also present in some foods and drinking water supplies, their presence in medicines is nonetheless considered unacceptable.

**Why are they present?**

The formation of nitrosamines is generally only possible when secondary or tertiary amines react with nitrous acid. Nitrous acid itself is unstable but can be formed in-situ from nitrites (NO2) under acid conditions. In the case of the sartan compounds, most contain a tetrazole ring and formation of this tetrazole ring employs the use of sodium nitrite. Coincidently the solvents employed either were amines, or contained traces of amines, and this likely afforded the observed NDMA and NDEA.

Evidence suggests that sources of nitrites or amines as unintentional contaminants of starting materials, reagents and solvents – such as dimethylamine in the common solvent dimethyl formamide (DMF) – may also provide circumstances in which nitrosamines may form. The carryover of nitrites or amines from subsequent steps may also afford opportunities for formation. Notably, contamination from external sources has been identified as a source of nitrosamine content. Contamination from the use of recycled materials and solvents that already contain levels of nitrosamines. A cited example of this involves the use of recycled DMF, which is quenched with sodium nitrite to destroy residual azide as part of the recovery process. Furthermore, the recycling of materials and solvents is often outsourced to third parties who may not implement adequate controls in view of the content of the materials they are processing. Materials and solvents can become cross-contaminated with nitrosamines or with impurities that could react downstream to form nitrosamine, if equipment is not adequately cleaned between product manufacturing cycles. Importantly, these additional mechanism, cross-contamination, are to varying degrees product non-specific and may affect products that would otherwise not be expected to be at risk of nitrosamine formation. These broader concerns have prompted the European Medicines Agency (EMA) to request that Marketing Authorisation Holders (MAHs) of all Finished Pharmaceutical Products (FPPs) conduct risk assessment to determine the risk of nitrosamine content.

**Nitrosamine impurities – current available regulatory guidance:**

- EMA: June 29, 2021 EMA/409815/2020 Rev.4 Jul 2021
- FDA: Control of Nitrosamine Impurities in Human Drugs, February 2021
- ANVISA: Public Consultation No. 1050, of May 31, 2021, Guidance No. 50, Version 1
- SWISSMEDIC: Potential nitrosamine contamination, April 16, 2021
- Health Canada: Update 2 of December 15, 2020

**Target timelines for Risk assessment and Confirmatory Testing:**

Table-1 is the summary of timelines provided by various key regulatory agencies for performing the Risk evaluation, Confirmatory testing and making changes to market authorization.

**Table-1**

| Reference Guidance | Scope | Step 1<br>Risk Evaluation | Step 2<br>Confirmatory testing | Step 3<br>Changes to the market authorization |
|---|---|---|---|---|
| EMA/409815/2020 / June 29, 2021 | Chemical Synthesis<br>Biological API | 31st March 2021<br>1st July 2021 | 26th September 2022<br>1st July 2023 | 26th September 2022<br>1st July 2023 |
| FDA / Feb 2021 | Chemical Synthesis<br>Biological API | March 31, 2021 | October 1, 2023 | October 1, 2023 |
| ANVISA, May 31, 2021 | Chemical Synthesis<br>Biological API | Since date of publication:<br>9 months-Very high risk products<br>12 months-High risk products<br>36 months-All other products | | |
| Swiss Medic, April 16, 2021 | Chemical Synthesis<br>Biological API | 31st March 2021<br>1st July 2021 | 26th September 2022<br>1st July 2023 | 26th September 2022<br>1st July 2023 |
| Health Canada, December 15, 2020 | Chemical Synthesis<br>Biological API | March 31, 2021<br>November 30, 2021 | October 1, 2022<br>November 30, 2023 | October 1, 2022<br>November 30, 2023 |

## Potential Sources of Nitrosamines

There are multiple reasons why nitrosamines can be present in drugs. FDA found the source of nitrosamines can be related to the drug's manufacturing process or its chemical structure or even the conditions in which they are stored or packaged. Table-2 explains the potential sources and risk as stated in USP<1469>

**Table-2**

| Potential Source | Risk |
|---|---|
| Solvents | 1. Residual dialkylamines/Tri-substituted amines can degrade to form intermediate, can further react with Nitrosating agents.<br>2. Presence of Nitrites, other Nitrosating agents<br>3. Presence of acid<br>4. Limited controls/Limits for re-cycled solvents<br>5. Poor quality of solvents |
| Water | 1. Presence of residual dialkylamines / impurities can degrade to form dialkylamines.<br>2. Presence of acids and Nitrosating agents |
| Raw material/Excipient | 1. Presence of Nitrites, other Nitrosating agents and/or nitrosamine impurities if applicable |
| API | 1. Use of Sodium Azide/Nitrites in Acid<br>2. Use of Di/trialkylamines -amides, in presence of nitrites and acid medium<br>3. Use of Rec. solvents contains Nitrosamines or their precursors.<br>4. Use of sanitized water ex. Chloramines<br>5. Insufficient purification<br>6. Degradation of API |
| Manufacturing Process | 1. Contamination<br>2. Use of Rec. solvents contains Nitrosamines or their precursors<br>3. Presence of Nitrous oxide in air<br>4. Carry over of relevant reactive species |
| API-Stability | 1. Secondary/Tertiary/Quaternary amine group in molecule of API<br>2. Presence of nitrate counter ions |
| Container Closures/ Packing material | 1. Containing vulnerable amines |

**Toxicity and Acceptable Intake (AI) limits of Specific Nitrosamine Impurities**

NDMA and NDEA belong to the so-called "cohort of concern", which is a group of highly potent mutagenic carcinogens that have been classified by the WHO's International Agency for Research on Cancer as probably human carcinogens. Despite the potency of these impurities, there is still a very low risk that nitrosamine impurities at the levels found could cause cancer in humans. Only limited impurity-specific toxicity data is available for NDMA and NDEA. Based on this information interim acceptable intakes for these specific impurities have been adopted by most major regulators, as indicated in the below table. Due to their structural similarity, NDIPA, NEIPA, and NMBA are considered by international regulators to exhibit a toxicological profile like NDMA and NDEA.

For a nitrosamine impurity that is not included in the table-3, the principles as outlined in ICH's M7 (R1) guideline are recommended to be used to determine an acceptable intake.

**Table - 3**

| Impurity | Code | CAS No. | EMA | FDA | ANVISA | Swiss Medic | Health Canada |
|---|---|---|---|---|---|---|---|
| | | | (ng/day) | (ng/day) | (ng/day) | (ng/day) | (ng/day) |
| N-Nitrosodimethylamine | NDMA | 62-75-9 | 96 | 96 | 96 | 96 | 96 |
| N-Nitroso-4-(methylamino)butyric acid | NMBA | 61445-55-4 | 96 | 96 | 96 | 96 | 96 |
| 1-Methyl-4-nitrosopiperazine | MNP/MeNP | 16339-07-4 | 26.5 | - | 26.5 | 26.5 | 96 |
| N-Nitrosodiethylamine | NDEA | 55-18-5 | 26.5 | 26.5 | 26.5 | 26.5 | 26.5 |
| N-Nitrosodiisopropylamine | NDIPA/DIPNA | 601-77-4 | 26.5 | 26.5 | 26.5 | 26.5 | 26.5 |
| N-Nitrosoethylisopropylamine | NEIPA/NIPEA/EIPNA | 16339-04-1 | 26.5 | 26.5 | 26.5 | 26.5 | 26.5 |
| N-Nitrosodibutylamine | NDBA | 924-16-3 | 26.5 | USP | 26.5 | 26.5 | 26.5 |
| N-Nitrosomethylphenylamine | NMPA | 614-00-6 | 34.3 | 26.5 | 34.3 | 34.3 | - |
| N-Nitrosomorpholine | NMOR | 59-89-2 | 127 | - | - | - | - |

**Testing method requirements:**

The sensitivity and reliability of analytical methods related to detection and quantitation of nitrosamines in pharmaceuticals is crucial due to the extremely low levels of these impurities determined acceptable by regulatory agencies. FDA has published methods including GC/MS-Head Space Analysis and LC-HRMS for detection of some of the familiar nitrosamines.

The generic industry intends to use the analytical methods recommended by FDA appropriately to analyze the API's and DP's. However, due to differences in the formulations and possibility of an analytical method not being adequate for analysis of all possible volatile and non-volatile nitrosamines, new methods should be developed and considered. For instance, there are possibilities of artifacts from excipients and other sources that could be misconstrued as nitrosamines, based on a particular method. Thus, once a nitrosamine is detected in an API or DP, the sponsors will confirm its presence unequivocally based on orthogonal methods and control studies to determine the need for additional action based on their analysis that establishes the presence of nitrosamines.

To assist in the testing of samples the USFDA has published several test methods that may be considered when determining nitrosamine content in the API or FPP.
https://www.fda.gov/media/124025/download
https://www.fda.gov/media/115965/download
https://www.fda.gov/media/130801/download
https://www.fda.gov/media/131868/download

Similarly, the Official Medicines Control Laboratories (OMCLs) Network of the Council of Europe has also published several methods that may be used when testing for nitrosamines and is available at this web address:
https://www.edqm.eu/en/ad-hoc-projects-omcl-network

Table-4 covers the Testing requirements of Nitrosamines from various Regulatory agencies:

**Table-4**

| Testing | EMA | FDA | ANVISA | Swiss Medic | Health Canada |
|---|---|---|---|---|---|
| Method | Validated sensitive method | Validated sensitive method | Validated sensitive method | Validated sensitive method | Validated sensitive method |
| Testing type | Quantitative | Quantitative | Quantitative | Quantitative | Quantitative |
| Sensitivity of the method | LoQ should be ≤ of the acceptable limit based on the relevant acceptable intake (AI) for the respective nitrosamine impurity | LoD/LoQ are reasonably practical for products MDD is high (>1 g)<br><br>If >1 nitrosamine listed, the method LOQ should be <0.03 ppm.<br><br>If MDD >1 g (e.g. 1200 mg), LOQ should be below 0.02 ppm | LoD or LoQ <10% of limit of AI | LoQ should be < 30 ppb (0.03 ppm) | LoQ should be ≤ to the acceptable limit for most potent nitrosamine detected in an API or drug product |

**General recommendation from Confirmatory Testing**

It was recommended to conduct confirmatory testing, when there is any risk for the presence of nitrosamine impurities. Due to nitrosamines' physiochemical properties (low molecular weights, some volatility and high toxicity), the analytical methods for nitrosamines need to have specificity, excellent chromatographic separation, and highly sensitive detection capability. Table-5 provides the recommendations from various regulatory agencies from the outcome of confirmatory testing

**Table - 5**

| Testing | Omission | Skip testing | Routine control |
|---|---|---|---|
| EMA | the LoQ of the analytical method employed should be ≤ 10% of the acceptable limit based on the AI | the LoQ of the analytical procedure employed should be ≤ 30% of the acceptable limit based on the AI | the LoQ should be ≤ of the acceptable limit based on the relevant acceptable intake (AI) for the respective nitrosamine impurity |
| FDA | Alternate approaches (e.g., upstream test of an intermediate) should be supported by sufficient process understanding and evidence of adequate statistical control and should be submitted to FDA in a supplement prior to implementation | | If a nitrosamine impurity is detected above the LOQ |
| ANVISA | Admitted the absence of nitrosamines when <10% of the AI limit | If results are >10% of AI limit, control must be included.<br>Other approaches can be justified, not exceeding the 30% limit.<br>If the >1 nitrosamine to be controlled, the limits must be adjusted in order to ensure the maintenance of negligible risk | |
| SWISSMEDIC | The detection of every nitrosamine impurity must lead to an investigation of the causes, and appropriate CAPAs should be taken in accordance with GMP. As with any case of an identified problematic risk, companies must follow the standard procedure and inform Swiss medic immediately if nitrosamines are detected in APIs or medicinal products – regardless of the quantities – and submit a risk evaluation. | | |
| HEALTH CANADA | NA | NA | The API specification should include a test and acceptance criterion for each nitrosamine impurity when the risk for nitrosamine presence is considered to be high and/or when the concentration of any nitrosamine is found to be at significant levels (e.g. greater than 30% of the acceptable intake) during confirmatory testing. |

**Life Cycle Management:**

The original risk assessment related to the API or DP will be revisited in the event of changes which have the potential to modify the risk profile of the product. Some examples of changes which may entail re-evaluation of the risk profile are provided below:

For API's, a change in the source of RSM, change in the source of solvents (e.g. decision to use recycled solvents), changes in the process which may incorporate risk of nitrosamines, changes in the reagents or solvents, and any other change which may be relevant to levels of nitrosamines in the API.

For DP's, a change in the source of API, excipients, reformulation of the finished dosage form, changes in packaging which may incorporate higher risk of nitrosamines, changes in the process, and any other changes that could impact the levels of nitrosamines in the drug product.

**Conclusion:**

The generic industry commits to taking pro-active steps to ensuring the quality of the generic medicines meets the highest safety standards as determined by the FDA. The generic industry is eager to work with FDA to adopt a balanced risked-based approach to addressing the nitrosamine issue. This said, we would like to request the FDA revisit and potentially reassess the set safety limits of the common nitrosamines in pharmaceuticals based on new developments from recent studies, such as consideration for the duration, acute to chronic, use of a product.

The generic industry stands ready to work with the FDA so that we can strike the right balance, that of quality and safety. Further we stand ready to work with the FDA to mitigate creating or potentially exasperating unintended consequences, such as drug shortages, process improvements that are overly burdensome and unsustainable for the FDA and industry, as we refine risk-based approaches to better manage the concerns nitrosamines present.

**References:**


1.U.S. Food and Drug Administration; "FDA updates on angiotensin II receptor blocker (ARB) recalls including valsartan, losartan and irbesartan https://www.fda.gov/drugs/drugsafety/ucm613916.htm

2.FDA Updates and Press Announcements on NDMA in Zantac (ranitidine), https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-zantacranitidine

3. EMA/189634/2019 - Information on Nitrosamines for Marketing Authorization Holders

4. ICH M7 (R1) – Assessment and Control of the DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk

5. Health Canada - Information to Marketing Authorization Holders (MAH) of Human Pharmaceutical Products Regarding Nitrosamines Impurities, letter from October 2, 2019

6. EFPIA decision tree "Drug substance manufacturing process risk assessment for presence of N-nitrosamines"

7. IPEC Europe. Questionnaire for Excipient Nitrosamines Risk Evaluation. Guidance 5. Conducting purge assessments

8. AAM White Paper – Ensuring the Future of Accessible Medicines in the US file:///C:/Users/lisa/Downloads/AAM-Whitepaper-Ensuring-Future-of-Generic- Medicines.pdf

9.Information Note Nitrosamine impurities, World Health Organization; https://www.who.int/medicines/publications/drugalerts/InformationNote_Nitrosamine- impurities/en/

# INFORMATION

## G. Rangachari Memorial (PG Pharmacy Fellowship) Awards 2021

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

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

This is 24th year of this project, we have received 236 (196+40) applications from 6 different branches of M. Pharm & Pharma D

This year we have received applications from 19 institutions. All synopses were sent to Dr. G. Krishna Mohan, Center for Pharmaceutical Sciences, Jawaharlal Nehru Technological University, Kukatpally, Hyderabad & his team for evaluation. Based on the ranking, 25 students have been selected for Awards as per the following details:

**PHARMACEUTICS**

| Rank | Name | College | Mark | Prize Amount (Rs.) |
|---|---|---|---|---|
| I | Ms. Sanskruti Shrenik Patil | JSS College of Pharmacy, Ooty | 46 | 12,000 |
| II | Ms. Sweety Kuriakose | COP, SRIPMS, Coimbatore | 45 | 10,000 |
| III | Ms. Archana Ramakrishnan | JSS College of Pharmacy, Ooty | 40 | 8,000 |
| III | Ms. K. Chandraleka | RVS College of Pharmaceutical Sciences, Coimbatore | 40 | 8,000 |

## PHARMACEUTICAL CHEMISTRY

| Rank | Name | College | Mark | Prize Amount (Rs.) |
|---|---|---|---|---|
| I | Mr. Dhinesh Kumar. M | JSS College of Pharmacy, Ooty | 43 | 12,000 |
| II | Mr. Benin Thanka Solomon | JSS College of Pharmacy, Ooty | 41 | 10,000 |
| II | Ms. G. Sathya Pooja | COP, SRIPMS, Coimbatore | 41 | 10,000 |
| III | Mr. Navinkumar. M | JSS College of Pharmacy, Ooty | 40 | 8,000 |

## PHARMACEUTICAL ANALYSIS

| Rank | Name | College | Mark | Prize Amount (Rs.) |
|---|---|---|---|---|
| I | Mr. Vinothkumar. P | COP, SRIPMS, Coimbatore | 45 | 12,000 |
| II | Ms. Vani. S | JSS College of Pharmacy, Ooty | 44 | 10,000 |
| III | Mr. M. Sivaganesh | Periyar College of Pharmaceutical Sciences, Tiruchirappalli | 40 | 8,000 |
| III | Ms. Geetha. M | COP, SRIPMS, Coimbatore | 40 | 8,000 |

## PHARMACOLOGY

| Rank | Name | College | Mark | Prize Amount (Rs.) |
|---|---|---|---|---|
| I | Ms, Neha Roy | JSS College of Pharmacy, Ooty | 46A | 12,000 |
| II | Ms. Vanitha. N | KMCH College of Pharmacy, Coimbatore | 46B | 10,000 |
| III | Ms. Akhina Tom | JSS College of Pharmacy, Ooty | 46C | 8,000 |

## PHARMACOGNOSY

| Rank | Name | College | Mark | Prize Amount (Rs.) |
|---|---|---|---|---|
| I | Ms. D. Susmitha | College of Pharmacy, Madras Medical College, Chennai | 46 | 12,000 |
| II | Ms. K. Robina Rahmath Aara | COP, Mother Theresa Post graduate and Research Institute of Health Sciences, Puducherry | 44A | 10,000 |
| III | Ms. N. Sandhiya | College of Pharmacy, Madras Medical College, Chennai | 44B | 8,000 |

## PHARMACY PRACTICE

| Rank | Name | College | Mark | Prize Amount (Rs.) |
|---|---|---|---|---|
| I | Mr. Santhosh Kumar M | JSS College of Pharmacy, Ooty | 48 | 12,000 |
| II | Ms. Ranjitha. K. R | COP, SRIPMS, Coimbatore | 46 | 10,000 |
| III | Mr. Gunasekar. M | PSG College of Pharmacy, Coimbatore | 43 | 8,000 |
| III | Mrs. Janusha. J | KMCH College of Pharmacy, Coimbatore | 43 | 8,000 |

## PHARM D

| Rank | Name | College | Mark | Prize Amount (Rs.) |
|---|---|---|---|---|
| I | Mr. Arun. G.R, Ms. Swetha. B, Ms. Anuba. P.A | SRM College of Pharmacy, SRMIST, Chennai | 48 | 15,000 |
| II | Ms. Jerlin Michelle. I, Mr. Dhivakaran. K, Mr. Nidhish Raj. V, Mr. Ajithkumar. A | SRM College of Pharmacy, SRMIST, Chennai | 46A | 12,000 |
| III | Ms. Priyanka. R, Ms. Reethika. A, Ms. Rinta Sara Dency Johnson, Mr. Saravanan. K.S. | COP, SRIPMS, Coimbatore | 46B | 10,000 |

## Shri. G. Swaminthan Memorial Award - Essay Competition 2021 – Final Year B. Pharm Students

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

This year we have received 71 applications from 17 colleges and this was evaluated by **Dr. D. Narasimha Reddy,** Principal, Vivekananda College of Pharmacy, Bangalore – 560055. Based on the rating -- 3 students have been awarded as below

| Rank | Name | College | Prize Amount (Rs.) |
|---|---|---|---|
| I | Mr. Nirmal. P | C.L. Baid Metha College of Pharmacy, Chennai | 10,000/- |
| II | Mr. G. E. Thillai Govindarajan | Faculty of Pharmacy, Dr. M.G.R. Educational and Research Institute, Chennai | 8,000/- |
| III | Ms. Zaiba Fathima. F | P.S.V. College of Pharmaceutical Science & Research, Krishnagiri | 7,000/- |

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

# EVENTS

## 60th National Pharmacy Week

### 1. Indian Pharmaceutical Association, Tamilnadu State branch

The 60th National Pharmacy week celebration, valedictory was organized by IPA (Tamilnadu State Branch) on 27th December, 2021.

The theme of this program "Pharmacist: An integral part of healthcare". Dr. B Suresh, Pro Chancellor of JSS Academy of Higher Education and Research, Mysuru was the Chief Guest of the function. Mr. S. V Veerramani, Chairman our Trust was guest of honour.
Dr. S. Manivannan, President, TN, IPA welcomed the gathering. He welcomed Dr. B Suresh and Mr. S. V. Veerramani and other trustees of our trust. He highlighted the need of pharmacist and their important role in health care system .

Mr. J. Jayaseelan, Vice President, IPA, announced various awards instituted by Tamilnadu Pharmaceutical Sciences Welfare Trust. This year PG Fellowship awards were given to 22 M. Pharm & 3 Pharm D students& Essay competition awards to 3 B.Pharm students. The total cash price amount of Rs. 2.76 lakhs given by the trust. The awards were given by Chief Guest Dr. B. Suresh, to the awardees.

The Best Pharmacist Awards was announced by Mr. R. Narayanaswamy, Editor – Pharma Web Newsletter. He announced the Best Pharmacist award 2020 to Mr. Rajesh H Bhandari, Partner M/s. Lanchand Bhim Raj, Chennai, and the Best Pharmacist Award 2021, was given to Dr. R. Ilavarasan, Assistant Director & Institute In-charge, A. Lakshmipathy Regional Ayurveda Research Institute, CCRAS, Ministry of AYUSH, Govt. of India, Chennai.

The function was honored by the Chairman of Tamilnadu Pharmaceutical Sciences Welfare Trust, Mr. S. V. Veerramani. He address that the Pharma Sales in India is around 2110 crores (21 billion) in domestic market and 2444 (24.44 billion) crores in export. (FY 2020-2021). Indian Pharma industry is called as the "pharmacy of the world" because we export medicines to over 200 countries and saving trillions of people across the world. No other products from India reach to this many countries.

Dr. B. Suresh, Pro Chancellor, JSS Academy of Higher Education and Research was the Chief Guest for the function. Pharmacists are not just drug oriented but should be people oriented. They ensure that the patient has the right drug, in right amount, for right length of time, with minimum side effects.

Pharmacist should be specialized in patient care, drug information and should update information to medical and allied people on new and existing drugs.

Mr. T. Sathish, Secretary IPA TN, proposed the vote of thanks.


Best Pharmacist Awardees with Guests on the Dias


Awards of M. Pharm from various Institutions


Awardees of Pharm D from various Institutions

## 2. Excel College of Pharmacy, Komarapalayam

Excel College of Pharmacy hosted a seven-day event to commemorate the 60th National Pharmacy Week (NPW) on the theme of **"Pharmacist: An integral part of health care"** from **15th to 20th November 2021.**

On 15th November, the inaugural session began with the lighting of a lamp and Ganesh vandana in the seminar hall. **Dr. R. Manivannan, Principal, Excel College of Pharmacy**, welcomed the audience and gave a presentation on how pharmacists in India work tirelessly in all situations across the country and are now in the process of transitioning from invisible work to visible patient-centered care roles in a variety of healthcare settings. **Prof. Dr. G. Maheswari, Principal, Excel College of Nursing**, was present to honour the occasion. She emphasized the importance of Pharmacists and how they play a larger role in society.

Different events were organized by the students as well as faculties to make this special day as a function of Pharmacist. Various events were held throughout the week, including essay writing, elocution, singing, badminton, cricket, volley ball, and dancing competitions, among others.

On 20th November 2021, the NPW celebration was made closure by Valedictory function, with the presence of Chief Guest **Dr K BOMMANA RAJA, Executive Director, Excel Technical Campus and Principal, Excel Engineering College**. He gave a captivating speech on the NPW theme. He urged the students to strive for a goal that will distinguish them not only in the pharmaceutical industry, but also in the field of research. And he talked about how to improve communication and social skills, as well as topic knowledge, to put them in a better position. **Dr. R. Manivannan, Principal, Excel College of Pharmacy**, felicitated the Chief Guests with memento and the celebrations preceded with prize distribution, vote of thanks followed by national anthem

## PCPS Student Wins Medal from The T.N. Dr. M.G. R. Medical University, Chennai


The postgraduate student V. Arun Nivas of Periyar College of Pharmaceutical Sciences, Tiruchirappalli was bestowed with a Medal for securing the highest mark in Master of Pharmacy – M.Pharm (Pharmacognosy) in the University examination held during October 2020 from The Tamilnadu Dr. M.G. R Medical University, Chennai. Honourable Governor of Tamil Nadu and Chancellor of the University, Thiru. R.N. Ravi, awarded the medal to the student during the 34th Convocation held at the Silver Jubilee Auditorium of the University on 20th December 2021 in the presence of Honourable Chief Minister Thiru. M.K. Stalin. Hon'ble Health and Family Welfare Minister Thiru. Ma. Subramanian, Hon'ble Higher Education Minister Thiru. K. Ponmudi, Health Secretary Dr. J. Radhakrishnan, Hon'ble Vice-Chancellor Dr. Sudha Seshayyan and senior officials participated in the 34th Convocation ceremony. The Management, Principal, Faculty and Students congratulated the medalist for his academic achievement.

# NOTIFICATION

## MINISTRY OF AYUSH

### NOTIFICATION

New Delhi, the 1st October, 2021

**G.S.R. 716(E)**.—Whereas the draft of certain rules further to amend the Drugs Rules, 1945 was published as required under section 33N of the Drugs and Cosmetics Act, 1940 (23 of 1940) (hereinafter referred to as the said Act), in the Gazette of India, Extraordinary, Part-II Section 3, Sub-section (i), dated the 17th March, 2021 vide notification of the Government of India, in the Ministry of AYUSH number vide GSR. 197(E), dated the 17th March, 2021, for inviting objections and suggestions from all 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, the said Gazette was made available to the public on 18th March, 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 section 33N of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, after consultation with the Ayurveda, Siddha, Unani Drugs Technical Advisory Board, hereby makes the following rules further to amend the Drugs Rules, 1945, namely:-

**1. Short title, and commencement:-** (1) These rules may be called the Drugs (4th Amendment) Rules, 2021. (2) They shall come into force on the date of their publication in the Official Gazette.

2. In the Drugs Rules, 1945 (hereinafter referred to as the principal rules), in PART XVI, in the heading for the brackets and words "(INCLUDING SIDDHA)", the word "SIDDHA" shall be substituted.

3. In rule 151 of the principal rules, for the brackets and words "(including Siddha)", the word "Siddha" shall be substituted.

4. For rule 153 of the principal rule, the following rule, shall be substituted namely:-

**"153. Application for licence to manufacture Ayurvedic, Siddha or Unani drugs**.-(1) An application for the grant of licence to manufacture for sale of Ayurvedic, Siddha or Unani drug, shall be made -

(a) as defined under clause (a) of section 3 of the Act, in Form 24D to the licensing authority alongwith a fee of rupees two thousand; and

(b) as defined in sub-clause (i) of clause (h) of section 3 of the Act, in Form 24D to the licensing authority alongwith a fee of rupees three thousand for the first ten products and after the said ten products, an additional fee of rupees two thousand per product, through the portal e-AUSHADHI (www.e-aushadhi.gov.in) as per the format provided in the said portal, pertaining to the licence for manufacture for sale of Ayurvedic, Siddha or Unani drugs.

Provided that this rule shall not be applicable to licence obtained under Form 25D prior to the date of commencement of the Drugs (4th Amendment) Rules, 2021 and such licence holder having a Good Manufacturing Practices Certificate on the date of its renewal has to deposit a onetime licence retention fee of rupees one thousand for existing licenced drugs falling under clause (a) of section 3 of the Act; and rupees one thousand for first ten products and a fee at the rate of rupees one thousand per product over and above the said first ten products for existing licenced drugs falling under sub-clause (i) of clause (h) of section 3 of the Act.

Provided further that till the portal e-AUSHADHI (www.e-aushadhi.gov.in) shall come to effect within six months of the commencement of the Drugs (4th Amendment) Rules, 2021 and during this period either of online and offline process of licence application shall be accepted.".

5. For rule 153A of the principal rules, the following rules shall be substituted, namely:-

**"153A. Application for loan licence to manufacture Ayurvedic, Siddha or Unani drugs**.-(1) An application for grant of a loan licence to manufacture for sale of Ayurvedic, Siddha or Unani drug, shall be made-

(a) as defined under clause (a) of section 3 of the Act, in Form 24E to the licensing authority alongwith a fee of rupees two thousand; and

(b) as defined in sub-clause (i) of clause (h) of section 3 of the Act, in Form 24E to the licensing authority alongwith a fee of rupees three thousand for the first ten products and after the said ten products, an additional fee of rupees two thousand per product, through the portal e-AUSHADHI (www.e-aushadhi.gov.in) as per the format provided in the said portal, pertaining to the loan licence for manufacture for sale of Ayurvedic, Siddha or Unani drugs.

Provided that this rule shall not be applicable to licence obtained under Form 25E prior to the date of commencement of the Drugs (4th Amendment) Rules, 2021 and such licence holder having a Good Manufacturing Practices Certificate of the manufacturing facilities he intends to avail on the date of renewal of its licence has to deposit a onetime licence retention fee of rupees one thousand for existing licenced drugs falling under clause (a) of section 3 of the Act; and rupees one thousand for first ten products and a fee at the rate of rupees one thousand per product over and above the said first ten products for existing licenced drugs falling under sub clause (i) of clause (h) of section 3 of the Act.

Provided further that till the portal e-AUSHADHI (www.e-aushadhi.gov.in) shall come to effect within six months of the commencement of the Drugs (4th Amendment) Rules, 2021 and during this period either of online and offline process of licence application shall be accepted.

Explanation—For the purposes of this rule, a "loan licence" means a licence issued by the Licensing Authority to an applicant who does not have his own arrangements for manufacture but intends to avail himself of the manufacturing facilities owned by a licencee in Form 25D.

**153B. Application for Certificate of Good Manufacturing Practices for Ayurvedic, Siddha or Unani drugs manufacturing unit-**(1) An application for the grant of a Certificate of Good Manufacturing Practices for Ayurvedic, Siddha or Unani drugs manufacturing unit shall be made in Form 24E-1 to the licensing authority along with a fee of rupees five thousand.

(2) Every application in Form 24E-1 shall be made for a unit having premises and other requirements as prescribed under Schedule T.

(3) The application shall be made through portal e-AUSHADHI (www.e-aushadhi.gov.in) as per the format provided in the said portal, pertaining to the Good Manufacturing Practices for Ayurvedic, Siddha or Unani drugs manufacturing units.".

6. For rule 154 of the principal rule, the following rule shall be substituted, namely:-

**"154. Form of licence to manufacture Ayurvedic, Siddha or Unani drugs.** — (1) Subject to the conditions of rule 157 being fulfilled, a licence to manufacture for sale of any Ayurvedic, Siddha or Unani drugs shall be issued in Form 25D within a period of two months from the date of receipt of the application or from the date of compliance by the applicant of shortcomings, if any, highlighted by the licensing authority, as the case may be.

(2) A licence under this rule shall be granted by the licensing authority after consulting such expert in Ayurvedic, Siddha or Unani Systems of medicine, as the case may be, which the State Government may approve in this behalf.

(3) The application shall be processed through portal e-AUSHADHI (www.e-aushadhi.gov.in) and the licence in Form 25D shall be issued online as per the format provided in the said portal.".

7. For rule 154A of the principal rule, the following rule shall be substituted, namely:-

**"154A. Form of loan licence to manufacture for sale of Ayurvedic, Siddha or Unani drugs**.—(1) A loan licence to manufacture for sale of any Ayurvedic, Siddha or Unani drugs shall be issued in Form 25E within a period of two months from the date of receipt of the application or from the date of compliance of shortcomings, if any, highlighted by the licensing authority, as the case may be.

(2) A licence under this rule shall be granted by the Licensing Authority after consulting such expert in Ayurvedic, Siddha or Unani systems of medicine, as the case may be, which the State Government may approve in this behalf.

(3) The Licensing Authority after being satisfied that the manufacturing unit licenced under Form 25 D has adequate equipment, staff and capacity for manufacture and facilities for testing, to undertake the manufacture on behalf of the applicant for a loan licence shall grant a loan licence.

(4) The application shall be processed through portal e-AUSHADHI (www.e-aushadhi.gov.in) and licence in Form 25E shall be issued online as per the format provided in the said portal.".

8. The Rule 155 and 155A of the principal rules, shall be omitted.

9. In rule 155B of the principal rules, -

(i) in sub rule (1), for the words "for a period of five years", the words figures and letter "in form 26 E-1" shall be substituted;

(ii) sub rule (2) shall be omitted.

10. For rule 156 of the principal rules, the following rule shall be substituted, namely:-

**"156. Duration of licence**—(1) A licence issued in Form 25D shall remain valid perpetually:

Provided that the licencee shall submit a self declaration of adherence to the conditions of licence and the provisions of the Drugs and Cosmetics Act and the rules made thereunder, every year from the date of issue of licence in form 25 D or from the date of submission of last self declaration, as the case may be .

Provided further that such self declaration shall be made within three months, of completion of one year from the date of issue of licence in form 25 D or from the date of submission of last self declaration, as the case may be, and in the event of non submission of such self declaration, within the time mentioned in the licence of the said product shall be suspended temporarily and if the licensee fails to submit the self declaration within a further period of three months, the licence of the said product shall be deemed to have been cancelled.".

11. For rule 156A of the principal rules, the following rules shall be substituted, namely:-

**"156A. Duration of loan licence**-A loan licence issued in Form 25E shall remain valid perpetually:

Provided that the licencee shall submit a self declaration of adherence to the conditions of licence and the provisions of the Drugs and Cosmetics Act and the rules made thereunder, every year from the date of issue of licence in form 25 E or from the date of submission of last self declaration, as the case may be .

Provided further that such self declaration shall be made within three months, of completion of one year from the date of issue of licence in form 25 E or from the date of submission of last self declaration, as the case may be, and in the event of non submission of such self declaration, within the time mentioned in the licence of the said product shall be suspended temporarily and if the licensee fails to submit the self declaration within a further period of three months, the licence of the said product shall be deemed to have been cancelled.

**156B. Duration of Certificate of Good Manufacturing Practices for Ayurvedic, Siddha or Unani drugs manufacturing units -**(1) A certificate issued in form 26E-1 shall remain valid unless it is cancelled by the Licensing Authority subject to deposit of a certificate retention fee of rupees one thousand before the expiry of a period of every succeeding five years from the date of its issue.

(2) If the licencee fails to pay certificate retention fee on or before the due date as referred to in sub-rule (1), he shall be liable to pay certificate retention fee alongwith a late fee calculated at the rate of two per cent of the certificate retention fee for every month or part thereof up to six months, and in the event of non-payment of such fee, the certificate shall be deemed to have been cancelled.

**156C. Inspection for grant of licence and verification of compliance.-**(1) Before a certificate in Form 26E-1 is granted, the licensing authority shall cause the establishment in which the manufacture of drugs is proposed to be conducted or being conducted to be inspected by one or more inspectors appointed by the State Government under this Act, with or without an expert in the field concerned and the inspector or inspectors shall examine the establishment intended to be used or being used for the manufacture of drugs.

(2) The inspectors shall verify the self declaration of adherence to the conditions of licence and the provisions of the Drugs and Cosmetics Act and the Drugs Rules once in five years or as needed as per risk based approach.

Provided that the inspectors are allotted the inspection duty in a randomized manner ensuring that the same inspector is not assigned inspection of a particular establishment consecutively for two terms of not less than five years duration.

Provided further that if the premises is not inspected within the period of the validity of the GMP certificate or even after submission of retention fee, the GMP certificate shall be deemed to be continued for further term of five years.

**156D. Report by Inspector**−(1) The Inspector or Inspectors shall examine all areas of the premises, plant and appliances and also inspect the process of manufacture intended to be employed or being employed along with the means to be employed or being employed for standardizing and testing the drugs to be manufactured or being manufactured and enquire into the professional qualifications of the technical staff to be employed and he shall also examine and verify the statements made in the application in regard to their correctness, and the capability of the applicant to comply with the requirements of competent technical staff, manufacturing plants, testing equipments and the Requirements of Good Manufacturing Practices and Plant and Equipments as laid down in Schedule T.

(2) The Inspector after completion of his inspection shall forward a detailed report giving his findings on each aspect of inspection alongwith his recommendations, to the Licensing Authority.

**156E.-Procedure of Licensing Authority.**-(1) If the Licensing Authority after such further enquiry, if any, as he may consider necessary, and after being satisfied that the requirements of the provisions referred to in the rules under the Act have been complied with and that the conditions of the licence shall be observed, shall issue a licence under this Part.

(2) If the Licensing Authority is not satisfied of the requirements under sub-rule(1), shall issue a memorandum of shortcoming, and the conditions which shall be satisfied before a licence is granted and shall supply the applicant a copy of the inspection report.

(3) The applicant within two months of issue of such memorandum under sub-rule (2) shall reply the same.

(4) On non submission of requirements under sub-rule (2), the Licensing Authority shall reject the application and shall inform the applicant, the reasons for such rejection.

(5) For this purpose, the licensing authority shall intimate the applicant and process the application through portal e-AUSHADHI (www.e-aushadhi.gov.in).

**156F.- Further application after rejection.** −If the applicant, within a period of six months from the rejection of an application for a licence or Certificate of Good Manufacturing Practices, as the case may be, informs the Licensing Authority that the conditions laid down have been complied with and deposit an inspection fee of rupees one thousand, the Licensing Authority may, after a further inspection, if any, is satisfied that the conditions for the grant of a licence or certificate have been complied with, issue a licence or certificate under this Part.".

12. In rule 157 of the principal rules,

(i) in the heading, the words " or renewal" shall be omitted;

(ii) in the opening portion, the words, figures and letter "or renewed in Form 26-D" shall be omitted;

(iii) in sub-rule (1), for the brackets and words "(including Siddha)", the words "Siddha" shall be substituted;

(iv) in sub-rule (1A), the words "or renewal" shall be omitted;

(v) for sub-rule (1D), the following sub-rule shall be substituted namely:-
"(1D) Whoever contravenes the provisions of sub-rules (1B) and (1C) shall be punishable in accordance with the provisions of the Act." ;

(vi) sub-rule (1E) shall be omitted.

13. In rule 157A of the principal rules, the following proviso shall be inserted namely:-

"Provided that the applicant shall submit the record online through portal e-AUSHADHI (www.e-aushadhi.gov.in) as per the format provided in the said portal and such records shall be retained by the manufacturer for a period of one year after the submission.".

14. In rule 158 of the principal rules, for sub-clause (c), the following sub clause shall be substituted, namely:-

"(c) The applicant and inspector shall submit the record online through e-AUSHADHI (www.e-aushadhi.gov.in) portal as per the format provided in the said portal.".

15. In rule 158A of the principal rules, for clause (e), the following clause shall be substituted, namely:-

"(e) The applicant and inspector shall submit the record online through e-AUSHADHI (www.e-aushadhi.gov.in) portal as per the format provided in the said portal.".

16. In rule 158C of the principal rules, the following Explanation shall be inserted, namely:-

"Explanation.-For the purposes of this rule, the applicant shall apply online and licensing authority shall issue such certificate online through portal e-AUSHADHI (www.e-aushadhi.gov.in) as per the format provided in the said portal.".

17. After sub-rule (1) of rule 160B of the principal rules, the following sub-rule shall be inserted, namely:-

"(1A) The licence shall be issued within a period of two months, from the date of receipt of the application or from the date of fulfillment of shortcomings, if any, as the case may be, communicated by the licensing authority.".

18. After rule 160J of the principal rules, the following rule shall be inserted, namely:—

"160K.-Information to be uploaded by the licencee on online portal.- (1) The applicant or licencee under this part shall register with portal, e-AUSHADHI (www.e-aushadhi.gov.in) and upload information, as per the format provided in the said portal, pertaining to licence application, renewal, tests carried out and other such information as required and shall be updated from time to time

(2) The information uploaded by the licencee in the portal under sub-rule (1) shall be verified by the concerned licensing authority.".

19. In the principal rules, for FORM 24 D, the following FORM shall be substituted, namely:—

**"FORM 24D**
**(See rule 153)**

Application for the grant of a licence to manufacture for sale of Ayurvedic, Siddha or Unani drugs

1 . I / W e ..... of.....hereby apply for the grant of a licence to manufacture Ayurvedic, Siddha or Unani drugs on the premises situated at..... .....

2. Names of drugs categorized according to Schedule T to be manufactured (with details)

3. Names, qualifications and experience of technical staff employed for manufacture and testing of Ayurvedic, Siddha or Unani drugs .....

4. A fee of rupees ..... has been credited to the Government under the head of account ..... and the relevant Treasury Challan/ online transaction slip is enclosed herewith.

Date..... Signature . .....
(applicant)

Note—The application should be accompanied by a Plan of the premises.".

20. In the principal rules for FORM 24E, the following FORM shall be substituted, namely:-

**"FORM 24E**
**(See rule 153A)**

Application for the grant of a loan licence to manufacture for sale of Ayurvedic, Siddha or Unani drugs

1 . I / We* ....., of!.....hereby apply for the grant of a loan licence to manufacture Ayurvedic, Siddha or Unani drugs on the premises situated at……C/o#…….

2. Names of drugs categorized according to Schedule T to be manufactured (with details).

3. The names, qualifications and experience of technical staff actually connected with the manufacture and testing of Ayurvedic, Siddha or Unani drugs in the manufacturing premises.

4. I / We* enclose,

(a) A true copy of a letter from me/us to the manufacturing concern whose manufacturing capacity is intended to be utilized by me / us.

(b) A true copy of a letter from the manufacturing concern that they agree to lend the services of their competent technical staff, equipment and premises for the manufacture of each item required by me/us and that they shall maintain the registers of raw materials and finished products separately in this behalf.

(c) Specimen of labels, cartons of the drugs proposed to be manufactured.

5. A fee of Rs ..... has been credited to Government under the head of account ..... and the relevant Treasury Challan/online transaction slip is enclosed herewith.

Date ..... Signature ..... ……

*Enter here the name of the proprietor, partners or Managing Director as the case may be.

! Enter here the name of the applicant firm and the address or the principal place of business.

# Enter here the name and address of the manufacturing concern where the manufacture will be actually carried out and also the licence number under which the latter operates."

21. In the principal rules for FORM 24E-1, the following FORM shall be inserted, namely:-

**"FORM 24E-1**
**(See rule 153B)**

Application for the Certificate of Good Manufacturing Practices for Ayurvedic, Siddha or Unani drugs manufacturing units.

1 . I / W e ..... of.....hereby apply for the grant of a Certificate of Good Manufacturing Practices for Ayurvedic, Siddha or Unani drugs manufacturing on the premises situated at..... …….

2. A fee of rupees ..... has been credited to the Government under the head of account ..... and the relevant Treasury Challan/ online transaction slip is enclosed herewith.

Date..... Signature .....
(applicant)

Note—The application should be accompanied by a Plan of the premises.".

22. In the principal rules for FORM 25D, the following FORM shall be substituted, namely:-

**"FORM 25D**
**(See rule 154)**

Licence to manufacture for sale of Ayurvedic, Siddha or Unani drugs

No. of Licence and date of issue……

1. …. ..... is / are hereby licenced to manufacture the following Ayurvedic, Siddha or Unani drugs on the premises situated at..... under the direction and supervision of the following competent technical staff: —

(a) Competent Technical staff (Names).

(b) Names of drugs categorized as per Schedule T (each item to be separately specified) with specific Product Code/QR Code for each approved drug.

2. The licence shall be in force from .....

3. The licence is subject to the conditions stated below and to such other conditions as may be specified in the Rules for the time being in force under the Drugs and Cosmetics Act, 1940.

Date ……. Signature ..... .....

Designation .....

**Conditions of Licence**

1. Any change in the Technical staff named in the licence shall be forthwith reported to the Licensing Authority.

2. This licence shall be deemed to extend to such additional items as the licencee may intimate to the Licensing Authority from time to time, and as may be endorsed by the Licensing Authority.

3. The licencee shall inform the Licensing Authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the Licensing Authority in the name of the firm with the changed constitution.

4. The licence unless sooner suspended or cancelled shall remain valid perpetually. However, the compliance with the conditions of licence and the provisions of the Drugs and Cosmetics Act 1940 (23 of 1940) and the Drugs Rules, 1945 shall be assessed not less than once in five years or as needed as per risk based approach.

5. The licence is issued only after fulfillment of the requirements of Good Manufacturing Practices (GMP) of Ayurveda, Siddha or Unani drugs as laid down in Schedule T of the Drugs Rules, 1945.".

23. In the principal rules for FORM 25E, the following FORM shall be substituted, namely:-

**"FORM 25E**
**(See rule 154A)**

Loan Licence to manufacture for sale Ayurvedic, Siddha or Unani Drugs

1. Number of Licence……date of issue…….

2 ..... of. ..... is hereby granted a loan licence to manufacture for sale Ayurvedic, Siddha, or Unani drugs, on the premises situated at .....C/o.....under the direction and supervision of the following expert technical staff:

(a) Expert Technical staff (Names)…….

(b) Names of drugs categorized as per Schedule T (each item to be separately specified) with specific Product Code/QR Code for each approved drug.

3. The licence shall be in force from .....

4. The licence is subject to the conditions stated below and to such other conditions as may be specified in the Rules for the time being in force under the Drugs and Cosmetics Act, 1940.

Date ……. Signature .....

Designation .....

**Conditions of Licence**

1. Any change in the technical staff named in the licence shall be forthwith reported to the Licensing Authority.

2. This licence shall be deemed to extend to such additional items as the licencee may intimate to the Licensing Authority from time to time, and as may be endorsed by the Licensing Authority.

3. The licencee shall inform the Licensing Authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the Licensing Authority in the name of the firm with the changed constitution.

4. The licence unless sooner suspended or cancelled shall remain valid perpetually. However, the compliance with the conditions of licence and the provisions of the Drugs and Cosmetics Act 1940 (23 of 1940) and the Drugs Rules, 1945 shall be assessed not less than once in five years or as needed as per risk based approach.".

24. In the principal rules for FORM 26E2-I, the following FORM shall be substituted, namely:-

**"[FORM 26E2-I]**
**(See rule 158C)**
**State Drug Controller or Licensing Authority for Ayurveda, Siddha and Unani Medicines**
**Name of the State or Union territory……..**
**Free Sale Certificate**

It is certified that M/s. …….(Name of the company)……..situated at ……. (Address)..... is holding valid Ayurvedic/Siddha/Unani Drug Manufacturing Licence Number..... and certificate of Good Manufacturing Practices for the State or Union territory of ……....

It is also certified that the manufacturing plant situated at……..(Address)……..in which the Ayurvedic or Unani or Sidhha products are manufactured, conforms to the requirement of Good Manufacturing Practices and is subjected to inspection as per rules.

The firm has been permitted under Licence Number……..to manufacture and market the following products (attach list of products, if multiple) freely for sale in India under the provisions of the Drugs and Cosemtics Act, 1940 and the rules thereunder.

(i)……
(ii)……
(iii)……..

Date :..... (Seal of issuing Officer) … … … … … … … …

( Signature and Name)
State Drug Controller/Licensing Authority
Address……
Name of State or Union territory……]".

25. In the principal rules for FORM 26E2-II, the following FORM shall be substituted, namely:-

**"[FORM 26E2-II**
**(See rule 158C)**
**State Drug Controller or Licensing Authority for Ayurveda, Siddha and Unani Medicines**
**Name of the State or Union territory……..**
**Free Sale Certificate**

It is certified that M/s. …….(Name of the company)……..situated at ……. (Address) ..... is holding valid Ayurvedic/Siddha/Unani Drug Manufacturing Loan Licence Number..... ……and the valid certificate of Good Manufacturing Practices for the State or Union territory of ……

It is also certified that the manufacturing plant situated at……..(Address)……..in which the Ayurvedic or Unani or Sidhha products are manufactured, conforms to the requirement of Good Manufacturing Practices and is subjected to inspection as per rules.

The firm has been permitted under Loan Licence Number……..to manufacture and market the following products (attach list of products, if multiple) freely for sale in India under the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the rules thereunder.
(i)……
(ii)……
(iii)……..
Date :..... (Seal of issuing Officer) … … … … … … .

( Signature and Name)
State Drug Controller/Licensing Authority
Address……
Name of State or Union territory…… "

26. In the principal rules for FORM 26 E3, the following FORM shall be substituted, namely:-

**"FORM 26 E3**
**(See rule 158C)**
**State Drug Controller or Licensing Authority for Ayurveda, Siddha and Unani Medicines**
**Name of the State or Union territory……..**
**Non-Conviction Certificate**

It is certified that M/s. …….(Name of the company)……..situated at ……. (Registered Address) ..... is holding valid Ayurvedic/Siddha/Unani Drug Manufacturing Licence Number..... in Form 25D/25E and valid certificate of Good Manufacturing Practices/valid Good Manufacturing Practices certificate of principal or original manufacturer for the State or Union territory of ……....

As per the records of the State Drug Controller or Licensing Authority, as it may be, and affidavit (Annexure I) given by the company, the firm has not been convicted under the Drugs and Cosmetics Act, 1940 (23 of 1940) and the rules thereunder in the State or Union territory of …….., during the last three years of the issuing of this certificate.

This certificate shall be valid only for one year from the date of issue.

Date :..... (Seal of issuing Officer) … … … … … … … … … … … … … … .

( Signature and Name)
State Drug Controller/Licensing Authority for Ayurveda, Siddha and Unani Medicines.
Address……
Name of State or Union territory……

**[ANNEXURE-1]**

(Proforma of Affidavit to be executed on appropriate non-judicial stamp paper of minimum value and attested by Notary Public)

I, ……S/O…….age…….working as …….of……..(Name and address of the company)……from ……to……do hereby solemnly affirm and declare as under:

1. That I, in the capacity of Authorized Signatory of ……(name and address of the company)….,am duly competent to depose and verify the present affidavit.
2. That I apply for Non-conviction Certificate on behalf of M/s. ……..
3. That I declare that I am aware of the details of my organization and day to day activities from….to….
4. That I hereby undertake that the Non-Conviction Certificate, if issued, will be utilized for the bona fide purpose only.
5. I declare that the aforesaid firm is not convicted under the Drugs and Cosmetics Act, 1940 and rules thereunder during the last three years.
6. That it is my true statement.

…….
Signature of Deponent Verification

Verified at……(Place and State)……..today on this……..…day of ….. (month) …. (Year) …..that the contents of the above affidavit are true to my Knowledge and belief and no part of it is false and nothing has been concealed there from.

…….
Signature of Deponent]

Witness with Address
1……...
2……...".

F.No. T-11011/7/2021-DCC(AYUSH)
KAVITA GARG, Jt. Secy.

**Note:** The principal rules were published in the Gazette of India vide notification No. F. 28-10/45-H(1), dated the 21st December, 1945 and last amended vide notification number G.S.R. 258 (E), dated the 7th April, 2021.

## MINISTRY OF HEALTH AND FAMILY WELFARE

**(Department of Health and Family Welfare)**

**NOTIFICATION**

New Delhi, the 18th October, 2021

**S.O. 4326(E)**.—In pursuance of sub-sections (1) and (2) of section 5 of the Drugs and Cosmetics Act, 1940 (23 of 1940) and in supersession of the notification of the Government of India in the Ministry of Health & Family Welfare, No. S.O. 1929(E) dated the 15th May, 2018, the Central Government hereby reconstitutes the Drugs Technical Advisory Board (DTAB) consisting of the following members, namely:—

| S. N. | Name/Official Designation of the Member | Status in DTAB | Section of the Drugs and Cosmetics Act, 1940 under which appointed/ nominated/ elected |
|---|---|---|---|
| (1) | (2) | (3) | (4) |
| 1 | The Director General of Health Services, New Delhi | Chairman ex-officio | Appointed under Section 5(2)(i) of the Act |
| 2 | The Drugs Controller, India, New Delhi | Member ex-officio | Appointed under Section 5(2)(ii) of the Act |
| 3 | The Director, Central Drugs Laboratory, Kolkata | Member ex-officio | Appointed under Section 5(2)(iii) of the Act |
| 4 | The Director, Central Research Institute, Kasauli | Member ex-officio | Appointed under Section 5(2)(iv) of the Act |
| 5 | The Director, Indian Veterinary Research Institute, Izatnagar, Bareilly, U.P. | Member ex-officio | Appointed under Section 5(2)(v) of the Act |
| 6 | The Chairman, National Medical Commission, India | Member ex-officio | Appointed under Section 5(2)(vi) of the Act |
| 7 | The President, Pharmacy Council of India | Member ex-officio | Appointed under Section 5(2)(vii) of the Act |
| 8 | The Director, Central Drug Research Institute, Lucknow | Member ex-officio | Appointed under Section 5(2)(viii) of the Act |
| 9 | Commissioner, FDA, Madhya Pradesh | Member | Nominated under Section 5(2)(ix) of the Act |
| 10 | Commissioner, FDCA, Gujarat | Member | Nominated under Section 5(2)(ix) of the Act |

| S. N. | Name/Official Designation of the Member | Status in DTAB | Section of the Drugs and Cosmetics Act, 1940 under which appointed/ nominated/ elected |
|---|---|---|---|
| (1) | (2) | (3) | (4) |
| 11 | Prof. (Dr.) Shailendra Saraf, University Institute of Pharmacy, Pt. Ravishankar Shukla University | Member | Elected under Section 5(2)(x) of the Act |
| 12 | Dr. Vijay Oza, Member (PGMEB), NMC | Member | Elected under Section 5(2)(xi) of the Act |
| 13 | Shri Sudhir Mehta, Chairman, Torrent Pharmaceuticals | Member | Nominated under Section 5(2)(xii) of the Act |
| 14 | Dr. Jerin Jose Cherian, Scientist D, Division of Basic Medical Sciences, ICMR | Member | Elected under Section 5(2)(xiii) of the Act |
| 15 | Dr. J.A. Jayalal, National President, Indian Medical Association | Member | Elected under Section 5(2)(xiv) of the Act |
| 16 | Dr. T.V. Narayana, President, Indian Pharmaceutical Association | Member | Elected under Section 5(2)(xv) of the Act |
| 17 | Government Analyst, Drugs Testing Laboratory, Bengaluru, Karnataka | Member | Nominated under Section 5(2)(xvi) of the Act |
| 18 | Government Analyst, Food & Drugs Laboratory, Vadodara, Gujarat | Member | Nominated under Section 5(2)(xvi) of the Act |

2. The Drugs Controller (India) shall be the Member-Secretary of the Board.

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

[F. No. X-19012/2/2009-DFQC(Pt)]
Dr. MANDEEP K BHANDARI, Jt. Secy.

**MINISTRY OF HEALTH AND FAMILY WELFARE**

**(Department of Health and Family Welfare)**

**NOTIFICATION**

New Delhi, the 27th October, 2021

**G.S.R. 762(E)**.—In exercise of the powers conferred by section 10A of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government hereby makes the following amendment further to amend the notification of the Government of India in the Ministry of Health and Family Welfare, number G.S.R. 577(E), dated the 23rd July, 1983, namely:—

In the said notification, in the Table, in the entry at serial number 12, after the words “test and analysis”, the following words and letters shall be inserted, namely:—

"and Oxytocin Active Pharmaceutical Ingredient (API) imported exclusively to manufacture formulations for the purpose of export only”.

[F. No. X.11014/2/2018-DR]
Dr. MANDEEP K. BHANDARI, Jt. Secy.

**Note:** The principal notification was published in the Gazette of India, Extraordinary, Part II, Section3, Sub-section (i) vide G.S.R. 577(E), dated the 23rd July, 1983 and lastly amended vide notification number G.S.R. 180(E), dated the 16th March, 2020.

**MINISTRY OF HEALTH AND FAMILY WELFARE**

**(Department of Health and Family Welfare)**

**NOTIFICATION**

New Delhi, the 9th December, 2021.

**G.S.R. 848(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. 611(E), dated the 1st September, 2021, in the Gazette of India, Extraordinary, Part II, section 3, sub-section (i), dated the 1st September, 2021, 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 1st 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 (7th Amendment) Rules, 2021.

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

2. In the Drugs Rules, 1945, in rule 43A, for the words "Inland Container Depot Dhannad", the words "Inland Container Depot at Dhannad and Tihi" shall be substituted.

[F. No. X.11014/17/2021-DR]
Dr. MANDEEP K BHANDARI, Jt. Secy.

**Note** : The Drugs Rules, 1945 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. 839(E), dated the 29th November, 2021.

**MINISTRY OF HEALTH AND FAMILY WELFARE**

**(Department of Health and Family Welfare)**

**NOTIFICATION**

New Delhi, the 27th October, 2021

**G.S.R. 766(E).**—Whereas a draft of certain rules further to amend the Drugs Rules, 1945, was published, as required under sub-section (1) of sections 12 and sub-section (1) of 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. 533(E), dated the 3rd 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 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 3rd 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 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 (5th Amendment) Rules, 2021.
(2) They shall come into force on the date of their publication in the Official Gazette.

2. In the Drugs Rules, 1945, in rule 90,—

(i) in sub-rule(2), for the word and figures "Form 29", the word and figures "Form 30" shall be substituted;
(ii) after sub-rule(2) as so amended, the following sub-rule shall be inserted, namely:—

"(3) The license in Form 29 may be granted by the licensing authority within a period of seven working days from the date of receipt of the application duly completed in Form 30, and in case where no communication is received by the applicant from licensing authority within the said period of seven days, the licensing authority shall be deemed to have granted the license."

[F. No. X. 11014/2/2021-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. 716(E), dated the 1st October, 2021.

**MINISTRY OF HEALTH AND FAMILY WELFARE**

**(Department of Health and Family Welfare)**

**NOTIFICATION**

New Delhi, the 29th November, 2021

**G.S.R. 839(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. 618(E), dated the 7th 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 7th September, 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 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 (6th Amendment) Rules, 2021.
(2) They shall come into force on the date of their publication in the Official Gazette.

2. In the Drugs Rules, 1945 (hereinafter referred to as said rules), in rule 24, in sub-rule (3), the words "or for a duplicate copy of the license issued under this rules, if the original is defaced, damaged or lost" shall be omitted.

3. In the said rules, in rule 24A, in sub-rule (7), the words "or for a duplicate copy of the Registration Certificate, if the original is defaced, damaged or lost" shall be omitted.

[F. No. X.11014/8/2021-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. 766(E), dated the 27th October, 2021.

**MINISTRY OF HEALTH AND FAMILY WELFARE**

**(Department of Health and Family Welfare)**

**NOTIFICATION**

New Delhi, the 10th December, 2021

**S.O. 5139(E).**—Whereas, there has been an outbreak of COVID-19 pandemic in India and worldwide;

Whereas, the Central Government is satisfied that making available suitable COVID-19 vaccines is essential to meet the requirements of emergency arising due to the pandemic COVID-19 and, therefore, in public interest, it is necessary and expedient to regulate the testing of COVID-19 vaccine for prevention and management of COVID-19 infection;

Whereas, the Central Government, in consultation with the Drugs Controller (India), is of the considered view that the supply of COVID-19 vaccine must not get affected and the vaccine must remain available to the public;

Now, therefore, in exercise of the powers conferred by sections 6 and 26B read with section 33P of the Drugs and Cosmetics Act, 1940 (23 of 1940) and rule 3 of the Drugs Rules, 1945, the Central Government, hereby directs that the National Institute of Biologicals, Noida, in addition to its existing functions shall perform the function of Central Drugs Laboratory as an additional facility in respect of COVID-19 vaccine and the functions of the Director in respect of COVID-19 vaccine shall be exercised by the Director of the said Institute.

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 requirements of emergency which have arisen due to COVID-19 pandemic.

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

4. The notification shall remain into force for a period up to 30th November, 2022.

[F. No. 18-35/2020-DC/DR]
Dr. MANDEEP K. BHANDARI, Jt. Secy.

**MINISTRY OF HEALTH AND FAMILY WELFARE**

**(Department of Health and Family Welfare)**

**NOTIFICATION**

New Delhi, the 31st December, 2021

**G.S.R. 918(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. 877(E), dated the 23rd 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 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 23rd 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), 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, 2021.
(2) These rules shall come into force on the date of their publication in the Official Gazette.

2. In the Medical Devices Rules, 2017, for rule 46, the following rule shall be substituted, namely:—

"46. Unique device identification of medical device.— With effect from such date as the Central Government may, by order specify, every medical device approved for manufacture for sale or distribution or import, shall bear a unique device identification in the manner as may be specified in such order.".

[F.No. X.11014/30/2021-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. 102(E), dated the 11th February, 2020.

F.No X-11026/030/2019-PRO (1)
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(Public Relation Office)

FDA Bhawan, New Delhi
Date: 10-12-2021

**Public Notice**

In continuation to this Directorate's Public Notice of even number dated 04.10.2019 regarding public hearing by respective division at Public Relation Office, CDSCO (HQ), New Delhi is operational in following manner to strengthen the process of regulatory guidance to stakeholders and innovators:

| Day | Officials of the Division in forenoon | Officials of the Division in afternoon |
|---|---|---|
| Monday | Medical Devices& IVD | CDAC & Blood Bank |
| Tuesday | New Drugs & SND | FDC & GCT |
| Wednesday | Cosmetics & Veterinary | International Cells & CDAC |
| Thursday | Import & Registration | Biological & LVP |
| Friday | Ayush & Ethics Committee | CDAC & BA/BE Export |

All stakeholders may avail the facilities as per their requirement.

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

**Copy To,**

1. JDC(SER)/JDC(PBN)/JDC (AKP)
2. All DDC(I)s/ADC(I)s at CDSCO(HQ)
3. IT cell –for uploading on web site of CDSCO
4. Guard File

**File No. 4-01/2013-DC (Misc. 13 PSC Part II)**
**Govt. of India**
**Directorate General of Health Services**
**Central Drugs Standard Control Organization**
**(FDC Division)**

**FDA Bhawan, Kotla Road**
**New Delhi-110002**
**Dated:** 06 JAN 2022

## NOTICE

**Subject: Evaluation of certain pre 1988 permitted Fixed Dose Combinations (FDCs) de novo for manufacture for sale in the country without due approval from Central Licensing Authority -regarding.**

This is in continuation to this office notice dated 27.12.2021 whereby the meeting of the Expert Committee was postponed which was scheduled to be held on 29th & 30th December 2021.

Now, the expert committee again invites the concerned stakeholders for hearing through WebEx (Video Conference) on 27th & 28th January 2022 w.r.t. FDCs mentioned under Annexure A. Date and time of hearing is also mentioned under **Annexure A**.

It is requested that the concerned stakeholders may kindly make it convenient to give a presentation through WebEx (Video Conference) before the Expert Committee on these FDCs. In the event that the Stakeholders does not attend the hearing, the Committee reserves the right to make its decision on the basis of information available before it.

You are requested to kindly confirm your participation through e-mail at fdc@cdsco.nic.in by 24.01.2022 and also submit Power Point presentation (PPT) alongwith the presenter details, Mobile number, email ID, s. No. of FDC as per **Annexure-A.**

This is for information of all the concerned.

**(Sanjeev Kumar)**
**Deputy Drugs Controller (India)**

**Copy to:**

1. Dr. M.S. Bhatia, Prof. & Head, D/o Psychiatry, UCMS, New Delhi, Chairman, Expert Committee.
2. To all the experts committee members.
3. Indian Drug/Pharmaceuticals Association (IDMA/FOPE/CIPI/IPA/OPPI, etc.,) with the request to communicate it to your members and publicize it widely so that all concerned can avail this opportunity.
4. Website of CDSCO for information and necessary action by concerned stakeholders.

**Annexure-A**

| S.No. | FDC Name | Date & Time of Hearing |
|---|---|---|
| 1 | Nimesulide +Paracetamol dispersible tablets | 27.01.2022 11:30 AM to 06:00 PM |
| 2 | Paracetamol + Phenylephrine + Caffeine | |
| 3 | Amoxicillin + Bromhexine | |
| 4 | Pholcodine + Promethazine | |
| 5 | Imipramine + Diazepam | |
| 6 | Chlorpheniramine maleate+ Dextromethorphan+ Dextromethorphan + Guaifenesin + Ammonium chloride + Menthol | |
| 7 | Chlorpheniramine Maleate +Codeine syrup | |
| 8 | Ammonium Chloride + Bromhexine + Dextromethorphan | |
| 9 | Bromhexine +Dextromethorphan +Ammonium Chloride +Menthol | |
| 10 | Dextromethorphan +Chlorpheniramine + Guaifenesin +Ammonium Chloride | |
| 11 | Caffeine +Paracetamol +Phenylephrine + Chlorpheniramine | 28.01.2022 11:30 AM to 06:00 PM |
| 12 | Paracetamol + Bromhexine +Phenylephrine +Chlorpheniramine + Guaifenesin | |
| 13 | Salbutamol + Bromhexine | |
| 14 | Chlorpheniramine +Codeine phosphate +Menthol syrup | |
| 15 | Phenytoin + Phenobarbitone sodium | |
| 16 | Paracetamol + Propyphenazone + Caffeine | |
| 17 | Ammonium Chloride + Sodium Citrate + Chlorpheniramine Maleate + Menthol | |
| 18 | Salbutamol + Hydroxyethyltheophylline (Etofylline) + Bromhexine | |
| 19 | Chlorpheniramine Maleate + Ammonium Chloride + Sodium Citrate | |

## PARLIAMENT QUESTION AND ANSWERS

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

**LOK SABHA**
**UNSTARRED QUESTION NO. 2237**
**TO BE ANSWERED ON 10th DECEMBER, 2021**

### NATIONAL PHARMACUETICAL STOCKPILE OF LIFE SAVING DRUGS

**2237: SHRI SHANMUGA SUNDARAM K.:**
**SHRI VELUSAMY P.:**

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

(a) whether the Government is undertaking a weekly review of the status of life saving drugs availability in India, if so, the details thereof;

(b) whether the Government is having any proposal to create National Pharmaceutical Stockpile (NPS) of life saving drugs like the system adopted in USA under the Strategic National Stockpile (SNS);

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

(d) whether the Government proposes to consider the State of Tamil Nadu as one of the location for stockpiling of essential medicine to meet any kind of emergency similar to severe shortage of medicines faced during second wave of COVID-19 pandemic; and

(e) if so, the details thereof and the steps taken in this regard?

**ANSWER**

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

(a) to (e): Ministry of Health and Family Welfare has formulated guidelines for Buffer stock Management of COVID-19 drugs. The said guidelines have been communicated to all States/UTs advising the States/UTs including Tamil Nadu to set up buffer stocks of critical drugs for Covid-19 management for addressing any further surge in Covid-19 cases.

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

**LOK SABHA**
**UNSTARRED QUESTION NO. 3266**
**TO BE ANSWERED ON 17th DECEMBER, 2021**

## EXPORT OF COVID-19 MEDICINES

**3266: SHRIMATI RANJANBEN DHANANJAY BHATT:**

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

a) whether the Government proposes to resume export of medicines used for the treatment of COVID-19;

(b) if so, the details thereof;

(c) the steps taken by the Government in this regard; and

(d) if not, the reasons therefor?

**ANSWER**

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

(a) to (d) : As on date there is no prohibition on exports of medicines used for treatment of COVID-19.

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

**LOK SABHA**
**UNSTARRED QUESTION NO. 3319**
**TO BE ANSWERED ON 17th DECEMBER, 2021**

## SPURIOUS MEDICINES DURING SECOND WAVE OF COVID-19

**3319: SHRIMATI HARSIMRAT KAUR BADAL:**
**DR. ALOK KUMAR SUMAN:**

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

(a) whether the Government is aware of the widespread exchange of spurious medicines in the country, if so, the details thereof;

(b) whether the Government has noted that during the second wave of COVID-19, spurious medicines were sold to patients of COVID-19 consequently affecting their recovery;

(c) if so, whether the Government has prepared any report in this regard;

(d) whether the Government has initiated any action against all those persons pedaling fake and spurious medicines for putting patients' lives at risk; and

(e) if so, the details thereof and the outcome thereof along with other steps taken to stop the use of spurious drugs in the country?

**ANSWER**

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

(a) to (e): Enforcement of the provisions of the Drugs and Cosmetics Act and the Rules made thereunder primarily lies with the State Drug Controllers/State Licensing Authorities. The Central Drugs Standard Control Organisation (CDSCO) has requested all States/UTs Licensing Authorities through several advisories to instruct their enforcement staff to keep strict vigil and to take stringent action against the offenders in cases related to medicines of suspected quality.

As per information available from various State Licensing Authorities, in cases of fake & spurious Covid management drugs, various enforcement actions like Drug seizure, arrests of accused persons / registration of FIR etc. have been carried out by the State Licensing Authorities.

Amidst reports of black-marketing/hoarding/ overcharging of Covid-19 management drugs received, CDSCO has requested all States/UTs Licensing authorities through several advisories to instruct their enforcement staff to keep strict vigil especially at sensitive places and to take stringent action against the offenders by conducting special drive of monitoring and investigation.

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

**LOK SABHA**
**UNSTARRED QUESTION NO. 3363**
**TO BE ANSWERED ON 17th DECEMBER, 2021**

## STORAGE OF VACCINES IN RURAL AREAS

**3363. SHRI TAPIR GAO:**
**SHRI ANIL FIROJIYA:**

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

(a) whether the Government has provided financial and technical assistance to the State/UTs for proper storage of vaccines in rural areas especially in view of the insufficient supply of power;

(b) if so, the details thereof and the assistance provided during the last three years and the current years, State/UT-wise;

(c) whether the Government proposes to encourage the use of solar power operated refrigerators and vaccine coolers for the storage of vaccines in rural areas; and

(d) if so, the details thereof?

**ANSWER**

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

(a) & (b) Government has provided financial and technical assistance to the States and UTs for proper storage of vaccines in the country including rural areas having inadequate power supply.

Under the Universal Immunization Programme (UIP), states/UTs are provided with Ice lined Refrigerators (ILRs), Deep Freezers (DFs), Walk-in-coolers (WIC), Walk-in Freezers (WIF), Solar refrigerators, cold box, vaccine carrier and Ice packs for proper storage and distribution of vaccines. The State/UT wise details of cold chain equipment provided in the last three years and current year are given in Annexure 1a and 1b. The Ice lined Refrigerators (ILRs) storing vaccines are able to maintain the vaccine storage temperature for 24 hrs. with as little as 8 hrs. of intermittent power supplies. Refrigerator Mechanic/ Technicians are provided to State/UTs for maintenance and functioning of these cold chain equipment and they are also provided in service training for repair & maintenance of these equipment. In addition, the States/UTs are also provided financial support for cold chain maintenance. The State/UT wise details of fund provided are given in Annexure 2.

© & (d) Government has already provided 441 solar power operated refrigerators and vaccine coolers for the storage of vaccines to 22 States/UTs across the country. The details are as follows:

Andaman & Nicobar Islands-7, Arunachal Pradesh-80, Assam-62, Bihar-5, Chhatisgarh-21, Himachal Pradesh-5, Jammu and Kashmir-16, Ladakh-5, Jharkhand-6, Karnataka-2, Madhya Pradesh-24, Maharashtra-18, Manipur-30, Meghalaya-19, Mizoram-13, Nagaland-26, Odisha-26, Rajasthan-19, Sikkim-10, Tripura-11, Uttar Pradesh-17 and Uttarakhand-19.

**Annexure-1a**

**States/UTs wise details of cold chain equipment supplied during last three years and current year**

| S. No. | State/ UT | Supplied in 2018-19 | | Supplied in 2019-20 | | Supplied in 2020 – 21 | | | | Supplied in 2021 – 22 (as on 12th December 2021) | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | ILR | DF | ILR | DF | ILR | DF | WIC | WIF | ILR | DF | WIC | WIF | SDD |
| 1 | Andaman & Nicobar Islands | 0 | 0 | 0 | 0 | 13 | 5 | 0 | 0 | 3 | 4 | 0 | 0 | 0 |
| 2 | Andhra Pradesh | 0 | 0 | 0 | 0 | 568 | 71 | 0 | 0 | 158 | 547 | 4 | 1 | 0 |
| 3 | Arunachal Pradesh | 0 | 0 | 0 | 50 | 71 | 25 | 0 | 0 | 49 | 70 | 0 | 0 | 4 |
| 4 | Assam | 0 | 0 | 0 | 0 | 389 | 138 | 0 | 0 | 70 | 268 | 1 | 1 | 4 |
| 5 | Bihar | 0 | 15 | 0 | 0 | 752 | 306 | 1 | 1 | 184 | 606 | 8 | 3 | 0 |
| 6 | Chandigarh | 0 | 0 | 0 | 0 | 19 | 10 | 0 | 1 | 20 | 28 | 0 | 0 | 0 |
| 7 | Chhattisgarh | 30 | 30 | 0 | 0 | 226 | 68 | 0 | 0 | 45 | 174 | 2 | 1 | 0 |
| 8 | Dadra & Nagar | 0 | 0 | 0 | 0 | 53 | 12 | 0 | 0 | 2 | 10 | 0 | 0 | 0 |
| 9 | Daman & Diu | 0 | 0 | 0 | 0 | 10 | 2 | 0 | 0 | 1 | 3 | 0 | 0 | 0 |
| 10 | Delhi | 75 | 68 | 0 | 0 | 263 | 86 | 0 | 1 | 17 | 203 | 1 | 0 | 0 |
| 11 | Goa | 0 | 0 | 5 | 10 | 10 | 2 | 0 | 0 | 17 | 2 | 0 | 0 | 0 |
| 12 | Gujarat | 0 | 0 | 0 | 0 | 308 | 30 | 0 | 0 | 50 | 111 | 2 | 1 | 0 |
| 13 | Haryana | 0 | 68 | 5 | 31 | 147 | 94 | 0 | 1 | 76 | 195 | 0 | 0 | 0 |
| 14 | Himachal Pradesh | 0 | 0 | 0 | 0 | 111 | 70 | 3 | 2 | 9 | 3 | 0 | 0 | 1 |
| 15 | Jammu & Kashmir | 0 | 0 | 0 | 0 | 214 | 108 | 1 | 1 | 186 | 203 | 0 | 1 | 5 |
| 16 | Jharkhand | 0 | 0 | 0 | 0 | 130 | 27 | 0 | 0 | 28 | 54 | 4 | 2 | 0 |
| 17 | Karnataka | 0 | 0 | 50 | 0 | 930 | 125 | 0 | 0 | 158 | 1072 | 2 | 2 | 0 |
| 18 | Kerala | 0 | 0 | 0 | 0 | 232 | 27 | 0 | 0 | 70 | 204 | 2 | 1 | 0 |
| 19 | Ladakh | 0 | 0 | 0 | 0 | 29 | 10 | 0 | 0 | 56 | 43 | 0 | 0 | 0 |
| 20 | Lakshadweep | 0 | 0 | 0 | 0 | 16 | 12 | 0 | 0 | 0 | 1 | 0 | 0 | 0 |
| 21 | Madhya Pradesh | 0 | 60 | 0 | 18 | 436 | 131 | 0 | 0 | 14 | 202 | 3 | 5 | 0 |
| 22 | Maharashtra | 0 | 0 | 95 | 40 | 687 | 146 | 0 | 0 | 299 | 561 | 9 | 2 | 0 |
| 23 | Manipur | 0 | 0 | 0 | 0 | 40 | 12 | 0 | 0 | 0 | 18 | 0 | 0 | 3 |
| 24 | Meghalaya | 21 | 4 | 0 | 0 | 140 | 10 | 0 | 0 | 0 | 40 | 0 | 0 | 3 |
| 25 | Mizoram | 0 | 0 | 0 | 0 | 41 | 42 | 0 | 0 | 35 | 35 | 0 | 0 | 3 |
| 26 | Nagaland | 0 | 0 | 0 | 0 | 54 | 16 | 0 | 0 | 20 | 37 | 0 | 0 | 3 |
| 27 | Odisha | 0 | 20 | 0 | 0 | 380 | 41 | 0 | 0 | 10 | 147 | 6 | 2 | 0 |
| 28 | Puducherry | 0 | 0 | 0 | 0 | 23 | 4 | 0 | 0 | 40 | 21 | 0 | 0 | 0 |
| 29 | Punjab | 0 | 0 | 0 | 0 | 193 | 136 | 0 | 0 | 154 | 87 | 1 | 0 | 0 |
| 30 | Rajasthan | 0 | 0 | 101 | 0 | 616 | 180 | 0 | 0 | 42 | 254 | 5 | 2 | 0 |
| 31 | Sikkim | 0 | 0 | 0 | 0 | 15 | 21 | 0 | 0 | 30 | 16 | 0 | 0 | 0 |
| 32 | Tamil Nadu | 0 | 0 | 0 | 0 | 764 | 210 | 3 | 2 | 78 | 396 | 0 | 1 | 0 |
| 33 | Telangana | 0 | 0 | 0 | 0 | 498 | 163 | 0 | 0 | 13 | 1010 | 3 | 2 | 0 |
| 34 | Tripura | 0 | 0 | 0 | 0 | 143 | 16 | 0 | 0 | 10 | 25 | 0 | 0 | 1 |
| 35 | Uttar Pradesh | 0 | 0 | 0 | 0 | 938 | 1040 | 0 | 0 | 689 | 905 | 8 | 3 | 0 |
| 36 | Uttarakhand | 0 | 0 | 0 | 0 | 352 | 133 | 1 | 0 | 290 | 320 | 2 | 1 | 3 |
| 37 | West Bengal | 0 | 0 | 27 | 38 | 534 | 57 | 0 | 0 | 174 | 351 | 7 | 1 | 0 |
| **Total** | | **126** | **265** | **283** | **187** | **10345** | **3586** | **9** | **9** | **3097** | **8226** | **70** | **32** | **30** |

**ILR-Ice Lined Refrigerators, DF-Deep Freezers, WIC-Walk-in-Coolers, WIF-Walk-in-Freezers, SDD- Solar Direct Drive equipment**

**Annexure 1b**

## State/UT wise Details of available Cold Chain Equipment as on 12-12-2021

| | | ILR | DF | WIC | WIF | SDD |
|---|---|---|---|---|---|---|
| 1 | Andaman & Nicobar Islands | 69 | 65 | 1 | 0 | 7 |
| 2 | Andhra Pradesh | 3016 | 2700 | 7 | 1 | 0 |
| 3 | Arunachal Pradesh | 372 | 322 | 2 | 0 | 80 |
| 4 | Assam | 1581 | 1394 | 6 | 2 | 62 |
| 5 | Bihar | 2507 | 1812 | 28 | 8 | 5 |
| 6 | Chandigarh | 107 | 94 | 1 | 1 | 0 |
| 7 | Chhattisgarh | 1114 | 1171 | 7 | 3 | 21 |
| 8 | Dadara & Nagar Haveli | 83 | 52 | 0 | 0 | 0 |
| 9 | Daman & Diu | 37 | 20 | 0 | 0 | 0 |
| 10 | Delhi | 1076 | 752 | 2 | 1 | 0 |
| 11 | Goa | 103 | 64 | 1 | 0 | 0 |
| 12 | Gujarat | 2880 | 2503 | 12 | 3 | 0 |
| 13 | Haryana | 1235 | 1123 | 7 | 3 | 0 |
| 14 | Himachal Pradesh | 685 | 651 | 8 | 3 | 5 |
| 15 | Jammu and kashmir | 1353 | 1087 | 5 | 3 | 16 |
| 16 | Jharkhand | 824 | 759 | 9 | 5 | 5 |
| 17 | Karnataka | 4671 | 4497 | 11 | 6 | 6 |
| 18 | Kerala | 2389 | 2044 | 8 | 2 | 2 |
| 19 | Ladakh | 130 | 90 | 0 | 0 | 0 |
| 20 | Lakshadweep | 42 | 28 | 0 | 0 | 0 |
| 21 | Madhya Pradesh | 2300 | 2171 | 15 | 10 | 24 |
| 22 | Maharashtra | 5164 | 4746 | 24 | 6 | 18 |
| 23 | Manipur | 145 | 130 | 2 | 0 | 30 |
| 24 | Meghalaya | 328 | 264 | 3 | 0 | 19 |
| 25 | Mizoram | 196 | 192 | 1 | 0 | 13 |
| 26 | Nagaland | 188 | 172 | 1 | 0 | 26 |
| 27 | Odisha | 2125 | 1865 | 18 | 4 | 26 |
| 28 | Puducherry | 140 | 100 | 0 | 0 | 0 |
| 29 | Punjab | 1471 | 1258 | 6 | 2 | 0 |
| 30 | Rajasthan | 3774 | 3583 | 20 | 6 | 19 |
| 31 | Sikkim | 137 | 121 | 0 | 0 | 10 |
| 32 | Tamil Nadu | 3577 | 3249 | 21 | 6 | 0 |
| 33 | Telangana | 1699 | 2306 | 7 | 3 | 0 |
| 34 | Tripura | 332 | 251 | 2 | 1 | 11 |
| 35 | Uttar Pradesh | 5038 | 5860 | 32 | 11 | 17 |
| 36 | Uttarakhand | 1335 | 1058 | 8 | 2 | 19 |
| 37 | West Bengal | 3204 | 2294 | 25 | 5 | 0 |
| Total | | 55427 | 50848 | 300 | 97 | 441 |

ILR-Ice Lined Refrigerators, DF-Deep Freezers, WIC-Walk-in-Coolers, WIF-Walk-in-Freezers, SDD- Sola
Direct Drive equipment

**Annexure 2**

**State/UT wise details of Cold Chain maintenance funds alllocated during last three years and current year (in lakh)**

| S.N. | States | 2018-19 | 2019-20 | 2020-2021 | 2021-22 |
|---|---|---|---|---|---|
| 1 | Andhra Pradesh | 12.82 | 15.95 | 20.2 | 21.93 |
| 2 | Andaman & Nicobar Islands | 1.00 | 0.92 | 1.00 | 1.00 |
| 3 | Arunachal Pradesh | 6.08 | 8.87 | 7.57 | 6.75 |
| 4 | Assam | 11.12 | 17.52 | 17.52 | 17.52 |
| 5 | Bihar | 35.86 | 19.3 | 19.3 | 52.85 |
| 6 | Chandigarh | 1.6 | 2.00 | 1.24 | 1.24 |
| 7 | Chhattisgarh | 14.6 | 14.27 | 13.6 | 14.4 |
| 8 | Dadra & Nagar Haveli | 0.5 | 0.5 | 0.00 | 0.00 |
| 9 | Daman & Diu | 0.00 | 0.00 | 0.00 | 0.00 |
| 10 | Delhi | 8.94 | 8.94 | 7.5 | 8.3 |
| 11 | Goa | 0.6 | 0.6 | 0.6 | 0.6 |
| 12 | Gujarat | 19.34 | 26.55 | 35.07 | 37.33 |
| 13 | Haryana | 8.66 | 14.03 | 18.46 | 14.33 |
| 14 | Himachal Pradesh | 2.04 | 7.34 | 0.00 | 0.00 |
| 15 | Jammu & Kashmir | 12 | 12.71 | 15.07 | 11.5 |
| 16 | Ladakh | - | - | 1.31 | 1.31 |
| 16 | Jharkhand | 8.24 | 8.92 | 8.03 | 10.03 |
| 17 | Karnataka | 23.9 | 25.28 | 25.28 | 38.39 |
| 18 | Kerala | 8.4 | 11.5 | 11.11 | 14.97 |
| 19 | Lakshadweep | 0.3 | 0.3 | 0.3 | 0.3 |
| 20 | Madhya Pradesh | 20.56 | 29.75 | 31.74 | 31.75 |
| 21 | Maharashtra | 44.26 | 47.5 | 46.9 | 35.08 |
| 22 | Manipur | 2.11 | 5.00 | 5.5 | 5.5 |
| 23 | Meghalaya | 3.61 | 4.54 | 4.54 | 4.49 |
| 24 | Mizoram | 1.7 | 0.5 | 3.05 | 3.07 |
| 25 | Nagaland | 2.84 | 4.12 | 4.1 | 4.1 |
| 26 | Odisa | 28.14 | 28.14 | 28.14 | 93.97 |
| 27 | Puducherry | 1.00 | 1.00 | 1.00 | 1.00 |
| 28 | Punjab | 20.89 | 20.89 | 13.99 | 13.98 |
| 29 | Rajasthan | 20.4 | 34.05 | 35.18 | 35.89 |
| 30 | Sikkim | 1.00 | 1.65 | 2.00 | 1.66 |
| 31 | Tamil Nadu | 20.42 | 25.51 | 32.6 | 40.54 |
| 32 | Telangana | 7.99 | 9.02 | 10.00 | 10.00 |
| 33 | Tripura | 3.39 | 3.3 | 3.46 | 3.34 |
| 34 | Uttar Pradesh | 28.36 | 37.25 | 33.5 | 33.5 |
| 35 | Uttarakhand | 8.13 | 8.13 | 8.13 | 8.16 |
| 36 | West Bengal | * | * | 368.7 | 429.71 |
| **Grand total** | | **390.8** | **455.85** | **835.69** | **1008.49** |

* Budget for Cold Chain Maintenance is provisioned under Bio-Medical Equipment Maintenance Programme (BMMP). For BMMP, it was Rs. 2863.81 Lakh for the year 2018-19 and Rs.2510.52 Lakh for the year 2019-20.

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

**LOK SABHA**
**UNSTARRED QUESTION NO. 3382**
**TO BE ANSWERED ON 17th DECEMBER, 2021**

## BANNING OF DICLOFENAC FOR VETS

**3382: DR. ARVIND KUMAR SHARMA:**
**SHRI SHANKAR LALWANI:**
**DR. BHARATIBEN DHIRUBHAI SHIYAL:**
**SHRI VISHNU DATT SHARMA:**

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

(a) whether the Government has banned or is taking steps to ban Diclofenac for vets as it has been cited as the cause for depletion of vulture population;

(b) if so, the details thereof; and

(c) if not, the reasons therefor?

**ANSWER**

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

(a) to (c): Central Government has already prohibited the manufacture, sale and distribution of diclofenac and its formulations for animal use as per the Gazette notification vide GSR No. 499 (E) dated 4th July, 2008.

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

**LOK SABHA**
**UNSTARRED QUESTION NO. 3447**
**TO BE ANSWERED ON 17th DECEMBER, 2021**

## HIGH COST OF DRUGS FOR THE TREATMENT OF SPINAL MUSCULAR ATROPHY

**3447. SHRI FEROZE VARUN GANDHI: SHRI HANUMAN BENIWAL:**

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

(a) the total number of reported cases of spinal muscular atrophy in the country, State/UT-wise;

(b) whether the Government is aware of the high cost of drugs for the treatment of spinal muscular atrophy particularly the injections used in its treatment and if so, the details thereof;

(c) the customs duty, GST and other taxes levied on such drugs;

(d) whether the Government has taken any steps to control the prices of SMA drugs, and if so, the details thereof; and

(e) if not, whether the Government proposes to undertake such steps to make the medicine/injection more affordable or proposes to bear the high expenditure on medicine/injection for treatment of patients including children?

**ANSWER**

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

(a) ICMR has initiated a National Registry wherein epidemiological data is collected for Rare diseases and other inherited disorders. Data of a total of 4001 rare disease cases (storage disorders, small molecular inborn errors of metabolism, primary immune deficiency disorders, skeletal dysplasia, neuromuscular disorders, haemoglobinopathies and bleeding disorders) have been collected till 31st October, 2021. The number of patients of Spinal Muscular Atrophy enrolled in the registry portal is 295. Information specific to each State/UT is not maintained centrally.

(b) & (c) As informed by the Department of Revenue, Ministry of Finance, for general imports, medicines used in the treatment of Spinal Muscular Atrophy attract Basic Custom Duty of 10% and IGST of 12%. However, individuals are allowed to import medicine for Spinal Muscular Atrophy without payment of Customs Duty and IGST (Nil Custom Duty and Nil IGST) if the following conditions are satisfied:

(I) the goods are imported by an individual for personal use;

(ii) it is certified in the Form as applicable, by the Director General or Deputy Director General or Assistant Director General, Health Services, New Delhi, Director of Health Services of the State Government or the District Medical Officer/Civil Surgeon of the district, in each individual case

(iii) the importer produces the said certificate to the Deputy Commissioner of Customs or the Assistant Commissioner of Customs, as the case may be, at the time of clearance or gives an undertaking to furnish the said certificate.

(d) &(e) In order to help the patients in terms of affordable medicines, Department of Pharmaceuticals has initiated the implementation of Production Linked Incentive Scheme for Pharmaceuticals. The Scheme provides for financial incentives to manufactures selected under the Scheme for domestic manufacturing of various product categories, which also include Orphan drugs. The Guidelines for the Scheme are available on the website of the Department of Pharmaceuticals under the tab 'Schemes'.

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

**RAJYA SABHA**
**UNSTARRED QUESTION NO. 1866**
**TO BE ANSWERED ON 14TH DECEMBER, 2021**

**NEW LEGISLATION FOR REGULATION OF MEDICINES, COSMETICS, E-PHARMACY AND MEDICAL DEVICES**

**1866: SHRI SANJAY RAUT:**

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

(a) whether it is a fact that the Ministry is seriously thinking of bringing new legislation to regulate medicines, cosmetics, e-pharmacy and medical devices;

(b) if so, the details thereof and shortcomings identified in the existing legislation;

(c) whether Government is also considering to curtail import dependency of medicines and devices in the country; and

(d) if so, the details thereof?

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

(a) to (d): The Ministry has constituted a committee for drafting "Drugs, Cosmetics & Medical Device Bill". The Department of Pharmaceuticals has launched three schemes for promoting domestic manufacturing of pharmaceutical drugs including Active Pharmaceuticals Ingredients (APIs) by attracting large investments in the sector to ensure their sustainable domestic supply and thereby reduce Indian's import dependence on other countries.

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

**RAJYA SABHA**
**STARRED QUESTION NO.21**
**TO BE ANSWERED ON THE 30TH NOVEMBER, 2021**

## IMPORT OF MEDICAL DEVICES, SURGICAL SUPPLIES AND EQUIPMENTS

**21 SHRI SANJAY SETH:**

Will the Minister of Health and Family Welfare be pleased to state:

(a) whether it is a fact that 70 per cent of the demand of medical devices, surgical supplies and equipments are imported from abroad;

(b) if so, the details of items imported during the last two years;

(c) whether Government is planning to set up Medical Device Park in the States especially in Uttar Pradesh; and

(d) if so, the details thereof?

**ANSWER**
**THE MINISTER OF HEALTH AND FAMILY WELFARE**
**(SHRI MANSUKH MANDAVIYA)**

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

**STATEMENT REFERRED TO IN REPLY TO RAJYA SABHA**
**STARRED QUESTION NO. 21* FOR 30TH NOVEMBER, 2021**

(a) & (b) Based on the information provided by Department of Pharmaceuticals, the status of medical devices forming the top 5 categories of the total imports is as below:

| S. NO. | Segment | Imports F.Y. 2019-20 | Imports F.Y. 2020-21 | % share F.Y. 2019-20 | % share F.Y. 2020-21 |
|---|---|---|---|---|---|
| 1 | Electronics Equipment | 3646.53 | 3568.64 | 62.38 | 57.18 |
| 2 | Surgical Instruments | 180.10 | 103.62 | 3.08 | 1.66 |
| 3 | Consumables & Disposables | 1076.23 | 1470.77 | 18.41 | 23.57 |
| 4 | IVD Reagent | 527.20 | 871.89 | 9.02 | 13.97 |
| 5 | Implants | 415.35 | 225.63 | 7.11 | 3.62 |
| | **TOTAL** | **5845.41** | **6240.55** | | |

© & (d) Department of Pharmaceuticals in the Ministry of Chemicals & Fertilizers, vide letter dated 24.09.2021, has given in-principle approval for providing financial assistance for creation of common infrastructure facilities in the medical device park to be developed by State Government of Uttar Pradesh under the scheme "Promotion of Medical Devices Parks".

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

**RAJYA SABHA**
**UNSTARRED QUESTION NO. 2678**
**TO BE ANSWERED ON 21st DECEMBER, 2021**

## NON-AVAILABILITY OF DIAGNOSIS AND MEDICINES FOR TREATMENT

**2678 SHRI K.R.N. RAJESHKUMAR:**

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

(a) whether Government has taken cognizance that necessary facilities for diagnosis and medicines for treatment are not adequately available during the outbreak of seasonal diseases;

(b if so, the reaction of Government thereto;

(c) whether such kind of incidents are often seen in the rural and semi-urban areas in the country and, if so, the reasons therefor; and

(d) the steps taken by Government to make available adequate stock of necessary drugs for treatment of seasonal diseases in all the health centres or civil hospitals of the country so that no death takes place due to non-availability of drugs?

**ANSWER**

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

(a) to (d):
Public Health & Hospital is a State/UT subject, the State/UT Governments are to take prompt measures for prevention and containment of outbreaks due to seasonal diseases including necessary facilities for diagnosis and medicines for treatment of the patients.

Diseases such as acute diarrheal diseases, chicken-pox, dengue, diphtheria, malaria, measles, mumps, Hepatitis A & E, Rubella, Chikungunya, seasonal influenza, enteric fever, etc. have exhibited higher incidence with seasonal variations. Depending on seasonality, required technical support such as treatment protocols and advisories are provided to the States/UTs by Government of India for effective management of diseases.

The Government of India provides financial and technical support under the National Health Mission to the States / UTs for strengthening their healthcare delivery system including support for provision of essential diagnostic & drugs free of cost to those who access public health facilities. This support under NHM includes provision of a host of free services related to maternal health, child health, adolescent health, family planning, universal immunization programme and for major diseases such as Tuberculosis, HIV/ AIDS, vector borne diseases like Malaria, Dengue and Kala Azar, Leprosy etc.

**Free Diagnostics Service Initiative (FDSI)**: The initiative is intended to provide a set of essential diagnostics at various levels of care so that providers can make rational decisions regarding treatment and patients can benefit by getting their prescribed investigations/ tests conducted within the facility free of cost. The government envisages that this health intervention will reduce both direct costs and out-of-pocket expenditure and provision of accessible diagnostics in all public health facilities. The three components under FDSI are permitted such as Free Pathology/Laboratory services; Free Tele-radiology services and Free CT scan services at District Hospital.

**Free Drugs Service Initiative (FDSI)**: Financial support is provided to the States / UTs for provision of free essential medicines in public health facilities based on the requirements posted by them in their Programme Implementation Plans (PIPs) within their overall Resource Envelope. All the States/UTs have reported that they have notified free drug policy in their respective States/UTs. The number of essential medicines to be provided free of cost are decided by the States/UTs and varies from State to State. However, the Ministry has provided illustrative list of essential medicines that should be provided at Sub Centres, Primary Health Centres, Community Health Centres and District Hospitals.

**GOVERNMENT OF INDIA**
**MINISTRY OF CHEMICALS AND FERTILIZERS**
**DEPARTMENT OF PHARMACEUTICALS**

**RAJYA SABHA**
**UNSTARRED QUESTION No. 2575**
**TO BE ANSWERED ON THE 21st December, 2021**

**Government assistance to foreign pharma companies**

**2575 Dr. Fauzia Khan:**

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

(a) whether foreign pharma industry has approached Government of India to help and assist the foreign pharmaceutical industry;

(b) if so, whether Government has considered various issues raised by such foreign pharma industry; and

(c) if so, the details thereof and the reaction of Government thereto?

**ANSWER**

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

(a) to (c): The department receives representations at times from multinational pharmaceutical companies for facilitation of their issues with the concerned regulators and also with respect to their taxation issues.

After examination, the representations are taken up with the concerned departments for consideration at their end.

**GOVERNMENT OF INDIA**
**MINISTRY OF CHEMICALS & FERTILIZERS**
**DEPARTMENT OF PHARMACEUTICALS**

**RAJYA SABHA**
**STARRED QUESTION NO. *246**
**TO BE ANSWERED ON 21st December, 2021**

**Selling medicines at higher prices**

**246 Shri K.R.N. Rajeshkumar:**

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

(a) whether Government has any information regarding the pharma companies which are selling medicines at prices higher than the price capped by National Pharmaceutical Pricing Authority(NPPA);

(b) if so, the detailed list thereof, State- wise;

(c) whether any action has been taken or notices been issued, so far, by NPPA to such companies; and

(d) if so, the details and the outcome thereof?

**ANSWER**

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

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

**Statement referred to in reply to Rajya Sabha Starred Question No. *246 for answer on 21.12.2021 by Shri K.R.N. Rajeshkumar regarding 'Selling medicines at higher prices'**

(a): National Pharmaceutical Pricing Authority (NPPA) under the Department of Pharmaceuticals (DoP) monitors the prices of both scheduled and non-scheduled formulations on regular basis as per provisions of the Drugs (Prices Control) Orders (DPCOs) to check overcharging by the pharmaceutical companies. Whenever companies are found to be overcharging the consumers in sale of medicine, NPPA issues notices to the companies to deposit the overcharged amount along with applicable interest and penalty, wherever applicable.

(b): The detailed list of overcharging cases where demand notices have been issued is available on NPPA's website www.nppaindia.nic.in.

(c) & (d): Up to 31st March, 2021, NPPA has issued about 2,128 demand notices (1345 cases under the DPCO, 1995 and 783 cases under DPCO, 2013) to pharmaceutical companies for their having overcharged consumers on the sale of formulations/medicines at prices above the ceiling/retail price notified by NPPA. The action for recovery of the overcharged amount is a continuous and on-going process, undertaken as per extant provisions of various DPCOs issued from time to time. The total demanded amount by NPPA works out to be about Rs. 9407.36 crore, out of which an amount of about Rs. 1308.58 crore has been deposited by the companies to the Government. In respect of 334 cases, the demands raised for overcharging amounting to Rs. 6,612.10 crore have been challenged in various courts.

**GOVERNMENT OF INDIA**
**MINISTRY OF CHEMICALS AND FERTILIZERS**
**DEPARTMENT OF PHARMACEUTICALS**

**RAJYA SABHA**
**UNSTARRED QUESTION No. 184**
**TO BE ANSWERED ON THE 30th November, 2021**

**Production of generic medicines by pharma companies**

**184 Shri Syed Zafar Islam:**

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

(a) whether Government has given any instructions to large pharma companies regarding compulsory production of generic medicines on a large scale in the country, including Uttar Pradesh;

(b) if so, the details thereof;

© if not, the reasons therefor; and (d) the details regarding the guidelines and its repercussions so far?

**ANSWER**

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

a): No, Sir. Government has not issued any instructions to large pharma companies regarding compulsory production of generic medicines on a large scale in the country.

(b): In view of reply to (a) above, does not arise.

(c): A predominant share of Medicines sold in India are off-patent (patent expired) and therefore generic medicines only.

(d): There are no guidelines on this subject.

**GOVERNMENT OF INDIA**
**MINISTRY OF CHEMICALS & FERTILIZERS**
**DEPARTMENT OF PHARMACEUTICALS**

**RAJYA SABHA**
**UNSTARRED QUESTION No. 2567**
**TO BE ANSWERED ON THE 21st DECEMBER, 2021**

**Efforts to boost manufacturing capacity in pharmaceutical sector**

**2567 # Smt. Geeta alias Chandraprabha:**

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

(a) the details of work done to boost India's manufacturing capacity in the pharmaceutical sector; and

(b) the number of manufacturers who have benefitted under the Production Linked Incentive Scheme in the pharmaceutical sector, the details thereof?

**ANSWER**

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

(a): With a view to attain self-reliance and reduce import dependence in critical APIs, a scheme called "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" was approved by the Government. The total outlay of the scheme is Rs.6,940 crore and financial incentive under the scheme is provided to the selected participants on incremental sales of 41 identified products in four different Target Segments for a period of six years.

Another Scheme called "Production Linked Incentive Scheme for Pharmaceuticals" was approved by the Government of India in March, 2021 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 total outlay of the scheme is Rs. 15,000 crore and financial incentives is provided to the selected participants on incremental sales for a period of six years.

(b): Under the PLI Scheme for Bulk Drugs, 50 applicants have been approved. Whereas under the PLI Scheme for Pharmaceuticals, 55 applicants have been approved. The details of approved applicants under both the Schemes are available at the website of the Department, viz., pharmaceuticals.gov.in.

**GOVERNMENT OF INDIA**
**MINISTRY OF CHEMICALS & FERTILIZERS**
**DEPARTMENT OF PHARMACEUTICALS**

**LOK SABHA**
**UNSTARRED QUESTION No. 1128**
**TO BE ANSWERED ON THE 3rd December, 2021**

**Imports of Raw Materials of Drugs**

**1128. SHRI PARVESH SAHIB SINGH VERMA:**

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

(a) whether India is dependent on import of many key Chinese raw materials or intermediates and active pharmaceutical ingredients of various essential drugs;

(b) if so, the details of such materials imported during the last three years;

(c) the reasons for the dependence on China for API imports;

(d) the schemes in place to reduce these imports and empower local producers; and

(e) whether India is also completely dependent on Chinese import of any specific drugs and if so, the details thereof?

**ANSWER**

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

(a) & (b): Many raw materials are imported from China for manufacturing of medicines. The details of imports of raw materials for the last three years is shown in the table below:

| Year | Total value of import | Value of imports from China | Percentage import from China |
|---|---|---|---|
| 2018-19 | 24850.07 Cr | 16777.43 Cr | 67.5% |
| 2019-20 | 24171.78 Cr | 16443.10 Cr | 68.02% |
| 2020-21 | 28528.97 Cr | 19402.60 Cr | 68.01% |

Source: DGCIS, Ministry of Commerce and Industry.

(c): Most of the imports of the Bulk Drug/APIs being done in the country are because of economic considerations.

(d): The Department of Pharmaceuticals has launched following three schemes for promoting domestic manufacturing of Pharmaceutical drugs including APIs by attracting large investments in the sector to ensure their sustainable domestic supply and thereby reduce India's import dependence on other countries:-

**(I) Production Linked Incentive (PLI) Scheme for promotion of domestic manufacturing of critical Key Starting Materials (KSMs)/ Drug Intermediates (DIs) and Active Pharmaceutical Ingredients (APIs) In India:** The scheme provides for financial incentives will be provided to manufacturers selected under the scheme for manufacturing of 41 Key Starting Materials (KSMs)/ Drug Intermediates (DIs) and Active Pharmaceutical Ingredients (APIs).The scheme provides for incentives on incremental sales to selected participants for a period of 6 years. The total financial outlay of the scheme is Rs. 6,940 crore and the tenure of the scheme is from FY 2020-2021 to 2029-30.

**(II) Scheme for Promotion of Bulk Drug Parks:** This scheme provides for grant-in-aid to 3 Bulk Drug Parks for creation of Common Infrastructure Facilities (CIF) with a maximum limit of Rs.1000 crore per park 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) financial assistance would be 90% of the project cost. The total financial outlay of the Scheme is Rs. 3000 crore and the tenure of the Scheme is from FY 2020-21 to 2024-25.

**(III) Production Linked Incentive Scheme for Pharmaceuticals:** The objective of the scheme is 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. One of the further objectives of the scheme is to create global champions out of India who have the potential to grow in size and scale using cutting edge technology and thereby penetrate the global value chains. Under this scheme, financial incentives will be provided to participants selected under the scheme for their incremental sales of eligible drugs manufactured in India. Eligible drugs under the scheme include Active Pharmaceutical Ingredients among other categories of pharmaceutical products. The scheme provides for incentives on incremental sales to selected participants for a period of 6 years. The total financial outlay of the scheme is Rs. 15,000 crore and the tenure of the scheme is from FY 2020-2021 to 2028-29.

(e): The Indian pharmaceutical industry is the world's 3rd largest by volume, providing 20-22 per cent of generic drugs globally and is one of the biggest supplier of low cost vaccines. In 2020-21, imports of medicines worth Rs. 49,436 crores against export of Rs. 1,80,551 crores indicate the strong capacity of domestic manufacturing. As per the data available from port offices of CDSCO, the imports from China include Antibiotics, Vitamins, Hormones, Antiviral, Anti-TB, Anticonvulsant, Analgesic, Antipyretic, Antidiabetic, Cardiovascular etc.

**GOVERNMENT OF INDIA**
**MINISTRY OF CHEMICALS & FERTILIZERS**
**DEPARTMENT OF PHARMACEUTICALS**

**LOK SABHA**
**UNSTARRED QUESTION NO. 3226**
**TO BE ANSWERED ON 17th DECEMBER, 2021**

## National Digital Drugs Databank

**3226. SHRI D.K. SURESH:**
**SHRIMATI SUMALATHA AMBAREESH:**

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

(a) whether the Competition Commission of India in a recent report has recommended for the creation of a National Digital Drugs Databank to ensure strict enforcement of drug quality standards and boost price competition among generic drugs in India;

(b) if so, the details thereof, whether the Government has taken any steps/proposes to take steps to create the said databank; and

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

**ANSWER**

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

(a) to (c): Competition Commission of India has released a report titled "Market Study on the Pharmaceutical Sector in India: Key Findings and Observations", wherein it has been recommended to create a National Digital Drugs Databank consolidating real-time data on active pharmaceutical manufacturing companies in the country, therapeutic class wise/ formulation-wise approved branded/unbranded products etc.

Drug and Cosmetics Rules, 1945, implemented by the Ministry of Health & Family Welfare, have already been amended in the year 2019 making it mandatory for manufacturing licensees to register with portal SUGAM operated by the Central Drugs Standard Control Organisation (CDSCO) and upload information pertaining to the licences granted for manufacture for sale or distribution of drugs.

National Pharmaceutical Pricing Authority (NPPA) under the Department of Pharmaceutics, in collaboration with the National Informatics Centre (NIC), has set up a Pharma Data Bank (PDB) through an Integrated Pharmaceutical Database Management System (IPDMS). This comprehensive online system provides a platform to the pharmaceutical manufacturer/ marketing/ importer/ distributor companies to file mandatory returns prescribed under the Drugs (Prices Control) Order, 2013 (DPCO, 2013). The application for price approval of 'new drug' in Form–I of DPCO, 2013 can also be filed through this portal. The portal provides industry with a user-friendly mechanism to comply with the mandatory requirement of filing returns and also help NPPA to monitor price compliance. As on 30th November, 2021, about 975 pharma companies have registered themselves under IPDMS and have registered 86,822 products.

**GOVERNMENT OF INDIA**
**MINISTRY OF CHEMICALS & FERTILIZERS**
**DEPARTMENT OF PHARMACEUTICALS**

**LOK SABHA**
**UNSTARRED QUESTION No. 3236**
**TO BE ANSWERED ON THE 17th December, 2021**

## Promotion and Expansion of Pharma and Medical Devices Industry

**†3236. SHRI NARANBHAI KACHHADIYA:**
**SHRI PARBATBHAI SAVABHAI PATEL:**

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

(a) whether there are enormous opportunities for participation in the field of manufacturing of medicine and medical equipments and if so, the details thereof;

(b) the details of expansion of existing pharmaceutical industry undertaken in the country; and

(c) the efforts made/being made by the Government to establish new pharmaceutical industry in the country including Gujarat?

**ANSWER**

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

(a) to (C): Yes, Sir.

India is the third largest player globally in Pharmaceuticals in terms of volume and is the largest supplier of low cost generics and vaccines to the world. The sector has immense growth potential in the sphere of generics, bulk drugs, vaccines and biosimilars. The potential for the Medical Device industry growth is the highest among all the sectors in the healthcare market. Various categories of devices starting from consumables to implantable medical devices are being manufactured in India. The Medical Device industry is highly capital intensive with a long gestation period and requires development/induction of new technologies.

The FDI Policy of India is very liberal for the pharmaceutical and medical device sector. For Pharmaceuticals investment in greenfield sector upto 100% is permitted under automatic route while Investment in brownfield sector upto 74% is permitted under automatic route. For medical device sector, investment is permitted upto 100% under automatic route.

The government is also taking steps in the form of various schemes to attract investments in both the sectors. The following are the details of the schemes:

**(I) Production Linked Incentive (PLI) Scheme for promotion of domestic manufacturing of critical Key Starting Materials (KSMs)/ Drug Intermediates (DIs) and Active Pharmaceutical Ingredients (APIs) In India**: The objective of the Scheme is to attain self-reliance and reduce import dependence in critical Starting Materials (KSMs)/ Drug Intermediates (DIs) and Active Pharmaceutical Ingredients (APIS). The tenure of the sub-scheme is from financial year 2020-21 to 2029-30, with the total financial outlay of Rs.6,940 crore. The Financial incentive under the sub-scheme is provided on sales of 41 identified products categorized into four Target Segments. Under the Scheme, 50 applicants have been approved with committed investment of Rs 4,498.38 crore and employment generation of about 10,743.

**(II) Production Linked Incentive Scheme for Pharmaceuticals:** The scheme provides for financial incentives to manufacturers for drug formulations, bulk drugs and IVDs in three categories. The incentives are to be given on incremental sales to selected participants for a period of 6 years. The total financial outlay of the scheme is Rs. 15,000 crore and the tenure of the schemes from FY 2020-2021 to 2028-29. Fifty-five (55) applicants have been selected under the scheme.

**(III) PLI Scheme for promoting Domestic Manufacturing of Medical Devices:** The Scheme intends to boost domestic manufacturing and attract large investments in the Medical Devices Sector. The financial incentive is to be given to selected companies on incremental sales of medical devices manufactured in India and covered under the Target segments of the scheme, for a period of five (5) years. The tenure of the scheme is from FY 2020-21 to FY 2027-28 with total financial outlay of Rs.3,420 crore. Under the Scheme, 42 applicants have been approved with a total Committed Investment of Rs. 1059.33 Crore and employment generation of about 6,411.

**(IV) Scheme for Promotion of Bulk Drug Parks:** The scheme provides for grant-in-aid to three (03) Bulk Drug Parks for creation of Common Infrastructure Facilities (CIF) with a maximum limit of Rs.1000 crore per park or 70% of the project cost of CIF, whichever is less. In case of North Eastern states and Hilly States (Himachanl Pradesh, Uttarakhand, Union Territory of Jammu & Kashrnir and Union Territory of Ladakh), the maximum limit of financial assistance would be Rs 1000 crore or 90% of the project cost whichever is less than total financial outlay of the Scheme is Rs. 3000 crore and the tenure of the Scheme is from FY 2020-21 to 2024. Proposals from 13 States have been received under the scheme which are under evaluation.

**(V) "Promotion of Medical Devices Parks":** Under this Scheme a onetime grant-in-aid will be provided for creation of common infrastructure facilities in selected Medical Device Park proposed by a State Government. The total financial outlay of the scheme is Rs. 400 crore (Rs. 100 crore for each MD Park). The tenure of the scheme is from FY 2020-2021 to FY 2024- 2025. Under the scheme, proposals seeking financial assistance from 16 States/Union Territories have been received. After evaluation of the proposals, the Government vide letter dated 24.09.2021 has in-principally approved financial assistance for common infrastructure facilities for 4 medical device parks i.e. Himachal Pradesh, Tamil Nadu, Madhya Pradesh and Uttar Pradesh.

**GOVERNMENT OF INDIA**
**MINISTRY OF CHEMICALS & FERTILIZERS**
**DEPARTMENT OF PHARMACEUTICALS**

**LOK SABHA**
**UNSTARRED QUESTION No. 3291**
**TO BE ANSWERED ON THE 17th December, 2021**

## Pharma Parks

**3291. SHRI PASUNOORI DAYAKAR:**
**SHRIMATI KAVITHA MALOTHU:**
**DR. G. RANJITH REDDY:**
**SHRI VENKATESH NETHA BORLAKUNTA:**

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

(a) the status of the proposed pharma parks in the country;

(b) the details of criteria prescribed for awarding pharma park;

(c) whether it is true that some States are opposing this move and, if so, details thereof and the reasons therefor;

(d) whether the Government has not taken into account planning, environmental clearances, availability of ecosystem conducive to API manufacturing, demand from industry, etc., while awarding pharma park to any State and if so, the details thereof; and

(e) the reason for emphasizing only on cost, incentives for awarding pharma park?

**ANSWER**

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

(a) to (e): The scheme "Promotion of Bulk Drug Parks" provides for grant-in-aid support for creation of Common Infrastructure Facilities to 3 bulk drug parks. Under the scheme "Promotion of Bulk Drug Parks", financial assistance would be provided for creation of Common Infrastructure Facilities (CIF) like (i) Central Effluent Treatment Plant(s) (CETP) (ii) Solid waste management (iii) Storm water drains network (iv) Common Solvent Storage System, Solvent recovery and distillation plant (v) Common Warehouse (vi) Dedicated power sub-station and distribution system with the necessary transformers at factory gate (vii) Raw, Potable and Demineralized Water (viii) Steam generation and distribution system (ix) Common cooling system and distribution network (x) Common logistics (xi) Advanced laboratory testing Centre, suitable for even complex testing/ research needs of APIs, including microbiology laboratory and stability chambers (xii) Emergency Response Centre (xiii) Safety/ Hazardous operations audits centre and (xiv) Centre of Excellence etc. The selection criteria is laid down in the detailed guidelines of the scheme, which are available on the website of the Department of Pharmaceuticals i.e. http://pharmaceuticals.gov.in.

Suggestions were received from the Government of Telangana, to consider the factors such as recognizing the readiness of the project including planning, environmental clearances, etc., availability of ecosystem conducive to API manufacturing, demand from industries to set up manufacturing units, setting up of management committee for the parks, consideration of
the already available common scientific infrastructure like testing labs, incubation centres, etc., while forming the guidelines.

Under this scheme, Department of Pharmaceuticals has received proposals from 13 states, including Telangana and the proposals are under evaluation.

Under the scheme, no park is awarded to any state so far. All the 13 States were instructed to furnish additional information to further evaluate their proposals.

**GOVERNMENT OF INDIA**
**MINISTRY OF CHEMICALS AND FERTILIZERS**
**DEPARTMENT OF PHARMACEUTICALS**

**LOK SABHA**
**UNSTARRED QUESTION NO. 3377**
**TO BE ANSWERED ON 17th DECEMBER, 2021**

**Exorbitant Price of Patented Medicines**

**3377. SHRI SHANMUGA SUNDARAM K.:**

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

(a) the details of steps taken by the Government to control the prices of abnormally high priced patented medicines of MNCs in the country;

(b) whether the Government proposes to opt for Negotiated Pricing Model instead of adopting Reference Pricing System; and

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

**ANSWER**

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

(a): National Pharmaceutical Pricing Authority (NPPA) under the Department of Pharmaceuticals fixes the ceiling price of scheduled medicines specified in the National List of Essential Medicines (NLEM) as included in the Schedule- I of the Drugs (Prices Control) Order, 2013 (DPCO, 2013). Any medicine (patented or non-patented) included in Schedule-I of DPCO, 2013 comes under purview of price control. In case of non-scheduled medicines (including non-scheduled patented drugs), increase in Maximum Retail Price (MRP) is limited to 10% of the previous year's price.

However, a manufacturer producing a new drug patented under the Indian Patent Act, 1970 is exempted from provisions of DPCO, 2013 for a period of five years from the date of commencement of its commercial marketing by the manufacturer in the country.

(b) and (c): The prices of drugs are regulated as per provisions of DPCO, 2013, which is based upon the National Pharmaceutical Pricing Policy, 2012 (NPPP, 2012), which follows the principles of essentiality and market-based pricing. Changes, if any, in the method of price regulation of drugs will require a change in the extant pricing policy.

**GOVERNMENT OF INDIA**
**MINISTRY OF CHEMICALS AND FERTILIZERS**
**DEPARTMENT OF PHARMACEUTICALS**

**LOK SABHA**
**UNSTARRED QUESTION No. 3412**
**TO BE ANSWERED ON 17th December, 2021**

**Awareness Compaign for Generic Medicines**

**3412. SHRI ACHYUTANANDA SAMANTA:**

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

(a) the number of Pradhan Mantri Bhartiya Jan Aushadhi Pariyojana (PMBJP) Centres functioning in the country, State-wise;

(b) the details of steps being taken by the Government to ensure that medicines are consistently available at these Centres at reasonable prices, so that patients are not compelled to buy medicines at higher prices; and

© the details of the steps being taken by the Government to enhance awareness regarding the efficacy of generic medicines and build confidence in the same?

**ANSWER**

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

(a): As on 12.12.2021, about 8,578 Pradhan Mantri Bhartiya Janaushadhi Kendras (PMBJKs) are functional under the Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) covering all districts of the country. State/Union Territory-wise list of PMBJKs is enclosed as **Annexure.**

(b): In order to make Janaushadhi medicines more accessible, Information Technology (IT) enabled End-to-End supply chain system with Point-of-Sale (PoS) application for value added services has been implemented under the scheme. The medicines to individual Kendras are supplied through three warehouses at Gurugram, Chennai and Guwahati and 39 distributors appointed across the country.

(c): Pharmaceutical & Medical Devices Bureau of India (PMBI), the implementing agency for the scheme spreads awareness about generic medicines through various types of advertisements such as TV, FM Radio, Auto wrapping, Cinema, Bus Brandings, State Transport Bus Stands, Digital Screen Advertisement at Railway Stations, etc. In addition, PMBI also educates the public regularly about usages of Jan Aushadhi generic medicines through various social media platforms like Facebook, Twitter, Instagram, Youtube, etc. The Bureau also organizes seminars and workshops to spread awareness about the scheme. Further, to propagate achievements of the scheme and create awareness about its benefits Jan Aushadhi Diwas is celebrated every year on 7th March.

**Annexure**

**Statement referred to in part (a) of Lok Sabha Unstarred Question No. 3412 for 17.12.2021 raised by Shri Achyutananda Samanta regarding Awareness Compaign for Generic Medicines**

| State/UT- wise list of PMBJK's functional across the country as on 12.12.2021 | | |
|---|---|---|
| **Sl. No.** | **Name of the State/UT** | **Number of PMBJK** |
| 1 | Andaman & Nicobar | 3 |
| 2 | Andhra Pradesh | 183 |
| 3 | Arunachal Pradesh | 28 |
| 4 | Assam | 87 |
| 5 | Bihar | 272 |
| 6 | Chandigarh | 7 |
| 7 | Chhattisgarh | 241 |
| 8 | Delhi | 375 |
| 9 | Goa | 10 |
| 10 | Gujarat | 551 |
| 11 | Haryana | 234 |
| 12 | Himachal Pradesh | 63 |
| 13 | Jammu And Kashmir | 119 |
| 14 | Jharkhand | 75 |
| 15 | Karnataka | 956 |
| 16 | Kerala | 961 |
| 17 | Ladakh | 2 |
| 18 | Lakshadeep * | 0 |
| 19 | Madhya Pradesh | 240 |
| 20 | Maharashtra | 623 |
| 21 | Manipur | 33 |
| 22 | Meghalaya | 15 |
| 23 | Mizoram | 22 |
| 24 | Nagaland | 16 |
| 25 | Odisha | 345 |
| 26 | Puducherry | 18 |
| 27 | Punjab | 304 |
| 28 | Rajasthan | 137 |
| 29 | Sikkim | 3 |
| 30 | Tamil Nadu | 862 |
| 31 | Telangana | 158 |
| 32 | DNH & D&D | 36 |
| 33 | Tripura | 24 |
| 34 | Uttar Pradesh | 1178 |
| 35 | Uttarakhand | 215 |
| 36 | West Bengal | 182 |
| **Grand Total** | | **8,578** |

* Medicines are directly supplied to the administration of Union Territory of Lakshwadeep

## NEWS

### S V Veerramani Elected Unopposed as Vice-Chairman of Pharmexcil

Former president of the Indian Drug Manufacturers' Association (IDMA) and the CMD of Fourrts (India) Laboratories, S V Veerramani has been elected unopposed as the vice-chairman of the Pharmaceuticals Export Promotion Council of India (Pharmexcil) after being unanimously supported by all members of the director board.

"It is an honour to be elected unopposed as the vice-chairman of the Pharmexcil and I would like to thank all the members of the administrative board for their support. With everybody's support, I hope Pharmexcil can make big strides in the services for Pharma exporters in the years to come," said Veerramani.

Responding to the new assignment given to the veteran Pharma industry leader in Chennai, the principal health secretary to the Government of Tamil Nadu, Dr J Radhakrishnan, has informed Pharmabiz that he feels happy and proud to learn about his new position as vice-chairman of the Pharmexcil. He hopes that Veerramani will bring his rich experience to his new endeavor as vice-chairman for the benefit of the industry.

Mahesh H Doshi, president of the Indian drug manufacturers association has opined that Veerramani will further prove to be a great asset for the industry as well as to the Pharmexcil.

Daara B Patel, secretary general of the IDMA, recollected Veerramani's tenure as president of the IDMA and said he is filled with knowledge, administrative skills and leadership qualities. He expects that Veeramani's management skills and knowledge about the international Pharma market will enable him to lead Pharmexcil to greater heights.

S K Janimiya, chairman of the Telangana state board of the IDMA said Veerramani is the right person to hold the senior post in the pharmaceutical export promotion council. "He has been working for the welfare of the Pharma industry in various positions in different organizations. He knows the requirements of the industry, understands the problems of the entrepreneurs and is always available with everybody for the growth of the industry. The present leadership will give him more confidence to perform much better," he added.

Utpal Moitra, past chairman of the West Bengal state board of the IDMA and director of Emcee Pharmaceuticals Pvt Ltd in Kolkata has commented that Veeramani's new position will help the Indian pharmaceutical industry greatly and the pharmaceutical exporters from West Bengal are proud of him.

Dr Ramanathan, president of the Kerala based Ayurveda Medicine Manufacturers Organisation of India (AMMOI) is expecting more support from Pharmexcil when Veeramani becomes the vice-chairman. He said Pharmexcil can help increase exports of Ayush products from Kerala.

Welcoming the new appointment of Veerramani, the chairman of the Tamil Nadu branch of the IDMA, J Jayaseelan said his new position will be useful for the growth of the MSME companies who are striving for exports. He said Veerramani is always a leader who guides and promotes the small and medium enterprises.

Source: *Pharmabiz,* 30th October 2021

## IPC Adds New Impurities and Reference Standards

The Indian Pharmacopoeia Commission (IPC) has added 23 new impurities standards and 7 new Indian Pharmacopoeial Reference standards.

- Citicoline Impurity B,
- 3-Piperidylpropiophenone HCl,
- Betaxolol Impurity A,
- Bezafibrate Impurity A,
- Bisacodyl Impurity E,
- Carbimazole Impurity A,
- Clobetasol Impurity J,
- Desoxycortone Acetate Impurity,
- Dipivefrine Impurity B,
- 3-Ketofusidic Acid,
- Homatropin Hydrobromide Impurity C,
- Homatropin Impurity B,
- Leflunomide Impurity C,
- Levodropropizine Impurity B,
- Meloxicam Impurity A,
- Methotrexate Impurity C,
- Paroxetine Impurity A,
- Benzyl Penicillin Potassium,
- Repaglinide Impurity A,
- Rivastigmine related compound A,
- Simvastatin Impurity B,
- Thiamine Impurity C,
- Tolbutamide Impurity A.
- Amphotericin B,
- L-Histidine,
- L-Isoleucine,
- L-Phenylalanine,
- L-Leucine,
- Luliconazole
- Citicoline sodium

Impurity standards are used to perform the system suitability, qualitative and quantitative parameters for compliance to Indian Pharmacopoeia monograph.

The commission stated that certain monographs require the use of a chemical reference substance or a biological reference preparation or a reference spectrum.

These are authentic specimens chosen and verified on the basis of their suitability for intended use as prescribed in the pharmacopoeia and are not necessarily suitable in other circumstances.

IP reference substances, abbreviated to IPRS are the official standards issued by the IPC. They are the official standards to be used in cases of arbitration.

The vision of IPC is to promote the highest standards of drugs for use in human and animals within practical limits of the technologies available for manufacture and analysis

IPC is created to set standards of drugs in the country. Its basic function is to update regularly the standards of drugs commonly required for treatment of diseases prevailing in this region.

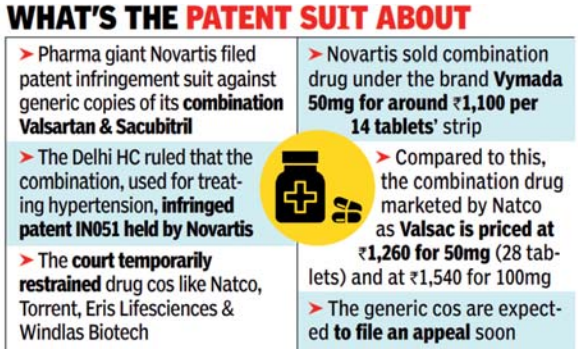
The mandate of the commission is to perform, inter-alia, functions such as revision and publication of the Indian Pharmacopoeia and National Formulary of India on a regular basis besides providing IP reference substances and training to the stakeholders on pharmacopoeial issues.

Source: *The Health Master,* 16th November 2021

## Cheaper Hypertension Drug Blocked

Affordable versions of a hypertensive combination drug, Valsartan, will go off retail shelves soon. The Delhi high court has temporarily restrained drug companies — including Natco Pharma, Torrent Pharma, Eris Lifesciences and Windlas Biotech — from marketing generic copies of the popular combination Valsartan and Sacubitril, responding to a suit filed by the MNC Novartis.

The court ruled that the generic versions infringed the patent held by Novartis (IN051) on the combination of Valsartan and Sacubitril, used for treating hypertension. The product is a 'supramolecular' complex of the two compounds, for which a patent application filed in 2007 is still pending, legal experts told TOI. The generic companies are also selling supramolecular versions of the drug.




A supramolecular complex is a structure where the two entities are arranged and bonded to form a single unit. As against this, in the patented version, the compounds are isolated, as in a physical mixture. The generic companies, including Natco, are expected to file an appeal soon.

The court held that the supramolecular complex is covered by the patent IN051 and is infringing it, the experts added. The order passed by Justice Jayant Nath hence upheld 'prima facie' validity of the patent. “Hence, merely because the plaintiffs have filed an application for registration of a supramolecular complex of the two components of Valsartan and Sacubitril, being application No. 4412, does not modify or change the position vis-a-vis interpretation of claim 1 of the suit patent. Prima facie, there is no merit in the said plea of the defendant,” the order, a copy of which is available with TOI, said.

The combination drug marketed by Natco as Valsac is priced at Rs 1,260 for the 50mg (28 tablets) and at Rs 1,540 for the 100mg, which was launched in 2019. Novartis markets the combination drug under the brand Vymada 50mg for around Rs 1,100 per 14 tablets' strip. When contacted, a company spokesperson said, “Novartis believes strongly in the intellectual property covering all our medicines and will continue to defend our IP rights.” Officials representing the generic

Officials representing the generic companies were not available for comments.

According to the defendant, "The plaintiff, it is stated, has misleadingly and falsely stated that the said supramolecular complex is covered under the suit patent IN051." Further, the plaintiff has deliberately suppressed the fact that the plaintiff has also a supramolecular complex which is covered by the pending patent application. In the said application, it is stated that the plaintiff has taken a stand that the supramolecular complex was invented much after the suit patent and was not known at the time of filing of the suit patent. Further, the defendant has also filed a counter-claim for revocation of the Indian patent IN051, the order said.

Source: *The Times of India,* 4th November 2021

## Pharmexcil to Explore Export Promotion Opportunities for Pharma Exporters by Holding B2B and BSM Meets

As the Covid-19 infections and hospitalisations began to decline globally, the venues for trade fairs and exhibitions have started to reopen. In India, the Pharmaceuticals Export Promotion Council (Pharmexcil), the apex organisation under the aegis of the Ministry of Commerce and Industry to promote exports of pharmaceuticals and neutraceuticals, is pondering over resuming exhibitions, physical B2B and BSM meets between Indian and overseas importers very shortly. Recently, Pharmexcil has elected S V Veeramani, the pharma industry stalwart and former president of Indian Drug Manufacturers' Association (IDMA) as the vice-president of the Council. He speaks to Peethaambaran Kunnathoor about the future plans of Pharmexcil in exploring export promotion opportunities for pharmaceutical exporters of the country. Excerpts.

**What are your plans to generate new export opportunities for small, medium and large scale industry exporters of Pharma in India?**

Pharmexcil has small, medium and large industry exporters as well as merchant exporters. It will be our endeavour to support all the groups for the benefit of the nation and for the exports. We will showcase the large exporters to the international community in order to build our image and performance, and in the same way we will support the small and medium scale shippers and the merchant exporters by organizing seminars, open-house sessions and buyer-seller meets. Pharmexcil will also help them get their incentives and remove all bottlenecks or procedural hurdles. Besides, we will try to arrange international regulators meetings to discuss on regulatory issues and approvals.

**As the vice chairman of the Pharmexcil what steps will you take to speed up reimbursement of product registration fees paid by the exporters?**

The Ministry of Commerce has introduced the export promotion scheme, MAI (Market Access Initiative), to promote the country's exports, and the scheme

reimburses the expenditure incurred by the exporters. It includes product registration cost and the facility inspection fees and BA/BE study expenses. Recently, the government has reduced the period for submission of applications to Pharmexcil from 90 days to 45 days, which is inadequate. So, Pharmexcil plans to put up one strong representation to the government to restore the 90 days.

**It is learnt that there are vacancies of director's in branch offices of Pharmexcil in Chennai, Bengaluru, Mumbai, Delhi and also headquarters office in Hyderabad. Why the Council is not taking any step to fill up them?**

We will be filling up the vacancies of Directors in Mumbai and Delhi branches shortly. As regards Chennai and Bengaluru, they are coordinated by the headquarter office.

**What steps will Pharmexcil take to increase exports of Indian made formulations to regulated markets like European Union?**

Already Pharmexcil is supporting exports of Indian pharmaceuticals to regulated markets by way of discussing with regulators of the US FDA, UK MHRA and others. Recently, the council has taken initiative for stepping up exports to Japan by holding dialogue with Japan's pharmaceuticals and medical devices regulatory agency, PMDA.

**India is manufacturing plenty of vaccines including Covid-19 vaccines, but they are not exported to other countries due to restrictions. Will Pharmexcil take any step for an unrestricted shipment of vaccines from home?**

Due to the huge requirements of vaccines in India, we had to restrict exports of vaccines. But, recently the government has announced that they will resume exports of vaccines. Pharmexcil is following-up on the same.

**Remdesivir injection is also in the restricted list. According to information from reliable sources, there are huge piles of stocks of remdesivir, but cannot be exported. How can Pharmexcil solve this issue?**

There is also a favourable view from the government side to remove restriction on export of remdesivir injection. Some procedural issues are to be sorted out.

**Small exporters want export incentives and subsidies from government to improve their overseas business. Do you have any plan to take their issues with the government?**

Small exporters are already being provided with incentives under MAI scheme and MDA Scheme. We request the government for continuation of CLCS scheme from MSME Ministry for project funding. Besides, we are moving on with the department of pharmaceuticals (DoP) to speed up announcement of PTUAS scheme for funding assistance for technology upgradation to WHO-GMP standards.

**Manufacturers of herbal products and neutraceuticals want to enter into export business. How will Pharmexcil help them?**

Pharmexcil is always supportive towards exports of herbal products and neutraceuticals. We are willing to support them as and when needed.

**Govt has ideas to boost exports of Ayush products. Does Pharmexcil has any plan to support the initiative of the government?**

Yes, Pharmexcil is keen to increase exports of Ayush products. But the Union ministry of Ayush is going ahead with a plan to set up an Ayush Export Promotion Council (AEPC).

**From 2020 onwards, due to Covid pandemic there has been no exhibition or trade show of pharma products and machinery. Delegates from other countries are not physically visiting here and no B2B meet is held. Will Pharmexcil organize such shows and trade fairs in the near future?**

Due to pandemic no physical meeting was possible, accordingly all physical programmes were cancelled. But, Pharmexcil conducted virtual buyer-seller meetings in the month of February 2021 with Latin America and African countries. Indo-CIS BSMs and Indo-ASEAN BSMs, both virtually, were conducted in the month of March 2021. Now that travel restrictions are getting slowly removed, so we are planning to conduct physical buyer-seller meetings.

Source: *Pharmabiz,* 10th November 2021

## Unable to Read Prescriptions by Physicians, Pharmacists Engage In P2P Chats for Grasping Drug Names

Finding that the scribbling of drug names by doctors is incomprehensible most often, the pharmacists in government and private pharmacies are forced to spend time in social media to grasp the medical terms through peer-to-peer (P2P) chats or by telephonic conversations after forwarding the baffling prescriptions to social networking platforms grouping pharmacist community.

The directives of the Union government and of the previous medical council of India are still like 'elephant in the room' as the doctors are unwilling to alter the way they write the prescriptions. Thanks to internet and social media platforms, as the pharmacists get through the testing times with the help of whatsapp chats and abrupt conversations over telephone and perceive what medicine names the doctor has indicated in his prescription pad. Unfortunately, the suffering lot is the poor patients who throng the outpatient wards of the hospitals to get the doctors' instructions are compelled to wait for hours before the pharmacies too.

The doctors' adamant insistence in sticking with their conventional way of prescribing continues uninterrupted despite repeated instructions given by the medical education regulator and various state governments. A study conducted three years ago revealed that about 7,000 people die every year due to the sloppy prescription writing by doctors. Either the pharmacists or doctors of other specialties are unable to read what the particular drug is written by a specialist. Although the pharmacists in India have been making representations to governments and medical council regularly, very few physicians have resorted to a change in their style of writing.

The medical council of India wanted the medical professionals with instructions through concerned authorities to write the drug names in capital letters with preference to their chemical names. But the doctors neither use capital letters nor indicate the generic names. The dispensers in the pharmacies are bewildered to decipher the brand names being written by the physicians. It is alleged that the medical professionals prefer the advice of medical companies to the directions of the government as regards their prescription writing. They want to promote the brands, but the brand names are also not written clearly for the pharmacists to read. As a result, dispensing errors happen occasionally, says K R Dinesh Kumar, a pharmacist and PCI member in Kerala.

Last week, a doctor from a hospital in Madurai in Tamil Nadu gave a prescription of four medicines to his pharmacy for dispensing to his patient. Unable to read the drug names, the pharmacist took the photocopy of the prescription and posted on his whatsapp group for help. The member-pharmacists, in turn, forwarded the same to various other social media sites to become the prescription with illegible hand-writing of the doctor viral among pharmacists. Although, it has passed hundreds of whatsapp groups of community and hospital pharmacists, nobody could comprehend the names fully. Finally a pharmacist from Haryana could make out the names, which were Oleanz 5 mg (for treating schizophrenia), Lotranz 2 mg (for for reducing short term anxiety), Lupirtin P (pain relieving) and Mega-3 capsule (used for heart diseases, brain and kidney diseases).

In the meantime, a prescription written by a physician in Haryana also became viral among all the groups of pharmacists across the country and it was also indecipherable for the pharmacists. With the help of a doctor, a pharmacist from UP could peruse the name of the drug written there. That was Sonaxa NT 20, a drug used to treat depression.

When Pharmabiz discussed the issue with some doctors, many of them expressed different opinions. Dr R M Jayachandran, an ENT specialist in Kerala (General Hospital, Adoor), opined that the doctors should change their attitude and follow the advice of the medical council and the government for the benefit of the poor people in the country. He said he writes only in capital letters.

Source: *Pharmabiz,* 16th November 2021

## Chinese Med Imports Up 75%, Raises Concerns

India's attempt to be self-reliant in healthcare seems to have taken a hard knock, with imports of medtech and medical devices having jumped up to 75% from China alone, ringing alarm bells in industry circles. China, which was earlier in the third spot, has become the largest exporter of medical devices to India, overtaking US and Germany during 2020-21, despite the much-touted 'Make in India' policy and clamour against Chinese imports after the border skirmish.

Most of the increase is attributed to imports of critical items like oximeters, diagnostic instruments, digital thermometers and chemical reagents, which were needed during the pandemic as a quick scale-up

wasn't possible, industry experts said. What makes this starker is that the overall increase in medtech imports from all nations is just about 7%.

"Covid had a silver lining, for bringing into focus the medical devices industry for healthcare security of the nation, even as international supply chains initially got disrupted. The government needed to continue to protect investments in this field, rather than giving mixed signals by reducing duty on Covid-critical devices to zero temporarily, which subsequently led to a huge influx of imports, especially from China from May 2020. We are not against imports. But if these harm the domestic industry, then corrective policies by incentivising homegrown players need to be taken. The huge 75% increased influx of Chinese imports even after having a stated public procurement order that is supposedly in favour of domestic manufacturers should be of concern to policymakers seeking to make India 'Atma Nirbhar," said Association of Indian Medical Device Industry (AiMeD) forum coordinator Rajiv Nath.

Of the 151 eight-digit HS codes that cover med devices, there are 58 items where imports have jumped from more than 25% to over 42,000%, industry data shows. Typically, imports from China had risen 5-15% year-on-year in the last few years. More than 80% of medical devices are imported into India, with this year's import bill at nearly Rs 45,000 crore.

"Imports of medtech devices from China increased sharply during Covid. But except for PPE kits, masks & sanitisers, etc, there was no way to manage critical shortages. Medtech can't be 'Atma Nirbhar' in a few months. We need to build technology, quality, supply chain and it will take a decade to establish it, if there is undisturbed attention and right policy," said Vishwaprasad Alva, MD of critical care and ICU equipment manufacturer Skanray Technologies.

Significantly, the nil customs duty did not benefit consumers and, with no maximum retail price (MRP) printed on devices, there was massive profiteering due to the huge mark-ups. Besides masks & PPE kits, certain devices like ventilators witnessed robust growth due to the sudden and huge demand, with companies also becoming largely self-reliant. Industry observers pointed out that domestic players also need to develop expertise in neonatal & child care, OT & surgical, ICU, radiology & scanning, and cardiac care, with support from the private sector and government.

Max Ventilators founder & CEO Ashok Patel said, "Private sector procurement largely has not been supporting the 'Make in India' programme, with China continuing to be a major supplier. The Centre's bulk purchases have been mainly restricted to respiratory care and oxygen delivery equipment due to the pandemic. Hence, there hasn't been much impetus for players to build capacity/capability in other segments."

"During the pandemic, our local vendors — in a bid to reduce import dependence — developed several key components, as supply from the US and Europe was disrupted. But for imports of circuit boards, we were forced to shift to China this year from the US as distributors promised assured delivery," he added.

Source: *The Times of India,* 26th November 2021

## Central Drugs Standard Control Organisation for Infra Upgrade to Ensure Pandemic Readiness

The Central Drugs Standard Control Organisation (CDSCO) is in the process of finalising its pandemic-readiness report which is expected to be submitted to the Central government in the next 30 days, Dr. S. Eswara Reddy, Joint Drugs Controller, CDSCO, said.

The proposal includes scaling up the laboratory infrastructure and adding staff strength to the organisation. “This is essential to ensure that India is prepared for any more waves and even pandemics/ health emergencies in the future. This pandemic has been taken as a learning curve,” Dr. Reddy said.

Dr. Reddy was interacting with the media at the Central Drugs Laboratory (CDL), Kasauli which has been the centre of India's COVID vaccination campaign, and has tested and cleared for market release over 1,000 batches of COVID vaccines till November 2021

**Avoiding delays**

Speaking about the role of government testing labs, Dr. Reddy said even at the peak of the pandemic, work didn't stop and efforts were put in to ensure that no delay should happen in vaccine delivery while ensuring quality and timely market access to the public.

“We are looking at enhancing our permanent and contractual staff strength and have also singed MoUs with various countries, including Argentina and Brazil, where we are looking at sharing knowledge, best practices and also training. Collaboration is the way forward. This pandemic has taught us that we have to be prepared for any such incidents in the future and even COVID surges. The fight against COVID is a comprehensive one and all entities have to be strengthened to ensure public safety," he said.

Meanwhile, Dr. Arun Bhardwaj, director, CDL, Kasauli, said that till November 23, a total of 1,049 batches of COVID-19 vaccine have been released, comprising approximately 1,521 million vaccine doses.

“Even during the pandemic peaks, the CDL labs, which are comparable to the best in the world, were working to ensure that there is no delay in public access to vaccine,” Dr. Bhardwaj said, adding that the unprecedented pandemic saw several measures put in place to contain the situation.

**Public safety paramount**

“The concept of parallel, fast track testing was used for COVID vaccines and no samples were rejected on account of not meeting quality standards so far. This is also an assurance to the general public that the vaccines available in India are world class and must be taken in full dose. These have been allowed into the market after the strictest quality control. Any vaccine hesitancy on account of quality is totally unfounded,” he said.

COVID vaccines are tested for potency, sterility, biochemical or abnormal toxicity etc before approval is given for release in market for commercial use.

Source: *The Hindu,* 27th November 2021

## Madras HC Directs TN Govt to Amend Recruitment Rules for Pharmacists as per Eligibility Conditions Prescribed By PCI

Based on a counter affidavit filed by the Pharmacy Council of India (PCI), the Madras High Court has directed the Government of Tamil Nadu to amend the recruitment rules for the post of pharmacists in government hospitals as per the eligibility conditions prescribed by the PCI.

The court observed that a registered pharmacist with a degree in pharmacy (B Pharm) is also eligible for the post of pharmacist.

The court has given the government two months time to amend the recruitment rules so as to make B Pharm holders to participate in the written test and interview for selection of pharmacists and wanted the government pleader to submit the amended rules before the court on January 31 2022. The case will be further considered on that day for final verdict, it is learnt.

The court was considering a writ petition filed by a pharmacy graduate from Vellore district against a notification issued by the Tamil Nadu government with respect to recruitment, vacancies and qualification of candidates for pharmacist post in the health department.

The state medical services recruitment board (TNMSRB) had notified vacancies of pharmacists on March 1, 2019 and called for applications from pharmacists with diploma in pharmacy (D Pharm) as basic qualification for filling up the vacant posts. It barred pharmacists with higher qualifications (B Pharm and Pharm D) from participating in the recruitment process.

Against this notification, a pharmacy graduate from Vellore district filed one writ petition in the high court praying for an order declaring the rules related to the appointment of pharmacist post with basic qualification as D Pharm as well as the notification issued by the TNMSRB on March 1, 2019 as illegal, and null and void. The petitioner also prayed for a direction to the government to permit him to participate in the competition tests for the appointment of pharmacist.

The qualification prescribed in TN MSRB's notification for the pharmacist post was D Pharm and registration of certificate with the state pharmacy council. On Monday, November 29, 2021, while considering the case the court said the amended rules will be considered for making effective from March 1, 2019, the day the government issued the notification inviting applications.

The pleader appeared for the government in the court on last Monday and assured that the amendment would be made within eight weeks time.

Joining as an additional petitioner (joinder of party), the PCI filed an affidavit before the high court, in which the regulator of pharmacy profession in the country said, persons

holding D. Pharm or B. Pharm or Pharm. D qualification from an institution approved u/s 12 of the Pharmacy Act, 1948 are eligible for registration as a pharmacist to practice the profession of pharmacy. On the basis of this statement of the PCI, the court directed the government to amend the rules accordingly and inform the amended version to the court for consideration.

Source: *Pharmabiz,* 1st December 2021

## Despite Being World's Pharmacy, why Indian Pharma is Dependent on China for Bulk Drugs

**Ease of Doing Business for MSMEs:**

Despite having the third-largest pharmaceutical industry by volume in the world and being the largest manufacturer of generic medicines globally, India is heavily dependent on China for imports of active pharmaceutical ingredients (APIs). According to the Trade Promotion Council of India (TPCI), India's competitive position in the pharma sector, which has a significant share of MSMEs, is undermined by its high import dependence for bulk drugs or APIs, especially from China. APIs are essentially the ingredients or what the industry calls, active pharmaceutical substances required in drugs including capsules, tablets, etc., to deliver the intended outcome or result.

Akin to multiple other industries, the Indian pharma sector's import of essential inputs from China is overwhelming. In fact, India imports 70 per cent of its API requirements from China, particularly vitamins and antibiotics, according to industry data. The APIs are made through a fermentation process in which China is dominant. According to data shared by Chemicals Minister Mansukh Mandaviya in Rajya Sabha on Tuesday, import of APIs or bulk drugs and drug intermediates in FY21 were worth Rs 28,529 crore, of which 68 per cent or Rs 19,402 crore worth imports were from China. The quantity of such imports in FY21 was 3,90,475.7 metric tonnes.

"Earlier India was very strong in fermentation technology. But after the Drug Price Control Order (DPCO), which was initiated in 1995 by the government, Indian companies had to resort to China for import as APIs were cheaper there. This continued for 15-20 years and now businesses are habituated. Today, we cannot match API prices of China," J Jayaseelan, Vice President, Indian Pharmaceutical Association and Managing Director, Sai Mirra Innopharm. The order was amended in 2013.

The intent to introduce the order by the government was to make medicines available at a reasonable and controlled price for people. However, according to experts, it had pushed manufacturers to procure APIs from China to control their raw material costs. While large enterprises directly source APIs from China due to their large volume requirements, many MSMEs with lower volume capacity have to route it via domestic traders even as prices have risen tremendously.

"Big companies can directly import from China as they can afford it but small businesses like us cannot. For example, paracetamol has jumped from Rs 180 per kg to Rs 850 per kg, citric acid has gone up from Rs 60-70 per kg to Rs 240, and glycerol has increased around three times. We don't have the volume to import in tonnes like large businesses. Our requirement is only around 200 kg. All of this eventually comes from China. Even preservatives like potassium metabisulphite, Sodium propyl paraben, sodium benzoate, etc., come from China," S. Sivanandhan, Managing Director at Chennai-based contract manufacturer Ceego Labs told Financial Express Online.

According to Mandaviya, India is currently "heavily" dependent for as much as 58 APIs on China while the dependency rate on these APIs varies from 50 per cent to 100 per cent. Out of these 58 APIs, 29 APIs are manufactured through fermentation and 29 APIs are manufactured through chemical synthesis.

However, a bulletin by the Reserve Bank of India titled Drivers of Indian Pharmaceutical Exports in July this year had noted that the focus on finished formulations in the last two decades had resulted in negligence of in-house Indian manufacture of APIs. This consequently led to an increased reliance on China in particular. As per a Boston Consulting Group (BCG) and Confederation of Indian Industry (CII) report, the major medications for which APIs originate from China include painkillers like paracetamol, anti-infectives like Amoxicillin, antidiabetics like Metformin and anti-ulceratives like Ranitidine.

The upsurge in imports from China points towards China's large capacities (which are built up by the government and managed by private industry) and India's liberal approach in approving registrations for Chinese products, the bulletin had noted.

"Most APIs were earlier manufactured in India in the 1980s and 90s but in 90s itself, China had started supporting their industry in a big way to manufacture chemicals and APIs, and as a result, their industry expanded. The challenge for India hasn't been technology, it's been pricing," Viranchi Shah, Senior Vice President, Indian Drug Manufacturers' Association told Financial Express Online.

To reverse the current situation back to the 1970s-80s in fermentation and APIs, the government had introduced multiple production-linked incentive (PLI) schemes for the sector. This included a Rs 15,000 crore incentive on incremental sales to selected participants for a period of six years. Eligible drugs under the scheme included APIs among other categories of pharmaceutical products. A total of 278 applications were received as of August 31, 2021, against which 55 applicants were selected under the scheme.

Another scheme launched was Rs 6,940 crore worth PLI for the promotion of domestic manufacturing of 41 critical drug intermediates and APIs as well. As per Invest India, 47 applications with committed investments of Rs 5366.35 crore were approved under the PLI scheme. The government had also launched a scheme for the promotion of bulk drug parks to offer grant-in-aid to three bulk drug parks. The total financial outlay of the scheme was

Rs 3,000 crore. The selection process of parks is currently underway. Bulk drug parks are essentially common infrastructure facilities for manufacturing APIs or drug intermediates, etc.

However, it would be anything but an overnight change for the API sector in India that would eventually benefit MSMEs in formulation with reduced costs and better price control. "Government wants to give subsidy for domestic manufacturing through these PLI schemes and to compete with China. However, there's a catch. For fermentation-based materials like vitamins and antibiotics, which are imported from China, there has to be absolutely zero power cuts. In APIs, power is a very important factor and it is a 24×7 industry. There has to be a continuous and uninterrupted power supply for the fermentation process that takes days to complete. Moreover, in China, the power cost is significantly less than in India," added Jayaseelan.

Source: *Financial Express,* 22nd December 2021

## TN IPA Asks Govt to Establish Pharmacy Colleges in All Existing & Soon-To-Be-Opened 11 Medical Colleges

For the last 150 years, Tamil Nadu has had only two government pharmacy institutions, but the number of industries is increasing every year recruiting pharmacy graduates from other states.

According to information from the health department, Prime Minister Narendra Modi is likely to inaugurate 11 new medical colleges in the first week of January 2022, thereby the number of government medical colleges will rise to 54. If each medical college is attached with a pharmacy institution, the pharmacy education in the state will go up and more graduates in pharmaceutical sciences will come up, hope the office-bearers of the IPA Tamil Nadu.

According to the president of the TN IPA and the president of the TN Pharmacy Council, J Jayaseelan, the pharmacy college attached with the Madras Medical College (MMC) completes 150 years in 2022. Ridiculously, he says, Tamil Nadu is the only state in the country which has been running only two pharmacy institutions for the last one and a half centuries. Another pharmacy college is attached with the Madurai Medical College. These two institutions are the ones that conduct B Pharm courses consisting 60 seats each. This is insufficient for the total requirement of the pharma and allied industries in the state.

Within the last 10 years, the number of private pharmacy colleges across the state has crossed 90, says the TN PC president. Despite repeated pressures on the government every year, no government could increase the number of pharmacy institutions from the existing two. Jayaseelan said the association is hopeful now as both the health minister and the health secretary assured the IPA leaders for new openings.

Talking about the advantage of more

pharmacy institutions in the government sector, he said provided pharmacy colleges are established in all the medical colleges in all the districts, the poor students will get admission to the degree course (B Pharm). Unlike other medical courses like MBBS and BDS, B Pharm does not require passing the NEET exam for admission. So, students who wish to work in the health sector can go with pharmacy courses and work in industry or in the pharmacy sector. Similarly, the industry association has wanted the government to start the Pharm D program in any of the two government pharmacy colleges from next academic year.

When asked whether the TN pharma industry gets adequate number of qualified pharmacists from Tamil Nadu institutions, Jayaseelan who is also the chairman of the TN branch of the Indian Drug Manufacturers Association (TN IDMA), said 90 percent of the industry pharmacists in Tamil Nadu are from Andhra Pradesh, where 450 pharmacy colleges are working in government and private sectors.

In the case of diploma in pharmacy course (D Pharm), only three government institutions are conducting it, in the medical colleges in Madurai, Coimbatore and Tanjore.

Source: *Pharmabiz,* 28th Decemberr 2021

## Two More Vaccines and a Drug Join India's Fight against COVID-19

India has approved two more vaccines under emergency use authorisation and an antiviral drug, Molnupiravir, Health Minister Mansukh Mandaviya tweeted. Currently, India uses Covishield, Covaxin and Sputnik V in its vaccination programme.

Corbevax to be made by Hyderabad-based Biological-E is a protein sub-unit vaccine and Covovax, to be manufactured by Serum Institute of India, Pune, is a nanoparticle-based vaccine.

Corbevax is co-developed by Biological E, Baylor College of Medicine in Houston, United States, and American company Dynavax Technologies.

Covovax is produced by the Serum Institute of India under licence from Novavax, a U.S.-based biotechnology company. Covovax has been approved by the World Health Organisation (WHO) under its Emergency Use Listing and, therefore, will also be available globally as part of the COVAX initiative to ensure that at least 40% of world is vaccinated on priority.

Molnupiravir, that was approved this month by the U.S. Food and Drugs Administration (U.S. FDA), on the heels of Paxlovid by Pfizer Inc, is said to be a promising drug for those with mild and moderate disease and also easily administered as a pill. Thirteen companies in India are set to manufacture this drug. It has been approved under emergency use authorisation for treating adults with COVID-19 “who have high risk of progression to disease”.

The U.S. FDA in a recent statement said that because Molnupiravir works by introducing genetic errors into the virus, it ought to be prescribed with caution and was not recommended as a preventive and only in “certain adults” in whom alternative COVID-19 treatment options authorised by the FDA were not accessible or clinically appropriate. Paxlovid is yet to be approved in India.

Cipla, one of the licensee, said in a statement that it planned to launch Molnupiravir under the brand name Cipmolnu.

There were no details available on when these vaccines would be included in India's vaccination programme.

Prime Minister Narendra Modi announced on Saturday that from January 3 those aged 15-17 would be eligible for Covaxin. Healthcare workers, frontline workers and those above 60 with comorbidities who have already got two shots will be eligible for a third dose from January 10. There are no studies so far to show how effective the new vaccines will be in giving protection against symptomatic infection when employed as a third dose though the WHO's general observation is that same or mixed vaccine regimens "improve immunological response" are better protective against disease and death.

In June the Centre had said that it had "reserved" 30 crore doses of Corbevax. Though early trials had shown the vaccine to be safe and capable of eliciting an immune reaction, no results are yet available on its efficacy. In June, results from a Phase 3 clinical trial of Novavax enrolling 29,960 adult volunteers in the U.S. and Mexico showed that the vaccine demonstrated 90.4% efficacy in preventing symptomatic COVID-19 disease. It also showed 100% protection against moderate and severe disease.

Source: *The Hindu,* 28th Decemberr 2021

## Govt Mandates QR Code on Labels of All API's Manufactured and Imported

The Central government has mandated a Quick Response (QR) code on the label of all active pharmaceutical ingredients (APIs) manufactured or imported in India, at each level of packaging to enable tracking and tracing of the ingredients vide notification GSR No. 20(E) dt 18-01-2022.

The amendment to the Drugs Rules, 1945 in this regard was issued as final notification by the ministry of health and family welfare on January 18, 2022.

According to the notification, the new Rule, named Drugs (Amendment) Rules, 2022, inserts a sub-rule (5) after the existing sub-rule (4) under the Rule 96 of the Drugs Rules, 1945, related to the manner of labelling.

The new sub-rule says, "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 minimum particulars including unique product identification code, name of the API, brand name (if any), name and address of the manufacturer, batch number, batch size, date of manufacturing, date of expiry or retesting, serial shipping container code, manufacturing licence number or import licence number and special storage conditions required (if any).

The draft amendment to the Rule was published in the Gazette of India on August 8, 2019, inviting objections and suggestions from persons likely to be affected, within 30 days from the date of publication of the draft notification.

The copies of the Gazette were made available to the public on August 10, 2019 and

the objections and suggestions received from the public on the Rules were considered by the Central government before publishing the final notification now.

The authorities have been considering options to implement technology to track and trace the drugs and raw materials in the last few years.

The Drugs Technical Advisory Board (DTAB), in its meeting in November, 2021, has recommended the introduction of barcodes or QR codes in the top 300 brands of drug products available in the Indian market to help track and trace these brands, in line with the discussions it has been carrying out in the last couple of years.

In a meeting held in May, 2018 also, it deliberated the same matter and agreed for introduction of trace and track mechanism for major 300 pharmaceutical brands on a voluntary basis.

It was only based on its recommendations, the draft notification in August, 2019 was issued. However, a number of objections were raised from the industry, which were examined by the government.

Following this, the MoHFW constituted an Inter-Department Committee (IDC) on July 13, 2020 on the issue of implementation of barcode/QR code on packing of drugs including medical devices and as per its recommendations, the implementation of authentication mechanism for the top 300 drug formulation brands in the first phase was decided to be taken up.

A roadmap was also prepared to complete identification of the top 300 brands using technologies that can be used including cost, procurement of hardware, changes in packing lines and packing materials etc., and complete stakeholder consultation, obtaining their comments and rollout for top 300 brands and all items meant for government procurement, in systematic manner. It has also decided to constitute a committee to execute these activities.

Accordingly, it was proposed to consider the introduction of QR code in phase-wise manner, so that trace and track mechanism by QR coding system on packaging may be implemented initially for the top 300 brands through amendment in the Drugs Rules, 1945.

In the DTAB meeting in November, it was also decided to withdraw the draft notification issued in 2015, regarding track and trace mechanism through two dimensional barcode encoding unique and universal global product identification code in the 14 digits global trade item number format along with batch number at primary level packaging, one or two dimensional barcoding in secondary level packaging and one dimensional barcoding at tertiary level packaging.

Source: *The Health Master,* 21st January 2022

## மாத்திரைகளை 2-ஆக உடைக்கலாமா?

உடல் உபாதைகளுக்கு டாக்டர் பரிந்துரையின் பேரில் எடுத்துக்கொள்ளும் மாத்திரைகள் பெரிதாக இருந்தால் அதனை இரண்டாக உடைத்து விழுங்குவதை பார்த்திருப்போம்.

இது மிகவும் தவறான செயலாகும். மாத்திரைகளை முழுதாக சாப்பிடுவதுதான் உடலுக்கு நல்லது. ஏனெனில் மாத்திரைகளை இரண்டாக உடைப்பதனால், சில நேரங்களில் எடுத்துக் கொள்ளக்கூடிய டோசேஜ் அளவுகள் மாறுபடக் கூடும்.

மருத்துவரிடம், மாத்திரைகளை இரண்டாக உடைக்கலாமா என்று உறுதி செய்து கொள்வது நல்லது. ஏனெனில் மாத்திரைகளை உடைக்கும் போது, அவற்றின் அளவு வேறுபடுகிறது. இதனை உட்கொள்வதனால் உடலுக்கு பக்க விளைவுகளை ஏற்படுத்தும். எனவே ரத்த அழுத்தம், கை, கால் நடுக்கம் உள்ளவர்கள், ஆர்த்ரைட்டீஸ், இதயநோயாளிகள் ஆகியோர் மாத்திரைகளை உட்கொள்வதில் மிகுந்த கவனத்துடன் இருக்க வேண்டும். ஏனெனில் ஒவ்வொரு மாத்திரையும் தயாரிக்கப்படும் போது, அதில் சேர்க்கப்பட்டிருக்கும் மூலப்பொருட்களின் அளவும் வேறுபடும்.

நாம் மாத்திரையை இரண்டாக உடைக்கும் போது அவை சரியான அளவில் உடைபடும் என்றும், அதிலிருக்கும் மூலப்பொருளும் சமமாக பிரிந்திருக்கிறது என்றும் கூற முடியாது. வீரியமிக்க மருந்துகள் வயிற்றில் பிரச்சினை ஏற்படுத்தாமல் இருக்க கோட்டிங் செய்யப்பட்டிருக்கும். எனவே இவ்வகை மாத்திரைகளை முழுமையாக சாப்பிட்டால் தான் அவற்றின் பலன் கிடைக்கும்.

மாத்திரைகளை 2 - ஆக உடைத்து உட்கொண்டால், வீரியமிக்க மூலப்பொருள் நேரடியாக நமது உள்ளுறுப்புகளில் செல்லும். இதனால் நமது உடலில் வேறு சில உபாதைகளும் ஏற்பட வாய்ப்பு உள்ளது. மாத்திரைகளை இரண்டாக உடைத்தே தீர வேண்டும் என்ற கட்டாயம் இருந்தால், மாத்திரைகளை பிரித்தவுடன் சாப்பிட்டு விட வேண்டும்.

சில மாத்திரைகளில் ஈரப்பதம் படக்கூடாது, காற்றில் வைக்ககூடாது என்றெல்லாம் இருக்கும். அவற்றை 2 - ஆக உடைக்கிறேன் என வெளியில் நீண்ட நேரம் வைத்திருப்பதோ அல்லது இரண்டாக உடைக்க முடியாமல் இரண்டுக்கும் மேற்பட்ட வடிவங்களில் உடைப்பதனாலோ மாத்திரையின் முக்கியத்தன்மை இழந்து சிதைந்துவிடும். இதையெல்லாம் நினைவில் கொள்வது நல்லது.

Source: *Maalai Malar,* 13th November 2021

medopharm

*With best compliments from:*


# medopharm

*We Value... Life*

Corporate Office : "MEDO HOUSE" No. 25, Puliyur 2nd Main Road, Trustpuram, Kodambakkam, Chennai - 600 024, India
Phone: +91 44 40149999 Visit: www.medopharm.com

Factory : 50, Kayarambedu Village, Guduvanchery - 603 202, INDIA.