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TAMILNADU PHARMACEUTICALS SCIENCES WELFARE TRUST

25 Years

# Pharma Web

## Newsletter of Tamilnadu Pharmaceutical Sciences Welfare Trust

Apr. - May. - Jun. 2018

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Tamilnadu Pharmaceutical Sciences Welfare Trust

# Pharma Web

## Newsletter of Tamilnadu Pharmaceutical Sciences Welfare Trust

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TAMILNADU PHARMACEUTICAL SCIENCES WELFARE TRUST
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# EDITORIAL

Dear Readers,

I have great pleasure to be with you once again since our Chief Editor Mr. Narayanaswamy is away in U.S.A on his personal work. All the work has already been completed by him. I have to carry out corrections if any and write the editorial. So please pardon me in spite of corrections if still any mistakes persist.

We are happy to bring to you the 38th issue of Pharma Web Newsletter for **Apr – Jun 2018. (Pardon for the long delay)**

The following articles appear in this issue:

- **PDA Points to consider: Best Practises for Document / Data management and control and Preparing for Data Integrity Inspections** by Deb Autor, Zena Kaufman, Ron Tetzlaff, et al – The article is reproduced from PDA J Pharm Sci and Tech 2018, 72 332 – 337
- **The Regulation of Online Pharmacies (E-Pharmacy): The need for proper policy with combined efforts of Central and State Regulators by Dr. B R Jagashetty,** Former National Adviser (Drugs Control) to MoHFW, GOI & CDSCO and Former Drugs Controller of Karnataka State.

Gazette Notifications pertaining to the Pharma profession, Events, Pharma News Items appearing in different news papers, Question and answers of Lok Sabha and Rajya Shaba pertaining to Ministry of Health and Family Welfare / Ministry of Chemicals and Fertilizers, Department of Pharmaceuticals etc are other regular inclusions.

We are happy to inform our readers, that the next Training programme of the Pharma Knowledge and Training Institute on "Industrial Orientation " for B. Pharm / M. Pharm students will be taking place in the month of September 2018.

The Pharma Web is very much thankful to M/s. Fourrts (India) Laboratories Pvt. Ltd., M/s. Delvin Formulations, M/s. Medopharm, and M/s. Tablets (India) Ltd., for their continued support by giving advertisements, to sustain the cost of publishing of this newsletter.

We hope this Newsletter will benefit our readers. Any suggestions to improve the news letter are welcome.

With Best Regards,
**K. PRAFULLA CHANDRA**
**Associate Editor**

# TAMILNADU PHARMACEUTICAL SCIENCES WELFARE TRUST

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# ARTICLES

## PDA Points to Consider: Best Practices for Document/Data Management and Control and Preparing for Data Integrity Inspections

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**ABSTRACT:** The Parenteral Drug Association (PDA) has identified 11 current questions related to data management and control that have been frequently cited in U.S. Food and Drug Administration (FDA) inspections or have led to FDA regulatory actions. The purpose of this document is to help to clarify some of these issues for industry and to help facilitate better compliance by sharing PDA members' expertise in and understanding of current best practices.

Data integrity inspectional observations by health authorities can have a severe impact on a firm from a regulatory and public perception perspective and should not result from a lack of clarity by industry about what is required. In addition, firms are concerned that the inability to produce a requested record or document during an inspection, even if not a standard report or existing quality system document, could be construed as delaying, denying, limiting, or refusing inspection, which also has significant consequences.

The PDA acknowledges it may not be possible for a single firm or site to have a meaningful discussion of these issues in the context of an inspection or inspection response and is offering these best practices so that industry can proactively comply and properly prioritize its efforts to improve document management and control and good manufacturing practices in the most efficient and effective means possible. The PDA acknowledges there are many more questions to be addressed and hopes that there can be an ongoing dialogue between industry and regulators to facilitate answers.

### Background and Purpose

Based on its own experience and through a broad industry survey conducted with support from the Association for Accessible Medicines (AAM) and the Pharma & Biopharma Outsourcing Association (PBOA), the Parenteral Drug Association (PDA) has identified current questions related to data management and control that have been frequently cited in U.S. Food and Drug Administration (FDA) inspections or have led to

FDA regulatory actions. The PDA Data Integrity Task Force has selected 11 questions to address at this time and included recommended best practices for each situation. The purpose of this document is to help to clarify these issues for industry and to help facilitate better compliance by sharing PDA members' expertise in and understanding of current best practices.

Data integrity inspectional observations by health authorities can have a severe impact on a firm from a regulatory and public perception perspective and should not result from a lack of clarity by industry about what is required. In addition, firms are concerned that the inability to produce a requested record or document during an inspection, even if not a standard report or existing quality system document, could be construed as delaying, denying, limiting, or refusing inspection, which also has significant consequences.

**Question 1: Copies of Good Manufacturing Practice (GMP) Records**

**Context:** On a daily basis, there are many valid reasons why a firm may wish to make copies of GMP records, including records that contain a lot number, batch-specific data, test results, or other data. For example, firms may make a copy of a batch record to provide to a Technical Services group to conduct an investigation. Especially in light of recent 483 observations that highlight documents with batch information found in a shredder, it is unclear under what conditions it is permissible to treat copies of GMP records as uncontrolled, non-GMP records. Requiring that the issuance, management, and destruction of all of these documents be controlled by the Quality Unit imposes an unnecessary burden on industry. The key is for firms to be able to show how they assure that an original record is the original record and that the data in the record satisfy ALCOA (Attributable, Legible, Contemporaneous, Original, and Accurate) principles.

**Issue:** Is a copy of a GMP record (e.g., printout of the raw data or photocopy/scan of a paper original record) itself considered a GMP document?

**Clarification:** As long as firms have full control over original GMP documents and the original GMP document is retained as required by the firm's procedure, copies can be created and destroyed as needed. A copy of a GMP record need only be retained if additional GMP information (e.g., raw data) is recorded on the document copy. As a part of maintaining control over GMP records, it is advisable to make sure that copies can be readily distinguished from originals (e.g., copies are stamped as "copy" and/or originals are stamped as "original").

**Question 2: Documents Not Traditionally Considered GMP Records**

**Context:** In recent 483s, we have observed that documents not traditionally considered GMP records (e.g., e-mails and other communications) become the object of scrutiny and observations. A working definition of what the agency currently views as a GMP record for such things as e-mail, supervisor schedule, etc. would be helpful for industry. Firms communicate informally about production and quality-related activities on a continuing basis in order to facilitate operations. An e-mail regarding batch release may be essentially the written equivalent of a phone call from one colleague to another stating that a batch has been released. Requiring formal controls around all of these documents, or requiring that such documents cannot be printed and discarded/destroyed/shredded at will, creates a large burden on firms and their quality units.

**Issue:** Are e-mails or other papers that contain batchrelated information such as product name, lot number, or test results considered GMP records if local procedures are clear on what is the system of record?

**Clarification:** Whether a document is considered a GMP record depends on whether it is generated to satisfy a GMP requirement (see Data Integrity and Compliance with CGMP, Guidance for Industry, April 2016 draft, "When generated to satisfy a CGMP requirement, all data become a CGMP record."). For example, if e-mail is used as a record of batch release, it is a GMP document. If e-mail is used to communicate that a batch has been released, but the system of record for batch release is not e-mail, then the e-mail is not a GMP record. Similarly, drafts of risk assessments, investigation reports, etc. are not GMP (GMP) records until they have been reviewed and finalized. If companies use e-mails for GMP purposes, it is advisable to have a controlled process, governed by a standard operating procedure (SOP).

**Question 3: Personal Diaries**

**Context:** It is common for employees to use personal diaries or paper to record notes for themselves for non-GMP purposes, e.g., to-do list, training notes, personnel information. These notes are not considered to be GMP records by industry in general. Turning these notes into GMP records may in fact deter individuals from writing down information that is useful for effective time management or reinforcing one's own learning.

**Issue:** What types of entries/information can be recorded in a personal diary without being considered GMP records?

**Clarification:** If notes and diaries are used as personal and informal means of recording and are not the system of record for execution or documentation of GMP activities, then they are not considered to be GMP records. These informal recordings in personal notebooks might include to-do lists, training notes, coaching ideas, personnel information, etc.). Firms may want to consider controlling and spot-checking personal notebooks to ensure that they are being used only for non-GMP information. Firms may also want to train employees on what is and is not proper for recording in personal notebooks.

**Question 4: Drafts of GMP Documents**

**Context:** Firms generate many drafts of CGMP documents. It would be onerous and confusing to require that all of those documents be retained.

**Issue:** Are firms required to retain drafts of cGMP documents, such as reports of risk assessments, investigations, and validation?

**Clarification:** Once a final GMP document of record is created, drafts and documents used in the creation of the document of record no longer need to be retained.

This includes documents and drafts used or created in the course of conducting an investigation. The final document is the document of record. GMP Change Control processes come into effect once a GMP document is formally approved. As a part of maintaining control over GMP documents, it is advisable to make sure that drafts can be readily distinguished from final documents (e.g., they are stamped as “draft”).

**Question 5: E-mails as GMP Records**

**Context:** Firms use e-mail for a variety of GMP and non-GMP purposes. It is unclear to many firms which uses constitute GMP uses and whether a firm’s entire e-mail system becomes a GMP system due to its use.

**Issue:** Are e-mails considered to be GMP records?

**Clarification:** Whether e-mails are GMP records depends on whether they are being used to communicate GMP actions or content or capture GMP decision-making.

For example, if e-mail is used as the system of record for batch release, then those e-mails are GMP records, and local procedures should be clear on what is the system of record. If e-mail is used to communicate that a batch has been dispositioned,

but that decision is formally captured elsewhere in accordance with the firm's SOPs, then the e-mail is not a GMP record. Similarly, if e-mail is used as the official system for escalation of quality issues per a firm's SOPs, then those e-mails are GMP records. If e-mail is used for informational purposes to note that there has been an escalation, and there is a separate system of record for escalations, then the e-mail is not a GMP record. The use of e-mail in GMP process(es) should be welldescribed in the relevant SOP(s).

To create a GMP record that is separate from the e-mail system, and to avoid an e-mail system being used as a GMP system of record, a firm may wish to consider printing, signing/initialing, and dating all of the relevant e-mails that constitute a GMP record. All of this should be done in acordance with a written SOP.

**Question 6: Business Records That Are Not GMP Records**

**Context:** Recent inspections have delved into business records that are not GMP records, such as footage from security cameras, drafts of GMP documents such as investigations, uncontrolled document copies, and security key card access systems. FDA may choose to inspect these items and may even use them as a means of finding GMP violations. However, the fact that records may be inspected should not mean that these items are GMP records. Otherwise, it would create an enormous burden on the Quality Unit to review and control new kinds of records.

**Issue:** If non-GMP records, such as footage from security cameras, drafts of GMP documents such as investigations, uncontrolled document copies, and security key card access systems are inspected, does that mean that they are considered to be GMP records?

**Clarification:** No. When generated to satisfy a GMP requirement, all data become a GMP record. But the fact that a non-GMP record may be subject to inspection or may be the source of an inspectional observation pertaining to a GMP issue does not turn it into a GMP record. However, if a system is intended to provide documented evidence of a GMP function or GMP result, then it is a GMP system. For example, if a key card entry system is used beyond employee exit and entry and is used as a log to monitor time spent in an aseptic core for purposes of media fill compliance, then it is being used for GMP purposes and should be clearly defined as such by local procedure. However, if such a system is evaluated on an occasional retrospective basis as part of a GMP investigation to ensure that an employee did not over-stay in the aseptic core, then that does not mean it should be considered a GMP system. Of course, any

documentation from that system that is part of an investigation should be kept (in paper or electronic form) as a part of the investigation.

**Question 7: Use of Shredders**

**Context:** There is no GMP requirement prohibiting the placement or use of shredders in a facility. However, in light of recent observations relating to shredders and shredding, more guidance on shredders and document management would be helpful.

**Issue:** What restrictions pertain to the placement and use of shredders?

**Clarification:** There are no restrictions on the placement of shredders in a facility. However, due to the risk of unauthorized shredding of GMP records, it is recommended that firms prohibit shredders or other means of potential unauthorized document destruction in areas where GMP functions are performed. This especially includes those areas that create raw data, including production, warehouse, and laboratory areas, where the risk is more acute. It is acceptable to have shredders in areas that do not generate GMP records and/or documents, although procedural controls are advisable. These departments can include human resource, finance, and other management areas.

With respect to use of shredders, non-GMP records can be destroyed through whatever means a firm decides, including shredding (as long as such destruction does not violate corporate document retention policies). GMP records can be destroyed only when they have passed their retention period or if a true copy is being retained in place of original records.

For purposes of preserving confidentiality, firms may choose to provide secure bins for documents that require destruction in areas where there are not shredders. If those bins are in or near a GMP area, it is recommended that firms create procedures defining how destruction is accomplished. For example, Quality Unit review of bin contents may be appropriate in certain circumstances, such as during an audit or in cases of suspicion of inappropriate document or data management.

In a Research and Development (R&D) department, there may be GMP and non-GMP studies. It is advisable to create procedures and controls to prevent unauthorized destruction of GMP records in R&D.

Similarly, there are no restrictions on placement of correction fluid (e.g., Wite-

Out) and sticky notes such as Post-It Notes, but it is advisable to prohibit them in GMP areas.

**Question 8: Retention of Closed Circuit Television (CCTV)**

**Context:** Firms are unclear what is required for retention of closed circuit television (CCTV) footage.

**Issue:** For how long does a firm need to retain CCTV footage?

**Clarification:** CCTV footage from cameras that do not serve a GMP purpose, such as security cameras, should be handled in accordance with applicable firm procedures and retention policies. In general, there is not a GMP requirement to use CCTV. If CCTV footage are serving a GMP purpose, such as for batch release, then the footage should be retained as GMP documentation because it is part of the raw data supporting the disposition of the batch. It is not a GMP requirement to record aseptic process simulation/media fills, nor is retention of such videos required, unless the video is used as the primary documentation of a GMP operation (activity) that is not documented by other means (such as significant activities that are not documented on the batch record or control records for the process simulation batch). Please note, however, that it is a cGMP expectation to make a video of a smoke study validation. This video is the raw data supporting the qualification of a controlled environment, and the video should be retained as a GMP record. Aspects of local data privacy requirements also need to be considered in defining local procedures.

**Question 9: Data Capture Capabilities**

**Context:** Many pieces of production and laboratory equipment have extensive data capture capabilities.Firms are unclear whether they can disable unnecessary functions and/or rely on alternate recordkeeping systems.

**Issue:** If a piece of production or laboratory equipment has electronic data storage capability, is a firm required to utilize that capability?

**Clarification:** If production or laboratory equipment captures data that is required under GMPs, it must be used unless there is a reliable and complete alternate paper or electronic documentation system in place that meets GMP requirements. Please note, however, that if electronic raw data is dynamic, then a fixed/static paper or electronic record may not constitute a complete copy of the original record because that

record may be missing GMP-required data that is captured in the electronic system. Also, if there is an electronic audit trail, it should not be turned off in favor of a manual audit trail because a manual audit trail is necessarily less robust than an automatic one.

If an automated data capture system is disabled, it is advisable to document a good faith rationale for disabling the system. Firms should be prepared to defend the rationale during inspection if necessary, including.evidence that all data required by cGMP is capturedand retained by alternate system(s) as applicable.

If an electronic data capture system is not disabled and is not utilized for GMP purposes, firms' procedures should clearly identify what system is used as the source of rawdata and what system is not. It is also recommended that firms review the non-disabled system's data as a part of their procedures. The reason for this is that any data that is captured may be inspected by the FDA and could be the basis for concerns about data integrity, for example, in the case of discrepancies between data in the two different systems.

**Question 10: Quality Plans**

**Context:** Firms may be reluctant to create and document quality plans (documentation of their goals and timelines for quality system improvement) for fear of that plan being used as the source of 483 observations.

**Issue:** If a firm has a quality plan, will an FDA investigator use that plan as the basis for 483 observations?

**Clarification:** If a firm has a quality plan, an investigator may assess the sufficiency of that plan and whether the plan is being fully and timely executed. The fact that a firm has a reasonable quality plan in place may not prevent observations but can be evidence of a firm's willingness to self-identify and address issues. The adequacy of the firm's plan and the progress that the firm has made in executing the plan may be viewed by a regulator as a positive indicator of the firm's status. Using a firm's quality plan as a roadmap for negative observations could create a disincentive to creation of such plans. Regulators often encourage firms to proactively meet with them if the firm finds data integrity deficiencies, rather than waiting for those issues to be part of an inspection.

**Question 11: Questioning Investigator Actions in the Field**

**Context:** There is a diversity of FDA investigators in the field, and inspections can unfold in a variety of ways. Some firms are unsure of what to do if they perceive that an investigator is acting inappropriately or inspecting non-GMP records, documents, or facilities without cause.

**Issue:** If a firm believes that an FDA investigator is acting inappropriately or inspecting non-GMP records, documents, or facilities without an apparent cause, what should the firm do?

**Clarification:** The law defines the FDA's inspectional scope for a drug factory, warehouse, establishment, or lab as including "all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether" drugs are adulterated or misbranded or otherwise prohibited by the U.S. Food, Drug, and Cosmetic Act (FD&C Act). The only explicit limits on the FDA's inspectional authority are that it does not extend to financial data, sales data other than shipment data, pricing data, personnel data (other than data as to qualification of technical and professional personnel performing functions subject to inspection), and research data that is beyond the scope of FDA requirements (see FD&C Act 704).

Firms should be aware, however, that the FDA interprets its inspectional authority broadly. As the FDA has stated, the law "authorizes FDA to conduct inspections at reasonable times, within reasonable limits, and in a reasonable manner. Although the [law] does not specifically define 'reasonable,' FDA has long maintained that the inspectional authority . . . 'extends to what is reasonably necessary to achieve the objective of the inspection.'" [See Guidance for Industry, Circumstances that Constitute Delaying, Denying, Limiting, or Refusing a Drug Inspection (October 2014).] In 2012 the Food and Drug Administration Safety and Innovation Act (FDASIA), Public Law 112-144, was enacted. This law includes a provision that deems a drug to be "adulterated" if the drug "has been manufactured, processed, packed, or held in any factory, warehouse, or establishment and the owner, operator, or agent of such factory, warehouse, or establishment delays, denies, or limits an inspection, or refuses to permit entry or inspection". Under this law, drug manufacturers that delay, deny, limit, or refuse to permit entry or inspection are potentially subject to regulatory sanctions by the FDA including Import Alert, Warning Letter, and Seizure.

One issue that arises is what the FDA can inspect, such as whether the FDA can inspect the firm's e-mail system, phone messages, and individuals' offices. It has also been reported that FDA investigators have requested information or data in a format other than that which is generally used or maintained by the firm, and informed the firm that it would be a refusal of inspection if the firm does not produce the requested information or data in that format.

If a firm believes that an investigator is acting inappropriately or inspecting non-GMP records, documents, or facilities without an apparent cause, the first step is to raise that issue with the investigator. If the firm does not feel it can do so, or that effort is unsuccessful, the firm can contact the District Office at which the investigator works, the FDA Office of Regulatory Affairs (ORA) ombudsman, or others in ORA or management of the FDA Center for Drug Evaluation and Research to discuss the issue.

## Conclusion

The PDA acknowledges that it may not be possible for a single firm or site to have a meaningful discussion of these issues in the context of an inspection or inspection response and is offering these best practices so that industry can proactively comply and properly prioritize its efforts to improve document management and control and GMP in the most efficient and effective means possible. The PDA acknowledges there are many more questions to be addressed and hopes that there can be an ongoing dialogue between industry and regulators to facilitate answers.

## Conflict of Interest Statement

The authors declare no conflict of interest.

**Acknowledgement:** Reproduced from PDA J Pharm Sci and Tech 2018, 72, Page 332-337, we wish to acknowledge with thanks to Denyse Baker, Director, Science and Regulatory Affairs, Parenteral Drug Association

# The Regulation of Online Pharmacies (E-Pharmacy): The need for proper policy with combined efforts of Central and State Regulators

by

**Dr. B R Jagashetty**
Former National Adviser (Drugs Control) to MoHFW, GOI & CDSCO and
Former Drugs Controller of Karnataka State

While the power of the internet has proved a terrific boon for consumers seeking bargains and otherwise inaccessible products, pharmacy is one online sector where the benefits are mixed. E-pharmacies can be a game changer in delivering affordable medicines to all by increasing competition, driving costs down and helping to deliver drugs in remote areas.

During 2013, in China 45.8% of the population, in USA, 84.2% of the population and in Australia 83% of the population are found to be using internet. As of 2014, India was the third-largest online market with more than 167.2 million internet users, ranked only behind China and the United States and declaring itself as a market not to be ignored on the global stage. India's internet usage has registered 17% growth in first 6 months of 2015 as per IAMAI report. Of the millions of internet users in India, 38 percent of those who use the internet at home or work come from the 25-34 age brackets, a percentage which was higher than any other age group surveyed. Furthermore, men dominated internet usage with 61 percent to women's 39 percent. This statistic is important to start the discussion as you would observe that we must consider the reach it has and the manner it will grow, especially amongst the youngsters of our country, who we cannot ignore and allow them to access a tool, which will undermine their safety and health. If we fail to build the safety net around the consumers prior to sale of medicines on the internet in India, we would undermine the rights of our citizens on Safety, Efficacy and Quality health.

At any given time, globally, there are approximately 50,000 active online drug sellers worldwide and most of them are illegal online drug sellers [Source: Legit Script, LLC; generally consistent with the findings of WHO and National Association of Boards of Pharmacies (NABP)].The largest illegal online drug sellers can generate between $1 million and $2.5 million in sales each month. [Source: MIT's Technology Review; University of California San Diego (2011)]

Drugs are not just any other commodity that can either be sold or brought like any common merchandise. These are highly potent and their misuse or disuse could have serious consequences for human health, both for the person who consume them and in the longer run for the humanity at large. However, all drugs are not alike. At the same time, online sale of drugs, if properly regulated, has the potential to affect public health positively. There is, therefore, a need to leverage the technological advancements in e-marketing, ease of doing business and benefits of online sale of medicines to the patients. Keeping the fact that adopting technology should not pose risk to human health and any ill-effect of online sale of medicines could have irreversible effect and hence the approach has to be cautious.

The prerequisite for an online market could be the existence of robust system viz. Central portal/clouds, common Apps for patients, physicians, pharmacies, intermediary etc. Such a system will need to be developed and tested for it to be successful. Eleven percent (158 of 269) of those using the Internet for health care information indicated that they had used the Internet instead of seeing or speaking with their doctors. These respondents had also used the Internet for a variety of medical topics. However, compared to all respondents, a greater percentage indicated using the Internet for second opinions (69% vs 41%) and for information on complementary or alternative medicine (83% vs 41%). The two most common reasons respondents gave for using the Internet instead of their providers were that it was “more convenient to get 'on-line' advice” and “less expensive to get advice 'on-line'”. Of these 29 patients, several respondents wrote in additional reasons for using the Internet instead of their doctor. These included: “wanted to see if my problem warranted seeing my doctor,” “doctor wasn't open to discussion of my suggestions,” “little faith in doctors”, “not sure doctor understands my concerns” and “want more of an education on topic than doctor has time to give”.

From a consumer's point of view, online pharmacies seem to offer much potential value, although not necessarily on price. For housebound patients, the option of ordering medication from home and having it delivered to the door is obvious. For those living in remote areas and consumers who are short of time and for whom reaching the pharmacy is difficult, ordering online has obvious advantages. There are also those seeking personal products that prefer anonymity. However, there are scams and spam emails offering medicines at very cheap prices or without the need for prescriptions, that can cause financial and health problems. The reality is that, for an increasing number of people, given population ageing and the rise in chronic illness, online pharmacies will likely become an ever more favoured option.

Wherever possible it is preferable for consumers to obtain their prescription medicines at a traditional pharmacy, particularly when the prescription is for a new drug or for a serious condition. Even for over-the-counter products, it is wise to buy from a pharmacy to hear of any safety advice first-hand. The proliferation of online pharmacy prescription services and now online medical consultation services, points to another dilemma that seems set to become more prevalent. That is, the growing number of remote health assessments made possible by internet and telehealth where the doctor, pharmacist or other practitioner is not seeing the patient in person. It seems that circumstances, including time and commercial pressures, are combining to make these virtual consultations ever more frequent.

Some websites may also misuse patients' personal and financial information, infect their computers with viruses, may sell their information to other illicit websites and Internet scams, and charge them for products they never ordered or received and explain that legitimate online pharmacies always require a doctor's prescription, have a pharmacist available who can answer any doubts of patient, are licensed with the concerned drug regulatory in the state where they operate and have privacy and security policies that are easy to find and understand.

While many internet pharmacies sell prescription drugs only with a prescription, some do not require a pre-written prescription. In some countries, this is because prescriptions are not required. Some customers order drugs from such pharmacies to avoid the cost and inconvenience of visiting a doctor or to obtain medications their doctors were unwilling to prescribe. People living in the United States and other countries where prescription medications are very expensive may turn to online pharmacies to save money. Many of the reputable websites employ their own in-house physicians to review the medication request and write a prescription accordingly. Some websites offer medications without a prescription or a doctor review. This practice has been criticized as potentially dangerous, especially by those who feel that only doctors can reliably assess contraindications, risk/benefit ratios and the suitability of a medication for a specific individual.

It appears that electronic prescriptions should be valid especially in the light of the Section 4 and Section 5 of IT Act, 2008 read with Pharmacy Practice Regulations of 2015 declared by Pharmacy Council of India in January 2015. In these regulations, “Prescription” defined by regulation 2 (j) as 'means a written or electronic direction from a Registered Medical Practitioner…….'. On basis of existing regulations it appears that a scanned copy

of prescription will be perfectly considered as a valid prescription. However, whether such electronic prescriptions can be used to buy medicine from online pharmacies has been questioned.

Online pharmacies, especially those that are inventory led and dispense on their own, have the potential to bridge the healthcare gap. Health services management is a growing field, especially with technology adoption. Records management and lab results are all moving to electronic platforms and hospitals need to hire administrators to handle the data. Active leadership roles by physicians, innovative human resource strategies and a strong organizational culture can bridge the talent gap in healthcare.

E-pharmacy is a part of the Digital India campaign because from e-governance to e-learning, the idea of the movement is to transform the country into a digitally-empowered society. Currently, there are about 50 online pharmacy start-ups in India, revolutionizing the way business is done, in an industry that has been traditionally resistant to change. Leading e-pharmacies are evolving into holistic healthcare hubs that offer access to comprehensive information and medical e-consultation services. India has a dismal ratio of 0.7 doctors and 1.5 nurses per 1,000 people as against the WHO ideal average of 2.5 each of doctors and nurses per 1,000 people which reflects the immense human resource challenge. Therefore the challenge for E-pharmacies becomes tougher when hiring fresh graduates as their growth aspirations are high and it takes twice the effort to train and engage them.

The business model of online pharmacies is making the process of purchasing medicines not only more convenient, economical, organized and transparent. Whether it's insisting on valid doctor's prescription for disbursing certain drugs or even maintaining documentation of every transaction, digitalization of data is streamlining the distribution system. Over a period of time, the consumer medical database could be useful in planning public health policies.

As per the reports, the government is working on a policy that will ensure a level playing field for e-pharmacies vis-à-vis traditional retailers. The medicines have to be sold or taken against prescriptions especially those mentioned in Schedule H, H1, X and G appended to Drugs and Cosmetics Rules, 1945 and this definitely addresses the issue of self-medication via prescription drugs. Of course, it is necessary to emphasize on last mile delivery and associated complications is an obvious miss as along with it arises factors such as endorsing the prescription, among others.

There are two major issues as far as online pharmacy is concerned i.e. the one with regard to the type of prescription to be honoured and other one with regard to mode of delivery that is whether home delivery in person or by post or by courier.The reality is with the advent of technology consumers and patients today expect convenience and the ability to access medication in privacy and in the manner they feel comfortable rather than driven by laws and regulations. This is evident from the present practices adopted by the consumers to encourage illegal sale through telephone and the internet, even if it is a grey area as per our existing laws. The law enforcers are unable to check the menace of prescription medicines sold in India over the counter, with exceptions in few States. It is no secret that this convenience also comes with the added advantage of boosting the economy and creating thousands of new job opportunities for the unemployed or the under-employed.

Indian Internet Pharmacies are currently practicing the model where they are dispensing based on scanned or image of Prescription and this can be a serious threat to patient safety and rights of consumers. Unauthenticated scanned prescriptions can lead to several risks and safety issues, which are the major challenges before us such as risk of self-medication, risk of drug abuse, risk of black marketing, risk of not taking any responsibility, risk of proper authentication and also risk of image of Indian drug regulators.

**Advantages of Online Pharmacies:**

The foremost advantage that online pharmacies provide is lower prices. The lower prices are facilitated through the absence of many operating costs associated with traditional brick and mortar sites, which include building costs, property taxes, and labor and employee training costs. Online pharmacies also provide consumers the ability to comparison shop for drug price and availability.

Additionally, online pharmacies are extremely convenient. For example, elderly consumers who do not drive or who do not live in close proximity to a pharmacy can have medication delivered to their home. Ordering on the web is also time-efficient in that consumers can save their medical and pharmacological profiles online. This feature permits the ease of refilling prescriptions in a matter of minutes, which can be delivered directly to the patient's home or be picked up from a local site.

Using online pharmacies affords consumers with more privacy than the traditional doctor or pharmacy visit. Many websites allow consumers to participate in a virtual consultation where they can input their respective symptoms and conditions and receive a diagnosis with accompanying patient information. Sites such as these are therefore popular because of their high degree of privacy, since patients can forego face-to- face examinations

or visits to the pharmacist that can be embarrassing and uncomfortable.

Electronic prescription is the futuristic model of drug dispensing. Electronic Rx (E-Rx) is created by the doctor using software and it is electronically signed. It helps in doctor and pharmacy integration, prevents misinterpretation, avoids errors of reading the hand writing of doctors while dispensing. It stalls batch number and wrong expiry mismatch. It helps in easy moving of refills from one pharmacy to another as per customer choice with prescription (Rx) validity clearly known to the new pharmacy.

E-Prescription (e-Rx) gives FDA a much cleaner and better long term records than manual keeping. FDA can demand complete copy of Rx records on its own server if needed. The regulatory authority can view the entire end-to-end movement of Rx from prescribing to dispensing.

Besides, E-Rx setup modernizes overall healthcare establishment in the country and creates environment for only serious players which would also reduce healthcare costs tremendously while at the same time increasing patient safety.

E-prescription is a clear win-win for the regulator, government, patients, doctors, pharmacists and chemist shops. The concept is already in vogue in the US as 'VIPPS' program. The new EU regulation mandates online pharmacies to display the related logo which was enforced from July 1, 2015. It automatically presses for registering with the MHRA (Medicines and Healthcare Products Regulatory Agency) and displays the same in all the web-pages which confirms that the seller is a registered online pharmacy.

**Disadvantages of Online Pharmacies:**

In many respects, the benefits that online pharmacies offer are outweighed by the existing and potential damages they can cause to an individual's health and to society as a whole.

The ability to access prescription drugs without a confirmed face-to-face physician consultation creates a large risk of misdiagnosis which, in turn, results in the wrong prescription being dispensed.

Online pharmacies also provide a relatively effortless way for drug abusers and addicts to acquire prescription drugs. Furthermore, many web sites are breaking consumer protection laws by representing that certified doctors are offering their medical opinions and prescribing drugs when, in reality, a computer database is deciding the appropriate drug or remedy. The biggest risk that online pharmacies pose is to the patient's health.

Fabricated scanned prescription may cause legal implications for the doctor who's Rx has been copied. Scanned Rx including signatures can be easily copied using any editing software and leads to abuse and multiple dispensing.

Further, consumers face an increased health risk when they purchase prescription drugs from online pharmacies based in some other places. Many websites market products which are classified as vitamins, herbs, or dietary supplements as legitimate prescription drugs. In other instances, drugs that can only be purchased with a prescription such as those of antibiotics, habit forming, psychotropic etc., can be purchased without prescription from online pharmacy.

Appearance, dosages and even product names can differ. Another major issue with the increased use of online pharmacies is its simplicity of ordering prescription drugs thereby permitting children and drug abusers to acquire non- prescribed medication easily.

**Types of Online Pharmacies:**

Globally, the online pharmacy industry can be categorized into three major classifications. The first and most legitimate type of online pharmacy is the one that operates similarly to a traditional “brick and mortar” pharmacy. These types of online pharmacies most resemble the long existing mail order pharmacies. These pharmacies follow the regulations by employing Registered Pharmacists and they also require the consumer to obtain a prescription that is written by a RMP after an examination or consultation. Subsequently, the consumer has the option of having the physician phone, fax, or mail the respective prescription to the online pharmacy. After the pharmacy has received the prescription, the standard practice is to verify it with the physician and Registered Pharmacist and thereafter it will decide to dispense the prescribed drugs.

The second type of online pharmacy is more appealing to consumers because it offers consumers both physician services and pharmacist services. Initially, the consumer will fill out a medical questionnaire which provides the online doctor with the patient's health profile, current medications, and a medical history. Based on this information the online doctor will determine the patient's medical condition and prescribe a medication accordingly. Following the diagnosis, the patient can purchase the prescribed medication from the website. Some websites may charge for both the consultation and for the medication while others may solely charge for the medication. These types of pharmacies not only prove to be more convenient but also provide a higher degree of privacy appreciated by many consumers.

The final type of online pharmacy is classified as a “rogue” pharmacy. The lawmakers continue the battle to shut down these websites because they pose the highest risk to a patient's health. Lawmakers are extremely concerned with such rogue pharmacies because they essentially allow consumers to purchase prescription drugs without a physician's consultation and a valid prescription. Consumers simply have to log on to the site and fill out an order form requesting their choice of prescription drugs and quantity. These sites are popular for obtaining “lifestyle” drugs such as Viagra, whose prescriptions many consumers are hesitant and embarrassed to solicit from their physicians.

Considering all the above and coming back to our country's main law related to medicines i.e. as per Drugs & Cosmetics Act, 1940 and Rules 1945and IT Act, 2008 read with Pharmacy Regulations, 2015. It is not possible to get uploaded the required medicines especially prescription drugs on any website directly from patient or customer and then dispense.

Though the existing rules are sufficient to carry out legally and ethically online sales of medicines except that some provisions are to be made in the rules with regard to delivery of medicines / devices which can be covered in the recently announced guidelines by CDSCO on Good Distribution Practices, the major problem faced are that of not marking on the prescription about its dispensing by majority of brick & mortal retailers and physical presence of pharmacists in the retail outlet at the time of sale of medicines especially in big cities which may be due to weak regulation for whatsoever reasons.

However if Govt. considers Online sale of medicines (Online Pharmacies) is that of permitting the customer / patient to upload any medicines on a website of so called market place business people following steps may be considered keeping importance of safety of patient health.

- While finding solutions public awareness is to be considered as an important tool and priority for combating illegal online drug sellers, including by raising awareness with the consumers, healthcare professionals, government officials and regulators and the Internet commerce companies that advertise and facilitate online sales of medicines which may turn out as of spurious and NSQ product.
- Though “Online sale” is one of the mode of sales activities it has to be recognized under Drugs & Cosmetics Act, 1940 and rules there under probably by amending the said law suitably.

- Online Pharmacy or it's concept has to be defined in the Drugs and Cosmetics Act and suitable punishment clauses are to be included for any violations.
- Fixing the validity period for prescription.
- Define “OTC (Over the counter) drugs” whose sale can be done without prescription and without supervision of pharmacist. Once “OTC drugs” is defined list out such drugs [In the UK, GSL medicines are those that can be sold with reasonable safety without the supervision of a pharmacist, enabling supermarket sales]. Allow only such OTC drugs to get uploaded by patient / customer on the approved websites for the purpose.
- Define or recognize such “Intermediaries” under D & C Act fixing their role and responsibility and also suitable punishment clauses for any violations by such functionaries. Similarly other terminologies are to be defined like Delivery, Internet commerce companies, Authenticate, Authentication of Product History, Centralized Performance Database, Collaborative Pharmacy Practice, Collaborative Pharmacy Practice Agreement, Digital Signature, Distribute or Distribution, Electronic Signature, Emergency Prescription Drug Order, External Entities, Fine/Civil Penalty, Health Care Entity, Health Information, Mobile Pharmacy, Non-Prescription Drug, Nonresident Pharmacy, Pedigree, Pharmacist, Pharmacist Care, Prescription Drug, Prescription Drug Order, Protected Health Information, Public Health Emergency, Quality Self-Audit, Significant Adverse Drug Reaction, Temporary Pharmacy Facility (these have been defined under Model Act of NABP of VIPPs of USA which can be viewed at website *http://www.nabp.net/publications/model-act/)*.
- Such websites should have Retail License from respective State Licensing Authority to get identified who is running and then they should get registered with CDSCO for which requisite fees may be fixed and may be made to renew every year [Since 1 July 2015, any online seller of medicines based in Europe needs to be registered with their respective national regulator and display a common European logo. In the UK, medicine retailers must be registered with the Medicines and Healthcare products Regulatory Agency (MHRA), similarly in USA, VIPP system is existing].
- At present most of retailers are not following Rule 65 (11) (c) of D & C Rules, 1945 with regard to stamping the prescription for having dispensed which has to be properly mandated and may be considered for severe punishment forits violation.

- At present the ground reality is that in most of bigger cities pharmacists are not found to be present at retail outlet during business hours.
- There are no proper infrastructure i.e. required number drug inspector (DI) posts in most of the states except few states like Maharashtra, Gujarat, Uttaranchal, AP, TN etc. The ideal situation will be for every 250-300 sales outlets one DI and for every 30-40 Manufacturing units one DI is required.
- Govt. Analyst should be able to give the test and analysis report within 15 days of receiving it except in case of animal test, Microbiology or sterility test where it can be given within 45 days otherwise the purpose will not serve since the sale is not prohibited after drawing drug for test.
- In case of prescription drugs or drugs other than OTC drugs following points may be considered further
    - Rule 65(10) mentions about the prescription's model i.e. Prescription should be in writing and be signed by the person giving it with his usual signature and be dated by him; whereas Section 4 of IT Act 2008 recognises first portion i.e. “in writing” if it is made available in “Electronic Form”; similarly Section 5 of IT Act 2008 recognises the second portion i.e. “and be signed” if it is “in electronic signature”of prescriber.
    - Prescription has to be recognized only if it is in physical form or online form i.e. electronic form with electronic signature as defined under IT Act, 2008 read with Pharmacy Regulations, 2015.
    - Noting on the Prescription Dispenser's name, address and signature (including Registered Pharmacist's name and signature) has to be made compulsorily on the Prescription and if possible suitable punishment clauses may be incorporated for any violation of this.
- Suitable provision may be made under D& C Act / Rules for Prescription Audit by a suitable committee comprising the officers from medical field and drug control enforcement and any others with suitable punishment clauses for any violations. This audit is required for verifying even rationality of prescribing various medicines or diagnosis by the prescriber as it involves lot expenditure to the patient.

- Raise public awareness about the risks of illegal online drug sellers and how to purchase medicines safely;
    - Share consumer education videos
    - Speak publicly about the issue at widely-attended events
    - Educate key stakeholders about the problem and increasing threat
    - Share news and engagement media, educating journalists about the growing problem
    - Run a Public Education Campaign National video contest
    - Invite Alliance for Safe Online Pharmacies (ASOP) to speak with your meida, at public events or with policymakers
    - Use search engine advertising to share public education messages and tools that facilitate consumer safety Distribute a newsletter with online pharmacy key facts and developments.
- Sale of medicines through online may be restricted to respective Zones or States by fixing the jurisdiction as is done in some of the developed countries.
- Other allied Acts and rules like DPCO, DMR, and NDPS etc. are also to be considered while framing any guidelines / suggesting amendment to various relevant Acts and Rules.
- In order to regulate online pharmacies, a National Portal be created, which will be the nodal platform for transacting and monitoring online sale of drugs. It would be necessary to evolve a mechanism to register service providers which do not directly indulge in stocking, exhibiting, distribution for sale and sale of drugs. Since service providers are offering drugs, directly or indirectly or on behalf of others, they need to be regulated under rules as most of drugs are required to be prescribed by the registered medical practitioner, sold through professionals from the licensed premises and require patient counseling;
- All e-Pharmacies which plan to sell, offer or exhibit for sale medicines over internet, will need to be registered with Central Drugs Standard Control Organization (CDSCO) under the Drugs and Cosmetics Rules, 1945. No unregistered entity shall be permitted to undertake online sale of medicines

- Online sale of drugs may be permitted only on e-prescriptions or electronically generated and electronically signed in compliance with provisions of IT Act, 2000 and other rules under the said Act. Electronic prescriptions are medical prescriptions generated by electronic mode, gadgets, devices which are verifiable, can be printed and transmitted. Integrity and authenticity of prescription is crucial in any online sale of medicines. There is a possibility of misuse of prescription by patient for its multiple use and also chance of issue of prescription by fake doctors. To address these issues, it is recommended to accept only e-prescriptions or electronically generated and electronically signed prescriptions;
- Critical areas such as validity and verifiability of prescriptions, delivery of medicines, monopolistic practices, technology platform, policy for honoring prescriptions, database of medical practitioners, pharmacies, data integrity of patients identity and safety, patient counseling, track and trace, linking with Aadhar card and product recalls are need to be taken care at the time of making rules for online pharmacies;
- Delivery of medicines;
    - · Pharmacy shall ensure that the medicines are packed, transported and delivered in such a way that their integrity, quality and effectiveness are preserved
    - · All the e-pharmacies shall follow the Good Distribution Practices (GDP)
- To create the enabling environment for online sale of medicines, the Drugs and Cosmetics Rules, 1945 need to be amended for effective monitoring and proper enforcement of the Act, in achieving its aims and objectives.

## 70th Indian Pharmaceutical Congress

70th Indian Pharmaceutical Congress to be hosted by Indian Pharmacy Graduates' Association (IPGA), which is Federating Association of Indian Pharmaceutical Congress Association (IPCA) with the Theme as "Pharma Vision 2030: Indian Pharma Industry – A Global Leader"

Date: 21st – 23rd December 2018

Venue: Amity University Campus, Delhi NCR

For more details visit www.70ipc.in

# INFORMATION

## M.PHARM & PHARM D SCHOLARSHIPS 2017-18 AWARDED BY TNPSWT

**Profile of 1st Rank**

### *PHARMACEUTICS*

Name: Ms. Chenmala Karthika

Project Title: A Novel Combination of Flavonoids and 5-Fu Lipid Conjugate in self Nanoemulsion Drug Delivery System to Target Lymphatic System and Colon Carcinoma Cells

College: J S S College of Pharmacy, Ooty

Guide's Name: Dr. R. Suresh Kumar

### *PHARMACEUTICAL CHEMISTRY*

Name: Mr. D. Anand

Project Title: Isolation, Characterization and Evaluation of Anti-diabetic activity on Stem Bark of *Albizia procera (Roxb.)* Benth.

College: College of Pharmacy, Madras Medical College, Chennai

Guide's Name: Dr. M. Sathish

### *PHARMACEUTICAL ANALYSIS*

Name: Ms. Gullapalli Kowmudi

Project Title: Pharmacokinetic evaluation of Trigonelline extracted from seeds of Trigonella *foeum- graecum L. Fenugreek)* in albino rabbits

College: JSS College of Pharmacy, Ooty

Guide's Name: Dr. N. Krishnaveni

### *PHARMACOLOGY*

Name: Ms. Chennu Manisha

Project Title: Neuroprotective evaluation of combination of AT1 and NMDA receptor antagonists in ICV-STZ animal model of Alzheimer's disease.

College: JSS College of Pharmacy, Ooty

Guide's Name: Dr. A. Justin

## PHARMACOGNOSY

Name: Ms. G. Hemalatha

Project Title: *Syzygium aromaticum* (L.) Merril — its leaf essential oil nanospheres attenuates, rescues β amyloid pathalogy in transgenic *Drosophila melanogaster* model of Alzheimer's disease - a road to therapeutics

College: College of Pharmacy, Madurai Medical College, Madurai

Guide's Name: Dr. K. Periyanayagam

## PHARMACY PRACTICE

Name: Ms. Aswathy V.S

Project Title: Impact of Genetic Polymorphisms of RFC1-G80A and MTHFR C677T Genes on the Treatment Outcomes of Methortrexate in Rheumatoid Arthritis Patients – A PK-PD Approach

College: JSS College of Pharmacy, Ooty

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

## PHARM D

Name: Ms. Kezia Sam, Mr. Prince Wilfred, Mr. Regil C Varghese, Mr. Thomas Eipe

Project Title: A study to investigate the effect of vitamin D3 supplementation on iron status in iron deficient pregnant women.

College: J S S College of Pharmacy, Ooty

Guide's Name: Ms. Roopa B. S

## M.PHARM & PHARM D SCHOLARSHIPS 2017-18 AWARDED BY TNPSWT

**Profile of 2nd Rank**

### *PHARMACEUTICS*

Name: Mr. Sourodip Saha
Project Title: Terbinafine loaded Pluronic Lecithin Oragnogels for the treatment of Athlete's foot (tinea pedis)
College: JSS College of Pharmacy, Ooty
Guide's Name: Dr. Karri VVS Narayana Reddy

### *PHARMACEUTICAL CHEMISTRY*

Name: Mr. Rakesh Kumar Paul
Project Title: In-silico design, synthesis and evaluation of MurD and MurE dual inhibitors as robust antibacterial agents
College: JSS College of Pharmacy, Ooty
Guide's Name: Dr. Md. Afzal Azam

### *PHARMACEUTICAL ANALYSIS*

Name: Ms.Charu Baruah
Project Title: Isolation, Identification, Characterization and genotoxic evaluation for dreadful products, formed in the stability indicating studies of Methotraxate.
College: JSS College of Pharmacy, Ooty
Guide's Name: Dr. M. R. Jeyaprakash

### *PHARMACOLOGY*

Name: Mr. T. Sandeep
Project Title: Effect of Novel ER- β agonist in controlling Neuroinflammation and Apoptosis in Cerebral Ischemia in Rat model
College: PSG College of Pharmacy, Coimbatore
Guide's Name: Dr. M. Ramanathan

## PHARMACOGNOSY

Name: Mr. K. Anandan

Project Title: Development of Diatom biosilica Nano-Formulation of Grucillaria Sp. for the Treatment of Cancer.

College: College of Pharmacy. Madras Medical College, Chennai

Guide's Name: Dr. R. Vadivu

## PHARMACY PRACTICE

Name: Ms. Joffy Alex

Project Title: Dosing concepts and dialyzability of antibiotics in hemodialysis patients with end-stage renal impairment.

College: Sri Ramakrishna Institute of Paramedical Sciences, Coimbatore

Guide's Name: Dr. A.S Manjula Devi

## PHARM D

Name: Ms. M. Bakiya lakshmi, Ms. P. Neela, Ms. K. Shri Latha, Ms. S. Revathy

Project Title: Safety and Efficacy of Commonly Used Second line Oral Hypoglycaemic Agents Added to Metformin Monotherapy in Patients with Type 2 Diabetes Mellitus.

College: SRM College of Pharmacy, Kattankulathur

Guide's Name: Dr. T. M. Vijayakumar

# NOTIFICATION

## MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 1st June, 2018

**G.S.R. 521(E).**—Whereas a draft of certain rules further to amend the Drugs and Cosmetics Rules, 1945 was published as required under sections 12 and 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. 1367(E), dated the 3rd November, 2017, 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 Gazette were made available to the public on the 3rd November, 2017;

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

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

1. (1) These rules may be called the Drugs and Cosmetics (Sixth Amendment) Rules, 2018.
(2) They shall come into force on the date of their publication in the Official Gazette.

2. In the Drugs and Cosmetics Rules, 1945 (hereinafter to be referred as the said rules), in rule 36, in the second proviso, in clause (iii), after the word, figures and letter “Form 12 B”, the words “requiring the permit holder to give details of drugs imported and utilised on yearly basis” shall be inserted.

3. In the said rules, in Schedule A, in Form 12B, in paragraph 3, for the words “for a period of six months”, the words “till such time as the patient requires the drug as per the prescription of a registered medical practitioner and the permit holder shall submit details of drugs imported and utilised to the licensing authority on yearly basis” shall be substituted.

[F.No. X.11014/13/2017-DRS]
SUDHIR KUMAR, 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 was last amended vide notification number G.S.R. 408(E), dated the 26th April, 2018.

## MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 27th April, 2018

G.S.R. 411(E).—Whereas the Hon'ble High Court of Himachal Pradesh, Shimla, has, in its judgment dated 15.3.2016 in CWPIL No. 16 of 2014 titled 'Court on its own motion' versus State of Himachal Pradesh and others, observed that there is large scale clandestine manufacture and sale of the drug Oxytocin leading to its grave misuse, which is harmful to animals and humans;

And whereas, the said Hon'ble High Court also observed that the feasibility of restricting the manufacture of Oxytocin only in public sector companies and also restricting and limiting the manufacture of Oxytocin by companies to whom licenses have already been granted should be considered;

And whereas, the Drugs Technical Advisory Board constituted under section 5 of the Drugs and Cosmetics Act, 1940 (23 of 1940) considered the said issue in its meeting held on the 12th February 2018 and recommended that Oxytocin formulations for human use be regulated and restricted to be supplied only to registered hospitals and clinics in public and private sector to prevent misuse of the said drug;

And whereas, the Central Government, on the basis of the recommendations of the said Board and after examination of the matter, is satisfied that unregulated and illegal use of the drug Oxytocin is likely to involve risk to human beings or animals and that in the public interest it is necessary and expedient to regulate and restrict the manufacture, sale and distribution of the drug Oxytocin in the country to prevent its misuse by unauthorised persons or otherwise;

Now, therefore, in exercise of the powers conferred by section 26A of the said Act, and in supersession of the notification number G.S.R. 29(E) dated 17th January, 2014, the Central Government hereby directs that the drug Oxytocin shall be manufactured for sale or for distribution or sold in the manner specified below, namely:-

(I) The manufacture of Oxytocin formulations for domestic use shall be by public sector undertakings or companies only and the label of the product shall bear barcodes.

(ii) The manufacture of Oxytocin formulations for export purposes shall be open to both public and private sector companies and the packs of such manufacture for exports shall bear barcodes.

(iii) The manufacturers of active pharmaceutical ingredient of Oxytocin shall supply the active pharmaceutical ingredient only to the public sector manufacturers licensed under the Drugs and Cosmetics Rules, 1945 for manufacture of formulations of the said drug for domestic use.

(iv) The manufacturers of active pharmaceutical ingredient of Oxytocin shall supply the said active pharmaceutical ingredient to the manufacturers in public and private sector licensed under the Drugs and Cosmetics Rules, 1945 for manufacture of formulations of the said drug for export purpose.

(v) The Oxytocin formulations manufactured by the public sector companies or undertakings licensed under the Drugs and Cosmetics Rules, 1945 for domestic use shall supply the formulations meant for human and veterinary use only,-

(a) to the registered hospitals and clinics in public and private sector directly; or

(b) to the Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) and Affordable Medicines and Reliable Implants for Treatment (AMRIT) outlets or any other Government entity which may be specified by the Central Government for this purpose in the country which shall further supply the drug to the registered hospitals and clinics in public and private sector.

(vi) The Oxytocin in any form or name shall not be allowed to be sold through retail Chemist.

2. This notification shall come into force on the first day of July 2018.

[F. No. X.11014/3/2018-DR]
SUDHIR KUMAR, Jt. Secy.

## MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 26th April, 2018

**G.S.R. 408(E).**—Whereas a draft of certain rules further to amend the Drugs and Cosmetics 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. 1369(E), dated the 3rd November, 2017, for 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 November, 2017;

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

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

1. (1) These rules may be called the Drugs and Cosmetics (Fifth Amendment) Rules, 2018.

(2) They shall come into force on the 1st day of November, 2018.

2. In the Drugs and Cosmetics Rules, 1945 (hereinafter to be referred as the said rules), in rule 96, in sub-rule (1), in clause (xi),—
(a) for the portion beginning with the words “In addition to the’’ and ending with the words “in the above list:”, the following shall be substituted, namely:—

“In addition to the other particulars which are required to be printed or written under these rules, the label of inner most container of the following categories of drugs and every other covering in which the container is packed shall bear a caution or warning, as applicable, depending on whether the drug is covered under Schedule G or Schedule H or Schedule H1 or Schedule X, as specified in rule 97, in legible black coloured font size in a completely red rectangular box without disturbing other conditions printed on the label under these rules, namely:—

Narcotic analgesics, hypnotics, sedatives, tranquillisers, corticosteroids, hormones, hypoglycemic, antimicrobials, antiepileptics, antidepressants, anticoagulants, anti-cancer drugs and all other drugs falling under Schedules G, H, H1 and Schedule X whether covered or not in the above list:

Provided that if any of the drug referred above category is not covered under any of the Schedule, namely, Schedule G, Schedule H, Schedule H1 and Schedule X, the label of inner most container of drugs and every other covering in which the container is packed shall bear caution or warning, as the case may be, applicable for that drugs covered under Schedule H as specified in rule 97.”;

(b) In the Proviso, for the words "Provided that", the words "Provided further that" shall be substituted.

3. In the said rules, in rule 97, in sub-rule (1),—

(i) for clauses (a) to (e), the following clauses shall be substituted, namely:—

"(a) if it contains a drug substance specified in Schedule G, be labeled with following words in legible black coloured font size in completely red rectangular box:

**SCHEDULE G PRESCRIPTION DRUG – CAUTION**
It is dangerous to take this preparation except under medical supervision.

(b) if it contains a drug substance specified in Schedule H, be labeled with symbol Rx and conspicuously displayed on the left top corner of the label and shall also be labeled with thefollowing words in legible black coloured font size in completely red rectangular box:

**SCHEDULE H PRESCRIPTION DRUG – CAUTION**
Not to be sold by retail without the prescription of a Registered Medical Practitioner.

(c) if it contains a drug substance specified in Schedule H and comes within the purview of t h e Narcotic Drugs and Psychotropic Substances Act, 1985 (61 of 1985) be labeled with symbol NRx, which shall be in red and conspicuously displayed on the left top corner of the label and shall also be labeled with the following words in legible black coloured font size in completely red rectangular box:

**SCHEDULE H PRESCRIPTION DRUG – WARNING**
To be sold by retail on the prescription of a Registered Medical Practitioner only.

(d) if it contains a drug substance specified in Schedule X, be labeled with symbol Xrx, which shall be in red and conspicuously displayed on the left top corner of the label and shall also be labeled with the following words in legible black coloured font size in completely red rectangular box:

**SCHEDULE X PRESCRIPTION DRUG – WARNING**
To be sold by retail on the prescription of a Registered Medical Practitioner only.

(e) if it contains a drug substance specified in Schedule H1, be labeled with symbol Rx, which shall be in red and conspicuously displayed on the left top corner of the label and shall also be labeled with the following words in legible black coloured font size in completely red rectangular box:

**SCHEDULE H1 PRESCRIPTION DRUG – CAUTION**
− It is dangerous to take this preparation except in accordance with the medical advice.
− Not to be sold by retail without the prescription of a Registered Medical Practitioner.

(f) if it contains a drug substance specified in Schedule H1 and comes within the purview of the Narcotic Drugs and Psychotropic Substances Act, 1985 (61 of 1985) be labeled with symbol NRx, which shall be in red and conspicuously displayed on the left top corner of the label and shall also be labeled with the following words in legible black coloured font size in completely red rectangular box:

| **SCHEDULE H1 PRESCRIPTION DRUG – CAUTION** |
|---|
| − It is dangerous to take this preparation except in accordance with the medical advice. |
| − Not to be sold by retail without the prescription of a Registered Medical Practitioner |

4. In the said rules, in Schedule H, in the Note appended thereto, after paragraph 3, the following paragraph shall be inserted, namely:—

"4. The salts, esters, derivatives and preparations containing steroids for topical or external use shall also be covered under this Schedule.".

5. In the said rules, in Schedule K, against serial number 27, for the entries under the column "Class of Drugs", the following shall be substituted, namely:—

"Oral Rehydration Salts (Manufactured as per the following formula):-Composition of the formulation in terms of the amount in g, to be dissolved in sufficient water to produce 1000 ml.

- Sodium Chloride 2.6
- Dextrose (anhydrous) or 13.5
- Dextrose mono-hydrate 14.85
- Potassium chloride 1.5
- Sodium Citrate 2.9. ".

[F.No. X.11014/06/2016-DFQC]
SUDHIR KUMAR, Jt. Secy.

**Note:** The principal rules were published in the Gazette of India vide notification No. F.28-10/45-H (1) dated 21st December, 1945 and last amended vide notification number G.S.R. 385(E), dated the 19th April, 2018.

## MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 24th April, 2018

**G.S.R. 390(E).—**Whereas the Central Government is satisfied that the use of the drug Oxytocin and its formulation in any name or manner is likely to involve certain risk to human beings and animals and that it is necessary and expedient to prohibit the import of the said drugs in the public interest.

Now, therefore, 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 in the notification of the Government of India in the Ministry of Health and Family Welfare No. G.S.R. 577(E), dated the 23rd July, 1983, namely:—

In the table below to the said notification, after serial number 11 and the entry relating thereto, the following serial number and entry shall be inserted, namely:—

"12. Oxytocin and its formulation in any name or manner.".

[F. No. X.11014/2/2018-DR]
SUDHIR KUMAR, Jt. Secy.

**Note :** The principal notification was published in the Gazette of India vide G.S.R. 577(E), dated the 23rd July, 1983 and last amended by G.S.R. 433(E), dated the 7th June, 2012.

## Editorial Policy and Disclaimer

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## MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 19th April, 2018.

**G.S.R. 385(E).—**Whereas a draft of certain rules further to amend the Drugs and Cosmetics Rules, 1945, was published, as required by sub-section(i) of section 12 and sub-section(i) 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. 1368 (E), dated the 3rd November, 2017, published 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 3rd November, 2017;

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

Now, therefore, in exercise of the powers conferred under section 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 and Cosmetics Rules, 1945, namely:-

1. (1) These rules may be called the Drugs and Cosmetics (Fourth Amendment) Rules, 2018.
(2) They shall come into force on the date of their publication in the Official Gazette.

2. In the Drugs and Cosmetics Rules, 1945, in Schedule K, in the Table, for serial number 34 and the entries relating thereto, the following shall be substituted namely,–

| Class of Drugs | Extent and Conditions of Exemption |
|---|---|
| "34. Production of Oxygen 93 per cent. USP or Oxygen 93 per cent. IP, produced from air by the molecular sieve process or Oxygen 93 per cent. supplied from liquid Oxygen, by a hospital or medical institute for their captive consumptions | The provisions of Chapter IV of the Act and the rules made thereunder which require them to be covered by manufacturing licence under the rules, provided that the production facilities shall be open to inspections by an Inspector appointed under the Act, who can, if necessary, take samples for test.". |

[F. No. X-11014/17/2017-DRS]
SUDHIR KUMAR, Jt. Secy.

**Note :** The principal rules were published in the Official Gazette vide notification No. F.28-10/45-H (1), dated the21st December, 1945 and last amended vide notification number G.S.R. 360(E), dated the 10th April, 2018.

## MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 10th April, 2018.

**G.S.R. 360(E).—**Whereas a draft of certain rules further to amend the Drugs and Cosmetics Rules, 1945, was published, as required by sub-section(i) of section 12 and sub-section(i) 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. 429 (E), dated the 2nd May, 2017, published in the Gazette of India, Extraordinary, Part II, section 3, sub-section (i), dated the 2nd May, 2017, 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 2nd May, 2017;

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 and Cosmetics Rules, 1945, namely:-

1. (1) These rules may be called the Drugs and Cosmetics (Third Amendment) Rules, 2018.
(2) They shall come into force on the date of their publication in the Official Gazette.

2. In the Drugs and Cosmetics Rules, 1945 (hereinafter referred to as the said rules), in rule 71, in sub-rule (6), for the words “patent or proprietary medicines” at both the places where they occur, the word “drugs” shall be substituted.

3. In the said rules, in rule 71B, for the words “patent or proprietary medicines” at both the places where they occur, the word “drugs” shall be substituted.

4. In the said rules, in rule 76, in sub-rule (7), for the words “patent or proprietary medicines” at both the places where they occur, the word “drugs” shall be substituted.

5. In the said rules, in rule 76A, for the words “patent or proprietary medicines” at both the places where they occur, the word “drugs” shall be substituted.

6. In the said rules, in Schedule D, in the Table, against item 1, under the column “Class of drugs”, for the existing entries, the following entries shall be substituted, namely:-

“Substances not intended for medicinal use excluding those intended to be used as drugs after further purification or rendering them sterile.”.

[F.No. X.11014/2/2014-DFQC]
SUDHIR KUMAR, Jt. Secy.

**Note :** The principal rules were published in the Official Gazette vide notification No. F.28-10/45-H (1), dated the 21st December, 1945 and last amended vide notification number GSR 277(E), dated the 23rd March, 2018.

## MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 23rd March, 2018.

**G.S.R. 277(E).—**Whereas the draft of certain rules further to amend the Drugs and Cosmetics 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) in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i) 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. 1357(E), dated the 1st November, 2017 inviting objections and suggestions from all persons likely to be affected thereby before the expiry of a period of forty-five days from the date on which copies of the Official Gazette containing the said notification were made available to the public;

And whereas, the copies of the said Official Gazette were made available to the public on 1st November, 2017;

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

Now, therefore, in exercise of the powers conferred by section 12 and section 33 of the said Act, the Central Government, after consultation with the Drugs Technical Advisory Board, hereby makes the following rules further to amend the Drugs and Cosmetics Rules, 1945, namely,-

1. (1) These rules may be called the Drugs and Cosmetics (Second Amendment) Rules, 2018.
(2) They shall come into force on the date of their publication in the Official Gazette.

2. In the Drugs and Cosmetics Rules, 1945, in Schedule H, after serial number 537 and the entries relating thereto, the following serial numbers and entries shall be inserted, namely,-

"538. Alclometasone
539. Beclomethasone
540. Betamethasone
541. Desonide
542. Desoximetasone
543. Dexamethasone
544. Diflorasone diacetate
545. Fluocinonide
546. Fluocinolone acetonide
547. Halobetasol propionate
548. Halometasone
549. Methylprednisone
550. Prednicarbate
551. Triamcinolone acetonide. ".

[F. No. X-11014/14/2017-DRS]
SUNIL SHARMA, Jt. Secy.

**Note :** The principal rules were published in the Gazette of India vide notification No. F.28-10/45-H (1) dated 21st December, 1945 and last amended vide notification number G.S.R. 222(E), dated 13th March, 2018.

## MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 13th March, 2018.

**G.S.R. 222 (E).—**Whereas a draft of certain rules further to amend the Drugs and Cosmetics Rules, 1945, was published, as required under sub-section (I) of sections 12 and sub-section (I) 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. 302 (E), dated the 30th March, 2017, published in the Gazette of India, Extraordinary, Part II, section 3, sub-section (i), inviting objections and suggestions from persons likely to be affected thereby before the expiry of a period of forty-five days from the date on which the copies of the Official Gazette containing the said notification were made available to the public;

And whereas copies of the Gazette were made available to the public on 30th March, 2017;

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 the section 12 and section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, after consultation with the Drugs Technical Advisory Board, hereby makes the following rules further to amend the Drugs and Cosmetics Rules, 1945, namely:-

1. (1) These rules may be called the Drugs and Cosmetics (First Amendment) Rules, 2018.
(2) They shall come into force on the 13th day of September, 2018.

2. In the Drugs and Cosmetics Rules, 1945, in rule 96, in sub-rule (1), in clause (i), in sub-clause (A), for the portion beginning with the words “For this purpose” and ending with the words “name and shall be”, the words “For this purpose, the proper name of the drug or fixed dose combination drug other than fixed dose combinations of vitamin and other fixed dose combinations containing three or more drugs, shall be printed or written in a conspicuous manner which shall be in the same font but at least two font size larger than the brand name or the trade name, if any, and in other cases the brand name or the trade name, if any, shall be written in brackets below or after the proper name and shall be” shall be substituted.

[F. No. X.11014/5/2017-DRS]
SUNIL SHARMA, Jt. Secy.

**Note:** The principal rules were published in the Official Gazette vide notification No.F.28-10/45-H (1), dated 21st December, 1945 and last amended vide notification number G.S.R. 1380(E), dated the 10th November, 2017.

**F No. 18-13/2018-DC (Part-1)**
**Directorate General of Health Services**
**Central Drugs Standard Control Organization**
**FDA Bhawan, Kotla Road, New Delhi**
**(O/o DCG (I))**

Dated: 22 JUN 2018

**PUBLIC NOTICE FOR COMMENTS ON PROPOSED NOTIFICATION**

**Subject: Proposal to include all implantable medical devices and other high end equipment under the purview of Section 3 (b) (iv) of the Drugs and Cosmetics Act, 1940 as Medical Devices–regarding.**

In pursuance of sub-clause (iv) of clause (b) of Section 3 of the Drugs and Cosmetics Act, 1940 (23 of 1940), Drugs Technical Advisory Board (DTAB) in its 79th meeting held on 16.05.2018, deliberated and recommended for the proposal to specify the following medical devices under the definition of drug.

1) All implantable medical devices
2) CT scan equipment
3) MRI equipment
4) Defibrillators
5) Dialysis machine
6) PET equipment
7) X-Ray machine
8) Bone marrow cell separator

This will be notified in the official Gazette of India and it will come into force after a period of twelve months from the date of its publication. All the stakeholders are requested to forward their comments/suggestions within 21 days of issue of this notice prior to finalization of the notification, through email at dci@nic.in and dccdtab@cdsco.nic.in or in hard copies to the O/o DCG(I), CDSCO, FDA Bhawan, Kotla Road, New Delhi-110002.

22/6/18

**(Dr. S. Eswara Reddy)**
**Drugs Controller General (India)**

CC: pps to JS (R)

डॉ. स. ईश्वरा रैड्डी एम.फार्म,पीएच.डी.
औषधि महा नियंत्रक (भारत)
केन्द्रीय औषधि मानक नियंत्रण संगठन
स्वास्थ्य सेवा महानिदेशालय
स्वास्थ्य एवम् परिवार कल्याण मंत्रालय
भारत सरकार
एफ. डी. ए. भवन, कोटला रोड़,
नई दिल्ली-११०००२

सत्यमेव जयते

**Dr. S. Eswara Reddy** M.Pharm, Ph.D.
Drugs Controller General (India)
CENTRAL DRUGS STANDARD CONTROL, ORGANISATION
DIRECTORATE GENERAL OF HEALTH SERVICES
MINISTRY OF HEALTH & FAMILY WELFARE
GOVERNMENT OF INDIA
F.D.A. BHAWAN, KOTLA ROAD,
NEW DELHI-110002

**F. No. 18-17/2018-DC**

**Dated** 12 JUN 2018

To

All State/UT Drug Controllers

**Subject: Providing a separate shelf / rack for generic medicines in retail shops visible to the consumers - Regarding.**

Sir,

Issue of having a separate shelf / rack of generic medicines in every retail outlet in the country so as to promote the availability of generic medicines has been under consideration for quite sometimes now.

The matter has also been deliberated in the meetings of Drugs Consultative Committee (DCC) and Drugs Technical Advisory Board (DTAB) and it has been decided that every retail outlet should provide a separate shelf / rack reserved exclusively for stocking generic medicines in the licensed premises separated from other medicines, which shall be visible to the consumers.

In view of the above, you are requested to direct all the outlets licensed to sell drugs by retail under your jurisdiction to provide a separate shelf / rack reserved exclusively for stocking of generic medicines in the licensed premises separated from other medicines, which shall be visible to the consumers.

Action taken in the matter may please be forwarded to this office at the earliest.

**Yours Sincerely,**

**(Dr. S. Eswara Reddy)**
**Drugs Controller General (India)**

Copy to:

1. PPS to JS(R)
2. PPS to AS & DG (CGHS)
3. President, AIOCD with request to inform all retailers.

Tel.:+91-11-23236965 Fax : +91-11-23236973 E-mail : dci@nic.in Website : www.cdsco.nic.in

## MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 1st June, 2018.

**S.O. 2237(E).—** In pursuance of the powers conferred by sub-rule (2) of rule 19 of the Medical Devices Rules, 2017, the Central Government hereby designates the laboratories specified in column (2) of the Table below having facilities for carrying out test and evaluation of medical devices, as Central Medical Device Testing Laboratory for the purposes of —

(a) testing and evaluation;
(b) functioning as an appellate laboratory; and
(c) to carry out any other function as may be specifically assigned to it by the Central Government, in relation to the medical devices specified in column (3) of the said Table.

| Serial Number | Name of Laboratory | Category of medical device |
|---|---|---|
| (1) | (2) | (3) |
| 1. | The National Institute of Biologicals, Noida | In-Vitro Diagnostics for human Immunodeficiency virus, Hepatitis B Surface Antigen and Hepatitis C Virus, Blood Grouping sera, Glucose Test Strip, Fully Automated Analyser Based Glucose Reagent |
| 2. | The Central Drugs Testing laboratory, Chennai | Condoms |
| 3. | The Central Drugs Laboratory, Kolkata | Surgical Dressings, Surgical Cotton, Surgical Bandages, Disinfectant |
| 4. | The Regional Drugs Testing Laboratory (RDTL), Guwahati | Disposable Hypodermic Syringes, Disposable Hypodermic Needle, Disposable Perfusion Sets, I.V. Cannulae |
| 5. | The Central Drugs Testing Laboratory, Mumbai | Intra Uterine Devices (IUD) and Falope Rings |

2. The laboratories designated above are duly accredited by the National Accreditation Body for Certification Laboratories.

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

[F.No. X.11035/22/2018-DR]
SUDHIR KUMAR, Jt. Secy.

## MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 15th May, 2018.

**S.O. 1929(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 and Family Welfare, No. S.O. 3298(E), dated the 29th December, 2014, the Central Government hereby reconstitutes the Drugs Technical Advisory Board consisting of the following members, namely:—

**TABLE**

| Sl. No. | Name/Official Designation of the Member | Status in the Board | 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 | Chairperson 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 President, Medical Council of 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. | Drug Controller, Assam | Member | Nominated under section 5(2)(ix) of the Act |
| 10. | Dr. Pallavi Jain Govil, Commissioner, FDA, Madhya Pradesh | Member | Nominated under section 5(2)(ix) of the Act |

| Sl. No. | Name/Official Designation of the Member | Status in the Board | Section of the Drugs and Cosmetics Act, 1940 under which appointed / nominated / elected |
|---|---|---|---|
| (1) | (2) | (3) | (4) |
| 11. | Prof. M. D. Karvekar, Bengaluru, Karnataka | Member | Elected under section 5(2)(x) of the Act |
| 12. | Dr. G. B. Gupta, Vice-Chancellor, Pt. Deendayal Upadhyaya Memorial Health Sciences and Ayush University of Chhattisgarh, Raipur | Member | Elected under section 5(2)(xi) of the Act |
| 13. | Shri Pankaj Patel, Chairman, Zydus Cadilla Group, Ahmedabad | Member | Nominated under section 5(2)(xii) of the Act |
| 14. | Dr. Nilima Kshirsagar, Chair in Clinical Pharmacology, ICMR, Mumbai | Member | Elected under section 5(2)(xiii) of the Act |
| 15. | Dr. R.N. Tandon, Honorary Secretary General, Indian Medical Association, New Delhi | Member | Elected under section 5(2)(xiv) of the Act |
| 16. | Dr. T.V. Narayana, Bengaluru, Karnataka | Member | Elected under section 5(2)(xv) of the Act |
| 17. | Shri M.S. Lokesh Prasad, Karnataka, Scientific Officer & Government Analyst, Drugs Testing Laboratory, Bengaluru, Karnataka | Member | Nominated under section 5(2)(xvi) of the Act |
| 18. | Dr. Vaishali N. Patel, 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)]
SUDHIR KUMAR, Jt. Secy.

## MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 23rd March, 2018.

**S.O. 1352(E).—**Whereas the Central Government is satisfied that the use of Antibody Detecting Rapid Diagnostic Tests for routine diagnosis of Malaria as serological testing is not practical for routine diagnosis of acute Malaria due to time required for development of antibody, the persistence of antibodies after clearance of an active infection and the fact that serology does not detect current infection but measures past exposure;

And whereas, malaria antibody detection is performed using the indirect fluorescent antibody test for a patient who is infected with Plasmodium, and because of the time required for development of antibody and also the persistence of antibodies, serologic testing is not practical for routine diagnosis of acute malaria;

And whereas, there is a rampant use of Antibody Detecting Rapid Diagnostic Tests due to low cost and free availability of these tests;

And whereas, the false positive rate in the endemic areas is also high as patients with fever due to other reasons, who test negative by antigen detection, test positive by Antibody Detecting Rapid Diagnostic Tests;

And whereas, the only tests used in diagnosis are Antigen Detecting Rapid Diagnostic Tests and blood smear examination, and, therefore, there would not be any problems faced for malaria diagnosis by banning the Antibody Detecting Rapid Diagnostic Tests;

And whereas, the matter has been examined by an Expert Committee appointed by the Central Government and the said Expert Committee recommended to the Central Government that the said drug is found to have no therapeutic justification;

And whereas on the basis of the recommendations of the said Expert Committee, the Central Government is satisfied that it is necessary and expedient to prohibit the use of the Antibody Detecting Rapid Diagnostic Tests for routine diagnosis of malaria in public interest;

Now, therefore, in exercise of the powers conferred by section 26A of the Drugs and Cosmetic Act, 1940 (23 of 1940), the Central Government hereby prohibits the manufacture for sale, sale and distribution of the test kits used in 'Antibody Detecting Rapid Diagnostic Tests for routine diagnosis of malaria' with immediate effect.

[F. No. X-11014/15/2017-DRS]
SUNIL SHARMA, Jt.. Secy.

## MINISTRY OF CONSUMER AFFAIRS, FOOD AND PUBLIC DISTRIBUTION

(Department of Consumer Affairs)
(BUREAU OF INDIAN STANDARDS)

NOTIFICATION

New Delhi, the 14th November, 2017.

**S.O. 3609(E).**—In pursuance of clause (b) of sub-rule (1) of Rule 7 of the Bureau of Indian Standards Rules, 1987, the Bureau of Indian Standards hereby notifies that amendments to the Indian Standards, particulars of which are given in the Schedule hereto annexed have been issued:

**SCHEDULE**

| Sl. No. | No. , Year and Title of the Indian Standards | No. and year of the amendment | Date of Establishment of the Amendment at column (3) | Date till which the Standard without amendment as mentioned at Column (3) shall remain in force |
|---|---|---|---|---|
| (1) | (2) | (3) | (4) | (5) |
| 1. | IS 3959 : 2004 Skin Powder – Specification (Second Revision) | Amendment No. 2 November 2017 | 10 Nov 2017 | 10 Nov 2017 |
| 2. | IS 4707 (Part 2) : 2017 Classification of Cosmetic Raw Materials and Adjuncts Part 2 List of Raw Materials Generally Not Recognized As Safe for Use in Cosmetics (Fourth Revision) | Amendment No. 2 November 2017 | 10 Nov 2017 | 10 Nov 2017 |
| 3. | IS 6356 : 2001 Toothpaste – Specification (Third Revision) | Amendment No. 2 November 2017 | 10 Nov 2017 | 10 Nov 2017 |
| 4. | IS 6608 : 2004 Skin Creams – Specification (Second Revision) | Amendment No. 2 November 2017 | 10 Nov 2017 | 10 Nov 2017 |
| 5. | IS 7669 : 1990 Shampoo, Soap Based – Specification (First Revision) | Amendment No. 5 November 2017 | 10 Nov 2017 | 10 Nov 2017 |
| 6. | IS 7679 : 1978 Specification for Hair Creams (First Revision) | Amendment No. 5 November 2017 | 10 Nov 2017 | 10 Nov 2017 |
| 7. | IS 7884 : 2004 Shampoo, Surfactant Based – Specification (Third Revision) | Amendment No. 4 November 2017 | 10 Nov 2017 | 10 Nov 2017 |

| Sl. No. | No. , Year and Title of the Indian Standards | No. and year of the amendment | Date of Establishment of the Amendment at column (3) | Date till which the Standard without amendment as mentioned at Column (3) shall remain in force |
|---|---|---|---|---|
| (1) | (2) | (3) | (4) | (5) |
| 8. | IS 8482 : 1995 Cologne – Specification (First Revision) | Amendment No. 4 November 2017 | 10 Nov 2017 | 10 Nov 2017 |
| 9. | IS 9245 : 1994 Nail Polish (Nail Enamel) – Specification (First Revision) | Amendment No. 5 November 2017 | 10 Nov 2017 | 10 Nov 2017 |
| 10. | IS 9255 : 1995 After-Shave Lotion – Specification (First Revision) | Amendment No. 3 November 2017 | 10 Nov 2017 | 10 Nov 2017 |
| 11. | IS 9339 : 1988 Specification for Pomades and Brilliantines Pomades and Brilliantines (First Revision) | Amendment No. 6 November 2017 | 10 Nov 2017 | 10 Nov 2017 |
| 12. | IS 9636 : 1988 Specification for Depilatories, Chemical (First Revision) | Amendment No. 5 November 2017 | 10 Nov 2017 | 10 Nov 2017 |
| 13. | IS 9875 : 1990 Lipstick Specification (First Revision) | Amendment No. 6 November 2017 | 10 Nov 2017 | 10 Nov 2017 |
| 14. | IS 10999 : 1999 Kum Kum Powder – Specification (First Revision) | Amendment No. 3 November 2017 | 10 Nov 2017 | 10 Nov 2017 |
| 15. | IS 14225 : 1995 Automotive Vehicles – Locking System and Door Retention Components – General Requirements | Amendment No. 2 November 2017 | 10 Nov 2017 | 10 Nov 2017 |
| 16. | IS 14318 : 1996 Liquid Foundation Make-Up – Specification | Amendment No. 5 November 2017 | 10 Nov 2017 | 10 Nov 2017 |
| 17. | IS 14649 : 1999 Sindoor – Specification | Amendment No. 5 November 2017 | 10 Nov 2017 | 10 Nov 2017 |
| 18 | IS 15152 : 2002 Cold Wax Hair Remover – Specification | Amendment No. 2 November 2017 | 10 Nov 2017 | 10 Nov 2017 |

| Sl. No. | No. , Year and Title of the Indian Standards | No. and year of the amendment | Date of Establishment of the Amendment at column (3) | Date till which the Standard without amendment as mentioned at Column (3) shall remain in force |
|---|---|---|---|---|
| (1) | (2) | (3) | (4) | (5) |
| 19. | IS 15153 : 2002 Face Pack – Specification | Amendment No. 2 November 2017 | 10 Nov 2017 | 10 Nov 2017 |
| 20. | IS 15154 : 2002 Kajal – Specification | Amendment No. 1 November 2017 | 10 Nov 2017 | 10 Nov 2017 |
| 21. | IS 15205 : 2002 Oxidation Hair Dyes (Emulsion Type) - Specification | Amendment No. 1 November 2017 | 10 Nov 2017 | 10 Nov 2017 |
| 22. | IS 15608 : 2005 Cream Bleach – Specification | Amendment No. 2 November 2017 | 10 Nov 2017 | 10 Nov 2017 |

Copy of these Amendments are available for sale with the Bureau of Indian Standards, Manak Bhavan, 9 Bahadur Shah Zafar Marg, New Delhi-110002 and Regional Offices: New Delhi, Kolkata, Chandigarh, Chennai, Mumbai and also Branch Offices: Ahmedabad, Bangalore, Bhopal, Bhubaneswar, Coimbatore, Guwahati, Hyderabad, Jaipur, Nagpur, Patna, Pune, Kochi. Online purchase of Indian Amendments can be made at http://www.standardbis.in.

[Ref : PUB/3/5/2017-18]
C. B. SINGH, Addl. Director General

# EVENTS

## Pharma Knowledge and Training Institute (Finishing School)
## 6th Training
## on
## Industrial Orientation Training for Production and Quality Management Personnel

The 6th Training programme for the fresh Pharmacy graduates by Pharma Knowledge and Training Institute (Finishing School) under the aegis of Tamilnadu Pharmaceutical Sciences Welfare Trust was held at School of Pharmaceutical Sciences, Vels University, Pallavaram, Chennai, from 2nd April 2018 to 30th April 2018. The trainees are final year B. Pharm students from Vels University. A total of 90 students were trained in this training programme. The students were given both theoretical and practical training on the subject of "Industrial Orientation Training on Production and Quality Management Personnel". The duration of the training programme was 4 weeks. The following subjects were taught during this training programme.

**Theoretical Training Programme**

- Overview of the Pharmaceutical industry and job opportunities for the Pharmacy graduates.
- Regulatory requirements of Production and QC under Drugs & Cosmetics Act and Rules, Role of Govt. Drug Testing Laboratories
- What is quality and why it is essential for manufacture of products. Quality Control and its relationship with Quality Assurance, Production, R&D and Regulatory divisions of Pharma Industry., What are the various divisions of Quality Control
- What is Pharmacopoeia, various Pharmacopoeias used world over, how to use a Pharmacopoeia, monographs, their explanation & General Notices in pharmacopeia and Reference Standards.
- Plant Design & Site Master File
- cGMPs for manufacturing including entry & exit procedures.
- ICH guidelines for Production & Quality Control of Pharmaceuticals
- Good Laboratory Practices - Schedule L1
- IQ, OQ, PQ and DQ of equipment of Production & QC, Validation, Qualification and Calibration
- Market complaints, CAPA, OOS and OOT etc., What is containment? Essential steps to control contamination, handling of deviation, risk assessment
- Change control, Deviation control and their importance
- Basic calculations in Quality Control, Dilutions, Statistical Analysis, Qualitative Analysis, Quantitative Analysis & Elemental Analysis.

- Air Systems, Water Systems, their sampling and testing
- Introduction to Chromatography & Spectrophotometry
- TLC, HPLC Instrumentation & application
- Chromatography in Isolation
- Detectors in Chromatography
- Gas Chromatography and its applications
- Tablets (Processes involved in the production of tablets such as size reduction, sieving, granulation, compression, coating etc., Various components of a tablet with examples of different materials used &, in-process tests to be carried during production of tablets)
- Types of tablets such as Plain Tablets, Press Coated Tablets, Tablet in Tablet, Film Coated Tablets, Enteric Coated Tablets, Delayed Release Tablets etc, their advantages, How to control and rectify (in case of failure) Weight Variation, Disintegration Time, Hardness, Friability, Dissolution, etc. during production, Different types of coatings of tablets, materials used for coating & coating process
- Preventive maintenance, Predictive maintenance & Break down maintenance
- Documentation and records in Production and QC
- Standard Operating Procedures
- Sampling of Raw Materials, Packing materials, In-process Materials and Finished products.
- Microbiology - An Introduction, microbiology for non-sterile preparations
- Dissolution & its Importance, methods used in Dissolution Testing
- Calibration of QC equipment, Reference Standards and Working Standards, Reference / retention samples storage
- Analytical Method Validation
- Stability Testing, Accelerated and Real Time Studies, Packaging Material Stability, their Testing, Their importance with respect to the Product Stability
- Different types of Oral Liquid Dosage Forms such as Liquids, Syrups, Suspensions, Emulsions, etc., facilities required and their methods of manufacture, in-process tests to be carried out during their manufacture.
- Selection of Packing Materials like Bottle packing, Strip Packing, Blister Packing, etc., selection of different materials according to stability of products viz: tablets, capsules, powders, etc.
- General requirements for Tablets, Capsule, Oral Liquids & external preparations like Ointments, Creams, Emulsions, Gargle solutions, Sanitizers, etc. Different types of equipment used for their manufacture, ingredients used and in-process tests to be carried during their production. Packing of the above products.

# PKTI – 6th Training Programme


Inaugural function of 6th PKTI Training


Address by Dr. V. Ravichadiran


Address by Dr. P. Swaminathan,
Vice Chancellor, VISTAS

Trainees during inauguration


Lecture by Mr. P. R. Abdul Hameed


Trainees during lecture

Trainees during lecture

Group Photo of the Trainees


Address by Prof. K. Chinnaswamy


Address by Dr. P. Shanmugasundaram


Certificate distribution to the trainees


Group Photo of Awardee

- Batch Manufacturing Records, Batch Packing Records and importance of online recording. Basics of Production Planning & Inventory Control.
- Quality by Desigh (QbD)
- Capsules – Processes involved in the production of capsules such as size reduction, sieving, granulation, filling, cleaning & polishing etc., various components of capsules with examples of different materials used.
- Different sizes of capsules available in the market, Filling of Capsules: Hand Filling, Machine Filling, High speed filling machines, in-process tests to be carried during production of capsules, How to control and rectify (in case of failure), Weight Variation, Disintegration Time, Dissolution, etc. during production of capsules.
- Powders for Dry Syrups: Main ingredients with examples of various materials used, equipment used for their manufacture, in-process tests to be done, their packaging Effervescent Powders - their main ingredients, manufacture and packing.
- Oral Rehydration Powders (ORS), Equipment used for their manufacture, WHO approved formula, materials used for formulation of ORS, in-process tests to be done and packing of ORS powders.
- Soft Skill

The following faculties gave lecture on the above subjects

**Mr. J. Jayaseelan,** Managing Director M/s. Sai Mirra Innopharm Pvt Ltd.

**Mrs. Shanthy Gunasekaran,** DDC(I), CDSCO, South Zone, Chennai.

**Mr. P.R. Abdul Hameed,** Executive Director - Technical, M/s. Medopharm

**Dr. N. Murugesan,** Director, CDTL, Chennai.

**Mr. Sanjay Kumar Dasmohapatra,** Vice President – Technical & Operations, M/s. Medopharm

**Mr. S. Vikraman,** Manager – R & D, M/s. Apex Laboratories P Ltd

**Mr. S. Jaya Kumar,** Head – Quality, M/s. Apex Laboratories Pvt Ltd.

**Mr. K. Saravana Kumar,** Corporate – QA Head, M/s. Fourrts (India) Labs Pvt. Ltd.

**Mr. D. Satish Kumar –** Senior Manager – Production, M/s. Fourrts (India) Labs Pvt. Ltd.

**Mr. M. Ramalingam,** Head (Plant II), M/s. Fourrts (India) Labs Pvt. Ltd.

**Mr. K. M. Sridhar,** Head – Quality Control (Plant I), M/s. Fourrts (India) Labs Pvt. Ltd.

**Mr. G.T. Arularasu,** Head – Quality Control (Plant II), M/s. Fourrts (India) Labs Pvt. Ltd.

**Mr. M. Radhakrishnan,** Senior Manager – Production, M/s. Fourrts (India) Labs Pvt. Ltd.

**Mr. M. A. Mujibur Rahman,** Asst Manager – Microbiology, M/s. Fourrts (India) Labs Pvt. Ltd.

**Mr. S. Murali,** GM – Plant Operations, M/s. Apex Laboratories P Ltd.

**Mr. D. Srinivasa Rao,** GM – Plant Operations, M/s. Apex Laboratories P Ltd.

**Mr. S. Ganesan,** GM – Works, M/s. Tablets (India) Ltd.

**Dr. R. Venkidesh,** GM – Quality Control, M/s. Saimirrah Innopharm Pvt. Ltd.,

**Mr. S. Saravanan,** IICMS (Indian Institute of Chromatography and Mass Spectrometry), Chennai

**Dr. Devasena Kannan,** IICMS, Chennai

**Dr. Balaji,** IICMS, Chennai

**Mrs. Bhavani,** IICMS, Chennai

**Mr. K. P. Lucas Mani,** Ex. Vice President, Microlabs

**Mr. N. Chandar,** Pharma Consultant,

**Dr. D. Natarajan,** Pharma Consultant

**Mr. M. Sridharan,** Manager – Production (Plant II), M/s. Fourrts (India) Labs Pvt. Ltd.

**Ms. Swetha,** Manager – L & D, Ripe Consulting Services Pvt. Ltd., Chennai

**Practical Training**

M/s. Fourrts (India) Laboratories Pvt. Ltd., Chennai, M/s. Apex Laboratories Pvt. Ltd., Alathur, Chennai, M/s. Medopharm, Guduvanchery, Chennai, M/s. Tablets (India) Ltd., T H Road, Chennai, M/s. Sai Mirra Innopharm Pvt. Ltd., Ambattur, Chennai and M/s. The Madras Pharmaceuticals, OMR, Chennai offered their facilities for practical training to the trainees.

**Evaluation**

All the trainees were evaluated after each of the lecture programme as well as on the final day of the programme. On the basis of the evaluation, they were given merit award prizes during the valedictory function.

**Valedictory Function**

The Valedictory function was held at Vels University on 30th April 2018. Our Trust Chairman Mr. S. V. Veerramnai was the Chief Guest of the function. The guests of honour were Prof. K. Chinnaswamy, President – Tamilnadu Pharmacy Council, Mr. J. Jayseelan, MD M/s, Sai Mirra Innopharm Pvt Ltd., Dr. P. Shanmugasundaram, Director – School of Pharmaceutical Sciences, Vels University. Mr. R. Narayanswamy, Director, PKTI Welcomed the gathering and explained about the 6th training programme. Prizes were awarded to the trainees who had scored highest marks in the evaluation test. Dr. S. Jayakumari, HOD Dept of Pharmacognosy, School of Pharmaceutical Sciences, Vels University proposed vote of thanks.

## INAUGURATION OF IPA COIMBATORE LOCAL BRANCH

The Tamilnadu IPA Coimbatore Local Branch was inaugurated on Saturday, 5th May 2018 at Sri Velumaniammal Auditorium, Sri Ramakrishna Hospital campus. The association was inaugurated by Dr. S. Manivannan, Deputy Drugs Controller, CDCSCO, New Delhi and Mr. D. Lakshminarayanaswamy, Joint Managing Trustee, SNR Son's Charitable Trust, Coimbatore.

The inaugural program was also attended by Prof. K. Chinnasamy, President, TN State Pharmacy Council, Chennai, Dr. T.V. Narayana, National President Indian Pharmaceutical Association, Mumbai, Mr. Krishna Dev, Chairman, TANIPA Trust, Chennai, Mr. N. Sreenivasen, General Secretary, TNPSW Trust, Chennai, Mr. J. Jayaseelan, National Chairman, Industrial Pharmacy division, IPA, Mumbai, Mr. T. Sathish, Secretary, IPA TN State Branch, Chennai. The President of the IPA Coimbatore local branch Dr. T.K. Ravi, Principal, College of Pharmacy, SRIPMS welcomed the gathering and the Secretary Dr. M. Ramanathan, Principal, PSGCP proposed the vote of thanks. Other members felicitated the occasion. The Coimbatore Local branch IPA executive committee members were introduced by IPA National President Dr. T. V. Narayana.

On 5th and 6th May 2018a seminar on the topic “Industrial Pharmacy, Quality Control, Assurance and Management” was organized, in coordination with the College of Pharmacy, SRIPMS, Coimbatore. The following speakers have addressed the B.Pharm final Year and PG Students.

1. **Mr. Sanjay Kumar Dasmohapatra,** President, Technical & Operations, M/s. Medopharm, Chennai, Delivered a talk on the topic “Plant Design & Site Master File, cGMP's for manufacturing including entry & exit procedures, Good Laboratory Practices - Schedule L1”
2. **Mr. J. Jayaseelan,** Chairman, Industry Division, IPA Mumbai & Chairman, IDMA, Tamil Nadu, delivered the talk on the topic “Overview of the Pharmaceutical Industries and Job opportunities including Marketing for the Pharmacy graduates”
3. **Mr. K. Saravana Kumar,** Corporate Head – Quality Assurance, M/s. Fourrts (India) Labs Pvt Ltd, Chennai, Delivered a talk on the topic “Sampling of Raw Materials, Packing materials, In- process Materials and Finished products Documentation and records in Production and QC”
4. **Mr. S. Jaya Kumar,** Corporate Head – Quality Assurance, M/s. Apex Laboratories Pvt Ltd, Chennai Delivered a talk on the topic “Air Systems, Water Systems, their sampling and testing”

5. Mr. S. Sridhar, Vice President, Medopharm, Malur, Karnataka Delivered a talk on the topic “General requirements for manufacture of Tablets & its Method in various process like Granulation, Compression & Coating”

Around 300 students from Pharmacy colleges in Coimbatore were benefited from the seminar. The seminar was sponsored by Tamil Nadu Pharmaceutical Sciences Welfare Trust, Chennai and TANIPA Trust Chennai. The interactive session with industrial experts was unique and helped the students for their career selection. The outcome of the seminar was appreciated by the participants. The valedictory function was organized on 6th May 2018, were Prof K.Chinnasamy was the chief guest and distributed the certificates to the participants.




## INAUGURATION OF IPA SOUTH TN LOCAL BRANCH


IPA South TN local branch was inaugurated at Arulmigu Kalasalingam College of Pharmacy on 23rd June 2018. Dr. S. Shasi Anand, Vice President, Kalasalingam University & Anand Group of Institutions, Srivilliputtur graced the function as Chief Guest. Prof. K. Chinnaswamy, President, Tamilnadu Pharmacy Council, Chennai, Shri. J. Jayaseelan, Vice President, IPA Tamilnadu Branch, Shri. T. Sathish, Secretary, IPA Tamilnadu Branch, Shri. N. Sreenivasen, General Secretary, TNPWST, Chennai & Shri. R. Narayanaswamy, Joint Secretary, TNPWST, Chennai, were the Guest of Honor. Shri. M. N. Sridhar, Asst. Director of Drugs control, Madurai zone also graced the occasion Dr. S. Manivannan, President-IPA Tamilnadu Branch presided over the function and officiated the Office Bearers of IPA south TN Branch. Dr. N. Venkateshan, Secretary - IPA South TN Branch welcomed all the guests and guaranteed to uphold all the objectives of IPA. He assured to that IPA South TN local branch will actively work for the enhancement of the spirit of pharmacy profession.

To mark the inauguration, One day national seminar on “Industrial Pharmacy, Quality Control, Assurance and Management” was held on 23rd June 2018 in association with Tamilnadu Pharmaceutical Sciences Welfare Trust, Chennai, IPA – Tamilnadu Branch & TANIPA Trust. Dr. N. Murugesan, Director, Central Drug Testing Laboratory, Chennai and Dr. R. Venkidesh, General Manager - Quality Control, M/s. Saimirra Innopharm Pvt. Ltd., Chennai, were the resource persons. More than 600 delegates from various pharmacy institutions participated and benefited from the seminar. The function concluded with vote of thanks by Shri. J. Anburaj, Treasurer- IPA South TN Branch.

## Best Hospital Pharmacy Citation 2018


The Hospital Pharmacy Services of Sri Ramakrishna Hospital, Coimbatore has been awarded with "Best Hospital Pharmacy Citation 2018 in the Multi Specialty Category" by Indian Express Health Care Newspaper Group in recognizing the pivotal role of hospital pharmacies in healthcare delivery.

Dr. Isaac Christain Moses, Medical Director, Sri Ramakrishna Hospital, Coimbatore & Dr. T. K. Ravi, Principal College of Pharmacy, Sri Ramakrishna Institute of Paramedical Sciences, Coimbatore were receiving the award.

## University Gold Medalists
## The Tamil Nadu Dr. M. G. R. Medical University, Chennai

Ms. Christy Mary Varghese, Pharm. D., (Regular 2011 - 2017) College of Pharmacy, Sri Ramakrishna Institute of Paramedical Sciences received the University Gold Medal from the Honourable Vice - President of India Shri. Venkaiah Naidu during the 30th Convocation of the Tamil Nadu Dr. M. G. R. Medical University, Chennai on 08th July 2018.

## University Gold Medalists
## The Tamil Nadu Dr. M. G. R. Medical University, Chennai

Ms. Tharayil Nishi Nainan (Pharm. D. - Post Baccalaureate 2014-17), College of Pharmacy, Sri Ramakrishna Institute of Paramedical Sciences was also awarded with University Gold Medal.

## University Gold Medalists

## The Tamil Nadu Dr. M. G. R. Medical University, Chennai

Ms. Rittumol Varghese, M. Pharm., (Pharmacy Practice 2015 - 17) College of Pharmacy, Sri Ramakrishna Institute of Paramedical Sciences received the University Gold Medal from the Honourable Vice –President of India Shri. Venkaiah Naidu during the 30th Convocation of the Tamil Nadu Dr. M. G. R. Medical University, Chennai on 08th July 2018.

## Ph.D. Degree Awardees

Mrs. Subhadra Devi V., Associate Professor, Department of Pharmacology of College of Pharmacy, Sri Ramakrishna Institute of Paramedical Sciences, Coimbatore has been awarded with Ph.D., during July, 2018 in the 30 Convocation of the Tamil Nadu Dr. M. G R. Medical University, Chennai for her work entitled "Evaluation of Hepato-protective activity of certain Indian Medicinal Plants using vitro& in-viv o methods" and the work was carried out at College of Pharmacy, Sri Ramakrishna Institute of Paramedical Sciences, Coimbatore under the guidance of Dr. M. Gopal Rao,Vice- Principal & Head & Co-Guidance of Dr. M. Umamaheshwari, Professor, College of Pharmacy, Sri Ramakrishna Institute of Paramedical Sciences, Coimbatore.

**Mrs. S. Hurmath Unnissa,** Assistant Professor, Department of Pharmaceutical Chemistry of KMCH College of Pharmacy, Coimbatore has been awarded with Ph.D., during July, 2018 in the 30 Convocation of the Tamil Nadu Dr. M. G R. Medical University, Chennai for her work entitled **" Molecular Modelling, QSAR studies and synthesis of Novel Azolo Cinnoline analogs as anti tubercular agents"** and the work was carried out at College of Pharmacy, Sri Ramakrishna Institute of Paramedical Sciences, Coimbatore under the guidance of Dr. **T. K. Ravi,** Principal & Head & Co-Guidance of **Dr. Sonia George,** Associate Professor, College of Pharmacy, Sri Ramakrishna Institute of Paramedical Sciences, Coimbatore.

## NEWS

### China Eyes Indian Pharma as U.S. Trade Turns Cloudy

'Drugmakers may get Chinese licences within six months'

China is preparing to give swift regulatory approvals to India-manufactured drugs, the head of an Indian export promotion group said, as Beijing looks for new commercial partners ahead of what could be a protracted trade war with the United States.

Indian firms are looking to fill gaps in Chinese demand for generic drugs, software, sugar and some varieties of rice, trade officials in New Delhi said.

"We do feel that China is receptive at this time and it's all about making prices competitive," said a government official involved in the effort to promote trade with China. The official declined to be identified since he is not authorised to speak to the media. No concrete deals have been signed but the outlook for pharmaceutical sales from India is positive, according to officials from both nations.

India dominates the world's generic drugs market, exporting $17.3 billion of drugs in the 2017/18 (April-March) year, including to the U.S. and the EU. But only 1% of that went to China, the world's second-largest market for pharmaceuticals, industry data shows.

Dinesh Dua, chairman of the Pharmaceuticals Export Promotion Council (Pharmexcil), which falls under India's trade ministry, told Reuters in an interview that Indian firms could expect to win licences to export to China within six months of application.

"We understand internally that Chinese authorities have issued instructions that EU-approved Indian suppliers should be granted the industrial drug licence in an expeditious manner so they can enter the Chinese market within six months," Mr. Dua said.

The EU is already one of India's key export markets for medicines, and accounted for about 15% of overall drug exports in 2016/17, according to Pharmexcil.

**U.S. market woes**

Swift regulatory approvals in China would allow Indian companies to boost revenue at a time when pricing scrutiny and regulatory troubles have hurt U.S. sales.

Some of India's largest drugmakers, Sun Pharmaceutical and Lupin as well as Aurobindo Pharma, have been trying for years to expand in the massive Chinese market, which is second only to the U.S.

The China Food and Drug Administration (CFDA) did not respond to a Reuters' request for comment.

But Chinese Foreign Ministry spokeswoman Hua Chunying said this week that China was moving forward on giving greater market access to Indian drug makers.

"China and India are witnessing a growth in pharmaceutical trade, and the two sides are in sound communication on opening the Chinese market to drugs from India and conducting dialogue and co-operation between the two sides' pharmaceutical industries," Ms. Hua told reporters.

"The relevant departments have formulated specific measures on promoting China-India pharmaceutical trade cooperation and

granting greater access to drugs from India. We believe that stronger pharmaceutical trade co-operation will contribute to the well being of the people in our two countries."

In May, China exempted import tariffs on 28 drugs, including all cancer drugs, a move that would help India reduce its trade imbalance with China, Luo Zhaohui, the Chinese ambassador to India said.

China has been touting greater access to cancer drugs and pushing to lower prices in a bid to soothe a major social issue in the country, where traditionally many patients with serious illness have had to pay out of their pocket for cutting-edge drugs or have had to buy medicines through unapproved grey market channels.

China also lags far behind in terms of drug approvals versus developed markets.

The issue was highlighted in a recent film that went viral in China which echoed the U.S. Dallas Buyers Club about a Chinese cancer patient who had helped others getting unapproved cancer drugs at lower prices shipped in from India.

About 250 product applications from Indian drug firms are pending before the CFDA, some of them for years, an Indian trade ministry official said.

**Source:** *The Hindu, 12th July 2018*

## Chemists Must Display Generic Medicines

### Drug Controller-General writes to States

Soon, chemists across the country will have to prominently display generic medicines — medicines that are off-patent, locally manufactured and much cheaper than the original formulations they're based on — in a dedicated rack in their shops.

A letter dated June 12, recently made public, by India's Drug Controller-General Eswara Reddy, directed State Drug Controllers to ensure that "…all outlets licensed to sell drugs…to provide a shelf/rack exclusively for stocking of generic medicines, which shall be visible to the consumers." Dr. Reddy's letter follows a decision by India's Drugs Technical Advisory Board — an expert group — to ensure generic drugs are available more widely. The push for generic medicines has been growing since Prime Minister Narendra Modi, last April, said the government was contemplating a law requiring doctors to prescribe generics.

The Indian Medical Association has also supported the push for generics.

However, doctors and pharmaceutical associations have mixed opinions. Several manufacturers of generic drugs didn't meet quality standards. "What we would not want is to prescribe a drug whose quality is not assured," said Neelam Mohan, director, Paediatric Gastroenterology, Medanta, The Medicity.

**Source:** *The Hindu, 10th July 2018*

## Firms Marketing Medicines May Soon be Liable for Drug Regulation Violations

Companies marketing medicines in India will soon be liable for violations of drug regulations that could lead to spurious or substandard medicines even if they aren't manufacturers of these medicines, deputy drug controller of India Shanthy Gunasekaran said.

The Drugs Technical Advisory Board had recently approved a proposal to amend the Drugs and Cosmetics Act to check lapses in the quality of medicines and penalise marketing firms that violate the regulations, she said at the fourth edition of the Pharmac South, India Drug Manufacturers' Association meeting held in Chennai.

"A Pharmaceutical major may buy medicines manufactured by smaller companies. In case of a violation, neither of them is willing to own responsibility. As per the existing law, only the manufacturer is responsible. The idea of the amendment is to make everyone feel responsible," she said. The draft copy of the amendment will be available for public opinion soon, she added.

About 4.5% of the drugs in the Indian market are substandard, according to a survey by the Central Drug Standard Control Organization, the official regulatory authority. "But a bigger problem is that of packaging and labelling information," said Tamil Nadu state drug controller Sivabalan.

"The problem occurs because many times it is the marketing company, not the manufacturer that does the packaging and labelling. It contains important information such as dosage and usage instructions. A lot of information is lost when the manufacturer does not provide it," he said.

The meeting is held to give small industries an opportunity to exhibit their strength and capacity to larger companies. "We have been doing extremely well in both imports and exports in the past few years. Last year, our growth was slow because of the GST variations, but now the market has stabilised and growth is in two digits. We export products worth $17 million and bigger companies are increasingly using idle capacity in smaller companies. This is one of the platforms for them to meet," said S V Veerramani, past national president, Indian Drug Manufacturing Association.

**Source:** *ET Healthworld, 9th July 2018*

## China Agrees to Cut Tariffs on Indian Cancer Drugs: Foreign Ministry

India and China have reached an agreement on reduction of tariffs on the import of Indian medicines, particularly cancer drugs, to China, the Foreign Ministry said here today, days after a Chinese movie on a leukaemia patient highlighted the need for paving the way for import of cheap Indian medicines.

However, it is not yet clear whether China has agreed to grant licences to Indian companies to sell cancer drug in the huge market here, which could be a major step.

About 4.3 million people are diagnosed with cancer annually in China, according to a report of the state-run China Central Television. Indian drugs, specially cancer curing medicines, are in big demand

in China as they are far cheaper than their western counterparts.

"We have seen China and India have reached agreement on the reduction of tariffs on medicines. For specifics, I will refer you to relevant competent authorities," Chinese Foreign Ministry spokesperson Hua Chunying told a media briefing here today.

"We believe expansion of imports and slashing of tariffs on anti-cancer medicines will also usher in great opportunities for India and other countries in the region," she added without providing any further detail.

Earlier in May, China had lifted tariffs on the import of cancer drugs. It was not clear whether Hua was referring to that announcement.

The May announcement had, however, failed to enthuse Indian companies as they cannot legally market their drugs in China as it requires license from the country's food and drug administration.

India has been demanding opening of China's IT and pharmaceutical sectors as part of measures to reduce over USD 51 billion trade deficit in over USD 84 billion bilateral trade.

While announcing the agreement, Hua referred to a new Chinese film on the plight of a leukaemia patient, highlighting the pressing need for China to pave the way for import of cheap Indian cancer drugs.

"There is a popular movie now in China called 'Dying to Survive'. That movie is about zero tariffs imposition on anti-cancer medicines in China," she said.

About the general reduction of tariffs, Hua said, "We have decided to expand our imports as well as opening up. This is what China needs in order to uphold the free trade and against protectionism. This is also in keeping up with our own pace of development and opening up."

"On July 1, the outcome of the round of negotiations under the Asia Pacific Trade Agreement released a document and we have agreed to slash tariffs by 33 per cent. So according to my understanding the slashing of tariffs by the Indian side is also part of this negotiation...We will also impose a negotiated agreed tariff rate on relevant items in accordance with our regulations," she said.

Both the sides have stepped up negotiation to import Indian rice, sugar and pharmaceuticals after a meeting between Prime Minister Narendra Modi and Chinese President Xi Jinping during the April 28 Wuhan informal summit.

**Source:** *ET Healthworld, 9th July 2018*

## Pharma Sector May Post 17% Revenue Growth in June Quarter: Report

The pharmaceutical industry is likely to report a 17 per cent revenue growth in the June quarter, driven by strong domestic growth and currency tailwinds, said a report.

"Overall revenue for the pharma sector is likely to grow 17 per cent YoY (year-on-year) and PAT 50 per cent YoY," Edelweiss Securities said in its report.

"Domestic sales are likely to spike 26 per cent on the back of a low base due to GST-related disruption," it added.

The US sales in constant currency is expected to grow 6 per cent in annual terms, but fall 2 per cent in quarterly terms, on lack of any meaningful launch during the June quarter, according to the report.

Currency tailwinds, namely the rupee's 4 per cent depreciation against the US dollar and 11 and 5 per cent fall against the euro and yen, respectively, are likely to drive EBITDA margin expansion of 350 bps in annual terms and 100 bps in quarterly terms in the June quarter, it said.

Edelweiss Securities said that the optimism is on favourable regulatory environment.

The US Food and Drug Administration (USFDA) approval rate rebounded to 198 nods after a temporary hiatus in the March quarter, with 109 approvals due to extra documentation requirements for elemental impurities, the report revealed.

Following the recent USFDA clearance of Sun Pharma's Halol plant, the report said piled-up filings are expected to keep the approval rate buoyant for domestic pharma companies.

"On the regulatory front, favourable inspections at Cadila's topicals plant, Dr Reddy's Medak, Srikakulam SEZ, UK, and Sun Pharma's Halol plant demonstrate that the worst in terms of regulatory issues is over," it said.

Edelweiss Securities, however, said that the pricing challenges in the US is still cause of concern.

"Though the Q1FY19 results will be seemingly better, we believe underlying growth will remain muted. However, initial signs of rebound in domestic markets is key positive," it said.

The domestic pharmaceutical sector accounts for 3.1-3.6 per cent of the global pharmaceutical industry in value terms and 10 per cent in volume terms.

It is expected to grow to $100 billion by 2025, according to the report.

**Source:** *ET Healthworld, 8th July 2018*

## UK's Unsafe Syringes Found their Way to Indian Hospitals: Report

Syringes declared unsafe for use by the UK's state-funded National Health Service (NHS) found their way to India and are likely to have been used in some hospitals in the country, a media report said here today.

According to 'The Sunday Times', banned Graseby syringe drivers were given to hospices and medical organisations in countries such as India, South Africa and Nepal. It followed the phased withdrawal of the devices from the NHS in 2010 following safety alerts dating back as far as 1995.

As part of its investigation, the newspaper found a notice issued by the Isle of Wight NHS Trust in December 2011, which advised staff that in order to "comply with a department of health alert" all Graseby MS 16 and MS 26 syringe drivers would be replaced. It added: "They will be donated to a 3rd world charity."

Other donations were more informal, with one nurse from Somerset in England writing in a 2014 blog that she had been allowed to take several Graseby drivers with her when volunteering at a hospice in India. In the same year, another doctor mentioned a Graseby syringe driver being given to him before he attended a medical charity expedition in Nepal.

Peter Walsh, the chief executive of safety charity Action against Medical Accidents, said, "Obviously the safety of patients in any part of the world should be of concern to us in the UK. What would worry me most is if the countries or institutions concerned weren't fully briefed on the risks with these particular devices."

The syringe pumps have been implicated in NHS deaths over a 30-year period, the newspaper had recently revealed.

The pumps led to the rapid infusion into the bloodstream of dangerous doses of drugs. The two syringe types, which were easily confused, were used at GosportWar Memorial Hospital, Hampshire, where Dr Jane Barton worked between 1988 and 2000. Last month, she was found responsible for the deaths of as many as 650 people as part of a culture in which opiates, or opium-based drugs, were recklessly prescribed.

Last month, Health Secretary Jeremy Hunt told medical directors to make "absolutely sure" that the banned Graseby syringe drivers were no longer in use in Britain.

A project organised by UK Rotary clubs in 2011 sent more than 100 Graseby syringe drivers to South Africa's growing hospice care community as part of the 'Abundant Life' programme.

Rotary International in Great Britain & Ireland said, "The donation of the syringe drivers was made in good faith for the project by the NHS, and helped hundreds of people who otherwise would have suffered tremendously during their final stages of life."

The devices have also been banned elsewhere, including in New Zealand and Australia, but remained in use in the NHS until 2015.

**Source:** *ET Healthworld, 8th July 2018*

## Ramifications of Rationalizing Trade Margins of Medical Devices from Landed Cost will Have A Catastrophic Impact on Indian Export

Prominent public health experts and industry insiders are of the opinion, if India isn't cautious in the method of calculating trade margin rationalisation, it may face implications on its exports of medical devices.

India's Export-Import policy is constantly under the scanner of the south Asian countries and there have been far too many pieces of evidence. For instance, immediately after the price capping of stents by the Indian government, Pakistan, Sri Lanka and Bangladesh followed suit and got a similar line of price control.

In February 2017, India slashed the price of coronary stents by 80%. Immediately, in the same month, Pakistan's senate committee on health directed the health ministry and the Drug Regulatory Authority of Pakistan to formulate a pricing policy on stents within a month.

Consequently, in April, Bangladesh too joined the bandwagon; the Directorate General of Drug Administration, contemplated bringing down the current price by half. 6-months later, Sri Lanka followed suit – the prices of the bare-metal stent and the drug-eluting stent was reduced at a similar rate.

This clearly proves that any Export-Import policy which GOI will try to implement is clearly pursued by the neighboring countries.

Albeit, India is considering trade margin rationalisation as an alternative mechanism to price control, the medical device industry is concerned whether the calculation will be balanced and agreeable. The neighboring countries may again take a page out of India's book and implement similar margins by including only the landed cost. If these countries exporting Indian medical devices also demand a landing cost based selling price, it will be catastrophic for 16 billion USD worth Indian drugs/ device export of India.

"The market-based price control mechanism of DPCO 2013 evolved from the past learnings of imposing price control. For instance, when the DPCO in 1995 practised cost-based price capping, it impacted both patients and the industry. There was no new entrant in the market nor any production capacity, as a result, the competition was stagnant, implicating growth and innovation. More importantly, industries ability to invest in enhancing capability building was curtailed. All these are well documented in National Pharmaceutical Pricing Policy 2012. Hence, the government should refrain from going back to the past landed cost/ manufacturing cost-based price capping mechanism and tear down the nascent medical device industry as was the case for bulk drugs," said Avirup Bose, Associate Professor, Jindal Global Law School.

The National Medical Regulatory Authority of Sri Lanka has also initiated the process of trying to match the prices of import with that of the country of origin and other SAARC countries. Subsequently, the Bangladesh Government is also planning to control margins from landing cost for imported medicines. If GOI opts to calculate only the landed cost and the margin, the Indian subsidiaries operating abroad may also suffer and the off-shore subsidiary level expenditure will have to be cut-off severely, affecting Indian export.

"A global company's subsidiary should be viewed as a domestic firm, with added costs not borne by the typical domestic firm, for purposes of the Trade Margin computation. Trade margin rationalization should be based on a comparable PTT (Price to trade) and not landed cost basis in the case of imports, as it does not consider other intermediate expenses such as training clinicians on the technology, providing technical support to clinicians or patients for the product, investment on creating therapy awareness and skill development of clinicians, financing sales and collection costs in India, paying Indian corporate taxes, and other normal expenses for developing and serving the Indian market," said, Ritesh K Singh, a Public Health Expert and Group Chief Economist, Raymond Limited.

Trade margin rationalization based on Department of Pharmaceuticals report on high trade margin rightly addresses the issue of high trade margin escalation as the reason for MRP enhancement. If trade margin proposal is implemented, it is estimated to reduce the MRP by 73 %. This will not only bring inpatient affordability but also allow access to quality healthcare. It will keep the door open for innovation and capability enhancement of the clinicians on newer technologies.

So, adopting this proposal to calculate from the first point of sale would encourage innovation, increase affordable access to quality care, support skilling and training and have a significant impact in reducing prices for patients, thereby enhancing India's competitiveness edge. This presents a win-win situation for all.

**Source:** *ET Healthworld, 6th July 2018*

## Zydus Cadila Gets USFDA Nod to Market 2 Drugs

Drug firm Zydus Cadila said it has received final approval from the US health regulator to market Nifedipine extended-release tablets and Cholestyramine for oral suspension in the American market.

The approval from the US food and Drug Administration (US FDA) is to market Nifedipine extended-release tablets in the strengths of 30 mg, 60 mg, and 90 mg, the company said in a BSE filing.

The product will be manufactured at the group's manufacturing facility at Moraiya, Ahmedabad, it added.

The tablets are used to treat high blood pressure and angina, Zydus Cadila said.

The company has also received the USFDA nod to market Cholestyramine for oral suspension 4 g resin per pouch or scoopful, which is used along with a proper diet to lower cholesterol, it added.

The product will be manufactured at the group's formulations manufacturing facility at Baddi in Himachal Pradesh, Zydus Cadila said.

**Source:** *ET Healthworld, 5th July 2018*

## NPPA Fixes Prices of 58 Drug Formulations

The national drug pricing regulator NPPA has fixed the retail and ceiling prices of 58 formulations used for treatment of various ailments, including cardiac conditions, anxiety disorders, Hepatitis C and diabetes.

While the National Pharmaceutical Pricing Authority (NPPA) has fixed the retail prices of 56 formulations, it has also capped the ceiling prices of two formulations, a notification on the regulator's website said.

The prices have been fixed/revised under the Drug (Prices Control) Order, 2013, it added.

The regulator has fixed the retail prices of drugs manufactured and marketed by various firms. The drugs include Sofosbuvir and Ledipasvir tablets used for treatment of hepatitis C.

It has also fixed the retail price of Teneligliptin Metformin tablet (Teneblu M Forte) used for treatment of diabetes.

The NPPA has capped the ceiling prices of Digoxin and Furosemide oral liquids.

The regulator is mandated to fix/revise the prices of controlled bulk drugs and formulations and to enforce prices and availability of the medicines in the country.

It also monitors the prices of decontrolled drugs in order to keep them at reasonable levels.

The NPPA implements and enforces the provisions of the Drugs (Prices Control) Order.

It is also entrusted with the task of recovering amounts overcharged by manufacturers for the controlled drugs from the consumers.

**Source:** *ET Healthworld, 6th July 2018*

## Unichem Labs Gets USFDA Nod for Asthma Drug

Drug firm Unichem Laboratories today said it has received final approval from the US health regulator for its Montelukast chewable tablets used for prevention and treatment of asthma.

The company has received final abbreviated new drug application (ANDA) approval from the United States Food and Drug Administration for generic Montelukast chewable tablets in the strengths of 4 mg and 5 mg, Unichem Laboratories said in a BSE filing.

The product is a generic version of MerckSharp & Dohme Corporation's Singulair tablets in the same strengths, it added.

"The product will be commercialised from Unichem's Goa Plant," the company said.

The tablets are indicated for prophylaxis and chronic treatment of asthma in adults and pediatric patients - 12 months of age and older, it added.

They are also used in treatment of seasonal allergic rhinitis in adults and patients - 2 years of age and older, and perennial allergic rhinitis in patients - 6 months of age and older, Unichem said.

**Source:** *ET Healthworld, 4th July 2018*

## Indian Origin Scientist Wins Funding for Futuristic 'Brainy Skin' Project in UK

An Indian-origin scientist working on creating a robotic hand covered in so called "brainy skin" that mimics the human sense of touch has won 1.5 million pounds in funding for the project.

Professor Ravinder Dahiya, Professor of Electronics and Nano engineering at the University of Glasgow's School of Engineering, said the futuristic "thinking skin" concept is inspired by the incredibly complex elements of real skin. The super flexible, hypersensitive skin may one day be used to make more responsive prosthetics for amputees, or to build robots with a sense of touch.

"Brainy Skin is critical for the autonomy of robots and for a safe human robot interaction to meet emerging societal needs such as helping the elderly," said Dahiya.

Along with his Bendable Electronics and Sensing Technologies (BEST) team, the scientist has plans to develop ultra flexible, synthetic "Brainy Skin" that "thinks for itself". Brainy Skin reacts like human skin, which has its own neurons that respond immediately to touch rather than having to relay the whole message to the brain.

This electronic "thinking skin" is made from silicon based printed neural transistors and graphene an ultra thin form of carbon that is only an atom thick, but stronger than steel. The new version in the making is said to be more powerful, less cumbersome and would work better than earlier prototypes.

Dahiya explains, "Human skin is an incredibly complex system capable of detecting pressure, temperature and texture through an array of neural sensors that carry signals from the skin to the brain.

" Inspired by real skin, this project will harness the technological advances in electronic engineering to mimic some features of human skin, such as softness, bendability and now, also sense of touch. This skin will not just mimic the morphology of the skin but also its functionality." The research, dubbed neu PRINTSKIN (Neuromorphic Printed Tactile Skin), received the latest 1.5 million pounds in funding from the Engineering and Physical Science Research Council (EPSRC).

The team's work means tactile data is gathered over large areas by the synthetic skin's computing system rather than sent to the brain for interpretation. With additional EPSRC funding, which extends Dahiya's fellowship by another three years, he plans to introduce tactile skin with neuron like processing. This breakthrough in the tactile sensing research will lead to the first neuromorphic tactile skin, or "brainy skin".

To achieve this, Dahiya will add a new neural layer to the e-skin that he has already been developed using printing silicon nanowires.

Dahiya said that by adding a neural layer underneath the current tactile skin, neuprintskin will add significant new perspective to the e-skin research, and trigger transformations in several areas such as robotics, prosthetics, artificial intelligence, wearable systems, next generation computing, and flexible and printed electronics.

**Source:** *ET Healthworld, 4th July 2018*

## Pharma Companies Throng Gujarat to Set up New Units

Gujarat seems poised to regain its lost share in India's pharmaceutical production with firms choosing the state over tax havens for setting up new manufacturing facilities thanks to Good and Services Tax (GST). For pharma industry, GST has significantly narrowed the manufacturing cost difference between regions that offer incentives and states like Gujarat.

The rush for new plants in Gujarat is evident from the fact that Food and Drug Control Administration (FDCA), Gujarat, has approved constructions of 155 new pharmaceutical manufacturing facilities-entailing fresh investments worth Rs 3,000-3,800 crore, in the state since July 2017 when GST came into force.

These proposed plants, majority them currently under construction, are mainly for manufacturing drug formulations apart from medical devices and bulk drugs.

"With tax incentives, the manufacturing of pharma products in tax havens -- Himachal Pradesh, Jammu and Kashmir, Uttaranchal and Uttarakhand -- was 35% cheaper than states that did not offer exemptions. The cost benefit, however, has substantially reduced after GST," said HG Koshia, Food and Drug Control Administration (FDCA), Gujarat.

"As a result, scores of pharma companies are looking at Gujarat, which has a conducive environment and infrastructure for making quality drugs," he added.

Many drug firms had put their expansion plans on hold as they were waiting for clarity on tax slabs under GST. As per industry players, the manufacturing cost difference between exempted and non-exempted states is not more than 2%.

"Besides, the tax incentives in hilly states are also expiring during the period 2017 to 2020," added Viranchi Shah, chairman, Gujarat State Board, Indian Drug Manufacturers' Association (IDMA).

Gujarat is set to increase its share in India's pharmaceutical production once these plants go on stream. "At present, Gujarat has share is 31%-32% in India's Rs 2 lakh crore plus pharma market. The share is expected to rise 40-42% over the next five years," added Koshia.

Soon after the tax holidays were announced starting with Himachal Pradesh in 2003, exodus of pharma units to tax havens brought Gujarat's share down from peak 42% to less than 25% in the first decade of this century.

**Source:** *ET Healthworld, 5th July 2018*

## Diabetes Drug can Reverse Deadly Lung Disorder

A drug used to treat diabetes can reverse a fatal lung disorder, scientists have found for the first time.

Despite significant advances to reveal the pathological mechanisms of persistent fibrosis, effective treatment interventions are lacking.

Pulmonary fibrosis can develop after lung injuries like infections, radiation or chemotherapy, or it can have an unknown cause, as in idiopathic pulmonary fibrosis, or IPF.

IPF is a progressive, and ultimately fatal, lung disorder that strikes more than five million worldwide.

In experiments using lung tissues from patients with IPF, mouselung fibroblasts and a murine model of lung fibrosis, researchers from University of Alabama at Birmingham in the US showed the reversal of lung fibrosis and the underlying cellular mechanisms affected by the drug treatment.

Activation of AMPK in myofibroblasts from lungs of humans with IPF, using the drug metformin or another activator called AICAR, led to lower fibrotic activity.

AMPK activation also enhanced the production of new mitochondria, the organelles in cells that produce energy, in the myofibroblasts, and it normalised the cells' sensitivity to apoptosis.

The drug that accelerated the resolution of lung fibrosis is metformin, which is a safe and widely used agent for non-insulin-dependent diabetes.

The research focused on AMP-activated protein kinase (AMPK), an enzyme that senses energy state in the cell and regulates metabolism.

It found that AMPK activity was lower in myofibroblast cells within fibrotic regions of human lung tissue from IPF patients. Myofibroblasts deposit extracellular collagen fibre as part of the fibrosis process.

These myofibroblasts were metabolically active and were resistant to the programmed cell death called apoptosis, a natural process that removes more than 50 billion damaged or aged cells in adults each day.

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AMPK activation also enhanced the production of new mitochondria, the organelles in cells that produce energy, in the myofibroblasts, and it normalised the cells' sensitivity to apoptosis.

Using a mouse model for lung fibrosis elicited by the anti-cancer drug bleomycin, the research team found metformin treatment, starting three weeks after lung injury and continuing for five weeks, accelerated the resolution of well-established fibrosis.

Such resolution was not apparent in AMPK-knockout mice, showing that the effect of metformin was AMPK-dependent.

"Together, our studies support the concept that AMPK may function as a critical

metabolic switch in promoting resolution of established fibrosis by shifting the balance from anabolic to catabolic metabolism," researchers said.

"Additionally, we provide proof-of-concept that activation of AMPK by metformin or other pharmacologic agents that activate these pro-resolution pathways may be a useful therapeutic strategy for progressive fibrotic disorders," they said.

Anabolic metabolism builds up molecules in the cell from smaller units, while catabolic metabolism tears larger molecules into smaller pieces.

**Source:** *ET Healthworld, 4th July 2018*

## USP, Telangana Government Set up Pharma Training Institute

The United States Pharmacopeia (USP) has joined hands with the Telangana government to set up a training institute to help prepare university graduates and pharmaceutical professionals to contribute to a culture of quality in pharmaceutical manufacturing, it was announced on Friday.

USP Hyderabad Training Institute is a collaboration between USP, an independent, scientific non-profit organization that sets quality standards for medicines, dietary supplements, and food ingredients, and the state government.

The two parties on Friday signed a formal MoU for the institute, which is designed to help bridge the gap between university programmes and industry best practice, with intensive hands-on training aligned with regulatory guidelines and international medicines quality standards.

USP will invest more than $1 million in establishing the training institute, including building a state-of-the-art laboratory and classrooms at the G. Pulla Reddy College of Pharmacy.

The inaugural programme will start next month and the faculty will include experts in the field, as well as guest lectures from USP senior scientific staff and experts in industry and regulation.

The institute offer courses on quality control, quality assurance, and research and development, ranging from seven to eight weeks.

The agreement was signed by Telangana's Principal Secretary, IT, Electronics & Communications, Jayesh Ranjan, and USP's Senior Vice President, Global Sites, K.V. Surendranath in the presence of Telangana's Information Technology and Industries Minister K.T. Rama Rao.

The Telangana government has identified skill development as a critical component of its work to propel the growth of the life sciences sector in the state.

"Telangana government is developing the world's largest pharma city, medical devices park and also expanding the most successful life sciences cluster - genome valley 2.0 for rapid growth of pharma and life sciences industry in Hyderabad, and help reemphasize Telangana's position as a leader in life sciences," said Rama Rao

**Source:** *ET Healthworld, 30th June 2018*

## Aurobindo Pharma Gets Approval to Manufacture Pain Reliever Ibuprofen

Aurobindo Pharma has received final approval from the US health regulator to manufacture and market Ibuprofen capsules, used to relieve pain and reduce fever.

The approved product is a generic equivalent of Pfizer's Advil Liqui-Gels Capsules. The product will be launched in September 2018.

"The company has received final approval from the US Food and Drug Administration (USFDA) to manufacture Ibuprofen capsules OTC, 200 mg," Aurobindo Pharma said in a BSE filing.

Quoting Nielsen data, Aurobindo Pharma said the estimated market size of ibuprofen capsules OTC is USD 164 million for the twelve months ending March 2018.

The pharma company said it has now a total of 373 ANDA (Abbreviated New Drug Application) approvals (340 final approvals, including 17 from Aurolife Pharma LLC and 33 tentative approvals) from the USFDA.

**Source:** *ET Healthworld, 5th July 2018*

## Puma Biotech Gets EU Panel Nod for Breast Cancer Drug

Puma Biotechnology Inc won a key recommendation from a European Medicines Agency panel on its lead breast cancer drug, five months after the regulator recommended against approving it.

Shares of Puma, which on Tuesday signalled the committee was likely to give positive opinion on the drug, neratinib, was up over 5 percent in light pre-market trading on the Nasdaq.

The decision follows a reexamination of the negative opinion announced by the Committee for Medicinal Products for Human Use in February.

While final approvals are up to the European Commission, it generally follows the CHMP's recommendation and endorses them within a couple of months.

Neratinib is designed to treat early-stage breast cancer in patients with the HER2 genetic mutation in which the tumor has been surgically removed, and had been previously treated with Roche's Herceptin.

The experimental drug lowers the risk of the disease returning after initial treatment.

The U.S. Food and Drug Administration already approved Puma's drug last year.

Breast cancer is the most frequently diagnosed cancer in women, with HER2-positive breast cancer accounting for 20 percent to 25 percent of breast cancer cases.

**Source:** *ET Healthworld, 29th June 2018*

## Astrazeneca Wins Speedy Approvals for Cancer Drugs in Japan

AstraZeneca has won rapid regulatory approval for new uses of two of its important cancer drugs in Japan, less than six months after the first global approvals in Western markets.

The decisions by the Japanese Ministry of Health, Labour and Welfare reflect an increased urgency by officials in the country to access modern medicines, after many years of slow adoption.

AstraZeneca said on Monday that its Imfinzi immunotherapy drug had been approved for use in lung cancer patients with inoperable disease that had advanced locally but not spread widely around the body.

Imfinzi was only given a U.S. green light for treating such stage III lung cancer in February and it is still awaiting approval in the European Union.

Japan also approved Lynparza, which AstraZeneca markets with Merck & Co, for breast cancer. (Reporting by Ben Hirschler Editing by Keith Weir)

**Source:** *ET healthworld, 2nd July 2018*

## Dr Reddy's Recalls 2.36 Lakh Bottles of Cholesterol Lowering Tablets from US

Dr Reddy's Laboratories is recalling from the US over 2.36 lakh bottles of Atorvastatin Calcium tablets used for lowering cholesterol, as per a report by the US health regulator.

Dr Reddy's Labs Inc is recalling 2.30 lakh bottles of the tablets on account of "failed impurities/degradation specifications," regulator USFDA said in its Enforcement Report. These recalled tablets are in the strengths of 10 mg, 20 mg and 40 mg.

Out of the total bottles being recalled, 55,126 are of 10 mg strength, 44,894 bottles of 20 mg and 1,30,081 bottles are of 40 mg, it added.

The firm is also recalling 6,397 bottles of 80 mg on account of "presence of foreign substance: A product complaint was received for a defective tablet with an embedded foreign object observed in a bottle," the report said.

The tablets were manufactured by Dr Reddy's Labs at its Srikakulam facility, it said.

The voluntary recall for the 10 mg, 20 mg and 40 mg tablets from the US and Puerto Rico is a class III recall, it added.

For the 80 mg tablets, the recall is of class II, USFDA said.

As per USFDA, a class II recall is initiated in a "situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote."

A class III recall is initiated in a situation in which use of, or exposure to, a violative product is not likely to cause adverse health consequences.

**Source:** *ET Healthworld, 1st July 2018.*

## Govt Proposes over Rs 460 Cr Support for Development of Pharma Sector

The government has proposed over Rs 460 crore support for the development of pharmaceuticals industry with an aim to reduce cost of bulk drugs and medical devices through setting up of common facility centres and to help SMEs upgrade technology.

Announcing guidelines for five sub-schemes under the pharma development programme, the Department of Pharmaceuticals (DoP) said the objective is to reduce cost of production by 20-25 per cent in bulk drug parks.

Similarly, for medical devices also, the aim is to bring down the cost of production significantly in the dedicated medical device parks, thereby leading to better availability and affordability in the domestic market.

The government is looking at providing assistance to bulk drug industry by setting up common facility centres which is proposed as a central sector scheme with a total size of Rs 200 crore for 2018-2020, the DoP said in an announcement on its website.

"The scheme would be implemented through a one-time grant-in-aid to be released for creation of identified infrastructure and common facilities to a State Implementing Agency (SIA) set up for the purpose," it added.

The purpose of the grant is to render the financial assistance for establishment of common facilities in any upcoming bulk drug park promoted by state governments/state corporations, it added.

Another scheme for which the guidelines for implementation have been mooted is for assistance to medical device industry for setting up of common facility centres.

"The scheme termed as development of common facility centre for medical device (DCFCMD) is proposed as a central sector scheme," the announcement said.

The total size of the scheme is proposed as Rs 100 crore for DCFC-MD for 2018-2020, it added.

Assistance under the scheme will be admissible for creation of common facilities in medical device park and it will be implemented through a one-time grant-in-aid, the note said.

The third scheme proposed is for the assistance for cluster development.

"The scheme termed as cluster development programme for pharma sector (CDP-PS) as a central sector scheme and the total size of the scheme is proposed as Rs 20 crore for CDP-PS for 2018-2020," the note added.

It would be implemented on a public private partnership (PPP) format through one time grant-in-aid to be released in various phases for creation of identified infrastructure and common facilities to special purpose vehicles (SPVs) set up for the purpose, it added.

Besides, the DoP said the pharmaceutical promotion development scheme (PPDS) will aim at promotion, development and export promotion in pharma sector by extending financial support for conduct of seminars, conferences and exhibitions, among other activities.

Under the scheme, mounting delegations for promotion of exports as well as investments, conducting studies/ consultancies, for facilitating growth, exports as well as critical issues affecting pharma sector will be supported.

It further said a budgetary allocation of Rs 144 crore for 2018-2020 has been made for pharmaceutical technology upgradation assistance scheme (PTUAS).

It is possible to extend benefit of interest subvention to around 250 pharma SMEs under the scheme, it added.

The goal of this scheme is to facilitate small and medium pharma enterprises (SMEs) of proven track record to World Health Organisation (WHO)/Good Manufacturing Practices norms to enable them to participate and compete in global markets and earn foreign exchange.

**Source:** *ET Healthworld, 26th June 2018*

## Complex Generics, Biosimilars & Specialty to be Growth Drivers: Lupin

Drug firm Lupin is looking at complex generics, biosimilars and specialty medicines to be the main drivers of growth going forward, according an investor presentation by the company.

While sustaining and growing its presence in the generics segment, the company is planning to invest heavily in developing high barrier products in complex generics, the presentation said.

The focus in this segment will be to deliver on key complex generics, especially inhalation and injectables and successfully file and commercialise biosimilars, it added.

A complex generic is a generic that could have a complex active ingredient, complex formulation, complex route of delivery, or complex drug device combinations.

"Global Biosimilars opportunity is evolving as biosimilars have seen good adoption in Europe and gaining adoption in US," the presentation said.

The company has already filed its first biosimilar in Japan and is soon going to file it in Europe.

For the specialty business, the drug maker said it is "committed to building a strong specialty business."

This will be done by creating a meaningful women's health franchise in the US and focus will be on neurology, CNS in other developed markets, the presentation said.

Posting its fourth quarterly and annual results, the company had said its near-term priorities are resolution of the Warning Letter on Goa and Indore Unit 2, successful commercialisation of Solosec in the US and executing on meaningful product launches.

**Source:** *ET Healthworld, 10th June 2018*

## Alembic Pharma Gets USFDA Nod For Its Antibiotic Capsules

Drug firm Alembic Pharmaceuticals today said it has received approval from the US health regulator for its Doxycycline Hyclate capsules used for treatment of wide variety of bacterial infections.

The approval from the United States Food and Drug Administration (USFDA) is for the company's abbreviated new drug application (ANDA) for Doxycycline Hyclate capsules USP, in the strengths of 50 mg and 100 mg, Alembic Pharmaceuticals said in a filing to BSE.

The product is generic version of Pfizer Inc's Vibramycin capsules in the same strengths, it added.

"Doxycycline Hyclate capsules USP, 50 mg and 100 mg, have an estimated market size of USD 80 million for twelve months ending December 2017, according to IQVIA," Alembic Pharma said.

The company currently has a total of 73 ANDA approvals (65 final approvals and 8 tentative approvals) from USFDA, it added.

Shares of Alembic Pharmaceuticals today closed at Rs 506.55 per scrip on BSE, up 3.32 per cent from its previous close.

**Source:** *ET Healthworld, 15th June 2018*

## Cipla Posts Q4 Net Profit at Rs 153 cr

Drug major Cipla today reported a consolidated net profit of Rs 153.25 crore for the quarter ended March 31, 2018 mainly on account of robust sales in key markets and reduction in expenses.

The company had posted a net loss of Rs 62.79 crore during January-March, 2016-17, Cipla said in a BSE filing.

Total income from operations stood at Rs 3,697.97 crore. It was Rs 3,582 crore for the same period a year ago.

For entire 2017-18, the company posted a net profit of Rs 1,416.57 crore. It was Rs 1,035.42 crore for the previous year.

Total income from operations during 2017-18 stood at Rs 15,219.25 crore. It was Rs 14,630.24 crore in the preceding year.

"This financial year (2017-18) our focus remained on strengthening our portfolio and deepening our presence in priority markets," Cipla MD and Global CEO Umang Vohra said.

The company's efforts on cost and efficiency improvement helped it deliver the full year margin ahead of its guidance range, he added.

"Our focus for next year will be to continue our growth trajectory in key markets and investments in portfolio for sustainable growth," Vohra said.

In a separate filing, Cipla said its board has approved raising up to Rs 4,000 crore via various instruments including non-convertible debentures.

**Source:** *ET Healthworld, 23rd May 2018*

## Lupin Gets USFDA Approval for Generic Contraceptive Drug

Drug maker Lupin today said it has received approval from the US health regulator to market Drospirenone, Ethinyl Estradiol, Levomefolate Calcium tablets, used to prevent pregnancy, in the American market.

The company has received final approval from the United States Food and Drug Administration (FDA) to market its product which is a generic version of Bayer HealthCare Pharmaceutical Inc's Beyaz tablets, Lupin said in a statement.

The product is indicated for use by women to prevent pregnancy and treat symptoms of premenstrual dysphoric disorder (PMDD).

The drug is also used to treat moderate acne for women at least 14 years old besides to raise folate levels in women who choose to use an oral contraceptive for contraception.

According to IQVIA MAT April 2018 data, Drospirenone, Ethinyl Estradiol, Levomefolate Calcium Tablets and Levomefolate Calcium Tablets, 3 mg/0.02 mg/0.451 mg and 0.451 mg had annual sales of around USD 82.2 million in the US.

**Source:** *ET Healthworld, 15th June 2018*

## Roche Looks to Bring Evidence-based Medicine Tech to India

Swiss drug maker Rocheis looking for startups in India that will help the company bring evidence-based medicine in India through its proprietary technology, according to the company's newly appointed India head.

Lara Bezerra, Roche Managing Director (India), who moved from the troubled Venezuela market to India, told ET that as part of its long-term strategy the company can bring applications of Flatiron, a tech company that it acquired this year to India.

Flatiron Health is a market leader in oncology-specific electronic health record (EHR) software, as well as the curation and development of real-world evidence for cancer research.

Roche during the acquisition of the company in February said that with its large network of community oncology practices and academic medical centres across the US, Flatiron Health has created a technology platform designed to learn from the experience of every patient.

"When we are having this vision for India we realised that whatever you do in India you can't do in short term. So we have to think something long term. So we are looking how should we bring Flatiron tech to India," said Benzerra. "May be there is startup in India that can work with Flatiron so we are looking at all these options."

Millions of patient profile is matched through this tech and the doctor is provided with the best possible outcomes that these kinds of patients have. So along with medical judgement the doctor has an option to lean into this data base too, explained V Simpson Emmanuel, Director, Market Access, Roche India.

**Source:** *ET Health World, 10th April 2018*

## Cipla Gets USFDA Nod for Generic Isuprel Injection

Drug firm Ciplaon Wednesday said it has received approval from the US health regulator for Isoproterenol Hydrochloride injection, used in the treatment of cardiac problems, in the American market.

The company has received final approval from the United States Food and Drug Administration (USFDA) for its product which is a generic version of Hospira Inc's Isuprel injection, Cipla said in a statement.

The Mumbai-based firm's product is indicated for serious episodes of heart block and cardiac arrest until electric shock or pacemaker therapy is available, it added.

According to IQVIA (IMS Health), Isuprel Injection and its generic equivalents had US sales of around USD 148 million for the 12-month period ending April 2018.

**Source:** *ET Healthworld, 14th June 2018*

## Lupin Launches Generic Antibiotic Inhalation Solution in US

Drug firm Lupin today said it has launched its antibiotic Tobramycin inhalation solution in the US market.

The company has launched the product as it has received an approval from the US Food and Drug Administration (USFDA) earlier, Lupin said in a filing to BSE.

The company's Tobramycin Inhalation Solution USP, 300 mg/5 ml, is the generic version of Novartis Pharmaceuticals Corporation's Tobi 300 mg/5 ml, it added.

The product is indicated for the management of cystic fibrosis patients with P aeruginosa, Lupin said.

As per IQVIA MAT April 2018 data, Tobramycin inhalation solution USP, 300 mg/5 ml, had annual sales of nearly USD 99 million in the American market, it added.

**Source:** *ET Healthworld, 14th June 2018*

## Natco Pharma Launches Hepatitis C Drug in India

Natco Pharma today said it has launched fixed dose combination of Sofosbuvir-Daclatasvir tablets for the treatment of Hepatitis C under the brand name Hepcinat Plus, in India.

The product is a generic fixed dose combination of Sofosbuvir 400 mg and Daclatasvir 60mg tablets, used for the treatment of patients with chronic Hepatitis C virus (HCV) infection, it said in a filing to BSE.

The company has launched the drug at a maximum retail price of Rs 17,500 for a bottle of 28 tablets, it added.

**Source:** *ET Healthworld, 2nd July 2018*

## Cipla Targets $1-billion Revenues from Domestic Market in FY19

Country's fourth-largest drug maker Cipla is bullish on growth and is looking for a billion dollar consolidated revenue for the domestic market in FY19, a senior company official said.

The company reported revenues of Rs 15,219 crore, growing 6 per cent, with income from the India operations seeing a 6.3 per cent jump at Rs 5,687 crore in FY18.

"In terms of the domestic business we are on a strong footing as growth was in healthy double digits," Cipla global CFO Kedar Upadhye said at an earnings conference here.

"We are quite confident and we are set for a billion dollar consolidated revenue in the domestic market in FY19," Upadhye added.

The drug maker expects the in-licensing deals with innovator companies, focus on certain therapeutic segments and sales force productivity optimisation measures to aid growth in India.

"This financial year, our focus remained on strengthening our portfolio and deepening our presence in priority markets. We are happy that our efforts on cost and efficiency improvement helped us deliver the full year margin ahead of our guidance range," Cipla managing director and global CEO Umang Vohra said.

The focus for next year will be to continue on the growth trajectory in key markets, he added.

Commenting on inorganic growth plans, Vohra said, "We have taken an enabling resolution, does not mean that we will be doing deals worth Rs 4,000 crore. As and when they become available, we will be hopeful (of acquisition), but we will not buy unless we see a synergy value in the transaction."

Last year the company had taken an enabling resolution to raise funds of about Rs 2,000 crore of debt and Rs 2,000 crore of equity.

The company is also looking at consolidating its position in South Africa, US, Europe and emerging markets.

"We will ramp up our US business, which is poised for good growth during this year with our key differentiated launches," Vohra said.

The company is also looking at significant investments in R&D to build a strong pipeline, with over 20 targeted filings in FY19. This year will also see higher investments towards clinical trials for key respiratory assets and focus on building specialty assets, Vohra added.

**Source:** *ET Healthworld, 10th June 2018*

## Health Ministry Bans over-the-counter Sale of 14 Steroid Creams

To prevent the indiscriminate sale of topical preparations containing steroids and antibiotics without prescription, the Health Ministry has banned over-the-counter sale of around 14 such creams.

In a notification issued on March 23, the ministry has put 14 steroid-based creams and ointments under the Schedule H category by making amendments to certain Drugs and Cosmetics Rules, 1945.

The decision was taken following consultation with the Drugs Technical Advisory Board (DTAB) which had recommended a ban on the sale of such creams without prescription and had also submitted their recommendations to the Central Drugs Standards Control Organisation (CDSCO).

The move come after dermatologists complained that pharmaceutical companies were selling steroid- based creams and ointments to patients who use them without medical guidance.

The revised rules will apply to skin creams that contain steroids or other prescription drugs and not for ordinary face-cleansing and moisturisers.

The creams which have been banned are alclometasone, beclomethasone, desonide, desoximetasone and flucinonide among others.

**Source:** *ET Health World, 8th April 2018*

## ED Attaches Rs 4,700-crore Assets in Sterling Biotech Crackdown

The Enforcement Directorate on Friday attached assets estimated to be worth more than Rs 4,700 crore belonging to Sterling Biotech group from Gujarat, in one of the biggest crackdowns in money-laundering cases.

Last October, the Central Bureau of Investigation registered a criminal case against Sterling Biotech, its directors and a then director of Andhra Bank for allegedly cheating public sector banks of Rs 5,383 crore. The main accused have reportedly fled the country. ED, a finance ministry wing that investigates money laundering cases, started probing the matter after the CBI filed the FIR.

From high-end luxury cars to farm houses, the ED attached movable and immovable properties including factories and apartments across Gujarat and Mumbai owned by the accused. Plant machinery and nearly 200 bank accounts of various companies of the group also have been provisionally attached.

Sterling Biotech is listed on the Bombay Stock Exchange and National Stock Exchange. Its business range from energy, port, SEZ and coal sectors. It has operations in the US, the UAE and elsewhere. According to CBI's FIR, the promoters — Nitin and Chetan Sandesara — had, on the basis of false and fabricated documents, obtained credit facilities of more than Rs 5,000 crore from a lenders' consortium, which was led by Andhra Bank and included UCO Bank, SBI, Allahabad Bank and Bank of India. The loans have since turned non-performing assets.

Companies that took loans include Sterling Biotech, Sterling Port, PMT Machines, Sterling SEZ & Infrastructure and Sterling Oil Resources, ED said. It has already obtained non-bailable warrants against the Sandesara brothers, alleged to have set up more than 300 shell and benami companies in India and abroad.

A statement issued by ED said, “The modus operandi of money laundering involved formation of shell/benami companies, manipulating balance sheets, inflating turnovers, insider share trading, etc. These shell and benami companies were controlled by the Sandesaras through dummy directors, who were/are employees of the various companies of the Sterling group. Bogus sale/purchase was shown between benami companies and Sterling in order to divert loan funds and inflate turnovers to obtain further loans from banks.”

ED had carried out nearly 50 raids across Mumbai, Surat, Ahmedabad and Delhi since last October as part of its investigations into the case.

It claims to have recovered “truckloads” of material pertaining formation and management of shell companies. The material included chequebooks, rubber stamps, company seals, original PAN cards and over ten lakh pages of “incriminating documents.” ED said some of the “diverted loan funds” were utilised to bribe public servants.

**Source:** *ET Healthworld, 2nd June 2018*

## India's Drug Regulator Expects to Finalise New Clinical Trial Rules in Two Months

India's drug regulator plans to finalise new rules for clinical trials in a couple of months that would shorten the review time, a senior official said on Wednesday, aiming to boost clinical research in the country after interest in recent years waned.

The country's 1.2 billion people and large burden of diseases make for an attractive patient pool for global pharmaceutical companies looking to test new drugs, but stringent rules in the last few years have caused some companies to move their research work to other countries.

New rules drafted by India's Central Drug Standard Control Organisation (CDSCO) aim to change that, reducing the approval time for review of applications to between 30 and 60 days, Ranga Chandrashekhar, a deputy drugs controller at the CDSCO said on the sidelines of a pharmaceutical conference in Mumbai.

"We have already received comment from stakeholders on our draft, and it should be finalised in about two months," Chandrashekhar said.

The draft was uploaded on the agency's website in February. If finalised, it would go to the country's health ministry for approval before being published, he added.

The agency tightened rules for clinical research a few years ago after cases

emerged of some patients being enrolled into trials without informed consent, and not being adequately compensated.

The new rules would let the 'ethics committees' - groups of medical experts - that oversee clinical trials decide on the level of compensation for patients who suffer adverse events, Chandrashekhar said.

Tougher compensation rules could turn the industry away from conducting trials at a time when companies have been gradually looking back to India for clinical work, warned D.G. Shah, secretary general of the Indian Pharmaceutical Alliance, which represents large Indian drugmakers.

"There has been some revival (of clinical research) based on some assurances given by the government and simplifications (of rules)," Shah said. But if compensation rules are adopted as mentioned in the draft released by the CDSCO, companies "will run away from here," he said.

"This is not conducive to doing innovation and research in India," Shah said.

As part of overhauling drug regulations in the country, the CDSCO is also planning to bring in new rules for the sale of over-the-counter drugs, and e-pharmacies in the coming months, Chandrashekhar said.

**Source:** *ET Healthworld, 31st May 2018*

## Roche Drug Dramatically Reduces Bleeds in Key Haemophilia Tests

Roche's new haemophilia drug Hemlibradramatically reduced bleeding in a broad population of haemophilia patients, results from two clinical trials showed on Monday, setting it up to take a dominant market position.

Hemlibra cut by 96 percent the incidence of treated bleeds in haemophilia A patients who did not get preventive treatment, and compared with patients who did get preventive treatment in the form of clotting factors it reduced them by 68 percent.

The positive results from the two trials known as HAVEN 3 and 4 included so-called non-inhibitor patients. Hemlibra's initial success was in patients with inhibitors, which are antibodies that cause resistance to replacement clotting factors.

Hemlibra's current regulatory approval is only for these inhibitor patients but Roche plans to submit the latest findings to authorities around the world to widen its use.

While the drug's latest success had been expected, the positive results seen in a wide range of patients should underpin demand for a medicine that Roche is relying on as several of its blockbuster cancer drugs face cut-price rivals.

Jefferies analysts said HAVEN 4 also showed there was a potential to treat both inhibitor and non-inhibitor patients on only a once-monthly basis. Currently, Hemlibra is given as a once-weekly injection.

"This sets Hemlibra up to become the new standard of care for haemophilia A, which we view as a $5 billion peak sales opportunity," they said.

The current standard of care for people with haemophilia A without inhibitors is replacement factor VIII clotting factor.

Hemlibra will shake up the market and pose a threat to established players reliant on factor replacement therapies, notably Shire, which has agreed to be acquired by Takeda Pharmaceutical.

Also being challenged are Bayer, CSL and Novo Nordisk, as well as Sanofi, which earlier this year bought U.S. haemophilia specialist Bioverativ .

New science also promises to bring further changes in the years ahead, with several companies working on haemophilia gene therapy, in which a harmless virus is used to introduce DNA to fix the faulty genes behind the disease, offering a possible one-off cure.

Data from the two Roche clinical studies were presented at the World Federation of Hemophilia congress in Glasgow, Scotland.

"With this data, we now have positive results from all four of our Phase III trials that reinforce the overall efficacy and safety of Hemlibra and its potential to improve care for all people with haemophilia A," said Roche Chief Medical Officer Sandra Horning.

**Source:** *ET Healthworld, 22nd May 2018*

## Govt Tightens Labelling Norms for High-risk Medicines

In a move to enhance consumer awareness and safety of drugs, the health ministry has tightened labelling norms for high-risk medicines, making it mandatory for pharmaceutical companies to print warnings prominently on such drug packs from November 1.

The new rules will be applicable to medicines such as cancer drugs, narcotics analgesics, sedatives, tranquillisers, steroids and anti-depressants which have either high risk of side effects or are to be used strictly under medical supervision.

The changes are part of the new labelling rules under the Drugs and Cosmetics (Fifth Amendment) Rules, 2018.

According to the norms, the label of the innermost container of such high risk or sensitive drugs— categorised under Schedule G or Schedule H or Schedule H1 or Schedule X in the Rules— will bear a caution or warning in legible black-coloured ink in a red rectangular box. These medicines also include some antimicrobials, anti-epileptics and anticoagulants.

The new rules also specify that if the medicine contains a drug substance specified in Schedule H, Schedule G or Schedule X, it will be labelled with symbol Rx.

In case of substances specified under Schedule H1, which comes within the purview of the Narcotic Drugs and Psychotropic Substances Act, 1985, the packaging will be labelled with symbol NRx, in red colour with caution statement on the left top corner.

The government's move is aimed at bringing in more transparency while also preventing sale of prescription drugs over the counter (without

doctor's instructions). Officials say the main objective is to empower the consumer to make an informed decision. “Prominent warning will ensure that consumers are aware of the risk and side-effects attached with a medicine before they consume it,” an official said.

The Indian drug retail market is pegged at over Rs 1 lakh crore annually, of which 75-80% are prescription drugs. Currently, 'OTC' or over the counter has no legal recognition in India and all drugs not included in the list of 'prescription-only' drugs are legally allowed to be sold over the counter by pharmacists. However, several 'prescription-only' medicines, listed in Schedules H and X of the Drug and Cosmetics Rules, are easily available OTC without prescription. The new labelling norms will address this issue.

The move also follows another significant labelling change which made it mandatory for pharmaceutical companies to print generic names of drugs in a font which is two-font sizes larger than the brand name.

The change in labelling, which is seen as a part of government's effort to push generic drugs, will come into effect from September 13.

Industry executives say frequent changes in labelling may result in temporary shortage of medicines or impact sales as companies will have to print new labels.

**Source:** *ET Healthworld, 22nd May 2018*

## Pharma Sector Likely to Report Weak Numbers in Q4

The troubled pharma sector is expected to report weak Q4FY18 numbers, with PAT likely to decline by 9 per cent (year-on-year) and appreciation in rupee may put pressure on realisations, industry analysts said.

"We estimate the pharma sector to report weak Q4FY18 numbers - while revenue is likely to grow at 3 per cent y-o-y, PAT is expected to decline 9 per cent y-o-y. We expect US revenue to dip 2 per cent y-o-y in constant currency (cc) - five consecutive quarters of decline - led by sustained pricing pressure due to customer consolidation and rise in competition," Edelweiss research analyst Deepak Malik told PTI here.

The rupee appreciation of 4 per cent y-o-y against the USD will put further pressure on realisations. However, this is likely to be partly offset by rupee depreciation against the Euro/Rand/Yen by 11 per cent, 6 per cent and 1 per cent y-o-y, Malik said.

We forecast domestic sales to grow 11 per cent y-o-y on a low base, he said.

While pricing controls keep the operating environment tough in the domestic market, pharma companies with strong brands in the OTC (over the counter) category are better placed to ride the slowdown.

Besides, earning growth also affected by waning new products approvals by USFDA(US Food and Drug Administration), which declined drastically during Q4FY18 to 109 from 249 in Q3FY18 due to additional documentation requirements for elemental impurities.

On the regulatory front, USFDA inspections of Cadila's Moraiya unit in Ahmedabad and Natco's Mekaguda unit were favourable, while Aurobindo's Hyderabad unit-IV, Cipla's Goa, Dr Reddy's Telangana and Sun Pharma's Halol units received observations, Malik added.

Indian pharmaceutical sector is estimated to account for 3.1 - 3.6 per cent of the global pharmaceutical industry in value terms and 10 per cent in volume terms. It is expected to grow to USD 100 billion by 2025. The market is expected to grow to USD 55 billion by 2020, thereby emerging as the sixth largest pharmaceutical market globally by absolute size.

Branded generics dominate the pharmaceuticals market, constituting nearly 80 per cent of the market share in terms of revenues.

The country's pharmaceutical exports stood at USD 16.8 billion in 2016-17 and are expected to grow by 30 per cent over the next three years to reach USD 20 billion by 2020, according to the Pharmaceuticals Export Promotion Council of India (Pharmexcil).

**Source:** *ET Healthworld, 8th April 2018*

## Pharmaceutical Companies Offering Freebies May Come Under GST Lens

Pharmaceutical companies offering buy-one-get-one-free schemes or 20% extra for the same price may have to pay goods and services tax (GST) on the extra quantities, raising prospect of the principle being applied to a broad spectrum of consumer products, said people with knowledge of the matter.

The tax heads of firms such as Novartis India, Sun Pharma, Cipla, Lupin have been summoned for meetings with tax officials, they said. The Director General of GST (Intelligence), an arm of the indirect tax department, has begun investigations and sought details of incentives given to distributors, stockists and customers by about 30 companies.

**Demand may Lead to Litigation: Experts**

The tax authorities want them to either pay GST or reverse input tax credits on the extra quantities.

"We did receive a query from the Director General of GST (DGGST) regarding trade discounts offered to stockists in one jurisdiction," a Novartis spokesman said. "We have responded to the query and believe that we are in full compliance with the law."

Cipla, Lupin and Sun Pharma did not respond to ET's queries.

People with knowledge of the matter said the tax department is set to extend its purview and more companies could get queries and tax notices in the coming months. "The approach is to either induce payment of tax on quantity given as bonus or have reversal of input tax credit," said one of them. "The view that the tax department holds is that bonus quantity not 'in furtherance of business' and tax credit needs to be reversed."

Experts said the practice has been followed by pharma companies for several years and the demand is likely to lead to litigation.

"Often pharma companies dish out promotional schemes, which is a business decision, and such transactions should typically neither be subjected to GST nor trigger reversals of credit," said Suresh Nair, partner, EY India. "If demand notices are issued, this could lead to litigation across the industry and could have a pan-India impact."

It could lead to similar tax demands on such programmes run by the fast-moving consumer goods sector (FMCG) and others, said Pratik Jain, partner, national leader, indirect tax, PwC India.

"This issue is not only limited to pharmaceutical companies but applies in wide spectrum of industries including FMCG, consumer electronics and so on," he said. "Therefore, this issue should be examined and appropriately clarified by the government."

Under the earlier tax regime, tax was not applicable on free samples as the law said there needed to be a monetary consideration for goods to be taxed.

However, many states had provisions that allowed the reversal of input tax credit for free samples. This was limited to value-added tax (VAT).

It is understood that many tax officials are equating freebies doled out by pharma companies with 'gifts' under the GST framework. There are specific regulations regarding gifts and in some cases GST is applicable or input credits need to be reversed for such items.

**Source:** *ET Healthworld, 30th May 2018*

# PARLIAMENT QUESTION – ANSWERS

## *In Lok Sabha & In Rajya Sabha*

***In Lok Sabha - Ministry of Chemicals & Fertilizers***

### *NEW DRUG POLICY*

***Lok Sabha Unstarred Question No. 5979***

***Shri. Gopal Chinayya Shetty***
***Shri. Kanwar Singh Tanwar***
***Shri. Kotha Prabhakar Reddy***

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

(a): whether the Government proposes to formulate a new drug policy to provide life saving drugs at affordable prices;

(b): if so, the details thereof along with the time by which the said policy is likely to be made effective;

(c): whether the Government has received the report of the task force constituted under the Chairmanship of Dr. Pronab Sen on Drug Pricing Control and if so, the details thereof; and

(d): the details of recommendation made by the task force on Drug Pricing Control and the action taken by the Government thereon?

**Answered on 03.04.2018**

**A.** (a)&(b): At present there is no concrete proposal of a new drug policy at Governmental level. A discussion draft eliciting the basic contents that should go into a draft pharmaceutical policy was discussed amongst some stakeholders which included:

- Making essential drugs accessible at affordable prices to the common masses;
- Providing a longer term stable policy environment for the Pharmaceutical sector;
- Making India sufficiently self-reliant in end to end indigenous drug manufacturing;
- Ensuring world class quality of drugs for domestic consumption & exports;
- Creating an environment for R&D to produce innovator drugs;
- Ensuring growth and development of the Indian Pharma Industry.

It was a preliminary discussion and no timeline has been fixed in this regard.

(c): In November, 2004 the Government set up a Task Force under the Chairmanship of Dr. Pronab Sen, Principal Advisor, erstwhile Planning Commission, to look into the issue of price control, option other than price control and other issues and to make recommendations for making available life saving drugs. The Pronab Sen Committee submitted its recommendation in September, 2005.

(d): The Task Force had recommended that the price regulation should be on the basis of essentiality of the drugs and it should be applied only for formulations and not to upstream products such as bulk drugs. The Department of Pharmaceuticals prepared a draft National Pharmaceutical Pricing Policy, 2011 (NPPP-2011) based on the criteria of essentiality on which comments were received from various stakeholders and the same was placed before the Group of Ministers (GoM). Based on the recommendations of the GoM, National Pharmaceuticals Pricing Policy-2012(NPPP-2012) was formulated for controlling and regulating the prices of medicines of specified dosages and strengths as under National List of Essential Medicines-2011. NPPP-2012 was placed before the Cabinet and after its approval by the Cabinet on 22.11.2012, NPPP-2012 was notified on 07.12.2012. Subsequently, the Drugs (Prices Control) Order, 2013 (DPCO, 2013) was also notified.

***Minister of State in the Ministry of Road Transport and Highways; Ministry of Shipping and Ministry of Chemicals and Fertilizers (Shri Mansukh L Mandaviya)***

## *PRICE FIXATION UNDER DPCO*

***Lok Sabha Unstarred Question No. 5879***

***Shri. M B Rajesh***

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

(a): the basis for fixing the ceiling price of medicines and medical devices under the Drug Price Control Order (DPCO);

(b): whether the Government proposes to fix the prices on the basis of cost of manufacturing; and

(c): if not, the reasons therefor?

**Answered on 03.04.2018**

**A.** (a) to (c): Pursuant to the announcement of National Pharmaceutical Pricing Policy, 2012 (NPPP, 2012), Government notified the Drugs (Prices Control) Order, 2013 (DPCO, 2013) on 15th May, 2013. All the medicines specified in the National List of Essential Medicines 2011 (NLEM, 2011) prepared by the Ministry of Health and Family Welfare were included in the Schedule - I of DPCO, 2013 and brought under price control. The National List of Essential Medicines 2015 (NLEM 2015) has been included in the DPCO, 2013 as Revised Schedule – I replacing the Original Schedule – I vide S.O. 701(E) dated 10.03.2016. National Pharmaceutical Pricing Authority (NPPA) follows the methodology defined in the para 4 and 6 of DPCO, 2013 for fixation of the ceiling prices of essential drugs, whereby ceiling price is fixed on the basis of the average 'price to retailer' plus sixteen percent of retailer margin.

There is no proposal to fix the prices on the basis of cost of manufacturing. Under NPPP, 2012, the regulation of prices of drugs is onthe basis of regulating the prices of formulations through Market Based Pricing (MBP). This is different from the earlier principle of regulating the prices through Cost Based Pricing (CBP) under the Drug Policy, 1994; wherein ceiling prices of drugs were fixed through a cost-plus-margin method using cost data provided by individual drug manufacturers.

The reasons for the shift in the methodology for price fixation from cost based to market based are as follows: Unlike cost based method, it is based on reliable and authentic data set available on regular intervals, hence accuracy and validity is maintained in the process. Also the entire procedure of ceiling price fixation is available in the public domain which ensures transparency and accountability of the process. Further, under Market Based Pricing, the interests of both consumers and producers/suppliers are protected by keeping a wider price band in comparison to cost based method. Not only that, the ceiling price fixed is subjected to annual revision on the basis of Wholesale price index (WPI) thereby maintaining price stability and ensuring un-interrupted supply of essential medicines. The new principle of price fixation has resulted in enormous amount of savings to the general public in terms of reduction in out - of - pocket health expenditure.

***Minister of State in the Ministry of Road Transport and Highways; Ministry of Shipping and Ministry of Chemicals and Fertilizers (Shri Mansukh L Mandaviya)***

## *MONITORING OF PHARMA COMPANIES*

***Lok Sabha Unstarred Question No. 5834***

***Shri. Chintamani Malviya***

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

(a): whether the Government proposes to monitor the plants of pharmaceutical companies once in every five years;

(b): if so, the details thereof; and

(c): the measures adopted by the Government to control the increasing pollution level in the areas near pharmaceutical plants?

**Answered on 03.04.2018**

**A.** (a),(b)&(c): As per Drugs & Cosmetics Rules, 1945 the licensed manufacturing premises shall be inspected jointly by the Drugs Inspectors of Central Government and State Government to verify the compliance with the conditions of license and the provisions of the Drugs & Cosmetics Act and Rules for not less than once in three years or as needed as per risk based approach. Further, the Ministry of Environment, Forest & Climate Change has informed that they have categorized Pharmaceuticals as a 'Red' category industry and these industries are required to obtain Consent to Operate from the State Pollution Control Board concerned every 5 years. They have also notified various environmental standards for Pharmaceutical industry, which are to be complied by the industrial units. Further, in respect of industrial projects for which environmental clearance has been accorded by them, post project clearance monitoring is carried out with the help of Regional Offices of the Ministry, Central Pollution Control Board and State Pollution Control Board. Ministry of Environment Forest and Climate Change, through State Pollution Control Boards/ Pollution Control Committees, is also carrying out monitoring of ambient air and water.

***Minister of State in the Ministry of Road Transport and Highways; Ministry of Shipping and Ministry of Chemicals and Fertilizers (Shri Mansukh L Mandaviya)***

## *LICENCES FOR NEW DRUGS*

***Lok Sabha Unstarred Question No. 5806***

***Shri. Ponnusamy Venugopal***

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

(a): whether the Central Drug Quality Regulator has prohibited the States from issuing manufacturing licences for new drugs, unless approval has been granted by the Drugs Controller General of India;

(b): whether the order has been issued in the wake of the National Pharmaceutical Pricing Authority's crackdown on leading pharmaceutical companies found selling over 200 medicines without price approval; and

(c): if so, the details thereof?

**Answered on 03.04.2018**

**A.** (a): As per the provisions of Drugs & Cosmetics Rules, 1945, no New Drug shall be manufactured for sale unless it is approved by the Licensing Authority as defined in clause (b) of Rule 21 of Drugs and Cosmetics Rules, 1945 i.e. Drug Controller

General of India (DCG(I)). Central Drugs Standard Control Organization (CDSCO) has issued circulars from time to time to the State/UT Drugs Controllers requesting them not to issue any licence for manufacturing for sale of new drugs falling under definition of new drug as defined in Rule 122E of Drugs and Cosmetics Rules 1945 without prior approval of DCG(I).

(b) & (c): As per the information received from CDSCO, circulars have been issued by them to ensure implementation of the Drugs and Cosmetics Rules in respect of New drugs and not in the wake of the National Pharmaceutical Pricing Authority's decision regarding new drugs launched without taking prior price approval.

***Minister of State in the Ministry of Road Transport and Highways; Ministry of Shipping and Ministry of Chemicals and Fertilizers (Shri Mansukh L Mandaviya)***

## *SETTING UP NIPER*

***Lok Sabha Unstarred Question No. 4073***

***Shri. Ramdas Chandrabhanji Tadas***

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

(a): whether the Government is in the process of setting up National Institute of Pharmaceutical Education and Research (NIPER) in every State in the country;

(b): if so, the time by which it is likely to be set up;

(c): whether the Government has received any proposal from the States of Rajasthan and Maharashtra; and

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

**Answered on 20.03.2018**

**A.** (a) &(b): No Madam, the Government is not in the process of setting up National Institutes of Pharmaceuticals Education and Research (NIPER) in every State in the country. Presently, there are seven functional NIPERs at Mohali (Punjab), Gandhinagar (Gujarat), Kolkata (West Bengal), Hyderabad (Telangana), Hajipur (Bihar), Guwahati (Assam) and Raebareli (Uttar Pradesh). Further, the Government has decided to set up four new NIPERs at Madurai (Tamil Nadu) and in the states of Rajasthan, Maharashtra and Chhattisgarh.

(c) & (d): The Government of Rajasthan has allotted 100 acres of land at Jhalawar for setting up the Institute. Further, the Government of Maharashtra has allotted 61 acres of land in Nagpur for the purpose. A combined Expenditure Finance Committee (EFC) proposal for establishment of the Institutes has been referred to the Ministry of Finance.

***Minister of State in the Ministry of Road Transport and Highways; Ministry of Shipping and Ministry of Chemicals and Fertilizers (Shri Mansukh L Mandaviya)***

## *PRICE MARGIN OF DRUGS*

***Lok Sabha Unstarred Question No. 1778***

***Shri. Rama Kishore Singh***

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

(a) whether the Government has decided to fix profit margin for inexpensive medicines as reported in the media and if so, the details thereof;

(b) whether heavy profit is being earned by the wholesalers and retailers of drugs in the country; and

(c) if so, the details thereof along with the works executed by the Committee set up by the Government in 2016 to cap profit margin on drugs as well as the National Pharmaceutical Pricing Authority (NPPA) in this regard?

**Answered on 06.03.2018**

(a): No Madam.
(b) & (c): In view of reply to (a) above, does not arise.

***Minister of State in the Ministry of Road Transport and Highways; Ministry of Shipping and Ministry of Chemicals and Fertilizers (Shri Mansukh L Mandaviya)***

## *PRRCE OF STENTS*

***Lok Sabha Unstarred Question No. 1725***

***Shri. Gopalakrishnan Chinnaraj***

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

(a): whether the National Pharmaceutical Pricing Authority (NPPA) has reduced the price of top end stents;

(b) whether it is true that many firms/ pharma companies had withdrawn their top end stents after the price cut;

(c): if so, the details thereof; and

(d) the action taken/being taken by the Government in this regard?

**Answered on 06.03.2018**

**A.** (a): National Pharmaceutical Pricing Authority (NPPA) in its meeting dated 13th Feb, 2017 fixed the ceiling price of the coronary stents at Rs 29,600/- for Drug eluting Stents (DES) and Rs. 7,260/- for Bare Metal Stents, resulting in reduction in the prices of coronary stents by upto 85%. The ceiling prices were later revised to Rs. 30,180/- for Drug eluting Stent and Rs. 7,400/- for Bare Metal Stent with effect from 1-April-2017, considering wholesale price index of 2016. NPPA in its meeting dated 5th February 2018 which continued on 8th February 2018 and 12th February 2018 re-fixed the ceiling prices at Rs. 27,890 for Drug eluting Stents and at Rs. 7,660/- for Bare Metal Stents.

(b) to (d): The sub-committee of the National List of Essential Medicines (NLEM) constituted in the Ministry of Health and Family Welfare in its meeting dated 25-Jan-2018 has stated that there is no sufficient evidence of any Drug eluting Stents (DES) being the superior over any other DES. Hence, the question of calling some brands as top end stent does not arise. As on date, technically no company has withdrawn any brand from Indian market after 12th Feb, 2018.

***Minister of State in the Ministry of Road Transport and Highways; Ministry of Shipping and Ministry of Chemicals and Fertilizers (Shri Mansukh L Mandaviya)***

## *WHO APPROVED MEDICINES*

***Lok Sabha Unstarred Question No. 1647***

***Shri. Nagarajan P***

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

(a) whether it is true that the World Health Organisation (WHO) has recently approved the use of anti-diarrhoea vaccine produced by Indian Pharma major, Bharat Biotech Worldwide;

(b) if so, the details thereof; and

(c): the total number of medicines and vaccines produced by Indian pharma companies which have been approved by WHO for use worldwide, as on date?

**Answered on 06.03.2018**

**A** (a) & (b): The Department of Biotechnology (DBT) has informed that the rotaviral diarrhoea vaccine called ROTAVAC®; developed by an Indian company (M/s Bharat Biotech International Limited-BBIL), has been pre-qualified by WHO for procurement by public health vaccination programmes across the world.

(c): Under the Drugs and Cosmetics Act, 1940 and Rules made thereunder, license for manufacturing of drugs is granted by State Licensing Authorities appointed by respective State Governments. Central Drugs Standard Control Organization has granted Marketing Authorization for Rotavirus Vaccine to M/s Bharat Biotech International Limited, Hyderabad vide permission dated 03.09.2013 for the indication of active immunization of infants from the age of 6 weeks for the prevention of Gastroenteritis due to rotavirus infection. Central Drugs Standard Control Organization has informed that there is no information regarding medicines and vaccines produced by Indian Pharma companies which have been approved by WHO for use worldwide.

***Minister of State in the Ministry of Road Transport and Highways; Ministry of Shipping and Ministry of Chemicals and Fertilizers (Shri Mansukh L Mandaviya)***

## *NEW PHARMACEUTICAL POLICY*

***Lok Sabha Unstarred Question No. 1623***

***Shri. Kunhalikutty, P.K.***

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

(a) whether the Government has any proposal to bring a new pharmaceutical policy;

(b) if so, the details and the method to fix the price of essential medicines;

(c) the likely impact on the prices of essential medicines due to the new drug policy;

(d) the steps being taken by the Government to ensure that doctors in private clinic are prescribing medicines from the National List of Essential medicines;

(e) whether the Government has taken steps to implement the Supreme Court directive to stick to cost-based pricing formula; and

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

**Answered on 06.03.2018**

(a): Yes Madam.

(b): No final decision has been taken as yet.

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

(d): The doctors including those operating from private clinics prescribe medicines depending on treatment requirements.

(e) & (f): The Government announced the 'Pharmaceutical Policy 2002' in February 2002. However, a public interest litigation filed in the High Court of Karnataka at Bangalore in WP No. 2168 of 2002 resulted in an Order dated 12-11-2002 which stopped the Government from implementing the price control regime of the Pharmaceutical Policy 2002. This Department filed a Special Leave Petition (SLP) before the Supreme Court of India against the Order of the Karnataka High Court. The Supreme Court vide its order dated 10.3.2003 directed the Government, inter-alia, that, "we suspend the operation of the order to the extent it directs that the Policy dated 15.2.2002 shall not be implemented. However we direct that the petitioner shall consider and formulate appropriate criteria for ensuring essential and life saving drugs not to fall out of the price control and further directed to review drugs, which are essential and life saving in nature till 2nd May, 2003".

The Department of Pharmaceuticals had prepared a draft National Pharmaceutical Pricing Policy, 2011 (NPPP-2011) based on the criteria of essentiality as per the medicines as under National List of Essential Medicines-2011 (348 drugs with specified dosage and strengths), as stipulated by the Ministry of Health & Family Welfare which was placed before the Group of Ministers (GoM). Based on the recommendations of the GoM, National Pharmaceuticals Pricing Policy-2012(NPPP-2012) was formulated and placed before the Cabinet. The Cabinet considered NPPP-2012 in its meeting held on 22.11.2012 and after approval, NPPP-2012 was notified on 07.12.2012.

***Minister of State in the Ministry of Road Transport and Highways; Ministry of Shipping and Ministry of Chemicals and Fertilizers (Shri Mansukh L Mandaviya)***

## *DRUG IMPURITIES*

***Lok Sabha Unstarred Question No. 2326***

***Shri. Ashok Mahadeorao Nete***

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

(a) whether the Government has made available the information regarding toxic and non-toxic impurities to the drug manufacturers who need to ensure purity and standardisation of medicines;

(b) if not, the reasons therefor;

(c) whether the Government has taken steps to make detailed impurities profile available at economical cost to small pharmaceutical units from the National Institute of Pharmaceutical Education and Research; and

(d) if so, the details thereof?

**Answered on 02.01.2018**

(a) & (b): Toxic and non-toxic impurities are regulated in pharmaceutical substances and products through related substances test in pharmacopoeias. Indian pharmacopoeia, which is published by Indian Pharmacopoeia Commission (IPC), under the aegis of Ministry of Health, specifies the impurities to be controlled in pharmacopoeial monographs. IPC publishes new edition of Indian pharmacopoeia every four years. The latest standards regarding impurity control to be followed by industry have been included in 2018 edition of Indian Pharmacopoeia.

(c) & (d): The impurity profiles are very specific to the synthetic process used by the manufacturer of Active Pharmaceutical Ingredient (API) or the formulation developed by the product manufacturer. So there are no standard impurity profiles that can be developed by National Institute of Pharmaceutical Education and Research (NIPER) or any agency. However, NIPER at SAS Nagar has been helping industry in their specific jobs for characterization of impurities, as and when approached. Furthermore, NIPER has been in forefront in proposing degradation chemistry, which is an intrinsic study for any drug and is very useful for the pharmaceutical industry. NIPER SAS Nagar has published more than 50 research reports on drug degradation behavior, a basic requirement for characterization and qualification of degradation products formed in drug formulations during their storage till shelf

***Minister of State in the Ministry of Road Transport and Highways; Ministry of Shipping and Ministry of Chemicals and Fertilizers (Shri Mansukh L Mandaviya)***

***In Lok Sabha - Ministry of Health & Family Welfare***

## *SETTING UP OF MEDICAL DEVICE TESTING LABORATORIES*

***Lok Sabha Unstarred Question No. 4792***

***Shri. Bidyut Baran Mahato***
***Shri. Sunil Baliram Gaikwad***
***Shri. T. Radhakrishnan***
***Shri. Chandrakant Gajanan Kirtikar***
***Shri. Kunwar Haribansh Singh***
***Shri. Naranbhai Kachhadia***
***Shri. Vijay Kumar S R.***

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

(a) whether the Government has taken note of the fact that medical equipments especially pre-owned medical electronic equipment is entering the country via imports without any safeguards and if so, the details thereof;

(b) whether the Government proposes to bring imaging and endoscopic equipment under the purview of the Drugs and Cosmetics Act, 1940;

(c) if so, the details thereof along with the aims and objectives thereto;

(d) the time by which it is likely to be brought under the purview of the said Act; and

(e) the measures being taken by the Government to set up medical device testing laboratories and make them available at affordable cost in the country?

**Answered on 23.03.2018**

(a): The Central Drugs Standard Control Organisation (CDSCO) under the Ministry of Health and Family Welfare regulates the Safety, Efficacy and Quality of 15 notified category of medical devices under the provisions of Drugs and Cosmetics Act, 1940 and Rules made thereunder. However,

Medical equipment are not notified as Medical device under section 3(b)(iv) of Drugs and Cosmetics Act, 1940.

(b) to (d): In the 78th meeting of Drugs Technical Advisory Board (DTAB) held on 12th February, 2018, the board has agreed to include ultrasound equipments and similar imaging equipments under the purview of section 3 (b) (iv) of the Drugs And Cosmetics Act, 1940 as medical devices, with a aim to regulate its import, manufacturing, distribution and sale.

(e): As per the Medical Device Rules, 2017, the Central Government may designate any laboratory having facility for carrying out test and evaluation of medical devices as central medical devices testing laboratory. In this regard, CDSCO has requested National Accreditation Board for Testing & Calibration Laboratories (NABL) accredited laboratories on 01.03.2018 which are having capacity and capability for testing and evaluation of the Medical Device including In Vitro Diagnostic, may get registered with CDSCO and inform details of their activities.

It may be mentioned that since Financial Year 2015-16, funds have been approved/disbursed under the erstwhile Assistance to States for infrastructure Development of Exports Scheme and the current Trade Infrastructure for Export Scheme for setting up of testing labs for medical equipment/common scientific facilities etc.

***The Minister of State in the Ministry of Health and Family Welfare (Shri Ashwini Kumar Choubey)***

## *SPURIOUS AND EXPIRED DRUGS*

***Lok Sabha Unstarred Question No. 4752***

***Shri. Neelam Sonker***
***Shri. Tamradhwaj Sahu***

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

(a) whether cases regarding circulation and marketing of spurious, substandard, expired and banned drugs being sold in Government Hospitals and in open market across the country have come to light;

(b) if so, the State/UT-wise number of such cases which came to light during each of the last three years and the current year and the number of such cases investigated and raided along with action taken by the Government against such persons and manufacturers;

(c) whether the present legal framework and manpower are adequate for monitoring and curbing the production/ marketing of such spurious and expired drugs, if so, the details thereof and if not, the reasons therefor; and

(d) the measures being taken by the Government to strengthen the present laws, infrastructure, manpower and monitoring system in this regard?

**Answered on 23.03.2018**

(a) & (b): In order to ensure the quality of drugs in the country, both the Central Drugs Standard Control Organisation (CDSCO) and the state drug regulators pick up a large number of samples of drugs from all over the country and have them tested and analysed in the laboratories of the Central and State Governments. In a few cases, the samples tested and analysed do not meet the

prescribed standards. The details of the drugs that do not meet the standards are immediately notified by the Central or State regulator concerned. As per information received from State/UTs, the details of the cases of sub-standard, spurious/ adulterated drugs, number of prosecution launched etc. and action taken against the offender during last three years are enclosed as Annexure-I. Such data in respect of cases of expired drugs detected during the last three years is placed at Annexure-II.

(c) & (d): The Mashelkar Committee had recommended one inspector for 200 sales outlets and one inspector for 50 manufacturing units. Keeping in view the size of Indian Pharma Industry and the number of sales units, around 3200 Drug Inspectors are required both at the Central and State levels. The current strength of the drug regulatory personnel in the country is not sufficient to meet the requirement of ensuring quality, safety and efficacy of medical products. Keeping this in view, the Government has approved a scheme for strengthening the drug regulatory structures both in the Centre and in the States at a cost of Rs 1750 Crore. This includes provision of manpower, upgradation of existing laboratory infrastructure, establishment of new laboratories and provision of Information Technology services.

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

***The Minister of State in the Ministry of Health and Family Welfare (Shri Ashwini Kumar Choubey)***

## *GENERIC MEDICINES*

***Lok Sabha Unstarred Question No. 217***

***Shri. George Baker***
***Shri. Richard Hay***

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

(a) the number of generic medical stores available/opened across the country to provide generic medicines, State/UT-wise including West Bengal, Gujarat, Kerala and Maharashtra;

(b) whether there is any gap between the commonly used medicines and their availability as generic medicines in the medical stores, if so, the details thereof along with the list of such commonly used medicines and their availability in the medical stores and the reasons therefor along with the action taken/being taken by the Government in this regard;

(c) whether there is any shortage of most prescribed generic drugs at the outlets opened specially at Government Hospitals across the country including West Bengal, if so, the details thereof and the reasons therefor;

(d) whether the Government has issued guidelines to the hospitals/doctors to prescribe the generic drugs to the patients and if so, the details thereof; and

(e) whether the Government has received any complaint regarding violation of these guidelines from any of the States, if so, the details thereof and the action taken by the Government thereon?

**Answered on 09.03.2018**

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

STATEMENT REFERRED TO IN REPLY TO LOK SABHA

STARRED QUESTION NO. 217* FOR 9TH MARCH, 2018

(a) to (c):- As on 05.03.2018, under Pradhan Mantri Bhartiya janaushadhi Pariyojana (PMBJP), 3214 Kendras have been opened in 33 States/Union Territories of the Country and are functional in order to make available quality generic medicines at affordable prices to all. A State/UT-wise list of 3214 functional PMBJP Kendras, including in West Bengal, Gujarat, Kerala and Maharastra, is annexed. Under 'Pradhan Mantri Bhartiya Janaushadhi Priyojna' (PMBJP), the product basket of the scheme now covers more than 700 medicines and 154 surgicals & consumables covering all major therapeutic groups such as Analgesics, Antipyretics, Anti-allergies, Anti-infectives, Anti-diabetic, Cardiovasculars, Anti-cancers, Gastro-intestinal medicines, Diuretics, etc. 666 medicines and 81 surgicals are available for supply under Pradhan Mantri Bhartiya Janaushadhi Priyojna.

There are no reports of any gap between commonly used medicines and their availability in the medical stores of the Government. There is no report indicating shortage of most prescribed generic drugs at the outlets opened at Central Government Hospitals in Delhi.

(d): Medical Council of India (MCI) has notified an amendment in Clause 1.5 of Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002, which stipulates that “Every physician should prescribe drugs with generic names legibly and preferably in capital letters and he/she shall ensure that there is a rational prescription and use of drugs”. Medical Council of India, vide its Circulars dated 21.04.2017, 22.11.2012 and 18.01.2013, has reiterated that all physicians should prescribe drugs with Generic names. Director, CGHS has vide Office Memorandum dated 08.09.2017, issued instructions to all CGHS Wellness Centres to ensure that prescription is only by generic name wherever generic drugs are available.eveery physician should prescribe drugs with generic names legibly and preferably in capital letters and he/she shall ensure that there is a rational prescription and use of drugs”. Medical Council of India, vide its Circulars dated 21.04.2017, 22.11.2012 and 18.01.2013, has reiterated that all physicians should prescribe drugs with Generic names. Director, CGHS has vide Office Memorandum dated 08.09.2017, issued instructions to all CGHS Wellness Centres to ensure that prescription is only by generic name wherever generic drugs are available.

(e): The MCI or the appropriate State Medical Councils have been empowered to take disciplinary action against a doctor for violation of the provisions of the aforesaid Regulations. As and when complaints are received against the violation of these, such complaints are referred by MCI to the concerned State Medical Councils where the doctors/medical practitioners are registered for appropriate action.

***The Minister of State in the Ministry of Health and Family Welfare (Shri Ashwini Kumar Choubey)***

## *DRUG TESTING LABORATORIES*

***Lok Sabha Unstarred Question No. 3110***

***Shri. Vishnu Dayal Ram***
***Shri . Hari Manjhi***

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

(a) whether inadequate number of drug testing laboratories is one of the major reasons for circulation of spurious drugs in the country, if so, the details thereof;

(b) the number of drug testing laboratories functioning and proposed to be opened in the country, State/UT-wise;

(c) the existing mechanism to review the functioning of drug testing laboratories;

(d) whether the Government proposes to launch a campaign to create awareness and ensure public participation against spurious drugs, if so, the details thereof; and

(e) the details of steps taken to reward the whistle blowers and ensure their security as well as to safeguard the interests of honest manufacturer and traders of medicines/drugs in the country?

**Answered on 05.01.2018**

(a): The prevalence of spurious drugs in the country has been estimated to be 0.0245% in a survey conducted to determine the problem of spurious and not of standard quality drugs in the country (2014-16). The prevalence of such drugs, as such, is very low.

(b): List of State drugs testing laboratories is at Annexure. Currently, there are seven Central Drug Testing Laboratories at Kolkata, Chennai, Mumbai, Chandigarh, Hyderabad, Guwahati and Kasauli. The Government has approved setting up of six Central laboratories for drugs / cosmetics / Medical devices and ten drug testing laboratories by States and Union Territories.

(c): All aspects relating to functioning of Central Drugs testing laboratories are reviewed and monitored regularly by Drugs Controller General (India) and the Ministry of Health & Family Welfare. Similarly, the States/UTs also review the functioning of their laboratories periodically.

(d): The Government is committed to ensuring that the quality, safety and efficacy of drugs are not compromised. With this in view, the Government has taken a series of measures including strengthening legal provisions, workshops and training programmes for manufacturers and regulatory officials and measures such as risk based inspections. However, no specific campaign is proposed in this regard.

(e): A Whistler Blower Scheme to encourage vigilant public participation for detection of movement of spurious drugs in the country is already in place. The scheme provides for suitably rewarding informers for providing concrete information to regulatory authorities in respect of movement of NSQ/misbranded/adulterated/spurious drugs.

Informers for providing concrete information to regulatory authorities in respect of movement of NSQ/misbranded/adulterated/spurious drugs.

As per Whistle Blower Policy, the identity of the whistle blower/informer is to be kept secret and will be known only to the concerned designated official. It will be the responsibility of the concerned officials to keep the details of the whistle blower/informer secret.

***The Minister of State in the***
***Ministry of Health and Family Welfare***
***(Shri Ashwini Kumar Choubey)***

## *SELLING OF MEDICINES*

***Lok Sabha Unstarred Question No. 3076***

***Shri. Nagarajan P.***

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

(a) whether the Government has any proposal to ban homoeopathy doctors from selling medicines from the premises they are practicing in, if so, the details thereof;

(b) whether chemists selling allopathic medicines are also allowed to sell homoeopathic medicines without having a separate licence; and

(c) if so, the details thereof and the reasons therefor?

**Answered on 05.01.2018**

(a): The sale of Homoeopathic medicines is dealt with under the provisions of Part VI-A of the Drugs and Cosmetics Rules, 1945. Rule 67 F of the said Rules specifies that no registered Homeopathic medical practitioner who is practising Homeopathy in the premises where Homeopathic medicines are sold shall deal in Homeopathic medicines. However, Homoeopathic Practitioners (Professional Conduct, Etiquette and Code of Ethics) Regulations, 1982, a Homoeopathic practitioner has a right to prepare and dispense his own prescription.

(b) & (c): To extend the availability of Homoeopathic Medicines in rural and other areas where Homoeopathic outlets are not available, the Drugs and Cosmetics Rules, 1945 have been amended vide G.S.R. No.1380 dated 10th November, 2017 allowing sale of Homeopathic Medicines from already registered / licensed allopathic outlets without any additional license.

***The Minister of State in the Ministry of Health and Family Welfare (Shri Ashwini Kumar Choubey)***

***In Rajya Sabha - Ministry of Chemicals & Fertilizers***

## *INCENTIVES FOR MANUFACTURE OF MEDICAL DEVICES DOMESTICALLY*

***Rajya Sabha Question No 4518***

***Shri. Derek O Brien***

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

(a) the total amount of grants allocated by the Ministry for manufacturing medical devices domestically, along with the details thereof;

(b) the public sector/private sector companies that have shown interest for this initiative so far, the details thereof; and

(c) the details of subsidies/incentives provided to the companies by the Government for manufacturing in India?

**Answered on 06.04.2018**

(a) to (c): No amount of grants has been allocated for manufacturing of medical devices domestically. However, Government has a proposal for a sub-scheme for Financial Assistance to Common Facility Centers (CFCs) in Medical Device Parks under the umbrella scheme for "Development of Pharmaceuticals Industry". No budget allocation has yet been made for the proposed scheme.

***Minister of State in the Ministry of Road Transport and Highways; Ministry of Shipping and Ministry of Chemicals and Fertilizers (Shri Mansukh L Mandaviya)***

## *OVERCHARGING BY PRIVATE HOSPITALS ON DRUGS AND CONSUMABLES*

***Rajya Sabha Question No 4521***

***Shri. D. Raja***

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

(a) whether it is a fact that an investigation by National Pharmaceutical Pricing Authority (NPPA) has found that four private hospitals in Delhi were profiteering by overcharging for the drugs and consumables;

(b) if so, the details thereof and the action taken on these hospitals based on the study report;

(c) whether it is also a fact that the Chairman of NPPA was transferred just ten days after this study report was released; and

(d) if so, the details thereof and Government's reaction thereto?

**Answered on 06.04.2018**

(a) & (b): Yes, Sir. Based on complaints and media reports on overpricing and inflated bills to the patients by four hospitals, National Pharmaceutical Pricing Authority (NPPA) had asked for details of billing from these hospitals under the provisions of the Drugs (Prices Control) Order, 2013 (DPCO, 2013). Based on the data submitted by the hospitals, NPPA has observed that there is an upward gap between the procurement prices of drugs and amounts at which the drugs are billed to the patients. Study reports prepared on the basis of information submitted by these hospitals is available at the website of NPPA. (www.nppaindia.nic.in). Public health being a State subject, the primary responsibility of management of hospitals lies with the State/Union Territory Governments. However, the National Council for Clinical Establishments, Ministry of Health & Family Welfare (MoH&FW) has approved a standard list of medical procedures and a standard template for costing of medical procedures and the same have been shared with the States for appropriate action.

(c) & (d): The transfer /posting of Government functionaries is a routine administrative decision.

***Minister of State in the Ministry of Road Transport and Highways; Ministry of Shipping and Ministry of Chemicals and Fertilizers (Shri Mansukh L Mandaviya)***

## *MECHANISM FOR MONITORING THE PRICES OF DRUGS*

***Rajya Sabha Question No 4527***

***Shri. Narayan Lal Panchariya***

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

(a) whether Government has created any mechanism for monitoring of prices of drugs and other medical devices;

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

(c) whether Government has devised any formula for fixation of drugs prices by pharmaceutical companies; and

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

**Answered on 06.04.2018**

(a) & (b): National Pharmaceutical Pricing Authority (NPPA) is effectively monitoring the prices of scheduled as well as non-scheduled medicines under the Drugs (Prices Control) Order, 2013 (DPCO, 2013) so that these formulations are available to public at the ceiling prices notified and any increase in price is limited to the provisions of DPCO, 2013. It takes action against companies found overcharging the consumers based on the references received from the State Drugs Controllers / individuals, samples purchased from the open market and reports from market based data and complaints received through the grievance redressal websites: 'Pharma Jan Samadhan' and 'Centralized Public Grievance Redressal and Monitoring System (CPGRAMS)'. The monitoring of increase in the price of formulations beyond the permissible limit is also done on the basis of market data submitted by All Indian Origin Chemists & Distributors Ltd. (AIOCD) (Pharmatrac Data) and individual complaints.

(c) & (d): NPPA follows the methodology defined in the para 4, 5 and 6 of DPCO, 2013 for fixation of the ceiling prices of essential drugs and retail prices of new drugs whereby prices are fixed on the basis of the average 'price to retailer' plus sixteen percent of retailer margin.

***Minister of State in the Ministry of Road Transport and Highways; Ministry of Shipping and Ministry of Chemicals and Fertilizers (Shri Mansukh L Mandaviya)***

## *WITHDRAWAL OF CORONARY STENT FROM MARKET BY MANUFACTURING COMPANIES*

***Rajya Sabha Question No 2453***

***Shri. Anand Sharma***

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

Government is aware that many coronary stent manufacturing companies propose to withdraw products from the Indian market following the Drugs

(a) whether prices Control Order of the National Pharmaceutical Pricing Authority;

(b) if so, the lists of the stent manufacturers who are likely to withdraw following the new ceiling prices; and

(c) whether Government have made an analysis about the impact of the stent manufacturers' withdrawal on the availability of affordable and quality coronary stents in the country?

**Answered on 16.03.2018**

(a) & (b): National Pharmaceutical Pricing Authority (NPPA) has received the request from three stent manufacturing companies for withdrawal of a few specific products from the Indian market. The lists are as follows:

Sl No
Name of the MNCs Name of stent
Reason for withdrawal

1. M/s Abbott Healthcare Pvt. Ltd
(a) Xience Alpine
(b) Absorb and Absorb GT1 (a) Commercial unviability post fixation of ceiling price. (b) Stoppage of manufacturing of this stent brand globally based on low commercial uptake

2. M/s Boston Scientific India Pvt. Ltd SYNERGY monorail Everolimus Eluting PtCr Coronary Stent System with Biodegradable Polymer Commercial unviability post fixation of ceiling price.

3. M/s India Medtronic Pvt. Ltd. Endeavour Sprint Rx Zotarolimus Eluting Coronary Stent System Unavailability due to stoppage of manufacturing of the product globally.

(c): NPPA collected data for the years 2016 and 2017 from manufacturers, both indigenous and importers; for opening stocks, manufacturing and imports and distribution etc. of stents to make an assessment of the actual impact of price ceiling on cardiac healthcare, the status of market of indigenous manufacturing and imports, increased affordability and access to cardiac healthcare etc. The analysis of data revealed that, during one year after price cap, stent market has witnessed increase in imports and manufacture of stents. The increased opening stocks of stents as on January 1, 2018 gives confidence that there will be increased capacity utilization in both imported and indigenously manufactured stents in the Indian market and shortage of stents should not be a concern on withdrawal of a few brands.

***Minister of State in the Ministry of Road Transport and Highways; Ministry of Shipping and Ministry of Chemicals and Fertilizers (Shri Mansukh L Mandaviya)***

## *SALE OF ESSENTIAL MEDICINES*

***Rajya Sabha Question No 2454***

***Shri. T. Rathinavel***

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

(a) whether stringent Government mandated price control, in haste, affected availability of essential medicines as retail data showed that sales of such items registered over two-fold growth in the pharma market;

(b) whether the sale of essential drugs grew by 7 per cent in 2016;

(c) whether Indian pharmaceutical market, which includes medicines outside price control, recorded a growth of 38 per cent in December, 2016;

(d) whether prices of medicines listed under NLEM are accepted by Government through the National Pharmaceutical Pricing Authority; and

(e) if so, the details thereof?

**Answered on 16.03.2018**

(a): The Drugs (Prices Control) Order, 2013 (DPCO, 2013) was not considered in a haste. It was notified on 15/05/2013 after the Cabinet had approved National Pharmaceuticals Pricing Policy, 2012 (NPPP, 2012) on 07/12/2012 after the Group of Ministers (GoM) had consulted all the stakeholders and submitted their recommendations.

(b) & (c): The All Indian Origin Chemists & Distributors Ltd.'s Advanced Working, Action and Correction System (AWACS) had indicated the growth rate for scheduled and non-scheduled formulations during the year ending 2016 as under:-

Type of Medicines* Year ended Dec 16
Scheduled Formulations 2%
Non-Scheduled formulations 13%
Overall 11%
*the classification of Scheduled/Non-Scheduled formulations is as per present status.

(d) & (e): The medicines included in National List of Essential Medicines (NLEM) announced by Ministry of Health and Family Welfare are included in the Schedule-I of DPCO, 2013. The ceiling prices of these medicines are fixed by National Pharmaceutical Pricing Authority (NPPA).

***Minister of State in the Ministry of Road Transport and Highways; Ministry of Shipping and Ministry of Chemicals and Fertilizers (Shri Mansukh L Mandaviya)***

## *RETAIL MARGIN ON GENERIC DRUGS*

***Rajya Sabha Question No 42***

***Shri. K.C. Ramamurthy***

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

(a) the details of countries that are prescribing generic medicines in place of branded ones;

(b) whether it is a fact that as per a study conducted by Indian Journal of Pharmacology, the retail margin on generic drugs is as high as 1000 per cent of manufacturing cost;

(c) if so, the response of Government on the above study; and

(d) the response of Government to some doctors' view that all generic drugs are not as effective as the branded ones?

**Answered on 02.02.2018**

(a): Every country has its own standards and its own laws and regulations for prescribing medicines which are done keeping in view of the particular requirements of the country.

(b): A Research Article published in Indian Journal of Pharmacology in April 2011 said that margins for retailer were very high for branded-generics. The retailer margin for five branded medicines examined in the study was in the range of 25-30%, but for their branded-generics versions manufactured by the same company, it was much higher.

(c): Both generic and branded medicines are treated alike for fixation of ceiling price under the provisions of Drugs (Prices Control) Order, 2013 (DPCO, 2013). As per DPCO, 2013, all manufacturers of Scheduled medicines (branded or generic) have to sell their products within the ceiling price fixed by the Government. The DPCO, 2013 provides that 16% of price to retailer shall be allowed as a margin to retailer, while fixing ceiling price of scheduled formulations and retail prices of new drugs.

(d): Manufacturing, sale and distribution of drugs in the country whether branded or generic, are regulated under the provisions of Drugs & Cosmetics Act, 1940 and Rules, 1945 made thereunder through a system of licensing and inspection. License for manufacturing, sale and distribution of Drugs are granted by State Licensing Authorities appointed by respective State Governments. Licensees are required to comply with all the conditions of license and follow Good Manufacturing Practices (GMP) to ensure that the drugs manufactured by them are safe and of standard quality.

***Minister of State in the Ministry of Road Transport and Highways; Ministry of Shipping and Ministry of Chemicals and Fertilizers (Shri Mansukh L Mandaviya)***

*In Rajya Sabha - Ministry Health & Family Welfare*

## *SCRUTINY OF OTC DRUGS*

***Rajya Sabha Question No 4125***

***Shri. Ranjib Biswal***

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

(a) whether the Ministry has sought regular scrutiny of drugs sold Over-The- Counter (OTC) to assess which of them were being abused for addiction;

(b) if so, the details thereof and the reasons therefor;

(c) whether any system to track the sale of OTC drugs has been put in place/ proposed to be put in place and if so, the details thereof; and

(d) the other steps taken by the Ministry in consultation with the Ministry of Home Affairs to focus on OTC drugs to prevent abuse?

**Answered on 03.04.2018**

((a): No.

(b): Does not arise.

(c): No.

(d): The manufacture, sale and distribution of drugs in the country is regulated under the provisions of Drugs & Cosmetics Act, 1940 and Rules, 1945 thereunder through a system of licensing and inspection. Licenses for manufacture, sale and distribution of drugs are granted by the State Licensing Authorities (SLAs) appointed by respective State Governments. SLAs are empowered to monitor/track the sale of drugs including the drugs allowed to be sold without prescription and take action in case of non compliance.

***The Minister of State in the Ministry of Health and Family Welfare (Shri Ashwini Kumar Choubey)***

## *SALE OF UNAPPROVED ANTIBIOTICS*

***Rajya Sabha Question No 4135***

***Shri. Ripun Bora***

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

(a) whether it is a fact that more than 64 per cent of antibiotics are sold in the country without the approval of Central Drugs Standard Control Organisation (CDSCO);

(b) if so, whether Government has received any survey report in this regard;

(c) whether it is also a fact that India rates as the highest consumer of antibiotics with more than unapproved 3300 brand names with different 118 types of formulations of Fixed Dose Combination; and

(d) if so, the action plan of Government to restrict the usage of unapproved drugs in the country?

**Answered on 03.04.2018**

(a) to (d): No drug can be sold in the country without due approval and valid license of the concerned licensing authority as stipulated in the Drugs & Cosmetics Act, 1940 and Rules, 1945 thereunder.

As per the said Act and the Rules, manufacture, sale and distribution of drugs including antibiotics in the country are regulated through a system of licensing and inspection. Licenses for manufacture, sale and distribution of drugs are granted by the State Licensing Authorities

(SLAs) appointed by respective State Governments.

As per Rule 122 E of Drugs & Cosmetics Rules 1945, the combination of two or more drugs i.e. Fixed Dose Combination (FDC) combined for the first time fall under the definition of New Drug and therefore permission from the Drugs Controller General (India) [DCG(I)] is required before these are licensed by State Licensing Authorities (SLAs) for manufacture for sale in the country. However it was observed that some SLAs were granting licenses for some such FDCs, including antibiotic combinations, without due approval from DCG (I).

DCG (I) had requested all States/UTs Drugs Controllers to ask the concerned manufacturers in their State to prove the safety and efficacy of such FDCs within a period of 18 months, failing which such FDCs would be considered for being prohibited for manufacture and marketing in the country. An Expert Committee under the chairmanship of Prof. C.K. Kokate was constituted to examine such applications and also for examining the safety and efficacy of these FDCs.

Based on the recommendations of the Prof. C. K. Kokate Expert Committee, the Central Government prohibited 344 FDCs vide notification dated 10.03.2016. Further the Central Government had also prohibited 5 FDCs vide notification dated 08.06.2017. Out of these 349 (344+5) FDCs prohibited, 46 FDCs were antibiotics (44 FDCs prohibited on 10.03.2016 and 02 FDCs prohibited on 08.06.2017).

It is pertinent to mention that the Central Government had also prohibited 5 antibiotic FDCs during the period from 1983 to 2001, which is still in force.

However, with respect to the said 344 FDCs including 44 FDCs of antibiotics, several writ petitions were filed in different High Courts across the country challenging the ban of the FDCs. After that, the High Court of Delhi vide its order dated 01.12.2016 quashed the said notification. The Union of India challenged the said order of Delhi High Court before the Supreme Court by way of filing Special Leave Petitions (SLPs). Further, about 20 cases against 5 FDCs prohibited on 08.06.2017 which were pending before various High Courts across the country, were also transferred to Supreme Court. Hon'ble Supreme Court vide its order dated 15.12.2017 directed that an analysis be made in greater depth and these cases of (344+5) FDCs should go to the Drugs Technical Advisory Board (DTAB) and/or a Sub-Committee formed by the DTAB for the purpose of having a relook into these cases.

Thus, Government has taken measures to prohibit manufacture and marketing of various FDCs as above, which have been found irrational.

Following measures have also been taken by the Ministry to curb the misuse of antibiotics:

- Antibiotics are included in Schedule H and H1 of the Drugs and Cosmetics Rules, 1945 and are required to be sold by retail only under the prescription of a Registered Medical Practitioner.
- A new Schedule H1 under the Drugs & Cosmetics Rules, 1945 containing 46 drugs which include antibiotic drugs, Anti TB drugs and certain habit forming drugs has been notified. The drugs falling under Schedule H1 are required to be sold in the country with certain strict conditions.

***The Minister of State in the Ministry of Health and Family Welfare (Shri Ashwini Kumar Choubey)***

## *EFFECTIVENESS OF CARDIAC STENT*

***Rajya Sabha Question No 4137***

***Shri. Anubhav Mohanty***

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

(a) whether it is a fact that studies have shown that the impact of the cardiac stent is a short term relief lasting 6 to 18-24 months but not a long term remedy;

(b) if so, whether the treating Doctors make their patients aware of the fact that the cardiac stent implant is a temporary relief and not a permanent solution; and

(c) whether the Ministry will consider issuing an advisory to the Doctors to provide complete information on the implant of the cardiac stent before the procedure to their patients?

**Answered on 03.04.2018**

(a): No, with Drug Eluting Stents, there is a nominal approximate 10-15% re-blockage in the treated segment of the artery over a period of 1-2 years. After the said duration most of the stents behave well on long-term.

(b) & (c): Doesn't arise.

***The Minister of State in the Ministry of Health and Family Welfare (Smt. Anupriya Patel)***

## *SAMPLING AUTHORITY OF DRUG INSPECTORS*

***Rajya Sabha Question No 3617***

***Dr. R. Lakshmanan***

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

(a) whether it is a fact that Drug Inspectors are authorised only to draw samples from the markets and not from drug manufacturing companies; and

(b) if so, reasons therefor and provisions of Drugs and Cosmetics Act, 1940 which stipulates that Drug Inspectors can draw samples only from market and not from drug manufacturing company?

**Answered on 27.03.2018**

(a) & (b): No. Under the section 22 of Drugs and Cosmetics Act, 1940, the Drug Inspectors are authorized to take samples of any drugs or cosmetic, "which is being manufactured or being sold or stocked or exhibited or offered for sale, or being distributed."

***The Minister of State in the Ministry of Health and Family Welfare (Shri Ashwini Kumar Choubey)***

## *MONITORING MECHANISM FOR QUALITY OF DRUGS*

***Rajya Sabha Question No 3634***

***Shri. T.K. Rangarajan***

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

(a) the mechanism Government has to monitor the quality and standards of various drugs and pharmaceutical companies appearing in the market;

(b) if there is such mechanism, whether any malpractices of the drug companies have been found; and

(c) if so, details thereof?

**Answered on 27.03.2018**

(a) to (c): The manufacture, sale and distribution of drugs in the country is regulated under the provisions of Drugs & Cosmetics Act, 1940 and Rules, 1945 thereunder through a system of licensing and inspection. Licenses for manufacture, sale and distribution of drugs are granted by the State Licensing Authorities (SLAs) appointed by respective State Governments. SLAs are legally empowered to take stringent action against violation of provision of the Act and Rules.

In order to ensure the quality of drugs in the country, both the Central Drugs Standard Control Organisation (CDSCO) and the state drug regulators pick up a large number of samples of drugs from all over the country and have them tested and analysed in the laboratories of the Central and State Governments. In a few cases, the samples tested and analysed do not meet the prescribed standards. The details of the drugs that do not meet the standards are immediately notified by the Central or State regulator concerned.

Number of drug samples tested, number of drug samples reported spurious/adulterated and sub-standard drugs and action taken against the offenders by the CDSCO in the last three years is enclosed as Annexure-I and by States/UTs is at Annexure- II.

Further, the Government is committed to ensuring that the quality, safety and efficacy of drugs are not compromised. With this in view, the Government has taken a series of measures including strengthening legal provisions, workshops and training programmes for manufacturers and regulatory officials and measures such as risk based inspections.

***The Minister of State in the Ministry of Health and Family Welfare (Shri Ashwini Kumar Choubey)***

## *EMPLOYMENT OPPORTUNITIES FOR PHARM. D GRADUATES*

***Rajya Sabha Question No 34***

***Shri. V. Vijayasai Reddy***

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

(a) whether out of about 350 Pharma. D colleges in the country, there are nearly 120 in Telangana and Andhra Pradesh;

(b) whether students who passed out Pharma. D course do not have proper employment opportunities since only NABH accredited hospitals are permitted to avail the services of Pharma. D graduates;

(c) if so, the efforts being made by the Ministry to accredit more and more NABH accredited hospitals in the country, particularly in Andhra Pradesh and Telangana; and

(d) whether, in view of the fact that Government is encouraging Registered Medical Practitioners (RMPs) and Private Medical Practitioners (PMPs), Pharma. D graduates also will be encouraged?

**Answered on 06.02.2018**

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

STATEMENT REFERRED TO IN REPLY TO RAJYA SABHA
STARRED QUESTION NO. 34* FOR 6TH FEBRUARY, 2018

a) Out of the total number of 233 Pharm.D colleges in the country, 59 Pharm.D colleges are in the State of Andhra Pradesh and 60 are situated in the State of Telangana.

b) There is no connection between employment of Pharm. D professionals and NABH accreditation. NABH does not put such demands of exclusiveness in employing Pharm. D professionals. Pharm. D is a approved registrable qualification for the purpose of registration as a pharmacist to practice the profession under the Pharmacy Act, 1948. Hence as per section 42 of the Pharmacy Act wherever dispensing of medicines is done on the prescription of a medical practitioner, persons holding Pharm. D qualifications are entitled for the same.

In the Pharmacy Practice Regulations, 2015 approved by the Ministry of Health and Family Welfare, Government of India, the Pharm. D qualification has been included for various categories of jobs like Senior Pharmacist, Chief Pharmacist and Drug Information Pharmacist.

c) NABH accreditation is a voluntary in nature through an independent external peer assessment of that organization's level of performance in relation to the standards. Presently, the State of Andhra Pradesh has 22 NABH accredited hospitals and additionally, the State Government has undertaken 17 more Government Hospitals for NABH accreditation. Similarly, the State of Telangana already has 59 NABH accredited hospitals, however, no further NABH accreditation has been undertaken by the State.

d) Yes. The following steps have been taken to encourage Pharm. D graduates:

- Letters have been written to all State/UT Governments and all concerned departments by the Council to amend their recruitment rules to include Pharm. D as a qualification for the post of pharmacist.
- The PCI Regulations called "Minimum Qualification for Teachers in Pharmacy Institutions Regulations, 2014" have been notified in the Gazette of India on 11th November, 2014. In the said Regulations, Pharm. D qualification has been included as an approved qualification for various teaching posts in pharmacy institutions in India.
- The Council has taken up the matter with Indian Council of Medical Research, New Delhi, to consider Pharm. D programme for Short Term Studentship/Scholarships programme, schemes for award of fellowship etc.
- Further, Indian Pharmacopoeia Commission, Ghaziabad, has been approached for inclusion of the Pharm. D qualification for the post of Pharmacopoeial Associates.
- Letters have been written to CDSCO, DGHS, New Delhi, for inclusion of the Pharm. D qualification for the post of Drug Inspector.
- The Accreditation Board for Hospitals and Healthcare Providers have been requested to write to all the accredited hospitals to utilize the services of Pharm. D degree holders to ensure high quality of pharmaceutical care in clinical departments.

***The Minister of Health and Family Welfare***
***(Shri Jagat Prakash Nadda)***

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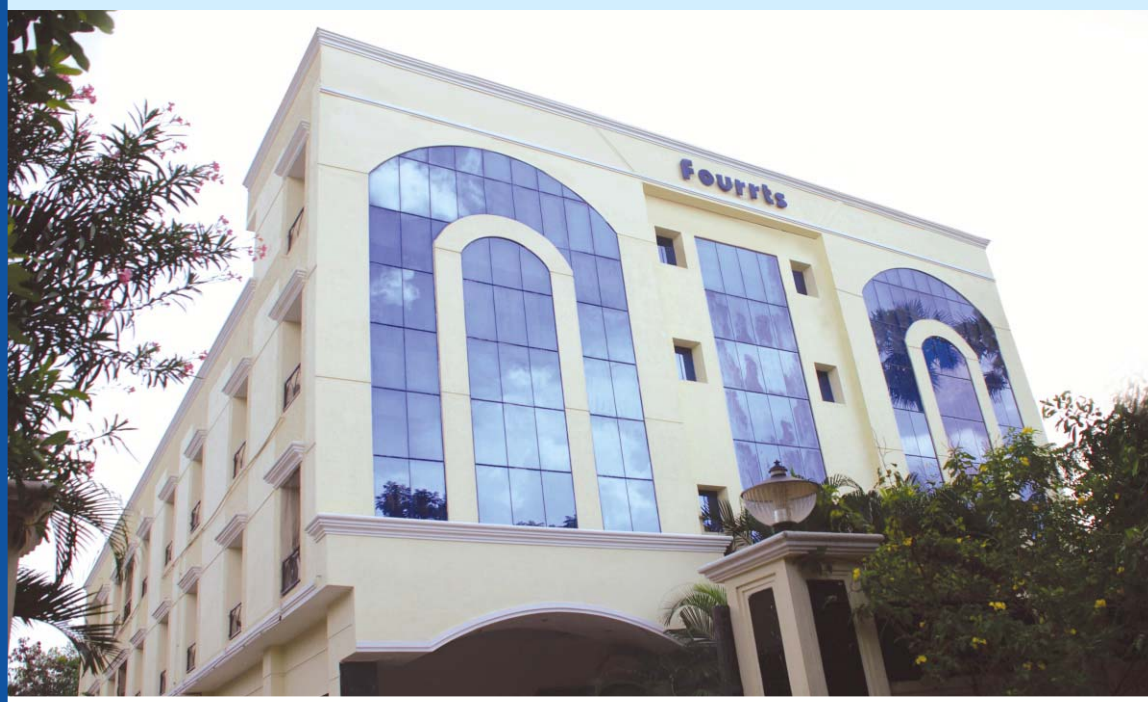


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