ISSUE No. 40

SILVER JUBILEE YEAR 2016

TAMILNADU PHARMACEUTICALS SCIENCES WELFARE TRUST

25 Years

# Pharma Web

## Newsletter of Tamilnadu Pharmaceutical Sciences Welfare Trust

Oct. - Nov. - Dec. 2018

# Delvin Formulations

*Destiny for Innovation*

# Moving Globally

- R & D and Manufacturing of API
- R & D and Manufacturing of Formulations
- International Marketing
- Domestic Marketing
- Medical Devices
- Surgicals


**Our Group of Companies**

| | | | | | |
|---|---|---|---|---|---|
| NURAY CHEMICALS PVT. LTD. | Sai Mirra Innopharm Pvt. Ltd. | Delvin Formulations | Numen Healthcare Pvt. Ltd. (Singapore) | Delvin Klarvoyant Biogenics Pvt. Ltd. | Delvin Surgicals |
| R & D and Manufacturing of API | R & D and Manufacturing of Formulations | Domestic Marketing | International Marketing | Medical Devices | Surgicals |

info@delvin.in | www.delvin.in

Tamilnadu Pharmaceutical Sciences Welfare Trust

# Pharma Web

## Newsletter of Tamilnadu Pharmaceutical Sciences Welfare Trust

ISSUE : 40 Oct. - Nov. - Dec. 2018



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



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

# EDITORIAL

Dear Readers,

We wish all our readers a very HAPPY NEW YEAR 2019.

We are happy to publish the 40th issue of Pharma Web Newsletter for Oct – Dec 2018.

We are happy to inform our readers, that Pharma Knowledge Training Institute, under the Trust has proposed to conduct the Pharmacovigilance programme for final year Pharm D / M. Pharm Pharmacology students in the last week of February 2019.

In this issue, we have published the following articles:

- Community Pharmacy Practice in Malaysia - by
  Dr. Shubashini Gnanasan, Dr. Mahmathi Karuppannan & Dr. Yogheswaran Gopalan

- The Leadership Challenges in the Pharmaceutical Sector - by
  Ms. Anusha. S, JSS College of Pharmacy, Ooty

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

The important events like National Pharmacy Week Celebration, IPA Best Branch award, IPA Fellowship awards, important news items connected to our Pharmacy profession appeared in various national news papers are also published in this issue.

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

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

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

With Best Regards,

**R. NARAYANASWAMY**
Chief Editor

# ARTICLES

## COMMUNITY PHARMACY PRACTICE IN MALAYSIA

**Health care system in Malaysia**

Dr. Shubashini Gnanasan

Dr. Mahmathi Karuppannan

Dr. Yogheswaran Gopalan

Malaysia is a Southeast Asian country with a population of 32 million. Health care in Malaysia is provided by the public and private sectors. Public health services are heavily subsidised by the government. The Ministry of Health (MOH) is the major provider of health services and is responsible for the health of the population, as stated in the Federal Constitution. Primary care services at health clinics are delivered almost free of charge, whereby each patient is charged a nominal fee of RM 1 (equivalent to₹16) for each outpatient visit.

The government provides primary, secondary and tertiary care through various types of health facilities. These facilities include hospitals, special medical institutions, national institutes of health, dental clinics, health clinics, mobile health and dental clinics and flying doctor stations. There are 144 government hospitals and nine special medical institutions with a total of 41,995 beds . On top of that, the private healthcare settings have also grown tremendously and it is the second major provider of health services, especially in urban areas. The increasing demand for high quality health services has contributed to the growth of the private health sector. The standard of care at private facilities was perceived to be of high quality with reduced waiting time. The quick service at a private general practitioner's clinic also offers convenient medical services, in particular to the nearby population. Private health providers complement the medical services provided by the government. Currently, there are about 187 private hospitals (with a total of 13,957 beds), 10 maternity homes, 17 nursing homes, two hospices, 73 ambulatory care centres, 4 blood banks, 423 haemodialysis centres, 7335 medical clinics and 1,992 dental clinics . The private sector charges user-fees to patients for utilising health services in order to operate and maintain their facilities. Access to private healthcare services is inevitably limited to the affluent population that can afford to pay high user fees as out-of pocket payments or co-payments (with coverage of private insurance). Other providers of health care include the traditional complementary medicine practitioners such as traditional Malay, Chinese and Ayurvedic treatments are well accepted by both rural and urban communities. Lack of integration between the public and private health sectors is a problem. At present, patients can go to any health care facilities but their medical records are not shared.

**Pharmacy practice**

Over the years, the pharmacy practice in Malaysia has shifted its focus from product-oriented services to patient-centred services. Pharmacists today work alongside with other medical professionals in an increasingly cohesive environment and together they play an active role in patient care. Ageing population, rising prevalence of non-communicable diseases as well as various environmental and communicable threats to health has increased the demand for medicine. Costs of pharmaceuticals and medical technologies have also continued to rise. The Pharmaceutical Services Programme of the MOH is entrusted to ensure that the public gets access to safe, efficacious and quality pharmaceuticals, protecting their interest via enforcement of the relevant legislations, and ensuring rational use of medicines by both healthcare providers and patients.

The increasing number of pharmacists in Malaysia encouraged the development of new pharmacy services in the public health sector. In 2004, the clinical pharmacy services evolved to include ward pharmacy, medication therapy adherence clinic (MTAC), home medication review (HMR) and methadone maintenance services. Since then, the number of health facilities offering MTAC has expanded to more than 660 facilities in less than 10 years.

MTAC is an ambulatory care services provided by trained pharmacists to patients in hospitals or health clinics which comprises of few sessions of follow-up visits. Patients will be monitored and counselled on specific modules that have been set according to each patient's needs. These services are provided at no extra cost. The aim of MTAC is to optimise medication therapy in chronic diseases such as diabetes mellitus, retroviral disease, asthma and chronic kidney disease. Over the years, MTAC services expanded to cover warfarin management, pain management, geriatric care and medication management in patients with neurological disorders, psychiatric problems, hypertension, stroke, rheumatoid arthritis, psoriasis, retroviral disease, renal transplantation, dialysis and hepatitis. Pharmacists educate patients on their medications, promote adherence to drug therapy and monitor safety and effectiveness of the treatment.

HMR is performed by a multi-disciplinary team of health care professionals consisting of pharmacists, nurses, physiotherapist and occupational therapist. It is a continuity of patients care from ward/MTAC to patients home. During the visit, the pharmacist will assess patients' medication regimen for the purpose of identifying and resolving drug-related problems, as well as reconciling the medications taken at home with what was prescribed at the time of discharge.

Besides MTAC and HMR, specialised clinical pharmacy services such as clinical pharmacokinetics services, the nutritional support services, and cytotoxic drug reconstitution services have provided the opportunity to individualise treatment based on patient needs. These services are provided for inpatients.

Technology and telecommunications have been integrated through innovative and creative ideas by the pharmaceutical services at the MOH to further improve drug delivery system. Some of the new services include the Integrated Drug Dispensing System, Drive through Pharmacy, 'Short Message Services (SMS) and Take', Drive-Thru Pharmacy, Medicines Delivery via Postal Service and Locker4U are some of the examples of innovative value-added pharmacy services. These new services have enabled patients to refill medications at their own convenience.

**Community pharmacy practice**

Pharmacists also practice in the private sector which include the community pharmacies, pharmaceutical industry as well as in academic institutions. Pharmacists in Malaysia practise under two different sets of legal-historical framework . Pharmacists working in government hospitals have complete control over the supply of medicines. However, community pharmacists in Malaysia are yet to have the full control over the supply of medicines as general practitioners are legally allowed to dispense medicines in their clinics. This doctor-dispensing practice has been allowed since the colonial era when Malaysia suffered from an acute shortage of all professionals .

One of the challenges in the community pharmacy practice in Malaysia is that there is a significant imbalance between the number of pharmacists and population, especially in the rural areas. Almost 10,500 pharmacists were registered with the Malaysian Pharmacy Board in 2016, giving a pharmacist to general population ratio of about 1:3013, and of which almost 4000 pharmacists are in the private sector . In line with the WHO recommendation, the MOH expects to achieve a ratio of 1:2000 (pharmacists to general population) by 2020 . Despite the increasing number of pharmacists in the country and the call for dispensing separation over the last 20 years, the government still believes that the separation cannot be implemented due to perceived difficulties to the public and the objections from medical practitioners. Thus, community pharmacists had since diversified their roles especially focussing on the supply of health supplements and beauty care. A study by Chua et al reported that the general public in Malaysia approached community pharmacists mainly to purchase medications or health supplement and to seek advice on minor health problem . On the other hand, several Asian countries namely South Korea, Taiwan, Indonesia, India and Japan are practising dispensing separation in both public and private sectors .

Under the Pharmacist Registration Act 1951 (revised 1989), only registered pharmacists can open and operate a retail pharmacy outlet. This requires a MOH recognized degree in pharmacy which takes 4 years to complete and a year of housemanship training. Community pharmacies in Malaysia are generally divided to independent pharmacies and chain pharmacies. Guardian Pharmacy and Watsons Group are examples of two giant chain pharmacies, followed by other local retail chains such as Caring Pharmacy, Constant

Pharmacy, Aeon Wellness and Tigas Pharma. This leads to another challenge for the community pharmacies – the price war. Some pharmacists indulge in price war by undercutting the market and overload customers with products to maximise their profit margin . Apart from that, community pharmacists also compete with chain pharmacies and doctors, who have the license to dispense drugs in Malaysia. It was common for pharmacists to mark-up their drug price 25 - 30% above costs. However lately, highly competitive market has forced community pharmacists to reduce the mark-up price to 15% above cost and some even sell drugs at below cost . Many initiatives have been taken by the Pharmaceutical Services Division in Ministry of Health, Malaysian Pharmaceutical Society (MPS) and Malaysian Community Pharmacy Guild to urge the government to regulate the drug prices and effectively enforce the Competition Act 2010 (An act that promotes economic development by promoting and protecting the process of competition, thereby protecting the interests of consumers and to provide for matters connected therewith).

Besides retailing and dispensing, community pharmacists also conduct medication reviews, blood glucose and blood pressure monitoring and engage in regular healthcare campaigns and awareness programmes. Some general practitioners have indicated that they would like to collaborate with community pharmacists on improving patient therapeutic outcomes and welcome patient referral from community pharmacies for further medical evaluation . Other community pharmacy initiatives to partner with public/private hospitals and health clinics with regards to medication review are being explored to expand the role of community pharmacists in the near future.


Dispensing in Green Life Pharmacy, Malaysia


Blood pressure monitoring by the pharmacist of City Wellness Pharmacy, Malaysia


Patient counselling at Spectrum Pharmacy, Negeri Sembilan, Malaysia

(All Photos with the authorization of the pharmacist)

## References


1. Health facts 2017, 2017, Health Informatics Centre: Malaysia, Ministry of Health Malaysia.
2. Wong, S.S., Pharmacy practice in Malaysia. Malaysian Journal of Pharmacy, 2001. 1: p. 2-8.
3. Hasan, S.S., et al., Influences on Malaysian pharmacy students' career preferences. American Journal of Pharmaceutical Education, 2010. 74(9): p. 166.
4. Chua, S.S., K.P. Lim, and H.G. Lee, Utilisation of community pharmacists by the general public in Malaysia. International Journal of Pharmacy Practice, 2013. 21(1): p. 66-69.
5. Kenny, K., & Madhavan, P., Dispensary separation: Perceptions of the public visiting primary care clinics in Malaysia. Malaysian Journal of Pharmaceutical Sciences, 2018. 16: p. 23-25.
6. Kho, B.P., et al., Challenges in the management of community pharmacies in Malaysia. Pharmacy practice, 2017. 15(2): p. 933-933.
7. Bitter pill for pharmacists., in The Star2016: Malaysia.
8. Ooi, G.S., et al., Assessment of Community Pharmacy Services in Malaysia: Perspectives from Community Pharmacists, General Practitioners, Consumers and Health Policy Stakeholders. Value in Health, 2016. 19(7): p. A827.



**Contributed by:**
Dr. Shubashini Gnanasan*, Dr. Mahmathi Karuppannan, & Dr. Yogheswaran Gopalan
Department of Pharmacy Practice, Faculty of Pharmacy, Universiti Teknologi MARA, Puncak Alam Campus, Selangor, Malaysia
Email: shubashini.gnanasan@gmail.com


Source : IPA CPD e-Times, Nov-Dec,2018

# THE LEADERSHIP CHALLENGES IN THE PHARMACEUTICAL SECTOR

by
**Ms. Anusha. S**
JSS College of Pharmacy, Ooty

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

## Introduction:

"Life is the most precious thing known in this entire universe", such a huge responsibility lies in the hands of pharmaceutical sectors also. One small mistake could really cost too much! Along with this huge responsibility, pharmaceutical sectors are also in a constant pressure to deal and adapt with various changes due to globalization, changing customer demands, new diseases, sagging economy etc. This pressure is passed onto the leaders of a pharmaceutical sector to meet the requirements of the company which makes it challenging.

## Leader or a boss??

The most important challenge for a leader is when he is unable to make out the difference between a leader and a boss. A boss demands blind obedience whereas a leader earns his authority through understanding and trust. A boss who don't listen to what others say will be eventually surrounded by people who have nothing to say. In short a leader leads but a boss drives. Therefore a leader should always give space to the fellow coworkers, appreciate and recognize their work.

## Deficiency of decision making

The deficiency of decision making is an indicator of leadership failure. This challenge starts right from an interview when a leader fails to choose a unique talent from a bunch of other people. This ability of a leader to choose wisely and make a team is quite challenging in current trends. A leader should also settle down problems wisely, because a biased leader leads to de-motivation. Solutions for a problem should be always independent of the interpersonal vengeance.

## Synthesis to sale

- There is a constant pressure for the leaders of the R and D department to come up with newer innovations to file for new patents and sustain their patents.
- Drugs with larger manufacturing costs are less affordable by the people which decreases the profit margin therefore it is challenging for the leaders to control the manufacturing price.
- Clinical trials have their own problems like complexity of trials spiraling costs, regulation etc. This poses its own challenges to the leaders.

- The time taken for a company to yield brand-name popularity, beat the existing brands and convince a doctor to prescribe your brand is obviously a challenge for leaders of marketing.

- Rare but fatal adverse reactions are difficult to find and it's quite challenging during a post marketing surveillance.

- Companies with collaborations often perform well when compared to other companies because of stricter rules, better technologies therefore a pharmaceutical firm has to strategically position itself to thrive in such a competition.

- Changing regulations andthe need for different regulations for different market is quite challenging.

**Ethics or money??**

- There is a low profit margin due to government pricing policies DPCO as 40 percent of the turnover is under DPCO and there is a constant pressure to search for loopholes like addition or changing one or more ingredients in a price controlled drug, non standard strengths of same drug, new non standard dosages etc.

- Most of the underdeveloped or developing countries do not have the startup up costs for research and development. Such countries and companies go for generics but due to unmerited patents generic companies are denied a chance.

- In some countries there were evidences that the bioequivalence studies carried out by generic manufacturers were fraudulent as they kept standard drugs for test.

- Such unethical practices by some leaders often pose challenge to ethical leaders of the pharmaceutical sector.

**Challenges of a Pharmacist**

The challenges faced by a community or a retail pharmacy is often unheard!

- Pharmacy industry revenues are shifting from traditional brand name drugs to specialty drugs. In the next few years specialty drugs will account for almost half of the pharmaceutical industry revenue as more of this products are dispensed by large specialty pharmacies, a community pharmacy must position itself to handle such pressure which is quite challenging.

- Nowadays people prefer OTC medicines, though it increases the revenue of a retail pharmacy it is the duty of a pharmacist to guide them about efficacious medicines and gently tell them the importance of meeting a health care professional without hurting the ego of a patient which is quite challenging.

- In some countries the population density to pharmacy and pharmacist ratios are poor which adds its own challenges to a pharmacist.

- The retail pharmacies are facing fierce competition that is forcing them to decrease their prescription profit margins.

- One of the major problems is medication adherence, half of the patients don't take their medicines as prescribed. Therefore a clinical pharmacist has to manage this by medication therapy management and counseling.

**Conclusion**

Pharmaceutical sector is one of the fastest growing health care profession, with the newer emerging technologies like artificial intelligence where a patient data is connected to smart machines decision making can be enhanced .But on the other hand we have to realize that every profession, every single leader have their own challenges and survival of a pharmaceutical firm depends on overcoming these challenges..In the verge of profit people have forgotten that “Service is above oneself” and are opting for unethical approaches for quick success.There should be always a balance between profit and ethics.

***Live and let live.***

# EVENTS

## National Pharmacy Week Celebration – IPA TN Branch

The 57th National Pharmacy Week (NPW) was celebrated from 18th to 24th November, 2018 The theme selected for this year is: **"Pharmacists for a Healthy India".**

## Workshop on Good Manufacturing Practices and Updates in Pharmaceutical Industry

The 57th National Pharmacy Week (NPW) was celebrated from 18th to 24th November, 2018 The theme selected for this year is: **"Pharmacists for a Healthy India".**


A 3 day's workshop was organised for the Pharmacy college faculties in Southern region of Tamillnadu from 22nd Dec' 18 to 24th December 2018 by The Tamilnadu Dr.MGR Medical University in association with IPA TNSB & IDMA TNPKSB. The inauguration programme was held on 22nd December 2018 at University Senate Hall, Presided by Vice Chancellor Prof.Dr.Geethalakshmi& Chief Guest IPA President Dr. S. Manivannan. Followed by the inauguration, lectures delivered by industry experts and one day industrial visit arranged for them.

## Seminar on Administration of Drugs and Drug Interaction



As a part of National Pharmacy Week Celebrations, this year conducted the different activity, Seminar on Drug Administration & Drug Interactions was Conducted by IPA Tamil Nadu State Branch.

Seminar was conducted on 22nd December 2018, Jointly with Apollo Hospitals. After noon conducted another programme in Global Hospital.

On 23rd December 2018 – Seminar was conducted IPA, TNSB jointly with KK College of Pharmacy at Vijaya Hospital, and followed by afternoon ACS Medical College & Hospital, Velappanchavadi, Chennai

The above all the programme lecture given by Dr. S. Sriram Professor & Head Pharmacy Practice, Ramakrishna Hospital's Coimbatore was the Speaker.

## National Pharmacy Week Celebration - Valedictory

57th National Pharmacy Week Celebration valedictory function was organised on 4thJanuary 2019 at 4.00 PM at **TN Rajarathinam Pillai Muthamizh Peravai Hall**, Chennai, Thiru. K. Pandiarajan, Minister for Tamil official Language and Tamil Culture, Govt of Tamilnadu, Chief Guest of the function. The Guest of Honours were Mr. K. Sivabalan, Director of Drugs Control, Tamilnadu, Prof. Dr. K. Chinnaswamy, President, Tamilnadu Pharmacy Council. Dr. S. Manivannan, DDC (I), CDSCO, New Delhi, welcomed the gathering. Mr. J. Jayaseelan, Vice President, addressed the gathering on the theme "Pharmacists for a Healthy India". Thiru. K. Pandiarajan, gave the address to the audience & students with his intellectual & astonishing way of delivering his talk with pharma instances & Pharma examples.










”Best Pharmacist Award” instituted by TN IPA & sponsored by M/s. Lalchand Bhimraj, Chennai, this year was awarded to Mr. J. Jayaseelan, Vice President, IPA TNSB, Vice President, Industry division, IPA Mumbai for the dedicated service to the profession of Pharmacy & for his untiring efforts in uplifting the industry & academia of Pharma.

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

## National Pharmacy Week Celebration – Coimbatore Local Branch

The 57th National Pharmacy Week Celebrations had been celebrated by the Indian Pharmaceutical Association, Coimbatore Local Branch. As part of the celebrations an awareness rally was organised in coordination with PSG College of Pharmacy, Coimbatore on the on 20th November 2018. To bring awareness about Pharmacist & Pharmacy profession to the community, Pharmacy colleges of Coimbatore region have joined together and participated in the rally. Around 600 students with 30 faculty members have participated in the rally.

Dr. M. Ramanathan, Secretary, IPA Coimbatore Local Branch & Principal, PSG College of Pharmacy, Coimbatore welcomed the gathering. Dr. T.K. Ravi, President, IPA Coimbatore Local Branch & Principal, College of Pharmacy, SRIPMS, Coimbatore addressed the Pharmacists on the theme. The rally was flagged off by Dr. S. Ramalingam, Dean, PSG IMSR & Hospitals, Coimbatore.

In continuation, a power point competition was also organised to the students of Pharmacy Colleges in Coimbatore zone in coordination with the Colleges of Pharmacy, SRIPMS, Coimbatore on 22nd November 2018. Total 08 candidates from different colleges have participated in the competition. Dr. T. K. Ravi, President, Dr. M. Ramanathan, Secretary, Dr. M. Gopal Rao and Dr. K.P. Sampathkumar, Executive Committee Member of IPA Coimbatore Local Branch were present during the Competition. The winners of the competition were awarded a certificate & cash prize for one 1st Place – Rs. 3,000/-, one 2nd Place – Rs. 2,000/- & two 3rd place – Rs. 1,000/-.


## IPA - Best State Branch Award


For the year 2018 best State branch award received for Tamilnadu State Branch, IPA during the 70th IPC held in New Delhi.

## IPA Fellowship award



Every year IPA is giving the Fellowship award to members of IPA, and scrutinized by the selection committee. For the year 2018 the awardees from our trust Mr. J. Jayaseelan, Joint secretary of Trust and Vice President, IPA TNSB, Vice President, Industrial division , IPA Mumbai and also Mr. T. Sathish, Trustee and Secretary, IPA TNSB.

# INFORMATION

## M. PHARM & PHARM D SCHOLARSHIP 2018 - 2019

In order to motivate the student community, every year the Tamilnadu Pharmaceutical Sciences Welfare Trust, Chennai awarded scholarship to selected M.Pharm & Pharm D final year students from various colleges in Tamilnadu & Puducherry for their on-going project work. The scholarship scheme was imitated in the year from 1998 for M.Pharm and 2013 for Pharm D. The received applications are codified, so that the identity of the student is not disclosed to the evaluator and sent to institutions outside the state of Tamilnadu for evaluation.

This is 21st year of this project, we have received 289 (219+70) applications from 7 different branches, from 17 institutions. All synopses were sent to **Prof. Shailendra Saraf, Vice Chancellor, Hemchand Yadav Durg University, Durg Chhattisgarh** & his team for evaluation. Based on the ranking, 21 students have been selected for awards as per the following details.

## M. PHARM / PHARM D. SCHOLARSHIPS 2018 - 2019 - RESULT

### PHARMACEUTICS

| Rank | Name | College | Amount |
|---|---|---|---|
| I | Ms. Divyabharathi. M | JSS College of Pharmacy, Ooty | 12,000/- |
| II | Ms. Ranjitha. R | COP, Madras Medical College, Chennai | 10,000/- |
| III | Ms. R. Priyadharshini | PSG College of Pharmacy, Coimbatore | 8,000/- |

### PHARMACEUTICAL CHEMISTRY

| Rank | Name | College | Amount |
|---|---|---|---|
| I | Ms. Naina Merin Joy | JSS College of Pharmacy, Ooty | 12,000/- |
| II | Mr. Kathiravan. M | COP, Madurai Medical College, Madurai | 10,000/- |
| III | Mr. A. Sathish | COP, Madurai Medical College, Madurai | 8,000/- |

### PHARMACY PRACTICE

| Rank | Name | College | Amount |
|---|---|---|---|
| I | Ms. Kousalya. B | SRIPMS, Coimbatore | 12,000/- |
| II | Ms. Aparna. A | SRIPMS, Coimbatore | 10,000/- |
| III | Mr. Sidharth C S | JSS College of Pharmacy, Ooty | 8,000/- |

## PHARMACEUTICAL ANALYSIS

| Rank | Name | College | Amount |
|---|---|---|---|
| I | Mr. Ramshankar Nayak | JSS College of Pharmacy, Ooty | 12,000/- |
| II | Mr. Lingamallu Venkata Sai Krishna | JSS College of Pharmacy, Ooty | 10,000/- |
| III | Ms. Ann Raichel John | JSS College of Pharmacy, Ooty | 8,000/- |

## PHARMACOLOGY

| Rank | Name | College | Amount |
|---|---|---|---|
| I | Mr. Tenzin Choephel | JSS College of Pharmacy, Ooty | 12,000/- |
| II | Ms. V. Shanthi Priya | Mother Theresa Post Graduate & Research Institute of Health Sciences, Puducherry. | 10,000/- |
| III | Ms. M. Megala | JSS College of Pharmacy, Ooty | 8,000/- |

## PHARMACOGNOSY

| Rank | Name | College | Amount |
|---|---|---|---|
| I | Ms. Ann Maria Alex | JSS College of Pharmacy, Ooty | 12,000/- |
| II | Ms. Sumithra. S | COP, Madras Medical College, Chennai | 10,000/- |
| III | Mr. K. Muthukrishnan | COP, Madurai Medical College, Madurai | 8,000/- |

## PHARM D

| Rank | Name | College | Amount |
|---|---|---|---|
| I | Muhammed Sufiyan,<br>Sai Laharika,<br>Roshini. S,<br>Sheena Varghese | K.K. College of Pharmacy | 15,000/- |
| II | Ms. Saumya Sam,<br>Ms. Sreeshna . J | SRIPMS, Coimbatore | 12,000/- |
| III | Ms. Akili Karuna | School of Pharmaceutical Sciences,<br>VISTAS (Vels University) | 10,000/- |

## ESSAY COMPETITION 2018 – FINAL YEAR B. PHARM STUDENTS

**TNPSWT** imitated a new activity from 2011 for Essay competition and this year subject being **"The Leadership Challenges in the Pharmaceutical Sector"**. This awarded is in the name of **"Shri G. Swaminthan Memorial Award"** -- Sponsored by M/s. Pharm Products Pvt Ltd. Thanjavur.

This year we have received 70 applications from 12 colleges and this was evaluated by **Ms. Anusuya R. Kashi**, Vivekananda Colleges of Pharmacy, Bangalore. Based on the rating -- 3 students have been awarded as below

| Rank | Name | College | Amount |
|---|---|---|---|
| I | Ms. Anusha. S | JSS College of Pharmacy, Ooty | 10,000/- |
| II | Ms. Sharon Christina Pearline. V | C. L. Baid Metha College of Pharmacy, Chennai | 8,000/- |
| III | Mr. Bala Baskar. N | Mother Therasa Post Graduate & Research Institute of Health Sciences, Pudhucherry | 7,000/- |

## UNIVERSITY MERIT AWARD

From year 2015 M/s. Fourrts India Laboratories Pvt. Ltd., sponsored university merit award for topper candidates, who have secured high marks in B.Pharm examinations passed during August 2018 of The Tamilnadu Dr. MGR Medical University, Guindy, Chennai

| Rank | Name | College | Amount |
|---|---|---|---|
| I | Ms. Shamuthabanu. S | K.M. College of Pharmacy, Madurai | 10,000/- |
| II | Ms. Sangeetha. V | COP, Sri Ramakrishna Institute of Paramedical Sciences, Coimbatore | 8,000/- |
| III | Ms. Soundarya. S | COP, Madras Medical College, Chennai | 7,000/- |

# NOTIFICATION

## MINISTRY OF HEALTH AND FAMILY WELFARE

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

**NOTIFICATION**

New Delhi, the 3rd December, 2018

**S.O. 5980(E)**.—In pursuance of sub-clause (iv) of clause (b) of section 3 of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, after consultation with the Drugs Technical Advisory Board, hereby specifies the following devices intended for use in human beings for the purposes referred to in the said sub-clause as drugs with effect from the 1st day of January, 2020, namely:-

(i) Nebulizer ;

(ii) Blood Pressure Monitoring Devices ;

(iii) Digital Thermometer ; and

(iv) Glucometer .

[F.No. X.11014/33/2018-DR]
DR. MANDEEP K BHANDARI, Jt. Secy.

## MINISTRY OF HEALTH AND FAMILY WELFARE

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

**NOTIFICATION**

New Delhi, the 7th December, 2018

**G.S.R. 1186(E)**.—Whereas the draft of certain rules further to amend the Drugs and Cosmetics Rules, 1945 was published as required under section 12 and 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. 721(E), dated the 30th July, 2018, 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 the 3rd August, 2018;

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

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

1. (1) These rules may be called the Drugs and Cosmetics (Ninth 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 rule 127, in sub-rule (2), at the end, the following words shall be inserted, namely:

   "except gelatine capsules wherein approved or permitted colour shall be used".

[F. No. X.11014/15/2018 -DR]
Dr. MANDEEP K. BHANDARI, Jt. Secy.

Note : The principal rules were published in the Gazette of India vide notification number F.28-10/45-H (1), dated the 21st December, 1945 and last amended vide notification number G.S.R. 1161(E), dated the 3rd December, 2018.

## MINISTRY OF HEALTH AND FAMILY WELFARE

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

**NOTIFICATION**

New Delhi, the 12th December, 2018

**G.S.R. 1193(E)**.—Whereas the draft of certain rules further to amend the Drugs and Cosmetics Rules, 1945 was published as required under sections 12 and 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. 1000(E), dated the 5th October, 2018 in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), inviting objections and suggestions from all persons likely to be affected thereby, before the expiry of a period of fifteen 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 10th October, 2018;

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 (Tenth 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 24,-

(a) in sub-rule (1),-

(i) for the words “one thousand rupees for a single drug and an additional fee at the rate of one hundred rupees”, the words “ten thousand rupees for a single drug and an additional fee at the rate of one thousand rupees” shall be substituted;

(ii) in the proviso, for the words “one hundred rupees”, the words “one thousand rupees” shall be substituted;

(b) in sub-rule (3), for the words “two hundred and fifty rupees shall be paid”, the words “one thousand five hundred rupees shall be paid for making amendment in the licence or” shall be substituted.

3. In the said rules, in rule 24A,-

(a) in sub-rule (3),-

(i) in clause (i), for the words and letters “one thousand and five hundred US dollars”, the words and letters “ten thousand US dollars” shall be substituted;

(ii) in clause (ii) and proviso thereto, for the words and letters “one thousand US dollars” wherever they occur, the words and letters “five thousand US dollars” shall be substituted;

(b) in sub-rule (5), for the words and letters “five thousand US dollars”, the words and letters “twenty five thousand US dollars” shall be substituted;

(c) in sub-rule (7), for the words and letters “three hundred US dollars or its equivalent in Indian rupees shall be paid”, the words and letters “one thousand eight hundred US dollars or its equivalent in Indian rupees shall be paid for making amendment in the registration certificate or” shall be substituted.

4. In the said rules, in rule 34, in sub-rule (3), for the words “one hundred rupees for a single drug and an additional fee of fifty rupees”, the words “five thousand rupees for a single drug and an additional fee of two thousand rupees” shall be substituted.

5. In the said rules, in rule 34A, in sub-rule (3), for the words “one hundred rupees for a single drug and an additional fee of fifty rupees”, the words “six hundred rupees for a single drug and an additional fee of three hundred rupees” shall be substituted.

6. In the said rules, in rule 122A, in sub-rule (1), in clause (b),-

(i) for the words “fifty thousand rupees”, the words “two lakh fifty thousand rupees” shall be substituted;

(ii) in the first proviso and in the second proviso, for the words “fifteen thousand rupees”, at both the places where they occur, the words “one lakh rupees” shall be substituted.

7. In the said rules, in rule 122D, in sub-rule (1), for the words “fifteen thousand rupees”, the words “fifteen thousand in case of application for manufacture of the fixed dose combinations and one lakh rupees in case of import application of the fixed dose combinations” shall be substituted..

8. In the said rules, in rule 129A,-

(a) in sub-rule (1), for the words and letters, “two hundred and fifty US dollars or its equivalent to Indian rupees for each brand of cosmetic”, the words and letters “two thousand US dollars or its equivalent to Indian rupees for each brand of cosmetic and a fee of fifty US dollars for each variant” shall be substituted;

(b) in sub-rule (5), for the words and letters “one hundred US dollars”, the words and letters “five hundred US dollars” shall be substituted.

[F. No. X.11014/32/2018-DR]
Dr. MANDEEP K BHANDARI, Jt. Secy.

Note: The principal rules were published in the Gazette of India vide notification number F.28-10/45-H(1), dated the 21st December, 1945 and last amended vide notification number G.S.R. 1186(E), dated the 7th December, 2018.

## MINISTRY OF HEALTH AND FAMILY WELFARE

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

**NOTIFICATION**

New Delhi, the 10th January, 2019

**G.S.R. 19(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. 629(E), dated the 11th July, 2018, in the Gazette of India, Extraordinary, Part II, section 3, sub-section (i), inviting objections and suggestions from persons likely to be affected thereby, before the expiry of a period of thirty days from the date on which the copies of the Official Gazette containing the said notification were made available to the public;

And whereas copies of the said Official Gazette were made available to the public on the 12th July, 2018;

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

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

1. (1) These rules may be called the Drugs and Cosmetics ( Amendment) Rules, 2019.

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

2. In the Drugs and Cosmetics Rules, 1945, after rule 84AA, the following rule shall be inserted, namely:—

   **"84AB. Information to be uploaded by the licensee on online portal SUGAM.**

   (1) The licensee granted license under this Part shall register with portal SUGAM (www.cdscoonline.gov.in) and upload information, as per the format provided in the said portal, pertaining to the licences granted for manufacture for sale or distribution of drugs and the information so provided shall be updated from time to time.

   (2) The information uploaded by the licensee with SUGAM portal under sub-rule (1), shall be verified by the concerned Licensing Authority.".

[F. No. X.11014/16/2018-DR]
Dr. MANDEEP K. BHANDAR, 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. 1193(E), dated 12th December, 2018.

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

**Dated:** 12 DEC 2018

**To,**

**All State/UT Drugs Controllers**

**Subject: Procedure to be followed for subsequent applicants in respect of FDCs declared as rational by Prof. Kokate Committee and approved by DCG(I) - regarding.**

This is with reference to this office letter dated 15.01.2013 whereby all the State/UT Drugs Controllers were requested to ask the concerned manufacturers in their State to prove the safety and efficacy of FDCs within 18 months which were permitted by State Licensing Authorities without due approval from the office of DCG(I).

After examination of such applications in consultation with Prof. Kokate Committee constituted by Ministry of Health and Family Welfare, concerned manufacturers were issued NOC for continued manufacturing and marketing in case of FDC held as rational.

The list of such FDCs for which NOCs have been issued so far in respect of the applicants under 18 months policy decision is already available on CDSCO website under the heading "List of FDCs (under category 'c') permitted for continued manufacturing and marketing under 18 month policy decision" with the following link :

***https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MjIzNg==***

Earlier, for grant of NOCs to such subsequent applicants, the applications were processed as per procedure suggested in this office letters dated 16.3.2017 and 5.6.2017 which are available in CDSCO website.

Subsequently, however, this Directorate received representations from various stake holders for issuance of permission to subsequent applicants of such FDCs which have been held as rational and approved by DCG(I).

The matter was examined by this Directorate in consultation with the Ministry of Health and Family Welfare, Govt. of India. With the approval of the Ministry, it has been now decided to follow the following pathway for grant of product license by State Licensing Authorities (SLA):

1. The applicants shall submit the TR-6 challan of Rs. 15000/- for each FDC to CDSCO.
2. The applicant along with copy of the TR-6 challan submitted to CDSCO shall submit applications directly to the concerned SLA as per the provisions of Drugs and Cosmetics Rules for grant of product manufacturing license giving the details of FDC, Sl. No. of the FDC in the list, stability studies data (3 months accelerated), test specification of the FDC along with Method of Analysis as well

as Label and other documents as required for grant of product license under Drugs and Cosmetics Rules.

3. State Licensing Authority shall grant the product license of such FDCs without seeking NOC from DCG(I), if other conditions of license under the Drugs and Cosmetics Rules, which need to be verified by SLA, are found to have been fulfilled. The SLAs shall verify the quality of such FDCs of each applicant/manufacturer, before grant of license as per Drugs and Cosmetics Rules, 1945.
4. Every manufacturer licensed to manufacture these FDCs shall submit the periodic safety update reports (PSURs) as per Schedule Y of the Drugs and Cosmetics Rules to the Licensing Authority under Rule 21(b) i.e. DCG(I). Failure to submit the PSURs shall be considered as contravention of these Rules.

In view of above, you are requested to ask the concerned manufacturers/ stakeholders to follow the above procedure for obtaining the product license w.r.t. FDCs declared as rational by Prof. Kokate Committee and approved by DCG(I).

You are however requested to ensure that no product license is granted in respect of the FDCs which are not approved by this Directorate under 18 months policy decision.

Yours faithfully,

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

**Copy to:-**

1. PS to JS(R), Ministry of Health and Family Welfare, Nirman Bhawan, New Delhi.
2. All Zonal/Sub Zonal offices of CDSCO
3. Indian Drug/Pharmaceuticals Association Forum
4. Website of CDSCO

**F.No.12-01/18-DC(Pt-238)**
**Government of India**
**Directorate General of Health Services**
**Central Drugs Standard Control Organization**
**New Drugs Division**

FDA Bhawan, Kotla Road
New Delhi
Dated: 19-12-2018

To
**All State/UT Drugs Controllers**

**Subject: - Safety guidelines for Isotretinoin - Regarding**

Sir/Madam,

Isotretinoin is an oral drug used for the treatment and prevention of severe acne.

Isotretinoin capsule 10mg/ 20mg was approved by CDSCO on 21.06.2002 for treatment of cystic and conglobate acne, severe nodular acne unresponsive to antibiotic therapy with various conditions including a box warning for female patients as the drug may cause severe birth defects and patients should sign a consent form as per specified format before undertaking the treatment of Isotretinoin. Copy of the approval/permission is enclosed for ready reference.

In light of concerns raised with regard to safety of Isotretinoin, the matter has been examined by CDSCO in consultation with the Subject Expert Committee (SEC) (Dermatology & Allergy) in its meeting held on 26.07.2018.

The SEC deliberated the matter in detail and opined that the drug has favorable risk/benefit profile for the indications approved in the country. However, the following conditions should be followed during manufacture, sale and distribution of the drug as already stipulated by CDSCO at the time of approval of the drug.

1. The drug should be sold by retail on the prescription of Dermatologists only.
2. Pack of the drug should carry following Box warning-

   > This medicine may cause severe birth defects; you must not take this medicine if you are pregnant or may likely become pregnant during treatment.
   >
   > You should also avoid pregnancy for 6 months after stopping the treatment.

3. The patients should also sign a Consent Form before undertaking the treatment of Isotretinoin as already stipulated in the new drug permission.

The committee also recommended that the manufacturers should provide package insert along with their product which should be in major vernacular languages. The retail chemists should maintain the details of retail sale of the drug which should be strictly on the prescription of Dermatologist only.

....

Accordingly, you are requested to direct the manufacturers/retail chemists under your jurisdiction to comply with the following:-

(i) For Manufacturers:

1. Label should contain the warning 'The drug should be sold by retail on the prescription of Dermatologists only.'

2. Pack of the drug should carry following Box warning-

| |
|---|
| This medicine may cause severe birth defects; You must not take this medicine if you are pregnant or may likely become pregnant during treatment.<br><br>You should also avoid pregnancy for 6 months after stopping the treatment. |

3. The patients should also sign a consent form before undertaking the treatment of Isotretinoin as per the format enclosed.

4. Manufacturer should provide package insert along with their product which should be in major vernacular languages.

(ii) For retailers:

The drug should be sold by retail only on prescription of Dermatologist and the details of the sale should be strictly maintained as per requirements of D&C Rules, 1945.

Action taken in this regard may be intimated to this office.

Yours faithfully

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

Copy for information and necessary follow up to:

All Zonal/Sub Zonal offices of CDSCO.

CDSCO website.

**CDSCO/IT/2018-(37)**
**Government of India**
**Ministry of Health & Family Welfare**
**Directorate General of Health Services**
**Central Drugs Standard Control Organization**

**FDA Bhawan, New Delhi**
**Dated:** 09.01.2019

**OFFICE MEMORANDUM**

**Subject: Payment of challan through Bharatkosh –reg.**

While making application for various purposes to CDSCO the fee is paid by online through Bharatkosh or offline at Bank of Baroda. In case of offline payment challan has to be uploaded on SUGAM portal along with the application. The Government of India has directed that all the fee payable has to be made through only Bharatkosh.

Therefore, it is decided that from 15-Feb-2019, the provision to upload challan on SUGAM portal will be disabled and all the fee has to be paid through Bharatkosh only. In case you have already made your payment at Bank of Baroda, you are advised to use the receipt within 15-Feb-2019.

This is for your information and necessary action.

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

**To**

**All Pharma Industry Associatons**
**IDMA/IPA/FOPE/CIPI/FICCI/OPPI/Others**

Copy to:

1. PPS to AS&DG, MoHFW
2. PPS to JS(R), MoHFW

# NEWS

## SV Veeramani receives 'Industry Crusader Award' at CPhI India 2018 in New Delhi

The immediate past president of the Indian Drugs Manufacturers Association (IDMA) and CMD of the Fourrts India Laboratories, Chennai, S. V. Veeramani, has been bestowed with the "Industry Crusader Award" at India Pharma Awards of UBM at CPhI India 2018 in New Delhi on December 12.

The award recognizes Veeramani's contribution to Indian pharma industry for the last 40 years. The award was handed over to him by Adam Anderson, Group Brand Director of Pharma- Informa, UK in the presence of Subodh Priolkar, a jury member of UBM India, who organises CPhI India, the largest and most comprehensive pharmaceutical industry event of south Asia, every year.

The award selection juries included 10 internationally acclaimed trade fair organisers. In every CPhI, Industry Crusader award is given to an industry captain.

During his tenure as president of IDMA, Veeramani has taken several initiatives with the central government for developing the pharma SMEs in the country. As a result, the government has now announced a technology upgradation fund (PTUAS) for SMEs. Now the small scale pharma manufacturers can apply for the fund for upgrading their technologies in the units.

As the chairman of Tamil Nadu Pharmaceutical sciences Welfare Trust (TNPWT), he encourages largely for the pharmacy education in the state. The Trust conducts essay competitions and give scholarships and awards to students of various pharmacy courses every year.

During 2016, Veeramani was the president of the Indian Pharmaceutical Congress Association (IPCA) which conducts the Indian Pharmaceutical Congress (IPC) every year.

While talking to Pharmabiz, Veeramanis said his services for the Indian pharma industry will continue further with a renewed spirit and vigour.

**Source:** *Pharmabiz,* 15th December 2018

## PCI Comes out with Draft Diploma in Pharmacy Exit Examination Regulations for New Pharmacy Diploma Pass Outs

The Pharmacy Council of India (PCI) has come out with a draft Diploma in Pharmacy Exit Examination Regulations (DPEE), 2018 to ensure that only competent D.Pharm pass outs having a better understanding of the subject and requisite professional skills get registered with the State Pharmacy Council.

The draft DPEE has been put on the PCI website inviting comments from stakeholders by December 31, 2018.

After passing Diploma in Pharmacy (D.Pharm) course in any of the PCI approved colleges, students will have to appear for the exit exam. They can go for registration after clearing the exam.

As per the draft, the exit examinations will be conducted by an authority to be established or designated by the PCI as the Prescribed Authority.

The candidates may appear for the exit examination conducted twice every year or as frequently as may be required as per the schedule of examination announced by the Prescribed Authority.

The date of examination and the examination centre will be allotted to the candidate by the Prescribed Authority based on the availability of the examination centres.

The exit exam shall have three papers of multiple choice questions in Pharmaceutics, Pharmacology, Pharmacognosy, Pharmaceutical Chemistry, Biochemistry, Hospital and Clinical Pharmacy, Pharmaceutical jurisprudence and Drug Store Management. The language of the examination shall be English. The test for each paper shall be of three hours' duration.

A candidate shall be declared as having passed only if he obtains a minimum of 50% marks in each paper separately. A candidate shall have to pass all the three papers in the same attempt.

However, there shall be no restriction on the number of attempts to appear in the examination. A certificate of eligibility for enrollment and practice shall be issued to the successful candidate which will be presented before the State Pharmacy Council for registration as a pharmacist.

In other words, after having passed the exit exam, a candidate shall be entitled to registration as a pharmacist.

After these regulations come into force, the candidates who have completed the approved course of Diploma in Pharmacy and having qualified in the exit exam will be eligible for registration as pharmacists, said Archna Mudgal, registrar-cum-secretary, PCI.

These regulation shall not apply to the persons whose names are already entered in the register of pharmacists for the state, she clarified.

Talking about objective of the exit exam, Mudgal said “The exam aims to ensure that a candidate applying for registration as pharmacist with the State Pharmacy Council has undergone pharmacy education and a comprehensive practical training programme in D.Pharm course and acquired core competencies in dispensing of medicines and other areas of pharmacy practice and to reinforce his discipline, integrity, judgment, skills, knowledge and quest for learning so that after having passed the examination he is able to become a registered pharmacist who is able to exercise his professional skills in addition to carrying his duty and responsibilities professionally.”

**Source:** *Pharmabiz,* 14th December 2018

## Madras High Court Bans Online Sale of Medicine till Centre Notifies Rules

The Madras high court on Monday issued a blanket ban on online sale of medicines till the central government notifies rules regulating it. The court has also set January 31, 2019 as deadline to issue the notification.

Justice Puspha Sathyanarayana passed the order while allowing a plea moved by the Tamil Nadu Chemists & Druggists Association.

According to the association, though online shopping might be convenient to consumers, purchasing medicines from unlicensed online stores could be risky as they might sell fake, expired, contaminated and unapproved drugs or unsafe products that are dangerous to patients and that might put their health at risk.

"Moreover, laws for pharmacies in India are derived from the Drugs and Cosmetics Act, 1940, the Drugs and Cosmetics Rule, 1945 and the Pharmacy Act, 1948. These laws were written prior to arrival of computers and India does not have any concrete laws defined for online sale of medicines. Though various amendments had been made to the Acts, no provision had been incorporated to utilise information technology for sale of medicines online," senior counsel for the petitioner A R L Sundresan said.

"Medicines are not simple items of commerce, they are an essential component of patients' health and they must be administrated to patients in a timely manner as prescribed by a registered medical practitioner and such drugs are provided under the direct supervision of qualified pharmacist for the benefit of patients," he added.

Opposing the plea, online pharma companies contended that most of them were licence holders under the Drugs and Cosmetics Act and others were just aggregators who act as couriers for licensed pharmacies.

They further informed the court that the Centre had framed draft rules to govern such online sale and the same would be notified soon.

**Source:** *ET Healthworld,* 17th December 2018

## Cipla Recalls 4,800 Bottles of Anti-HIV Tablets From US

Drug major Cipla is recalling 4,800 bottles of Nevirapine extended release tablets used for the treatment of human immunodeficiency virus (HIV) from the American market, according to a report by the US health regulator.

As per the latest Enforcement Report by the United States Food and Drug Administration (USFDA), the reason for the recall of the bottles is 'failed dissolution specifications'.

Nevirapine extended release tablets, 400 mg in the 30-count bottle have been manufactured by Cipla at its Goa facility for Cipla USA Inc, it added.

The US health regulator has not yet classified the voluntary recall by the company, the report said.

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

## Free Pharma Samples Come Under GST Lens

Top executives of India's $37-billion pharmaceutical industry have a new destination on their frequent travel plan – Kanpur. The director-general of the intelligence wing for goods and services tax (GST) in Kanpur has issued summons to drug makers, asking for voluminous data related to supplies for the past year. The companies are being prodded to reverse claims of input tax credit in respect of free samples supplied as part of their promotion efforts.

The executives have to frequent the city to record statements or make submissions before authorities.

GST, the one-nation, one-tax measure that led to the collapse of geographic boundaries within the country for businesses, has also opened up newer horizons – quite literally so – in terms of tax disputes.

Tax authorities are holding manufacturers responsible for loss of revenue at any level. The tax head of a leading pharma company, who did not wish to be identified, said most drug manufacturers have been affected. "It must have been decided to open up investigations in Kanpur, so most cases are here," he said.

The Indian Pharmaceutical Alliance (IPA) based in Mumbai approached the government with a representation earlier this month. IPA is a representative body of top research based drug companies including Sun Pharmaceutical Industries, Cipla and Lupin.

"The law is clear. The government has clarified the provision of law through FAQ. All doubts are removed. In spite of such clarity, when inspectors summon industry and start harassing them, the government ends up inviting the wrath and frustration of the industry. It is a pity the government is unable to claim credit for its reforms," said DG Shah, secretary-general, IPA.

The current investigation pertains to the popular practice of freebies offered by drug companies. Free samples, buy one and get one free and additional quantities for the same price are the fulcrum of marketing for key sectors such as pharma, FMCG, food chains and retailers. Under the GST law, a company is liable to reverse input tax credit on free samples.

The GST Law Review Committee had said in a report the total consideration paid for such goods should be chargeable to GST and input tax credit should not be denied in such cases, but the issue is yet to be taken up by the GST Council, the apex decision-making body for the tax regime that subsumed central and state indirect taxes.

The Council is scheduled to meet on December 22, but it is not clear whether this issue will figure in the deliberations. The IPA has sought government intervention to halt the ongoing investigation till the issue is taken up and clarified.

"The issue of discounts or incentives offered under various trade schemes is relevant for various sectors, including FMCG and consumer durables, in addition to the pharma industry," said Sumit Lunker, partner, indirect tax, PwC.

"We understand the issue is being examined by CBIC (Central Board of Indirect Taxes and Customs) and a detailed circular/clarification may be issued in consultation with the GST Council. It might be better to keep these investigations on hold in the interim."

**Source:** *ET Healthworld, 18th December 2018*

## Chennai : Machines to Dispense Drugs in Govt. Hospitals

Tamil Nadu is planning to launch an ATM-like vending machine that will dispense medicines to patients with chronic illnesses such as diabetes and hypertension. The aim is to reduce waiting time and out-of-pocket expenditure, officials said.

The unit works like a cash-vending machine. The medicine dispensing unit is proposed to be placed at government medical college hospitals and urban primary health centres in the pilot phase. It will be programmed to read barcoded prescriptions and dispense medicines, said health secretary Dr J Radhakrishnan. “The biggest advantage is that it allows us to keep track of patients with chronic ailments. Patients who need long-term therapy are asked to meet their doctors once in three months. The hospitals give them drugs for one month and ask them to come back for supplies for next two months. The third time, they meet the doctor,” he said. It will help the government tide over staff crunch in state pharmacies, ensure follow ups on patients and allow people from other sections of the society to avail the free services at the government hospitals.

Earlier this month, officials saw a demo of similar machines installed in states like Rajasthan and were impressed by its potential. The machine can detect repeat prescriptions and recommend doctor visits to patients, said state nodal officer for NCDs Dr Jerard Selvam. “If they scan a prescription twice and the patient is due for doctors' visit, it will not dispense the drugs,” he said. It will also maintain data on the number of people taking medications and those who skip it,” he said.

With increasing incidence of non-communicable diseases, Tamil Nadu boasts the largest treatment program in the world, with lakhs of people receiving free drugs that keep sugar and blood pressure levels under check and prevent strokes or heart attacks. Treatment of diseases like tuberculosis also may have a better outcome as the government will be able to track people who drop out of treatment.

Senior officials are also hoping to attract people from middle income groups towards using the facility. “Out-of-pocket expenditure is huge and many patients drop out of medications. If government hospitals offer such facilities more people will make use of them,” said Dr Selvam.

**Source:** *ET Healthworld,* 18th December 2018

## Ranbaxy to Ruins: How the Singh Brothers Turned from Business Whizkids to Fraud Accused

A storied business empire has turned into debris over which preside two quarrelling brothers facing probes and various criminal charges. The latest is Religare Finvest, a Religare subsidiary, lodging a criminal complaint with the Economic Offences Wing of the Delhi Police against promoters Malvinder Mohan Singh and Shivinder Mohan Singh. They are accused of cheating, fraud and misappropriation of funds to the tune of Rs 740 crore. This is the sorry decline of a mega business house that had risen up from the ground within a few decades.

### The Beginnings

After Partition, businessman Bhai Mohan Singh came to Delhi from Rawalpindi in Pakistan. He bought a debt-ridden company

from his cousins Ranjit Singh and Gurbax Singh, whose first names combined in the name of their company Ranbaxy. Decades later, it went on to become India's largest pharmaceutical company. Parvinder Singh, the father of Singh brothers, wrested control of the company from his father. The inherited company was later sold by Singh Brothers.

**The Whizkids**

The Singh brothers studied at elite Doon School, prestigious St. Stephen's College in Delhi and then Duke University's Fuqua School of Business in the US. They have been known to be suave, sophisticated and savvy businessmen with elite education. After the death of their father Parvinder Singh in 1999, they inherited 33.5% stake in Ranbaxy. They sold Ranbaxy at its peak and got much media attention for the money it fetched. They sold the company to Japanese drug maker Daiichi Sankyo in 2008 for $4.6 billion, out of which $2.4 billion went to them, the sale proceeds was fuelled their ambitions and they invested the money for expansion of Fortis Healthcare and Religare. Within a few years, they turned Fortis Healthcare into the country's largest hospital chain and Religare Enterprises into one of the largest NBFCs.

**The Unraveling**

A business empire led by two savvy and hard-working young men started unraveling when the reports of financial wrong-doings started coming out. A substantial part of the proceeds from the Ranbaxy sale was transferred to several family-owned companies. This money is at the centre of probes and controversies, including links to the Radha Soami Satsang Beas, a spiritual sect which is headed by their relative. Singh brothers have been accused of siphoning off Rs 500 crore from Fortis, a publicly-traded company. Amid probes and mounting charges, they had to relinquish control of Fortis and Religare. The brothers face probes by several government agencies including Serious Fraud Investigation Office. Government agencies started probing the brothers' role in the wrong-doings after an internal investigation by law firm Luthra and Luthra found mismanagement of funds.

**The Daiichi Case**

The Ranbaxy sale had raised eyebrows not just for the huge money it fetched but also for a twist that came after the sale. While Singh brothers were selling Ranbaxy, the company was facing probe by the US Food and Drug Administration and the Department of Justice. It was accused of falsifying data and test results in pending and approved applications. Later, the USFDA banned more than two dozen Ranbaxy drugs from entering the country. Ranbaxy had to pay $500 million in fines and restitution to US authorities as part of a settlement. Daiichi won an award of $550 million at a tribunal in Singapore against Singh brothers for concealing information about USFDA probes. Later, the award was upheld by the Delhi High Court. Before the charges of financial wrong-doings at Fortis and Religare, the Daiichi episode had left a stain on the reputation of Singh brothers.

**Brother Versus Brother**

The relationship between the Singh brothers came under pressure after the accusations of financial wong-doings, leading to various allegations and counter-allegations. In September, Shivinder made scathing allegations against elder brother Malvinder and Sunil Godhwani in his petition filed with the National Company Law Tribunal (NCLT). He alleged that Malvinder and Godhwani, the former chief of Religare, colluded to divert Rs 750 crore from Religare Finvest Ltd., a wholly owned subsidiary of Religare, and another Rs 473 crore from Fortis Healthcare to RHC Holding Pvt Ltd., the flagship holding company of the Singh brothers. He also alleged that

Malvinder forged the signature of his wife Aditi S Singh in RHC documents.

Shivinder alleged that the finances of the company were mismanaged while he had moved out in 2015 to serve full time at the spiritual retreat Radha Soami Satsang Beas. “I took public retirement to my spiritual home, Beas, to serve my Master, in 2015; leaving the thriving company I founded in 'trusted' hands and in a period of less than two years, it has moved towards disintegration and ruin of a national healthcare asset,” he said.

Later, Shivinder withdrew the petition on the ground that the brothers had agreed to settle things through a mediation by their ailing mother. However, he said, “In the event mediation fails, I intend to reassess and start a fresh action if that is what it takes to address all issues and start afresh.”

**Brothers come to Blows**

The feud between the brothers peaked recently when elder brother Malvinder accused Shivinder of physical assault. Malvinder posted a video accusing his brother of hurting, threatening and bruising him. It was a sad reversal since the two brothers were known to be very suave and sophisticated. The video posted by Malvinder showed that the mediation had failed. Reacting to Malvinder's accusation of physical attack, Shivinder said it was sad and shocking to see the chairman of the group resort to such embarrassing tactics. He said he had pulled out of the negotiation process with Malvinder after the latter demanded Rs 1,000 crore for amicable separation.

With a never-ending stream of accusations, allegations and formal charges against the brothers and between them, it is unlikely that the brothers will emerge out of the mess anytime soon. Behind them lies a soaring business empire run to the ground in just a few years.

**Source:** *ET Healthworld,* 20th December 2018

## DCGI Orders J&J Not to Use Talc Raw Material for any Production till Further Orders

The Drugs Controller General of India (DCGI) has ordered Johnson and Johnson not to use talc raw material from its Mulund plant in Mumbai and Baddi unit in Himachal Pradesh for any production till further directions.

On the directions of the Central Drugs Standard Control Organization (CDSCO), drug inspectors collected samples of Johnson and Johnson's baby powder from both the plants on Wednesday, amid reports that the product allegedly contained cancer-causing asbestos.

Besides, over 100 samples were collected from wholesalers, retailers and distributors across the country, which will be tested to see if these complied with all prescribed regulatory and manufacturing standards and also for the presence of asbestos.

A CDSCO official said according to the protocol, the manufacturer is "supposed to test for absence of asbestos" for all batches of talc raw material procured.

"It is learnt that the manufacturer is not testing for absence of asbestos for all batches of talc raw material procured and testing them randomly," the official said.

"We have prohibited the company from using any raw material, including talc, for the production of the Johnson and Johnson baby powder till further orders. The Baddi plant has around 82,000 kg of talc stored, while the Mulund unit has around 200 metric tonnes stored," he said.

The collected samples will be tested at the Central Drug testing Laboratory.

The company said on Wednesday they were "fully cooperating" with the CDSCO by providing tests and samples, and said Johnson & Johnson's baby powder is asbestos-free and doesn't cause cancer.

The CDSCO, under the Union Health Ministry, said that over the next four to five days, drug inspectors will collect samples of all brands of the Johnson & Johnson talcum powder from wholesalers and distributors from 12-15 locations across the country for testing.

"Samples of raw material as well as the finished product from retail stores are also being collected," the official said.

A team of 100 drug inspectors have been deployed for the purpose.

The effects of long-term unsafe asbestos exposure on human health are well documented and asbestos fibres are easily inhaled and carried into the lower regions of the lung where those can cause fibrotic lung disease (asbestosis) and changes in the lining of the chest cavity (pleura).

These diseases can lead to reduced respiratory function and death, while long-term inhalation of asbestos fibres also increases the risk of lung cancer and mesothelioma.

Some recent reports claimed that the American multinational pharmaceutical giant allegedly knew for decades about the presence of cancer-causing asbestos in their product.

The action by CDSCO came at a time the company is already embroiled in a controversy over its faulty hip implants.

The company Wednesday said they were "fully cooperating" with the CDSCO by providing tests and samples, and asserted that the characterisation of these visits as 'raids or seizures is "incorrect".

"The tests have been conducted in the regular way that the FDA collects samples," the company spokesperson said, adding, "We have scientific evidence to prove that our talcum powder is safe and beneficial for use."

The company pointed out that in the past, authorities in India like the FDAs and the CDSCO have confirmed that its products comply with Indian standards and are free of asbestos.
"We unequivocally stand by the safety of our products, are fully compliant with regulatory standards and requirements in India and will continue to work with the regulatory authorities," the spokesperson had said.

**Source:** *ET Healthworld,* 21st December 2018

## Ensure Isotretinoin is Sold by Retailers on Prescription by Dermatologists Only: DCGI

The Drug Controller General of India (DCGI) has asked drugs controllers in all states and Union Territories to ensure that Isotretinoin, used to treat severe cystic acne, is sold by retailers on prescription of dermatologists only. The Central Drugs Standard Control Organization (CDSCO), in a communique, said the packets containing the drug should carry a box warning stating 'this medicine may cause severe birth defects; you must not take this medicine if you are pregnant or may likely become pregnant during treatment' and 'you should also avoid pregnancy for six months after stopping the treatment'.

The patients should also sign a consent form before "undertaking the treatment of Isotretinoin" as already stipulated.

The communique stated the conditions should be followed during manufacture, sale and distribution of the drug as already stipulated by the CDSCO at the time of approval of the oral drug.

Isotretinoin capsule 10mg/ 20mg was approved by CDSCO on June 21, 2002, for treatment of cystic and conglobate acne, severe nodular acne unresponsive to antibiotic therapy, with various conditions.

In light of concerns raised regarding Isotretinoin, the matter has been examined by CDSCO in consultation with the Subject Expert Committee (Dermatology and Allergy) in its meeting held on July 26, the communique stated.

The Subject Expert Committee deliberated the matter in detail and opined that the drug has favourable risk benefit profile for the indications approved in the country. However, some conditions should be followed during manufacture, sale and distribution of the drug as already stipulated by CDSCO at the time of its approval, according to the communique.

"The committee also recommended that the manufacturers should provide package insert along with their product which should be in major vernacular languages. Retail chemists should maintain the details of retail sale of the drug which should be strictly on the prescription of Dermatologist only," it stated.

**Source:** *ET Healthworld,* 21st December 2018

## No Restrictions on Online Sales of Medicines for Now: Madras HC

A division bench of the Madras High Court on Thursday observed that there is no ban on the sale of online drugs until it delivers the final order.

The bench has reserved its orders on the plea to stay an earlier court order that banned the sale of medicines online from December 20, while asking the government to notify a draft regulation governing the sale of medicines online.

The bench observed that there is no ban until it delivers the final orders, ET has learnt.

India's nascent e-pharma sector was thrown into a state of confusion following the Madras

High Court's judgement on Monday banning the sale of medicines online until the government notified regulations for the industry.

According to industry executives, in the worst-case scenario, the move would have meant that 30-40 lakh patients could not have used online ordering and delivery services, and that industry would have taken a revenue hit of up to Rs. 300 crore over the next two months.

"We are happy with the Madras HC order suspending the ban on online sale of medicines. This ruling validates our commitment of providing affordable and accessible medicines to customers. As a fully-licensed pharmacy, Netmeds is committed to adhering to all the guidelines and standards as prescribed under the Drugs and Cosmetic Act of 1940," said Pradeep Dadha, founder of Netmeds, an epharmacy chain.

The online pharmacy industry rakes in revenue of ₹100-150 crore every month, with an annual turnover of Rs.1,500 crore to 1,800 crore, according to Prashant Tandon, president of the Indian Internet Pharmacy Association. About 30-40 lakh patients order medicines from epharmacies in India, and the sector directly and indirectly employs 15,000-20,000 people, said Tandon. Around 70% of the orders serviced by epharmacies are for repeat customers buying medicines for chronic ailments like diabetes and hypertension, he said.

A senior government official told ET that work is on to notify the draft rules "as quickly as possible", but did not specify how long it would take to do this. "There are a lot of comments (on the draft rules)... the health ministry is working on it," the official said, requesting anonymity.

"We are in favour of online pharmacies because our study has revealed that citizens find it convenient to buy medicines sitting at home — but it cannot come at the cost of health and safety," said Bejon Misra of the Patient Safety and Access Initiative of India.

"You can't let anything to do with health to go without regulation... all over the world, consultations are going on about how to regulate online pharmacies," he said.

According to PSA legal partner Dhruv Suri, whose client base includes some e-pharmacies, the types of checks and balances that most e-pharmacies have in place to ensure compliance with the D&C Act is something that the offline drug associations "refuse to acknowledge for vested reasons".

**Source:** *ET Healthworld,* 21st December 2018

## Torrent Pharma Recalls Losartan Hypertension Tablet in US

Indian pharmaceutical major Torrent Pharmaceuticals Ltd is voluntarily recalling two lots of Losartan potassium tablets used to treat hypertension in the US market due to detection of traces of unexpected impurity, the US Food and Drug Administration (USFDA) said.

"Torrent Pharmaceuticals Limited is voluntarily recalling two lots of Losartan potassium tablets, USP to the consumer level due to the detection of trace amounts of an unexpected impurity found in an active pharmaceutical ingredient (API) manufactured by Hetero Labs Limited," USFDA said in a statement.

According to USFDA, the impurity detected in the API is N-nitrosodiethylamine (NDEA), which is a substance that occurs naturally in certain foods, drinking water, air pollution, and industrial processes, and has been classified as a probable human carcinogen as per International Agency for Research on Cancer (IARC) classification.

To date, Torrent Pharmaceuticals Ltd has not received any reports of adverse events related to this recall, the statement said.

Losartan is used to treat hypertension, hypertensive patients with Left Ventricular Hypertrophy and for the treatment of nephropathy in Type 2 diabetic patients.

Patients who are on Losartan should continue taking their medication as the risk of harm to the patient's health may be higher if the treatment is stopped immediately without any alternative treatment, the statement added.

Patients should contact their pharmacist or physician who can advise them about an alternative treatment prior to returning their medication, the USFDA said.

The products subject to recall are 100 mg tablets with the expiration date 4/2019 and packed in 30/90/1,000 count bottles, the USFDA said.

**Source:** *ET Healthworld,* 21st December 2018

## Supernus Pharma's ADHD Drug Meets Main Goal in Study on Adolescents

Supernus Pharmaceuticals Inc said on Thursday its drug for attention deficit hyperactivity disorder met the main goal in a late-stage trial on adolescents, weeks after results from trials testing the drug on children failed to impress investors.

At daily doses of 200 mg and 400 mg, the drug, SPN-812, showed statistical significance in improvement in symptoms such as hyperactivity and lack of attention among 12-17 year olds, Supernus said.

SPN-812 is a non-stimulant and belongs to the same class of medicines as Eli Lilly and Co's Strattera and Shire Plc's Intuniv.

"SPN-812 demonstrated significant reduction in both hyperactivity and inattention sub-scales, a point of differentiation from Strattera which reportedly works better on inattention but not hyperactivity," Mizuho analyst Irina Koffler wrote in a note, calling the data a win for the company.

The drug had also met the main goal in two other late-stage studies testing the drug in children, the company said earlier this month, but its shares had then dropped 16 percent with analysts saying the drug failed to stand out from existing treatment options for ADHD.

"We now have positive data proving the efficacy and safety of SPN-812 in all ADHD patient populations; positive Phase III data in children 6-11 years old and adolescents 12-17 years old, and positive Phase IIa data in adults," Chief Executive Officer Jack Khattar said in a statement.

SPN-812 was well-tolerated and showed a statistically significant onset of action as early as first week into the treatment, when administered the 400 mg dose.

"In no way do we believe SPN-812 is a value detractor, and like in epilepsy, we think Supernus will execute with strong potential upside to our conservative about $220 million peak," Stifel analyst Annabel Samimy said.

Last week, the U.S. Food and Drug Administration had expanded approved the company's epilepsy drug Oxtellar XR to be used as a monotherapy in children aged six to 17 and in adults.

The company said it expects to announce data from the final late-stage trial of SPN-812 by the end of the first quarter of 2019, and submit a marketing application to the U.S. health regulator in the second half of 2019.

The company's shares were up 3 percent at $34.46 in early morning trading.

**Source:** *ET Healthworld,* 21st December 2018

## Industry and regulators collaborate to understand patient requirements at IPC 2018

Accept the need that a better working relationship between industry and regulators is crucial for future progress.

Day 2 of IPC 2018 saw industry captains and regulatory authorities come together with the aim of building better synergies and strengthen their relationship to serve patients better.

Eminent panelists discussed the various nuances of this relationship in the much-awaited session titled, 'Can industry and regulators go Hand in hand? To gain the Glory of pharma sector. It' was moderated by BR Sikri, Chairman LOC-70th IPC; Managing Director ABS Groups of Companies and President, FOPE.

SV Veeramani, Chairman and Managing Director, Fourrts Laboratories emphasized that regulators should be facilitators, educators and coaches to the industry. He opined that regulators need to guide the industry and requested the regulators to take the industry's views while creating new regulations.

He congratulated DCGI for creating a forum and inviting the industry to share and discuss their problems, suggestions and requirements. He also suggested that regulators should not keep amending the regulations too much and too often as it can adversely affect the growth of the industry and stop the process of innovation.

He stated that the same of the pharma Industry in Gujarat is because regulators and industry understands each other's problem and cooperate to resolve them effectively.

Dr S Eswara Reddy, Drugs Controller General (India), in his opening remarks, he said that though since the 1940 Drugs and Cosmetic Drugs Act the industry and regulators are working together, we need to further strengthen the relationship. He also pointed out that in comparison to other markets, we have minimal regulation. He also stated that our regulations have helped the pharma industry to grow phenomenally in India and global markets.

He said that regulators' intention is not to kill the industry but to oversee and standardize the processes. To protect public health, and control discrepancies, both

intentionally and unintentionally, we need to have a strong and effective regulatory system.

He said that before sharing any data with DTAB, he shares his industry agenda with the industry manufacturers forum to avoid any conflict of interest. He also raised a point that besides, AIDCOC, all the other industry associations are part of the Industry Manufacturers Forum and urged representation from AIDCOC.

He also mentioned that due to conflicts between industry and regulators, lawyers are getting benefited and both of them to need to put in more efforts to avoid such problems. He also said that better synergy between the industry and regulators would also help to better understand the patients' perspective.

Dr SM Mudda, Chairman, Regulatory Affairs, Indian Drugs Manufacturing Association, highlighted that there is a need for collaboration between the industry and regulators at the operation level. He briefly mentioned about the common challenges that the industry and the regulators are facing. He recommended that both should make more efforts to understand the global perspective and take adequate measures before it's too late.

He also stressed on building a cohesive environment where industry interacts with regulators without any hesitation and elaborated on how such an approach can benefit patients.

Dr Rajendra Kumar Sanghavi, Chairman, Medical Committee, Indian Drugs Manufacturing Association talked about the UCPMP code, cross-prescription by non-allopathic practitioners, non-availability of DPCO drugs, BCS class II and IV, clinical trials regulations like video recording, banning of drugs like Pioglitazone based on few response and later ban withdrawal and FDC etc. . He stressed that doctors should be allowed and sponsored to attend conferences, and should be involved in the decision-making processes between industry and regulators as many pharma companies are not really connected with the doctors.

He suggested the CDSCO to have doctors' representation in their decision-making process. He also highlighted that doctors and NGO interactions with industry and regulators are lacking and they need to be made a part of the process.

NK Ahooja, State Drug Controller, Haryana, emphasized on do's and don'ts for regulators. He suggested that in a proposal of changing a name of CDSCO we should consider making changes of drugs inspectors to drug controller officer, it will change the perspective and create positive vibes. He also suggested that any new or amended rule needs to be reviewed and discussed with all stakeholders including drug controllers. He also requested the DCGI to consider making drug controllers a part of the 'Industry Manufacturers Forum' and proposed that create a definition for New Cosmetics, scrutinize medical device regulations, and revisit the name change of Blood Bank to Blood Centre.

Dr HG Koshia, Commissioner, FDA- Gujarat, briefed the audience on pharma industry's problems and the furore during the implementation of Schedule – M. He also explained how his department convinced their state-based pharma companies to upgrade and it resulted in benefits for both, the industry as well as regulators. He also mentioned that in Gujarat, both of them are working to harmonize the norms and instead of working hand in hand they are working side by side.

Koshia also mentioned that continuous collaborative efforts need to be executed for the betterment of the society.

The session was well attended by different industry stakeholders and students. Many suggestions were made by speakers for the industry, regulators and patients' groups.

**Source:** *Express Pharma,* 22nd December 2018

## Drug Inspectors Seize Samples of J&J Baby Products for Testing

Following orders of Drug Controller General of India (DCGI), drug inspectors have seized samples of various baby products of Johnson and Johnson from wholesalers, retailers and distributors across the country on Friday, an official said. All the samples will be tested to see if they complied with all prescribed regulatory and manufacturing standards and also to check the presence of cancer causing asbestos, the government official said.

"Around 100 samples of Johnson and Johnson's baby shampoo, oil, soap, besides the baby powder have been lifted from wholesalers, retailers and distributors from across the country, which will be tested to see if these complied with all prescribed regulatory and manufacturing standards and to check the presence of asbestos," the official said.

The collected samples will be tested at the Central Drug Testing Laboratory.

The regulator on Thursday ordered Johnson and Johnson to not use talc raw material from its Mulund plant in Mumbai and Baddi unit in Himachal Pradesh for production till further direction.

The inspectors collected samples of Johnson and Johnson's baby powder from both the plants, amid reports that the product allegedly contained cancer-causing asbestos.

"We have prohibited the company from using any raw material, including talc, for the production of the Johnson and Johnson baby powder till further orders. The Baddi plant has around 82,000 kilogram of talc stored, while the Mulund unit has around 200 metric tonnes stored," he said.

The company said on Wednesday they were "fully cooperating" with the CDSCO by providing tests and samples, and said Johnson & Johnson's baby powder is asbestos-free and doesn't cause cancer.

The CDSCO, under the Union Health Ministry, said more samples of all brands of all products of Johnson & Johnson talcum may be collected from wholesalers and distributors from some more locations for testing.

A team of 100 drug inspectors have been deployed for this purpose.

The effects of long-term unsafe asbestos exposure on human health are well documented. Asbestos fibres are easily inhaled and carry into the lower regions of the lung where it can cause fibrotic lung disease (asbestosis) and changes in the lining of the chest cavity (pleura).

These diseases can lead to reduced respiratory function and death, while long-term inhalation of asbestos fibre increases the risk of lung cancer and mesothelioma.

Some recent reports claimed that the American multinational pharmaceutical giant allegedly knew for decades about the presence of cancer-causing asbestos in their product.

The action by CDSCO has come at a time when the company is already embroiled in a controversy over its faulty hip implants.

The company Wednesday said they were "fully cooperating" with the CDSCO by providing tests and samples, and asserted that the characterisation of these visits as "raids or seizures was incorrect".

"The tests have been conducted in the regular way in which the FDA collects samples," the company spokesperson said, "we have scientific evidence to prove that our talcum powder is safe and beneficial for use."

The company pointed out that in the past, authorities in India like the FDAs and the CDSCO have confirmed that its products comply with Indian standards and are free of asbestos.

"We unequivocally stand by the safety of our products, which are fully compliant with regulatory standards and requirements in India. We will continue to work with the regulatory authorities," the spokesperson had said.

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

## India Wants China to Allow Import of Drugs Cleared by US, Europe

India has requested China to allow imports of Indian drugs cleared by the drug administrators of the United States, European Union and Japan, as China recognises these approvals. It has also sought a special price category for Indian generics so that they don't compete with branded products.

Almost 1,500 Indian products have obtained clearances from the food and pharmaceutical regulators of the US, EU and Japan, but only 535 are registered with China and can be sold there.

“Our pharma export to China is a pittance. We have requested if China FDA (food and drug administration) could give suo motu registration to companies cleared by the US, EU and Japan because it recognises these,” an official told ET on condition of anonymity. “We want our generics in a special price category so that we don't get into competition with branded products.”

Though India is the world's largest supplier of generic medicines, with 20-22% share of global exports, it exported pharma products worth a meagre $41.07 million to China in 2017-18 and only $26.1 million in the first half of the current financial year. Commerce department officials have said that India's share in China's pharma imports is merely 1%.

Another issue that India has raised with China pertains to multiplicity of approvals as every Chinese province has different prices and rules for pharmaceutical imports.

India has, therefore, also sought a waiver of local provincial approvals for Chinese companies which import Indian generic injectable drugs. The provincial clearance is required even after the CFDA nod.

The move is aimed at increasing exports of pharmaceuticals to China and reduce the trade deficit. India's exports to China amounted to $33 billion in 2017-18 while imports from the country were more than double that at $76.2 billion. Indian industry has cited non-tariff barriers such as complicated procedures that hinder pharma exports to China. “We have requested again for familiarity of forms. We need clarity and handholding because their process is long, tedious and cumbersome,” the official said

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

## Simple Method Rescues Stressed Liver Cells : Study

Hepatocytes are responsible for detoxification of the blood, and constitute around 80% of the liver volume. They are used extensively in laboratory experiments, such as studies of drug uptake, metabolism, and toxicity. Freshly isolated human hepatocytes are not regularly available, however, as they can only be prepared by highly specialized laboratories. Therefore, researchers rely on deep-frozen (cryopreserved) cells to ensure continuous access. Unfortunately, freezing and thawing mammalian cells is very stressful and frequently results in loss of function.

“The cellular stress associated with isolation and freezing takes its toll on the hepatocytes, and many cells are too damaged to recover completely after thawing. When too many cells are damaged, they become practically useless for most applications,” says Magnus Ölander, a PhD student in the Drug Delivery group headed by professor Per Artursson at Uppsala University.

The research group used state-of-the-art mass spectrometry to compare the expression of thousands of proteins in damaged and healthy hepatocytes, and found that the damage involved apoptosis, a controlled form of cell death.

“Through further analysis, we noticed that the damaged cells were mostly in the early stages of apoptosis. We reasoned that if we could figure out a way to temporarily decrease the stress, we could give the cells a chance to recover,” says Magnus Ölander.

The researchers therefore treated hepatocytes with different stress-reducing compounds, and discovered that the damage could indeed be reversed by using a specific apoptosis inhibitor. Based on these findings, they designed a simple restoration protocol that improves the quality of suboptimal human hepatocyte preparations to the point where they can be used for most applications, with restored functionality in terms of drug uptake, metabolism, and toxicity. This is the first time that human hepatocytes of suboptimal quality have been 'rescued' from the freeze state, which has previously been considered a futile endeavor.

“Another novel aspect is the transient nature of our approach. The inhibitor is only used for a short time after thawing, and does not need to be included in the cell culture medium. We predict that our protocol can dramatically increase the availability of human hepatocytes of high quality, as suboptimal human hepatocytes can be found in deep-freezers in laboratories all over the world. This will ultimately give the scientific community improved access to these important cells,” says Magnus Ölander

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

## Aurobindo Pharma USA Recalls 80 Lots of Blood Pressure Drug from America

Aurobindo PharmaUSA Inc is recalling 80 lots of tablets used for treatment of high blood pressure and heart failure from the American market due to presence of impurity that may cause cancer in humans, the company said.

The voluntary recall of Amlodipine Valsartan tablets USP, Valsartan HCTZ tablets USP and Valsartan tablets USP to the consumer level is due to the detection of trace amounts of an unexpected impurity found in the finished drug product, according to a release by the company posted on the website of the US Food and Drug Administration (USFDA).

"The impurity detected in the finished drug product is N-nitrosodiethylamine (NDEA), which is a substance that occurs naturally in certain foods, drinking water, air pollution, and industrial processes, and has been classified as a probable human carcinogen as per International Agency for Research on Cancer (IARC) classification," it added.

To date, Aurobindo Pharma USA Inc has not received any reports of adverse events related to this recall, the release said.

Amlodipine Valsartan Tablets USP, Valsartan HCTZ Tablets USP and Valsartan Tablets USP were distributed nationwide to Aurobindo Pharma USA Inc's wholesale, distributor, repackager and retail customers, it added.

The company is notifying its distributors and customers by phone and in writing to immediately discontinue distribution of the specific lots being recalled and to notify their sub-accounts, the release said.

The company is arranging for return of all recalled products to Inmar/CLS Medturn. Instructions for returning recalled products are given in the recall letter, the release added.

**Source:** *ET Healthworld,* 1st January 2019

## Hetero Labs Limited Acquires Tarbis Farma in Spain

Hetero, one of India's leading generic pharmaceutical companies and the world's largest producer of anti-retroviral drugs, announced today that its European subsidiary Amarox Limited has acquired Tarbis Farma, S.L.U., a company operating in Spain from Grupo Ferrer Internacional, S.A. Tarbis Farma comes with a robust product portfolio and an extensive marketing network with well-experienced personnel in Retail business across Spain. The acquisition enables Hetero with a strong front-end marketing presence giving Amarox the required commercial infrastructure, product portfolio, manpower and a seamless entry into the Retail, Hospital and Tender business channels in Spain.

Mr. A V Narasa Reddy, Executive Director of Hetero Labs Limited, stated that this acquisition fits very well with Hetero's growth strategy in EU giving Amarox a platform to reach out to the customers in a robust way with the present portfolio and Hetero's pipeline of products.

The buyer and seller were advised by Crowe and Deloitte respectively.

**Source:** *ET Healthworld,* 2nd January 2019

## Sun Pharma Acquires Japan's Pola Pharma

Drug major Sun Pharma Thursday said it has completed acquisition of Japan-based Pola Pharma to strengthen its presence in dermatology segment across the globe. The acquisition of 100 per cent shares of Pola Pharma Inc Japan by the company's wholly owned subsidiary has been concluded, Sun Pharma said in a BSE filing.

Sun Pharma had entered into a definitive agreement to acquire Pola Pharma, which is engaged in research and development, manufacture, sale and distribution of branded, and generic products in Japan, it said in a regulatory filing dated 26 November 2018.

Pola Pharma's portfolio mainly comprises dermatology products. It has two manufacturing facilities in Saitama with capabilities to manufacture topical products and injectables, it added.

Sun Pharma had forayed into the Japanese prescription market in 2016 with the acquisition of 14 established prescription brands from Novartis.

Shares of Sun Pharmaceutical closed at Rs 435.35 per scrip on the BSE, down 1.12 per cent from its previous close.

**Source:** *ET Healthworld,* 4th January 2019

## Controversial Move by Pharma Department to Push up Drug Prices

In A Controversial Move, The Department Of Pharmaceuticals Appears To Have Ignored Concerns Raised By The Health Ministry And Removed The Price Cap From A Range Of Essential Medicines, Including Patented And "Orphan Drugs" Used In Treatment Of Rare Diseases.

Barely A Month Ago, Health Secretary Preeti Sudan Wrote To The Department Highlighting Concerns About "Exorbitant Cost Of Life Saving Drugs For Rare Diseases". She Specifically Stated, "May I Request You To Kindly Explore The Feasibility Of Capping The Price Of Drugs Used For Treatment Of Rare Disease So That Their Prices Become Reasonable And Affordable To The Patients."

Despite Sudan's Letter Addressed To Dop Secretary Jai Priye Prakash On November 29 Changes To Drug Price Regulation Were Notified On Thursday Removing Price Caps From Orphan Drugs. It Also Exempted All Patented Medicines From Price Control For Five Years, Expanding The Existing Incentive From Just Locally Developed And Manufactured New Drugs. Besides, It Also Allowed Leniency In Sourcing Data For Price Fixation.

The Move — Likely To Increase Prices Of A Range Of Imported Essential Medicines, Including For Cancer And Other Critical Diseases — Has Stirred Opposition In Several Quarters, Including Within Government. Senior Officials In The Health Ministry And Niti Aayog Expressed Reservations Over The Notification.

Sudan Also Said Because Of High Prices Of Such Drugs, "The Cost Of Treatment Is Unaffordable Even For Patients Who Are Not Poor", Urging The Department To Take Immediate Measures To Curb Prices.

**Source:** *ET Healthworld,* 5th January 2019

## Dept of Pharma Ignores Health Ministry Concerns, Removes Price Cap on Patented, Rare Disease Drugs

In a controversial move, the department of pharmaceuticals appears to have ignored concerns raised by the health ministry and removed the price cap from a range of essential medicines, including patented and "orphan drugs" used in treatment of rare diseases.

Barely a month ago, health secretary Preeti Sudan wrote to the department highlighting concerns about "exorbitant cost of life saving drugs for rare diseases". She specifically stated, "May I request you to kindly explore the feasibility of capping the price of drugs used for treatment of rare disease so that their prices become reasonable and affordable to the patients.

"Despite Sudan's letter addressed to DoP secretary Jai Priye Prakash on November 29 changes to drug price regulation were notified on Thursday removing price caps from orphan drugs. It also exempted all patented medicines from price control for five years, expanding the existing incentive from just locally developed and manufactured new drugs. Besides, it also allowed leniency in sourcing data for price fixation.

The move - likely to increase prices of a range of imported essential medicines including for cancer and other critical diseases - has stirred opposition in several quarters including within government. Senior officials in the health ministry and Niti Aayog expressed reservations over the notification.

Sudan also said that because of high prices of such drugs, "the cost of treatment is unaffordable even for patients who are not poor", urging the department to take immediate measures to curb prices.

"The department of pharma has suddenly issued the notification without consulting any other department. This is even as there is a separate committee for price fixation of patented medicines. The notification is industry friendly and has not taken into consideration the impact it will have on patients," a senior official in the health ministry said.

The latest move has also upset the Indian drug manufacturing industry as well patient groups

"The decision is not evidence based and was issued without any consultation, worse overriding the concerns expressed by the health ministry as recently as a month ago. It is unjustifiable that the government has taken a drastic step to favour foreign companies and which undermines its ability to protect public health," says All India Drug Action Network co-convenor Malini Aisola.

This assumes significance as over 70 million across the country are suffering from rare diseases and support for such patients from government is a subject matter of litigation in many cases.

In fact, the prices of these orphan drugs are so high the government had to recently withdraw its own policy because apparently it could not fund such exorbitantly priced drugs under public policy, an official said.

While there are around 7,000 rare diseases, only around 450 rare diseases have been recorded in India, the most common being haemophilia, thalassemia, sickle-cell anaemia and primary immuno deficiency

in children, auto-immune diseases, lysosomal storage disorders such as Pompe disease, Hirschsprung disease, Gaucher's disease, cystic fibrosis, hemangiomas and certain forms of muscular dystrophies.

The amendment to DPCO, 2013 was pending for a long time. In fact, the proposal for the changes was initiated by the government think tank Niti Aayog which felt the need to expand the purview of price control to drugs outside the list of essential medicines, and also include other medical consumables, diagnostics and medical devices. It had also suggested linking the price ceilings with pharmaceutical index.

While the Niti Aayog proposal, which was discussed at the level of Prime Minister's Office (PMO), is still pending, department of pharmaceutical's sudden move to introduce changes removing price caps from patented medicines for five years has surprised many.

"It is a move in favour of the industry and will have devastating impact on prices of crucial medicines," another senior official said. He said the DoP order will allow multinational companies to manipulate prices through data and in case of patented drugs, the order has left no provisions to control prices even in case of emergencies.

**Source:** *The Times of India,* 5th January 2019

## Pfizer Stops Manufacturing Operations in Aurangabad, Chennai

The US-based pharma major Pfizer on Wednesday ceased operations at its manufacturing units in Aurangabad in Maharashtra and Chennai due to long-term loss of product demand. The company's Irungattukottai unit in Tamil Nadu currently employs approximately 1,000 workers and Maharashtra's Aurangabad site employs around 700.

The plants had been part of its acquisition of US-based Hospira in 2015

"Pfizer has conducted a thorough evaluation of the IKKT (Irungattukottai) and Aurangabad sites and concluded that due to the very significant longterm loss of product demand, manufacturing at these sites is not viable," a Pfizer spokesperson said in Mumbai.

"As a result, both sites will immediately cease manufacturing with the intention to exit as soon as possible in 2019. The exact timing of the exit is to be determined."

A large number of employees were found standing outside the company in Waluj, Aurangabad, on Wednesday morning, making efforts to reach out to the executives and speak to them, but in vain

Some of the workers told TOI that a decision on the plant's closure was suddenly communicated to them on Tuesday, leaving them in shock and tears.

The plant at Aurangabad was purely into manufacturing for the export segment of the pharma major, which acquired Hospira, a leading manufacturer of injectables, in 2015. Since being acquired, the Aurangabad plant was in to the manufacturing and exporting of penicillin and penem API.

Sources said that Pfizer plans to cater to the export market, including the US, from its site in Vishakhapatnam, where the company is working on expansion of operations.

The news has come as a rude shock for the

industrial area in Aurangabad, which is still in the process of bouncing back after demonetisation, implementation of GST and the recent industrial riots.

Sources informed that the decision of closing the unit, apart from hitting over 700 direct employees and their families, also took a toll on scores of contractual labourers employed directly or indirectly with the company.

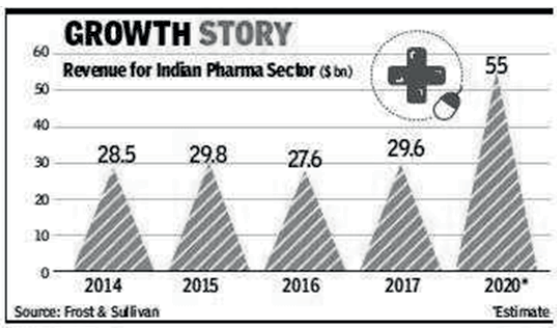
Pfizer clarified that the closing down of operations at these two locations will not affect the other Indian manufacturing sites in Goa, Vishakapatnam (Vizag) and joint venture site, ZHOPL, in Ahmedabad.

**Source:** *The Times of India,* 10th January 2019

## Online Pharma Sales to Hit Rs.25,000cr in 4 Years

The domestic epharmacy market is poised to touch Rs 25,000 crore by 2022, at a robust CAGR of 63%, buoyed by an increased access of medicines to a majority of under-served population, long term drug compliance for chronic conditions, and rising internet penetration.

Online sale of medicines, now at Rs 3,500 crore, could account for 15-20% of total pharma sales over the next 10 years — due to multiple factors including 'Digital India', e-healthcare initiatives, increasing health insurance, and schemes like Ayushman Bharat — says a report by Frost & Sullivan.




The e-platform is led by Medlife (about 30% market share), followed by Netmeds, 1MG, PharmEasy, Myra, CareOnGo and Pharmasafe. The global e-pharmacy market is led by North America and Europe, while major opportunity lies in addressing the vast unmet needs of the developing countries in Asia Pacific. Overall, organised pharma retail market valued around Rs 1.3 lakh crore is the third-largest in volume terms and the 13th-largest in value, globally. It grew from $28.5 billion in 2014 to nearly $30 billion in 2017, and is expected to clock a CAGR of 11.3% to reach $55 billion by 2020. The growth will be primarily driven by high disease burden, steady economic growth leading to higher disposable incomes, improvements in healthcare infrastructure, and an improved healthcare financing, it adds. Retail pharmacy — which is highly fragmented with over eight lakh chemists across the country — faces challenges of increased competition, rising pressure on price controls, lack of documentation/ tracking and poor inventory management, the study says. These issues can be addressed through a technological upgrade of the model for streamlining processes and computerisation of pharmacies.

**Source:** *ET Healthworld,* 3rd January 2019

medopharm

*With best compliments from:*


# medopharm

*We Value... Life*

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

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

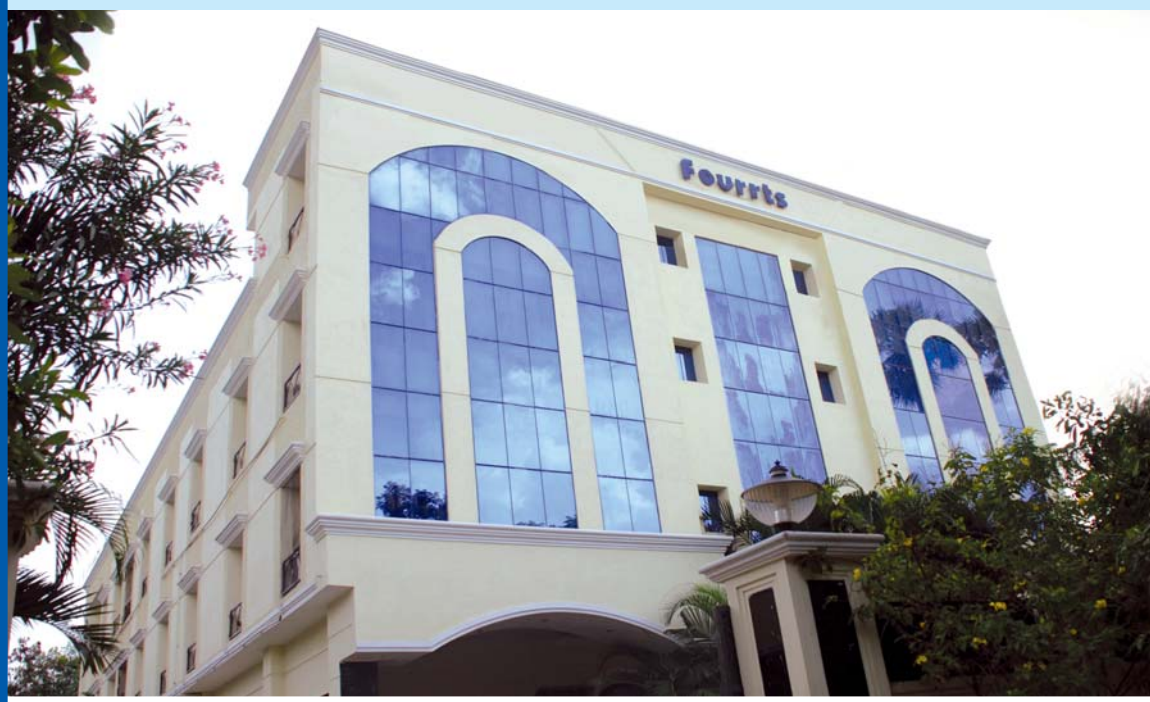
# Fourrts

(India) Laboratories Pvt. Limited

**Manufacturers and Exporters of**
**Quality Pharmaceutical Formulations**
**as per cGMP Standards**

**'7' Time Quality Excellence Award Winner**

ISO 9001
BUREAU VERITAS
Certification


AN ISO 9001:2008 CERTIFIED COMPANY

**Fourrts**

**Innovating for good health...**

**Corporate Office :** No. 1, Fourrts Avenue, Annai Indra Nagar, Okkiyam Thoraipakkam, Chennai - 600 097, India.
Phone : 91-44-4344 1880 Fax : 91-44-2458 1199 E-mail : admin@fourrts.com www.fourrts.com

**Works :** Vandalur Road, Kelambakkam, Tamil Nadu - 603 103, India.
Phone : 91-44-47404310 Fax. 91-44-27475083 E Mail : fourrts@plant.fourrts.com