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Pharma Web

Newsletter of Tamilnadu Pharmaceutical Sciences Welfare Trust

Tamilnadu Pharmaceutical
Sciences Welfare Trust

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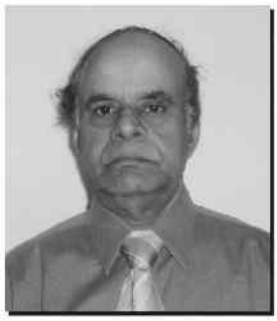
EDITORIAL



Dear Readers,

The first issue of this newsletter was released on 30th January 2009 in a grand function organized by Indian Pharmaceutical Association, Tamilnadu branch at hotel Palm Grove, Chennai. The meeting was presided over by Shri G. Rangachari, Chairman of our Trust who briefed the audience about the newsletter and its importance. The meeting was well attended by members of Indian Pharmaceutical Association T.N.Branch, Industrialists, Academicians, and Students etc. Mr. K. Sundaraswamy, the then Director of Drugs Controll (i/c), Tamilnadu was the chief guest of the function and released the first issue. The first issue was received by Mr. S. V. Veerramani, CMD, M/s Fourrts India Ltd, Chennai. The newsletter was circulated to all the Pharmaceutical Manufacturers, Pharmacy Colleges, various Professional Associations, Drugs Control departments and various Councils. I am very much delighted to share my views that many readers felt that the first issue was very informative and encouraged us to add more informations in the forth coming issues.

In the second issue we have five important articles namely Requirements of HVAC System in Pharmaceutical Facility, Legal Issues in Branding Medicinal Products, Good Pharmacy Practice, Pharm D-Doctor of Pharmacy in India, Procedure for Import Registration of Drugs and Pharmaceuticals; and these articles have been written by senior Pharmacy Professionals. This issue also includes enhancement of penalty for manufacture and distribution of spurious and adulterated drugs/cosmetics. I felt it is also essential to incorporate the various procedures and documents required for establishing drug wholesale outlet and also export of drugs etc. It is also important to give the information as regard to production and sale of drugs in our country. The statistical figures in this regard have been highlighted in this matter. It is pertinent to mention here that our "Trust" is interested to establish a database of the resumes of our professionals and fresh graduates who intend to seek fresh opportunity in their carrier. We will be collaborating with all the Pharma Industries as well as Pharma Colleges in Tamilnadu in order to help our Pharmacy professionals in their betterment of future. We are also including some of the advertisements in this issue, as well as in future issues also.

I hope the readers may utilize this journal/newsletter for their guidance and also give their valuable suggestions for future issues.

Best regards,
R. Narayanaswamy

Requirements of HVAC System in Pharmaceutical Facility

BY

DR. D. ROY

Central Drugs Standard Control Organization, Ministry of Health, Govt. of India

The basic requirement of Good Manufacturing Practices (GMP) is to protect the product from environmental contaminants as well as to protect the environment from the hazards of Pharma materials and products, otherwise catastrophic results may occur. Air which is most vulnerable & potential source of contamination can be controlled only by installation of HVAC (Heating, Ventilation & Air Conditioning) system which plays an important role in ensuring the manufacture of quality pharmaceutical products.

Pharmaceutical manufacturing area where Pharmaceutical starting materials and products, utensils and equipment are exposed to the environment should be controlled and the level of protection and air cleanliness for different areas should be evaluated based on the nature of the product & its susceptibility to degradation.

Number of factors are responsible for the contamination of the premises & production equipment.

- Due to movement of people, contact, hair fibers, skin fragments.
- Dirt, Dust traveling from out side or one part to another.
- Residues from other processes.
- Air currents within the plant carry pathogens & other contaminants from one part of the plant to another.
- Atomized droplets of liquids travel within the plant.

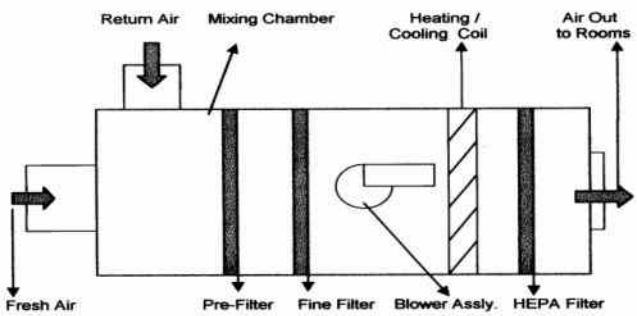
As per WHO working document QAS/02.048/Rev.2, the following table is an example of levels of protection.

Level	Condition	Example of area	Recommended filtration.
Level-1	General	An area with normal house keeping and maintenance, e.g. Warehousing, secondary packing etc.	Primary filters (10μ.)
Level-2	Protected	An area in which steps are taken to protect the exposed pharmaceutical starting material or product from contamination or degradation, e.g., Manufacturing, primary packing, dispensing etc.	Production facilities operating on 100% out side air; primary plus secondary filters (10μ+5μ).
Level-3	Controlled	An area in which specific environmental condition are defined, controlled & monitored to prevent contamination or degradation of the Pharmaceutical starting material or product.	Production facility operating on re-circulated plus ambient air, where potential for cross contamination exists- Primary + Secondary+ Tertiary filters (10μ+5μ+0.3μ).

HVAC air distribution is generally carried out through Air Handling Unit (AHU), schematic diagram of which is shown below.

AIR HANDLING UNIT

SCHEMATIC DRAWING OF AN AIR HANDLING UNIT



An AHU must take adequate quantity of fresh air from outside for two reasons:-

(a) Adequate supply of fresh air is required for the people working in the plant and

(b) Maintenance of positive pressure & flushing out of contaminants in the room by suitable air change.

Maintenance of positive pressure inside the clean area in comparison with the ambient is necessary to prevent the entry of dust and other contaminants from outside. The quantity of fresh air intake depends upon several factors, such as number of people working in the plant, cumulative size of the doors & other openings in the premises, traffic rate, any process exhaust etc

The design of the AHU or the environmental control system and its components for a given pharmaceutical process application will be dictated by criteria related to the specific product being processed. No matter what the product or resulting criteria, the air handling system must take into account the following:

(A) The main unit and all duct work should possibly be located outside the process room.

(b) The main unit should have a double wall and cleanable casing.

(c) Dampers should be single blade type.

(d) Arrangement should be made so that cooling coils can be thoroughly inspected and sanitized.

(e) The final filter should be located at the discharge end of the main unit.

(f) The system should have accessibility for inspection and sanitization to all components.

(g) The duct should be designed in round sections and must have facility for regular inspection.

(h) The AHU should have the ability to supply large amounts of filtered fresh air from outdoors during and after clean-up-cycles.

(i) The air distribution system should be designed to maintain dry walls and ceilings.

A well regimented inspection and cleaning schedule should be followed and documented.

Conclusion

In view of above discussion it may be concluded that HVAC system which play a pivotal role to prevent contamination & cross contamination during manufacturing, is often overlooked in the initial planning stages (DQ) and very often the contractors who have very little knowledge & exposure of pharmaceutical product manufacturing requirements, are involved in the design of HVAC system. As a result the overall objective is not achieved. The technical personnel associated with the manufacturing activity must understand the basic requirement of HVAC system related to production activity and accordingly the design should be approved for installation.

Good Pharmacy College Practice

BY

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Department of Pharmacy Practice, JSS College of Pharmacy, Ooty 643 001.

Introduction:

Student learning and development are complex, multifaceted functions at any institution and are a shared responsibility among many stakeholders like Students' families, the faculty, the managements of the institutions and other members of the college community all combine to support student growth and development. From its very beginning to the present, pharmacy profession consistently has acknowledged the primacy of the institution's mission in guiding the practice of student affairs on and off the campus. But the number of pharmacy colleges that provide such environment and support is questionable. Hence it becomes necessary to lay down a set of principles and procedures as "Good Pharmacy College Practice".

Whose Responsibility Is It?

College and university administrators, state and central officials, and accrediting authorities have the power to shape an environment that is favorable to good practice in pharmacy education. Teachers and students hold the main responsibility for improving the quality of pharmacy education. But they need a lot of support, encouragement and guidance from the aforesaid personnel and agencies.

What qualities must this environment have?

A strong mission and vision.

- Concrete support from administrators and faculty members for achieving those vision and mission.
- Adequate funding appropriate for the purposes.
- Policies and procedures consistent with the tasks.
- Continuing examination of how well the goals are being achieved.

The following standard practicing guidelines should be followed to set higher standards in the pharmacy colleges in our country.

- The management structure should be clearly defined and complemented by elaborate committee frameworks and procedures for decision-making should be effective.
- The administrators must develop systematic procedures for planning, monitoring and evaluating college operations. Internal communications between management and staff at all levels must be effective.
- Regular meetings should be conducted and the minutes of the same should be well documented and rigorously communicated between committees and departments.
- The responsibilities should be diversified to various department heads for monitoring the performance and achievements in their departments.
- Staff should be involved extensively in setting targets for their work.
- The administrators should be very accessible to both staff and students and employ an open and consultative style.
- Budget holders must receive timely reports of actual and committed expenditure against budget from the various heads of departments.
- Apart from promoting academic excellence, the managements of pharmacy colleges should provide a range of opportunities to extend the students' experience beyond the academic activities.
- The Administrators should involve parents and the community in the development of the College.

Crucial Role of Principal:

- The principal and senior management team should maintain a high profile and should take part, in the actual activity of the college (its teaching and student support).
- The principal should be easily accessible, with an open-door policy, and readily available to provide staff with quality time.
- Mechanisms should be in place, both formal and informal, to enable staff to air their views

and help shape college policy and practice. Opportunities should be provided for staff to talk about themselves. The college should prove responsive in meeting personal and professional needs of faculty.

- By maintaining a close interest and by exercising good judgment, the principals should 'know their staff', and able to identify their potentials and to encourage them to take responsibilities and extend their role within the college.
- Effective recruitment is necessary for college development with active involvement of Principal with a clear idea of the characteristics being sought. In addition to excellent teaching ability and an undiminished determination to promote student learning, enthusiasm, drive and aPersonal philosophy congruent with that of the college.
- Strategies and practices should be developed to increase social cohesion in the college and promote collaboration and team work.

Role of Teaching Staff:

- Staff should be encouraged to develop their talents, use initiative and take responsibility in teaching.
- High quality facilities should be provided, and be constantly improving. Finances must be managed to make it possible to respond to requests for resources, provided the impact on learning could be demonstrated.
- Care should be taken to protect hard-working and conscientious teachers from needless bureaucracy and initiative overload.
- All departments should be encouraged to develop their own styles to reflect the demands of the subject discipline and the personalities of the teachers.
- The role of the head of department should be pivotal, enabling college policy and practices to be translated into the departmental context, and to represent colleagues views in management forums.
- Mediocrity cannot be tolerated. Staff should be made accountable, on an annual basis in relation to student achievement.
- Identifying the potential of each student who enters the college, and putting practices and systems in place to ensure that potential is realized.
- Valuing each person (student and staff member) at the college as an individual, respecting diversity. This must be reflected in the interactions that take place, and in the working relationships formed.
- The staff handbook should be maintained for self-assessment reports. In the self-assessment report the college can identify the need for further developments.

Standards for the Teaching Profession:

- Care: Expressed through commitment to students' well-being and learning through positive influence, professional judgment and empathy in practice.
- Trust: Embodies fairness, openness, and honesty. The professional relationships with students, colleagues, parents, guardians and the public are based on trust.
- Respect: Encompasses honoring human dignity, emotional wellness, spiritual and cultural values, social justice, confidentiality, freedom, democracy and the environment.
- Integrity: Honesty, reliability and moral action are embodied in the standard of Integrity.

Purposes of the Standards for the Teaching Profession:

- To inspire members to reflect and uphold the honor and dignity of the teaching profession
- To identify the ethical responsibilities and commitments in the teaching profession
- To guide ethical decisions and actions in the teaching profession
- To promote public trust and confidence in the teaching profession.

Responsibilities of Teaching Professional:

- Leadership in Learning Communities: Participating in the collaborative, safe and supportive learning communities and recognizing their shared responsibilities and leadership roles in facilitating student success.
- Ongoing Professional Learning: Recognizing that ongoing professional learning is integral to effective practice and to student learning. Professional practice and self-directed learning are informed by experience, research, collaboration and knowledge.

- Professional Knowledge: Striving to be current in the professional knowledge and recognize its relationship to practice.
- Professional Practice: Applying professional knowledge and experience to promote student learning by using appropriate assessment and evaluation, resources and technology to the needs of individual students and learning communities.

Realizing Student Potential:

- Having a credible mechanism to allow students to identify their potential for achievement in terms of examination performance; and using this to promote self-esteem and to set targets.
- Having standardized processes, which enable staff and students to monitor progress on a regular and individual basis, and to revisit targets. Ensuring meticulous records of progress are maintained.
- Having uniform systems that enable the college to respond to the above review process in terms of appreciating high achievers, and to enable underachievers to get back on track.
- Having a high quality system of pastoral support for students to enrich their experience beyond the academic.
- College Meetings or Assemblies, meetings with faculty groups, aspects of the enrichment programme all should be used as opportunities to promote messages regarding college expectations relating to student attitudes and behavior.
- It should be made clear that each individual in the college is highly valued with dignity as adults and that all are perceived as being of equal importance.

Quality Assurance:

- 'Results do not come out of the sky'. Performance is questionable. Quality assurance is now a crucial feature of college activities.
- Quality assurance systems must be fair, thorough, and relevant to actual teaching, and applicable to all individuals.
- The key features must be to promote self-evaluation, and to identify strengths and weaknesses.
- Systems will be only effective if they are responsive. Strengths should be affirmed. Opportunities to address weaknesses should be provided in terms of further resources or training.
- An important and developing aspect of the quality assurance system should be the extent it enables good practice effectively shared across the college.
- Crucial to the system should be based on the interpretation of evidence which was credible, and focused on outcomes, especially on student achievement.
- An important feature of quality assurance is that it should be proactive rather than reactive.

Now it is the right time to think about the standards of Pharmacy colleges in our country. This write up is an initiation towards that direction. The apex body like PCI can work on this to bring out a set of standard practice guidelines for the pharmacy colleges to upgrade the quality of pharmacy education in India.

Procedure for Import Registration of Drugs and Pharmaceuticals

BY

Mr. R. Narayanaswamy

Dy. Drugs Controller (India) (Retd.)

Government of India, Ministry of Health and family welfare issued a notification wide GSR 604(E) on 24th August 2001 pertaining to import registration of drugs and Pharmaceuticals under part IV of Drugs and Cosmetics Act and rules thereunder. The site of the manufacturing premises in foreign country where all the bulk drugs as well as drug formulations are manufactured have to be registered along with the drugs to be imported. The following are the detailed procedure for applying import registration of drugs and pharmaceuticals as well as medical devices. The import application with all documents and the fees through a challan are to be sent to Drugs Controller General of India, New Delhi for getting Import Registration Certificate.

- Rule 24 A of Drugs and Cosmetics Act and rules prescribe the procedure of import registration.
- An application for issue of registration certificate shall be made in form 40 either by the foreign manufacturer himself having valid wholesale licenses or by his authorized A feagent in India having valid license either to manufacture for sale or having a valid whole sale license.
- Authorisation by the foreign manufacturer to his agent in India shall be documented by a power of attorney executed and authenticated either in India before a First class magistrate, or in a country of origin before such a equivalent authority, the certificate of which is attested by the Indian Embassy of the said country and the original of the same shall be furnished along with the application for registration certificate.
- A fee of one thousand and five hundred US dollar (or its equivalent in Indian rupees) shall also be paid along with the application of form 40 as registration fees for his premises meant for manufacturing of drugs intended for import into and use in India.
- A fee of one thousand US dollars [or its equivalent in Indian Rupees] shall be paid along with the application in Form 40 for the registration of a single drug meant for import into and use in India and an additional fee at the rate of one thousand US dollars for each additional drug.
- Provided that in the case of any subsequent application for registration of additional drugs by the same manufacturer, the fee to accompany shall be one thousand US dollars [or its equivalent in Indian rupees] for each drug.
- The fees shall be paid through a challan in Bank of Baroda at Kasturba Gandhi Marg, New Delhi or Rajaji Salai, Chennai Main Branch, Chennai-1 or Mumbai or Kolkata, under the head of account "0210 Medical and Public Health, 04 - Public Health, 104 - Fees and Fines".
- The applicant shall be liable for the payment of a fee of five thousand US dollars [or its equivalent in Indian rupees] for expenditure as may be required for inspection or visit of the manufacturing premises of drugs, by the licensing authority or by any other persons to whom powers have been delegated in this behalf by the licensing authority under rule 22.
- The applicant shall be liable for the payment of testing fees directly to a testing laboratory approved by the Central Government in India or abroad, as may be required for examination, tests and analysis of drug.
- A fee of three hundred US dollars [or its equivalent in Indian rupees] shall be paid for a duplicate copy of the registration Certificate, if original is defaced, damaged or lost.
- No registration Certificate shall be required under these rules in respect of an inactive bulk substance to be used for a drug formulation, with or without pharmacopeial conformity.
- Plant Master File Duly notarized.
- Schedule DI & DII forms shall be filled by the applicant and submit the same along with form 40.
- The applicant shall submit the product dossier of the drug to be registered or imported. The product dossier shall contain the information like chemical name of the product, chemical structure, procedure of manufacturing, stability data, standard of the product including its pharmacopoeial specification, testing procedure, pharmacological action, safety and efficacy of a product and its side effects, shelf life of the product and specimen label of product. All the documents and each page of the documents have to be notarized by the notary public in a country of origin.
- The applicant should also submit the regulatory status of the product / drug to be imported. The documents like registration of the product in a country authority by the National authority of the country, WHO GMP Certificate, COPP certificate and free sale certificate. All the documents and each page of the documents have to be notarized by the notary public in a country of origin.

- Copy of the manufacturing license issued by the respective states along with their wholesale drug license or wholesale drug license of the importer who intend to register the product by import registration are to be enclosed along with the application.
- The Import Registration Certificate is valid for 3 years.
- After getting the import registration certificate, the applicant shall apply for Form 10 license to DCGI office. To get Form 10 license, the documents like Form 8, Form 9 undertaking, copy of the import registration certificate and copy of the manufacturing or wholesale license of the applicant shall be forwarded to DCGI office. The fees for applying for Form 10 licenses are Rs. 1,000 and Rs. 100 for each product. The same challan used for import registration is applicable for applying for Form 10 license.
- The Form 10 License is valid for 2 years.
- Note: All forms, challan, etc. may be downloaded from the website www.cdsco.nic.in

Legal Issues in Branding of Medicinal Products

By
Zakir Thomas

Branding of a drug raises important trademark principles. Some of the important trademark law decisions have come up in the area of Pharmaceutical branding. This article examines these decisions, practices in the market and analyses legal issues surrounding trademark in pharmaceutical field.

Keywords:
Pharmaceutical branding, generic name, infringement, passing off, trademark law

Every medicinal preparation has an active ingredient that produces the therapeutic effect. The active ingredient, the drug, has a chemical name and a generic name. For reference purposes, the drug is known by its generic name in the scientific community. As it is non proprietary name, it is in public domain and is not protected by exclusive rights.

The medicinal preparation containing the drug will have a brand name, chosen by the entity marketing the medicine. The brand name is trademark of a medicine and is thus a proprietary name for which the trademark owner has an exclusive right to use.

If the drug is patented, only the patent holder or its licensee will be manufacturing the medicine containing the drug. Once out of patent, there will be multiple manufacturers, manufacturing the medicines under their own brands.

Trademark law provides legal protection to brands. Registration of trademark is not mandatory for obtaining protection. In the case of a registered trademark, the proprietor gets an exclusive right to use the trademark in relation to the goods or services in respect of which the trademark is registered and to obtain a relief in respect of infringement of this exclusive right to use the trademarks.

The brand names may be coined in such a way so as to recall the name of the active ingredient in the medicine to medical practitioners. Thus in the Pharmaceutical trade one finds names of various medicines almost similar to each other. The attempt in this article is to take a close look at the principles that the courts are following while upholding a trademark.

The Judicial Precedents

Trademark Principles

In Corn products Refining Co v Shangrila Food Products Ltd AIR 1960 SC 142 (1960), M/s. Shangrila Food, GLUVITA. M/s. Corn Products who were the owners of the registered trademark GLUCOVITA filed its objections to the registration of this mark. This question has to be approached from the point of view of a man

of average intelligence and imperfect recollection. The court found that the packets of both the products are almost same size, same color resemblance that one can be mistaken for another. Apart from the syllable "co" in the appellant's mark, the two marks are similar. The word involved is an English word which to the mass of Indian people is a foreign word. The mere presence of a syllable "co" will not be enabling the buyers in our country to distinguish one mark from another.

A two judge Bench of Supreme Court laid down certain significant principles with regard to trademarks of medicinal products in Hoffmann La Roche & Co Ltd v Geoffery Manner & Co (P) Ltd (1969) 2 SCC 716. The issue was whether the mark of the respondent DROPOVIT was deceptively similar to the registered mark PROTOVIT of the appellants.

In order to decide whether DROPOVIT is deceptively similar to PROTOVIT, the two Words must be compared as whole. The question of deceptive similarity has to be decided on the basis of class of goods to which the marks apply.

As there are about 57 trademarks in the register with suffix VIT, even customer would know that in respect of vitamin preparations, the word VIT occurs in a large number of trademarks and because of this he would naturally be on his guard and take special care against making a mistake. Having regard to all circumstances, the court held that the marks protovit and dropovit are not deceptively similar and that there was no reasonable probability of confusion of the words.

In M/s. Panacea Biotech Ltd v M/s. Recon Ltd, 1996 PTC (16) 561, the competing marks were Nemulid and Remulide. The active ingredient in both the drugs was Nimesulide, used for treatment of inflammatory conditions. If a manufacture uses the name of the basic drug of which a medicine is constituted no monopoly can be claimed by him with regard to the use of the word as his trademark.

In Biofarma v Sanjay Medical Store 1997 PTC (17) (Del), the Delhi High Court held that TRIVEDON is not deceptively similar to the registered trademark FLAVEDON. Both the drugs were used for the treatment of ischemic heart disease The medicines are schedule H drugs available only on doctors prescription, for heart diseases which is serious diseases in the medical world and hence the chance of deception or confusion is less. In SBL Ltd v Himalaya Drug Co, AIR 1998 Del 126, the competing marks were LIV 52 of the plaintiff and LIV-T of the defendant. the court noted that the possibility of deception or confusion is reduced to practically nil in view of the fact that the medicine will be sold only on medical prescription and by licensed dealers well versed in the field having knowledge of medicines.

The Cadilla Decision

The suit related to medicines sold under the brand name 'FALCIGO' by the plaintiff appellant and 'Falcitab' by the respondent defendant. Both the medicines were used for the treatment of Falciparum malaria.

The two products in question were Schedule L drugs which can be sold only to hospitals and clinics with the result that there could not even be a remote chance of deception and confusion. Unlike Schedule H drugs which are sold by the chemists only on prescription of the doctors, Schedule L drugs are sold only to hospitals and clinics and not to customers. On appeal to the Supreme Court, the court did not interfere with the order refusing interim injunction.

The court applied the principle that dissimilarity in essential features in devices and composite marks are more important than some similarity. The court ruled that the dissimilarities of the marks have to be given more importance than phonetic similarity or similarity in use of the word Picnic or Piknik. This decision was overruled by the division Bench stating that it was unable to agree with the principle that phonetic similarity has to be jettisoned when the manner in which the marks are written is different as it is against the decision of Amritdhara case, the products will be purchased by both village and townsfolk,

illiterate and literate and that the question was to be approached from the point of view of a man of average intelligence and imperfect recollection.

In passing off cases what is to be seen is whether the misrepresentation made by the defendant is of such nature as is likely to cause one product for another due to similarity of marks and other surrounding factors.

The Supreme Court held that where medicinal products are involved, the test to be applied for adjudging violation of trademark law may not be on par with cases involving non medicinal products. A stricter approach should be adopted while applying the tests to judge the confusing similarity in respect of medicinal products' trademarks as against other non medicinal products. While confusion in the case of non medicinal products may only cause economic loss to the plaintiff, confusion between two medicinal products may have disastrous effect on health and in some cases life itself. Stringent measures should be adopted especially where medicines are medicines of last resort as any confusion in such cases may be fatal or disastrous.

Post Cadilla Decisions

In Khandelwal Laboratories Ltd v FDC Limited 2001 PTC 864 (Del) The trademark of the plaintiff was CEFI and the defendant's ZIFI, both containing the drug Cefixime used for treatment of typhoid lower respiratory tract infection, urinary tract infection and otitis media. According to plaintiff defendant's trademark CEFI, sale of medicines under the trademark ZIFI by the defendant amounts to an act of passing off.

The plaintiff relied on the Cadilla decision, which was recent then. They asserted that there is no bar on coining a trademark based on a generic word. The plaintiff pointed out that the marks involved in that case was FALCIGO and FALCITAB derived from FALCIPARUM, a disease of cerebral malaria.

The court noted that the plaintiff's trademark CEFI is derived fro the chemical compound Cefixime. Many other companies are using the trademarks derived from Cefixime and many of them were in the market prior to launching of plaintiff's product based on these the court vacated an ex parte ad interim injunction granted in favour of the plaintiff.

In Cadilla Healthcare Ltd. v Swiss Pharm Pvt. Ltd, 2002 (24) PTC 708 (Guj), the plaintiff's drug was SPARDAC a medicine containing the drug Sparfloxacin, an anti bacterial medicine. They sought to restrain the defendants from using the mark SUPERDAC, a medicinal preparation containing Ciprofloxacin and Tinidazole.

The Court found that the two trademarks are not phonetically similar and that the appearances of twp products are different. Both the drugs were Schedule H drugs which cannot be sold without a prescription. As the two products are visually, structurally and phonetically dissimilar they are in likely to cause confusion in the minds of users, chemists or doctors. It may be noted that the court had considered the Cadilla decision as well as other decisions of various courts before coming to the above conclusion.

In Syncom Formulation v SAS Pharmaceuticals 2004 (28) PTC 632 (Del), the plaintiff respondents SAS Pharmaceuticals are manufacturers of ayurvedic preparation. REGULIN AND REGULIN FORTE. They sought an injunction against the defendant from using the trademark REGU 30. It observed that there was some visual or phonetic similarity between the marks Regulin Forte and Regu 30. The visual and phonetic similarity of the first four letters is enough to confuse or mislead an unwary customer. The court held that the plaintiff respondent had made out a strong prima facie case of passing off and the order of in junction was justified.

In Novartis AG v Wanbury Ltd & Anr 2005 (31) PTC 75 (Del), the plaintiffs were proprietors

of the registered trademark TRIAMINIC and TRIOMINIC for cough syrup. They sought to restrain the defendants from using the trademark CORIMINIC. Both the medicines are cough but their active ingredients are different. The plaintiff's syrup contained ChlorPheniramine Maleate and Phenylephrine Hydrochloride but that of the defendant contained Pseudophedrine Hydrochloride, Chlor Pheneramine Maleate and Menthol.

The Defendants pleaded that the word MINIC is derived from the word AMINE (Pheneramine) meaning this ingredient mimics certain functions of the central nervous system. A number of trademarks exist with Minic as prefix or suffix. The Court split the mark and found that devoid of the suffix Minic there is no phonetic similarity between CORI and TRIO. Visually also there was no similarity between the marks and the court refused to grant the injunction.

In Kalindi Medicure Pvt. Ltd v Intas Pharmaceuticals Ltd & Anr 2006 (33) PTC 477 (Del), the drugs involved were Loprin of the plaintiff and LOPARIN of the defendants. Both the drugs were used for treatment of heart ailment. LOPARIN is a coined word derived from low molecular weight heparin and the molecule Enoxaparin i.e. an amalgamation of low and Emoxaparin.

The plaintiff's product is taken orally and is sold as pill while defendant's product is intramuscularly injected by a syringe. LOPARIN is a critical care medicine and is normally used in intensive Coronary Care Unit while LOPRIN is a preventive medicine. The price difference is huge: the defendant's drug is expensive over 52 times. Considering these factors the court used to grant preliminary injunction even though the applicant had registered the trademark.

In Apex Laboratories Ltd v Zuventus Healthcare Limited 2006 (33) PTC 492 (Mad) (DB), the dispute has between Zincovit and Zinconia. The court observed that both are medicinal preparations containing Zinc. The word Zinc is common to trade and is publisci juris. The plaintiff cannot claim ownership over the said word. The words are phonetically dissimilar and visual impression is different and hence is unlikely to cause confusion in the mind of a common consumer.

In Wyeth Holdings Corporation Anr v Burnet Pharmaceuticals (P) Ltd 2008 (36) PTC 478, the plaintiffs were the proprietors of the registered trademark FOLVITE, registered in 1949 in respect of vitamin B complex. The defendant had initially adopted the mark FOLCACID for its products. Subsequently the mark was changed to FOLV and they sought to register it. They pleaded that when a word consists of a common elements greater emphasis must be paid on uncommon elements. Where the competing drugs are meant to cure same disease but compositions are different, mistaking one for another may result in serious consequences. The court rejected the contention of the defendant that FOLVITE should be seen as a combination of FOL and VIT. Each word must be taken as a whole and compared with another as a whole. Secondly, the register its validity cannot be questioned. In Bal Pharma Ltd v Wockhardt Limited, suit no. 1305/02 of Bombay High court, the Division Bench judgment dated 12.06.02 held that the mark AZIWOK was distinct from AZIWIN on the contention that various brands of azithromycin in tablet and syrup forms were being marketed by pharmaceutical companies and AZI was an abbreviation of the generic name often drug, common to the trade. The suffix WOK and WIN were regarded dissimilar.

Analysis

It is common practice to name a drug by the name of the organ or ailment which it treats or the main ingredient of the medicine. The purpose is to indicate to the doctors and chemists that a particular drug is for a particular disease. Hence at least a part of the mark will be common to another or even a number of marks.

But the settled law is that a mark should be regarded as a whole. The court then placed

greater regard to uncommon elements. It should be noted that the court did not give a finding whether Falcitab and Falcigo are deceptively similar stating that such finding require evidence.

Against this is the finding of the Hoffmann La Roche court, that the suffix VIT commonly indicates vitamin based products. Though the two judge bench of Cadilla referred to the Hoffmann ratio, the court did not dwell on this aspect restricted themselves to the ruling that marks must be compared as whole. The observation of the Court is below

"An attempt was made to argue that many customers may be ignorant and some of them may not even be literate and they are likely to commit error and would name one instead of another. It is difficult to swallow this argument. Such a customer may not be expected to wrongly name one medicine in place of another. In fact ignorant and illiterate customer would hardly go to purchase such a drug without a prescription. It is not possible to accept that such a customer would even remember the names of these two medicines. Even the name of one medicine may not be remembered by such a customer. In other words it is not likely that such a ignorant or illiterate customer may commit an error in naming a particular medicine."

The Court observed that the vendor would be a licensed dealer reduces the possibility of confusion to a considerable extent. In Cadilla, the drugs were Schedule L drugs which were meant to be sold only to hospitals and clinics. The court observed that this fact alone is not sufficient to prevent the confusion which is otherwise likely to occur.

The court noted that in practice Schedule H drugs are sold without prescription. In such cases both the customer and the chemist enter into transaction at their own risk.

This brings us to a core trademark question. Who is the customer in pharmaceutical trade, particularly in Schedule H or schedule L drugs? Is it doctor and chemists as mandated in the drugs Act or the customer who buys the scheduled drug across the counter without prescription at his own risk? The Cadilla court kept the interest of this customer in view and also observed that doctors and chemists are not infallible. In Hoffman, the Court observed that where vendor is a licensed dealer possibility of confusion is reduced. Depending on who is the customer, the approach of the courts may differ.

The Court treats pharmaceutical trademark as a class to which separate rules apply. But while taking this view, the Court did not dwell at length on the established practice of pharmaceutical industry to use part of the name of the disease or the molecule or the organ of the body in naming the product. This may create some unintended consequence affecting the public interest which the Court tried to protect.

A stricter trademark law in pharmaceutical industry as a class as stipulated in Cadilla may have to consider the peculiarities of the industry as such.

Disputes are bound to occur in the industry. Courts may have to adopt principles which take the established practices in the trademark into account and lay down principles which resolve the disputes in a predictable manner.

Conclusion

The branding of pharmaceutical products is an area where industry practices, trademark principles and public interest interact. The public interest involves in providing affordable health care and in removing confusion from the market place.

Footnote: zt@csir.res.in The author, an alumnus of Franklin Pierce Law Centre, US is the Head of Director General's Technical Cell of CSIR. He is also the Project Director of Open Source Drug Discovery Project of CSIR (www.osdd.net). He has been the Registrar of Copyrights.

Acknowledgement: Journal of Intellectual Property Rights, Vol 13 September 2008, pp 523-535

Note: This is the abridged version of original article published in Intellectual Property Rights, which is available in the library of Trust office.

Pharm. D. Doctor of Pharmacy in India

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Vice President, Tamil Nadu Pharmacy Council Vadapalani, Chennai - 26.

B. Pharm has been established in 20th century in India. Though, now pharmacy is a well recognized profession in our nation. However, the pharmacy profession has been quite unsuccessful in filling up the requirement of a 'high quality health' in our country. This may be mainly due to lacuna in the clinical aspect and mainly course projected to technical oriented subjects. Most of the B. Pharm passed out graduates mainly enter either pharmaceutical industry or R & D. The 'health care' aspect is totally lacking. A fresh graduate coming out of a pharmacy college in India is largely not knowing of these ground realities. With growing globalization of Indian pharmaceutical industry, the standards of pharmacy education need to be world class.

Pharmacy Council of India being striving to maintain the quality aspects and service of Pharmacy profession by projecting the global standards to the policy people with the professional leadership of Dr. B. Suresh, president PCI for last five years for this change and the Ministry of Health and Family Welfare, Government of India has finally approved starting of six year Pharm. D. -Doctor of Pharmacy course in India.

Perspectives of Pharm. D. Course:

The major scope of the Pharm D programme is to raise the standard of Pharmacy Profession in India in terms of Pharmacy Practices as well as making Pharmacy degree acceptable to various other countries including US and UK, since four year B. Pharm course is not eligible for appearing for Pharmacist license exams in US and UK. Developed countries like US, Australia and Europe rendering quality service in the pharmacy profession hence PCI strengthened its activities oriented with the quality aspects to project efficient service in India also.

The Pharm. D. Regulation framed is under section 10 of the Pharmacy Act 1948 (8 of 1948) as approved by Govt. of India, Ministry of Health, New Delhi. Pharm. D. shall consist of a certificate, having passed the course of study and examination as prescribed in the regulations, for the purpose of registration as a pharmacist to practice the profession under the Pharmacy Act, 1948. The Pharmacy Council of India (PCI) has approved 22 colleges to start Pharm. D. course from this academic year. The Council has already notified the procedures and fees structure for pharmacy institutions to apply for recognition to commence the course.

Duration and Syllabi:

There are two eligibility requirements to do Pharm. D. programme. The first eligibility is + 2 HSC certificate (Physics and chemistry is compulsory along with either one of the subject Maths or Biology). The duration of the course is six academic years (five years of study and one year of hospital internship or residency) full time, with each academic year spread over a period of not less than two hundred working days.

The second eligibility is for B. Pharm graduate students. That is Pharm. D. (Post baccalaureate). The duration of the course shall be three academic years (two years of study and one year of hospital internship or residency) full time with each academic year spread over a period of not less than two hundred working days.

Role of Pharm. D.:

The emerging field of Pharm. D. in India is the ultimate requirement necessary to achieve better patient compliance, necessary to control the adverse drug reactions, therapeutic drug monitoring, better drug dosage regimen

etc. are few among many which need to be achieved. It is also to achieve rational use of the therapeutic drugs for various ailments.

It is mainly pharmacy practice oriented, as evident from the fact that it's a compulsion that the colleges offering the course must have a hospital with 300 beds facility or adjoined hospital. Patient counseling is an important requirement for Pharm. D. programme. This hastens up the need of such a medical service that can overpower these drawbacks. Physicians are experts mainly in diagnosing a disease and prescribing drugs. But for ensuring patient compliance and acceptability, the job of a pharmacist comes into play. A Pharm. D. professional is trained in such a field. For further information contact - vishnuvardhr@gmail.com

Institutions Offering Pharm. D. Course

ANDHRA PRADESH

1. **Smt. Sarojini Ramulamma College of Pharmacy**
   Mahabubnagar 509 001.

2. **Raghavendra Institute of Pharmaceutical**
   Education & Research (RIPER)
   Anantapur 515 721.

3. **Deccan School of Pharmacy**
   Hyderabad 500 058.

4. **Talla Padmavathi College of Pharmacy**
   Warangal - 506 012.

5. **Bharat Institute of Technology**
   Mangalpalli Village Ibrahimpatnam (Mandal)
   Distt.RANGA REDDY 501 510.

6. **St. Peter's Institute of Pharmaceutical Sciences**
   Hanamkonda-506 001.

7. **Sri Venkateshwara College of Pharmacy**
   Hyderabad 500 081.

8. **GIET School of Pharmacy**
   Rajahmundry 533 294,

9. **Malla Reddy College of Pharmacy**
   Secunderabad 500 014.

10. **Shri Vishnu College of Pharmacy**
    Bhimavaram 534 202.

11. **Vaagdevi College of Pharmacy**
    Warangal 506 001.

12. **P. Rami Reddy Memorial College of Pharmacy**
    Kadapa 516 003.

KARNATAKA

13. **M.S. Ramaiah College of Pharmacy**
    Bangalore 560 054.

14. **Navodaya Education Trust's N. E. T.**
    Raichur - 584 101.

15. **Hyderabad Karnataka Education Society's College of Pharmacy**,
    Gulbarga - 585 105.

16. **Sri Jagadguru Mallikarjuna Murugharajendra College of Pharmacy**
    Chitradurga 577 502.

17. **B.V.V. Sangha's Hanagal Shri Kumareshwar College of Pharmacy**
    Bagalkot 587 101.

*18. **Manipal College of Pharmaceutical Sciences Manipal University**
Manipal 576 104,

*19. **Visweswarapura Institute of Pharmaceutical Sciences**
Bangalore 560 070.

*20. **J.S.S. College of Pharmacy**
Mysore 570 015.

*21. **KLE College of Pharmacy**
Belgaum 590 010.

MADHYA PRADESH

22. **Shri Ramnath Singh Institute of Pharmaceutical Sciences & Technology**
Gwalior 474 001.

MAHARASHTRA

23. **Bharti Vidyapeeth University Poona College of Pharmacy**
Pune 411 038.

TAMILNADU

*24. **Vel's College of Pharmacy**
Chennai - 600 117.

*25. **S.R.M. College of Pharmacy**
Kattankolathur 603 203.

*26. **P.S.G. College of Pharmacy**
Coimbatore - 641 004.

*27. **Vinayaka Mission's College of Pharmacy**
Salem 636 308.

*28. **J. S. S. College of Pharmacy**
Ootacamund - 643 001.

*29. **Sri Ramakrishna Institute of Paramedical Sciences**
Coimbatore 641 044.

*30. **Sri Ramachandra College of Pharmacy**
Chennai 600 116.

*31. **Department of Pharmacy Practice**
Faculty of Engineering & Technology
Annamalai University
Chidambaram. 608 002,

Source: Pharmacy Council of India, New Delhi

* Pharm. D. and Pharm. D. Post Baccalaureate courses are offered

Editorial Policy and Disclaimer

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इस भाग में भिन्न पृष्ठ संख्या दी जाती है जिससे कि यह अलग संकलन के रूप में रखा जा सके।
Separate paging is given to this Part in order that it may be filed as a separate compilation.

MINISTRY OF LAW AND JUSTICE

(Legislative Department)

New Delhi, the 5th December, 2008/*Agrahayana* 14, 1930 *(Saka)*

The following Act of Parliament received the assent of the President on the 5th December, 2008, and is hereby published for general information:—

THE DRUGS AND COSMETICS (AMENDMENT) ACT, 2008

No. 26 OF 2008

[*5th December,* 2008.]

An Act further to amend the Drugs and Cosmetics Act, 1940.

BE it enacted by Parliament in the Fifty-ninth Year of the Republic of India as follows:—

Short title and commencement.

1. (*1*) This Act may be called the Drugs and Cosmetics (Amendment) Act, 2008.

(*2*) It shall come into force on such date as the Central Government may, by notification in the Official Gazette, appoint:

Provided that different dates may be appointed for different provisions of this Act and any reference in any such provision to the commencement of this Act shall be construed as a reference to the commencement of that provision.

Insertion of new section 17E. Adulterated cosmetics.

2. After section 17D of the Drugs and Cosmetics Act, 1940 (hereinafter referred to as the principal Act), the following section shall be inserted, namely,— 23 of 1940

"17E. For the purposes of this Chapter, a costmetic shall be deemed to be adulterated,—

(*a*) if it consists in whole or in part, of any filthy, putrid or decomposed substance; or

(*b*) if it has been prepared, packed or stored under insanitary conditions whereby it may have been contaminated with filth or whereby it may have been rendered injurious to health; or

(*c*) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or

(*d*) if it bears or contains, for purposes of colouring only, a colour other than one which is prescribed; or

(*e*) if it contains any harmful or toxic substance which may render it injurious to health; or

(*f*) if any substance has been mixed therewith so as to reduce its quality or strength."

Amendment of section 18.

3. In section 18 of the principal Act, in cluase (*a*) , for sub-clause (*ii*), the following sub-clause shall be substituted, namely,—

"(*ii*) any cosmetic which is not of a standard quality, or is misbranded, adulterated or spurious;"

Amendment of section 26A.

4. In section 26A of the principal Act, for the word "prohibit", the words "regulate, restrict or prohibit" shall be substituted.

Insertion of new section 26B. Power of Central Government to regulate or restrict, manufacture, etc., of drug in public interest.

5. After section 26A of the principal Act, the following section shall be inserted, namely,—

"26B. Without prejudice to any other provision contained in this Chapter, if the Central Government is satisfied that a drug is essential to meet the requirements of an emergency arising due to epidemic or natural calamities and that in the public interest, it is necessary or expedient so to do, then, that Government may, by notification in the Official Gazette, regulate or restrict the manufacture, sale or distribution of such drug.".

Amendment of section 27

6. In section 27 of the principal Act,—

(*i*) in clause (*a*),—

(*A*) for the figures, letter and words "17B or which", the figures, letter and words "17B and which" shall be substituted.

(*B*) for the words "punishable with imprisonment for a term which shall not be less than five years but which may extend to a term of life and with fine which shall not be less than ten thousand rupees;", the words "punishable with imprisonment for a term which shall not be less than ten years but which may extend to imprisonment for life and shall also be liable to fine which shall not be less than ten lakh rupees or three times value of the drugs confiscated, whichever is more:" shall be substituted.

(*C*) the following provisos shall be inserted, namely:—

"Provided that the fine imposed on and released from, the person convicted under this clause shall be paid, by way of compensation, to the person who had used the adulterated or spurious drugs referred to in this clause:

Provided further that where the use of the adulterated or spurious drugs referred to in this clause has caused the death of a person who used such drugs, the fine imposed on and realised from, the person convicted under this clause, shall be paid to the relative of the person who had died due to the use of the adulterated or spurious drugs referred to in this clause.

Explanation.—For the purposes of the second proviso, the expression "relative" means—

(*i*) spouse of the deceased person; or

(*ii*) a minor legitimate son, and unmarried legitimate daughter and a widowed mother; or

(*iii*) parent of the minor victim; or

(*iv*) if wholly dependent on the earnings of the deceased person at the time of his death, a son or a daughter who has attained the age of eighteen years; or

(*v*) any person, if wholly or in part, dependent on the earnings of the deceased person at the time of his death,—

(*a*) the parent; or

(*b*) a minor brother or an unmarried sister; or

(*c*) a widowed daughter-in-law; or

(*d*) a widowed sister; or

(*e*) a minor child of a pre-deceased son; or

(*f*) a minor child of a pre-deceased daughter where no parent of the child is alive; or

(*g*) the paternal grandparent if no parent of the member is alive;";

(*ii*) in clause (*b*),—

(*A*) for the words "not be less than one year but which may extend to three years and with fine which shall not be less than five thousand rupees", the words "not be less than three years but which may extend to five years and with fine which shall not be less than one lakh rupees or three times the value of the drugs confiscated, whichever is more" shall be substituted;

(*B*) in the proviso, for the words "less than one year and of fine of less than five thousand rupees", the words "less than three years and of fine of less than one lakh rupees" shall be substituted;

(*iii*) in clause (*c*),—

(*A*) for the words "not be less than three years but which may extend to five years and with fine which shall not be less than five thousand rupees", the words "not less than seven years but which may extend to imprisonment for life and with fine which shall not be three lakh rupees or three times the value of the drugs confiscated, whichever is more" shall be substituted;

(*B*) in the proviso, for the words "less than three years but not less than one year", the words "less than seven years but not less than three years and of fine of less than one lakh rupees" shall be substituted;

(*iv*) in clause (*d*), for the words "and with fine", the words "and with fine which shall not be less than twenty thousand rupees" shall be substituted.

Amendment of section 27A.

7. In section 27A of the principal Act, for clauses (*i*) and (*ii*), the following clauses shall be substituted, namely,—

(*i*) any cosmetic deemed to be spurious under section 17D or adulterated under section 17E shall be punishable with imprisonment for a term which may extend to three years and with fine which shall not be less than fifty thousand rupees or three times the value of the cosmetics confiscated, whichever is more;

(*ii*) any cosmetic other than a cosmetic referred to in clause (*i*) in contravention of any provisions of this Chapter or any rule made thereunder shall be punishable with imprisonment for a term which may extend to one year or with fine which may extend to twenty thousand rupees, or with both.".

Amendment of section 28.

8. In section 28 of the principal Act, for the words "with fine which may extend to one thousand rupees or with both", the words "with fine which shall not be less than twenty thousand rupees or with both" shall be substituted.

Amendment of section 28A.

9. In section 28A of the principal Act, for the words "with fine which may extend to one thousand rupees or with both", the words "with fine which shall not be less than twenty thousand rupees or with both" shall be substituted.

Amendment of section 29.

10. In section 29 of the principal Act, for the words "five hundred rupees", the words "five thousand rupees" shall be substituted.

Amendment of section 30.

11. In section 30 of the principal Act,—

(*a*) in sub-section (*1*),—

(*i*) in clause (*a*),—

(*A*) for the words "not be less than two years but which may extend to six years and with fine which shall not be less than ten thousand rupees", the words "not be less than seven years but which may extend to ten years and with fine which shall not be less than two lakh rupees" shall be substituted;

(*B*) in the proviso, for the words "less than two years and of fine of less than ten thousand rupees", the words "less than seven years and of fine of less than one lakh rupees" shall be substituted;

(*ii*) in clause (*b*), for the words "shall not be less than six years but which may extend to ten years and with fine which shall not be less than ten thousand rupees", the words "shall not be less than ten years but which may extend to imprisonment for life and with fine which shall not be less than three lakh rupees" shall be substituted;

(*iii*) in clause (*c*), for the words "five thousand rupees", the words "fifty thousand rupees" shall be substituted;

(*b*) in sub-section (*2*), for the words "ten years, or with fine, or with both", the words "two years, or with fine which shall not be less than ten thousand rupees or with both" shall be substituted.

Amendment of section 32.

12. In section 32 of the principal Act, for sub-sections (*1*) and (*2*), the following sub-sections shall be substituted, namely:—

"(*1*) No prosecution under this Chapter shall be instituted except by—

(*a*) an Inspector; or

(*b*) any gazetted officer of the Central Government or a State Government authorised in writing in this behalf by the Central Government or a State Government by a general or special order made in this behalf by that Government; or

(*c*) the person aggrieved; or

(*d*) a recognised consumer association whether such person is a member of that association or not.

(*2*) Save as otherwise provided in this Act, no court inferior to that of a Court of Session shall try an offence punishable under this Chapter.".

Insertion of new section 32B.

13. After section 32A of the principal Act, the following section shall be inserted, namely:—

Compounding of certain offences.

"32B. (*1*) Notwithstanding anything contained in the Code of Criminal Procedure, 1973, any offence punishable under clause (*b*) of sub-section (*1*) of section 13, section 28 and section 28A of this Act (whether committed by a company or any officer thereof), not being an offence punishable with imprisonment only, or with imprisonment and also with fine, may, either before or after the institution of any prosecution, be compounded by the Central Government or by any State Government or any officer authorised in this behalf by the Central Government or a State Government, on payment for credit to that Government of such sum as that Government may, by rules made in this behalf, specify:

2 of 1974.

Provided that such sum shall not, in any case, exceed the maximum amount of the fine which may be imposed under this Act for the offence so compounded:

Provided further that in cases of subsequent offences, the same shall not be compoundable.

(*2*) When the accused has been committed for trial or when he has been convicted and an appeal is pending, no composition for the offence shall be allowed without the leave of the court to which he is committed or, as the case may be, before which the appeal is to be heard.

(*3*) Where an offence is compounded under sub-section (*1*), no proceeding or further proceeding, as the case may be, shall be taken against the offender in respect of the offence so compounded and the offender, if in custody, shall be released forthwith.".

Amendment of section 33.

14. In section 33 of the principal Act, in sub-section (*2*),—

(*i*) after clause (*dd*), the following clause shall be inserted, namely,—

"(*dda*) prescribe under clause (*d*) of section 17E the colour or colours which a cosmetic may bear or contain for the purposes of colouring;";

(*ii*) in clause (*p*), the word "and" occurring at the end shall be omitted;

(*iii*) in clause (*q*), the word "and" shall be inserted at the end;

(*iv*) after clause (*q*), the following clause shall be inserted, namely,—

"(*r*) sum which may be specified by the Central Government under section 32B.".

Amendment of section 33-I.

15. In section 33-I of the principal Act,—

(*a*) in sub-section (*1*),—

(*i*) for clause (*a*), the following clause shall be substituted, namely:—

"(*a*) any Ayurvedic, Siddha or Unani drug—

(i) deemed to be misbranded under section 33E,

(ii) deemed to be adulterated under section 33EE, or

(iii) without a valid licence or in violation of any of the conditions thereof, as required under section 33 EEC,

shall be punishable with imprisonment for a term which may extend to one year and with fine which shall not be less than twenty thousand rupees or three times the value of the drugs confiscated, whichever is more;";

(*ii*) in clause *(b)*, for the words "five thousand rupees", occurring at both the places, the words "fifty thousand rupees or three times the value of the drugs confiscated, whichever is more" shall be substituted;

(*iii*) after clause *(b)*, the following clause shall be inserted, namely:—

"(*c*) any Ayurvedic, Siddha or Unani drug in contravention of the provisions of any notification issued under section 33EED shall be punishable with imprisonment for a term which may extend to three years and with fine which may extend to fifty thousand rupees or three times the value of the drugs confiscated, whichever is more.";

(*b*) in sub-section (*2*), for the words "three months and with fine which shall not be less than five hundred rupees", the words "six months and with fine which shall not be less than ten thousand rupees" shall be substituted.

Amenment of section 33J.

16. In section 33J of the principal Act,—

(*a*) in clause (*a*), for the words "two thousand rupees", the words "fifty thousand rupees or three times the value of the drugs confiscated, whichever is more" shall be substituted;

(*b*) in clause *(b)*, for the words "five thousand rupees" occurring at both the places, the words "one lakh rupees or three times the value of the drugs confiscated, whichever is more" shall be substituted;

(c) in clause *(c)*, for the words "six months and with fine which shall not be less than one thousand rupees", the words "one year and with fine which shall not be less than twenty thousand rupees or three times the value of the drugs confiscated, whichever is more" shall be substituted.

Insertion of new sections 33KA and 33KB.

17. After section 33K of the principal Act, the following sections shall be inserted, namely,—

Disclosure of name of manufacturer, etc.

"33KA. Every person, not being the manufacturer of any Ayurvedic, Siddha or Unani drug or his agent for the distribution thereof, shall, if so required, disclose to the Inspector the name, address and other particulars of the person from whom he acquired the Ayurvedic, Siddha or Unani drug.

Maintenance of records and furnishing of information.

33KB. Every person holding a licence under clause *(c)* of section 33EEC shall keep and maintain such records, registers and other documents as may be prescribed and shall furnish to any officer or authority exercising any power or discharging any function under this Act such information as is required by such officer or authority for carrying out the purposes of this Act.".

Amendment of section 33N.

18. In section 33N of the principal Act, in sub-section (*2*),—

(i) in clause (*gga*), the word "and" occurring at the end shall be omitted;

(ii) after clause (*gga*), the following clause shall be inserted, namely,—

"(*ggb*) prescribe the records, registers or other documents to be kept and maintained under section 33KB; and".

Amendment of section 36A.

19. In section 36A of the principal Act, for the words "all offences under this Act", the words, brackets, figures and letters "all offences (except the offences triable by the Special Court under section 36AB or Court of Session) under this Act" shall be substituted.

20. After section 36A of the principal Act, the following sections shall be inserted, namely:— Insertion of new sections 36AB, 36AC, 36AD and 36AE.

'36AB. (*1*) The Central Government, or the State Government, in consultation with the Chief Justice of the High Court, shall, for trial of offences relating to adulterated drugs or spurious drugs and punishable under clauses (*a*) and (*b*) of section 13, sub-section (*3*) of section 22, clauses (*a*) and (*c*) of section 27, section 28, section 28A, section 28B and clause (*b*) of sub-section (*1*) of section 30 and other offences relating to adulterated drugs or spurious drugs, by notification, designate one or more Courts of Session as a Special Court or Special Courts for such area or areas or for such case or class or group of cases as may be specified in the notification. Special Courts.

Explanation.—In this sub-section, "High Court" means the High Court of the State in which a Court of Session designated as Special Court was functioning immediately before such designation.

(*2*) While trying an offence under this Act, a Special Court shall also try an offence, other than an offence referred to in sub-section (*1*), with which the accused may, under the Code of Criminal Procedure, 1973, be charged at the same trial. 2 of 1974.

36AC. (*1*) Notwithstanding anything contained in the Code of Criminal Procedure, 1973,— 2 of 1974. Offences to be cognizable and non-bailable in certain cases.

(*a*) every offence, relating to adulterated or spurious drug and punishable under clauses (*a*) and (*c*) of sub-section (*1*) of section 13, clause (*a*) of sub-section (*2*) of section 13, sub-section (*3*) of section 22, clauses (*a*) and (*c*) of section 27, section 28, section 28A, section 28B and sub-sections (*1*) and (*2*) of section 30 and other offences relating to adulterated drugs or spurious drugs, shall be cognizable.

(*b*) no person accused, of an offence punishable under clauses (*a*) and (*c*) of sub-section (*1*) of section 13, clause (*a*) of sub-section (*2*) of section 13, sub-section (*3*) of section 22, clauses (*a*) and (*c*) of section 27, section 28, section 28A, section 28B and sub-sections (*1*) and (*2*) of section 30 and other offences relating to adulterated drugs or spurious drugs, shall be released on bail or on his own bond unless—

(*i*) the Public Prosecutor has been given an opportunity to oppose the application for such release; and

(*ii*) where the Public Prosecutor opposes the application, the court is satisfied that there are reasonable grounds for believing that he is not guilty of such offence and that he is not likely to commit any offence while on bail:

Provided that a person, who, is under the age of sixteen years, or is a woman or is sick or infirm, may be released on bail, if the Special Court so directs.

(*2*) The limitation on granting of bail specified in clause (*b*) of sub-section (*1*) is in addition to the limitations under the Code of Criminal Procedure, 1973 or any other law for the time being in force on granting of bail. 2 of 1974.

(*3*) Nothing contained in this section shall be deemed to affect the special powers of the High Court regarding bail under section 439 of the Code of Criminal Procedure, 1973 and the High Court may exercise such powers including the power under clause (*b*) of sub-section (*1*) of that section as if the reference to "Magistrate" in that section includes also a reference to a "Special Court" designated under section 36AB. 2 of 1974.

Application of Code of Criminal Procedure, 1973 to proceedings before Special Court.

36AD. (*1*) Save as otherwise provided in this Act, the provisions of the Code of Criminal Procedure, 1973 (including the provisions as to bails or bonds), shall apply to the proceedings before a Special Court and for the purposes of the said provisions, the Special Court shall be deemed to be a Court of Session and the person conducting the prosecution before the Special Court, shall be deemed to be a Public Prosecutor: 2 of 1974.

Provided that the Central Government or the State Government may also appoint, for any case or class or group of cases, a Special Public Prosecutor.

(*2*) A person shall not be qualified to be appointed as a Public Prosecutor or a Special Public Prosecutor under this section unless he has been in practice as an advocate for not less than seven years, under the Union or a State, requiring special knowledge of law.

(*3*) Every person appointed as a Public Prosecutor or a Special Public Prosecutor under this section shall be deemed to be a Public Prosecutor within the meaning of clause (*u*) of section 2 of the Code of Criminal Procedure, 1973 and the provisions of that Code shall have effect accordingly. 2 of 1974.

Appeal and revision.

36AE. The High Court may exercise, so far as may be applicable, all the powers conferred by Chapter XXIX or Chapter XXX of the Code of Criminal Procedure, 1973, on a High Court, as if a Special Court within the local limits of the jurisdiction of the High Court were a Court of Session trying cases within the local limits of the jurisdiction of the High Court.'. 2 of 1974.

T. K. VISWANATHAN,
Secy. to the Govt. of India

Referance: The Gazette of India: Extraodinary (Part II - Section 1)

Brief Note on the above Amendment:

In nutshell, the above amendment comprises of the following:-

a) The penalty for manufacture, stock and sale of spurious drugs has been enhanced to 10 years or life imprisonment and fine to the tune of not less than Rs. 10 lakhs

b) The fine imposed shall be distributed to the patients or consumers affected by that drug.

c) The penalty for marketing of adulterated drug has been enhanced to seven years imprisonment with Rs. 3 lakhs as fine.

d) For marketing spurious and adulterated cosmetics, the penalty is 3 years of imprisonment and a fine of Rs. 50,000

e) For marketing of spurious Ayurvedha, Siddha or Unani drug, the imprisonment is extended to one year with a fine of Rs. 20,000

f) Separate judicial courts have been designated to try the cases of spurious and adulterated drugs.

INFORMATION:-

a) Requirements of documents for applying Wholesale Drug License to Tamilnadu State Drugs Controller

1. Covering letter addressed to Asst Director of Drugs Control Administration with all documents
2. Two nos. of Form 19 Application forms (Application for a Wholesale License) with court fees stamp 2 nos. of Rs. 2
3. Self addressed envelope with stamp for Registered Post
4. Property Tax receipt copy for the proof of building engaged for getting the Wholesale License
5. Rental agreement, minimum for 5 years between the owner & the tenant
6. Plan of the premises where the Wholesale Drug / Device Store to be established
7. Partnership Deed or Memorandum of Association in case of Ltd. company along with list of directors and their addresses
8. 2 nos. of photographs of the partners or directors, as the case may be
9. Qualified person:- Qualification certificate & experience certificates as per rule , their declaration and their photo and id (i.e. Registered Pharmacist or any graduate with 1 year experience in dealing with drugs or Passed Matriculation or equivalent with 4 year experience in dealing with drugs)
10. Storage:- Refrigerator and/or Air conditioner + Generator, along with copies of purchase invoices of the same and proper storage cabinets/racks for the devices
11. Challan with Fees Rs. 1500 + Rs. 1500 for 20B and 21B license
12. A minimum area of 10 sq m is necessary for the Wholesale Drug premises
13. A declaration Form duly filled & signed by the applicant / applicants

b) Check-list for application for Manufacturing Licenses to manufacture Pharmaceutical Products

1. Application in Form 24, 27 and 36, duly filled and signed by the applicant.
2. Original challan for Rs. 7,500/- being the license Fees remitted under correct heads of account.
3. Courts Fees stamp to the value of Rs. 2/- fixed on each application.
4. Xerox copies of Partnership Deed / attested copy of Memorandum and Articles of Association.
5. Plan of the manufacturing premises showing the various sections with measurements and duly signed by the applicant and by a licensed surveyor.
6. Xerox copy of Rent Agreement Deed, rent receipt, Lease Deed.
7. List of machineries/ plants / equipment provided for the manufacture of the drugs and for the analysis of raw materials / finished products with xerox copies of purchase invoices.
8. Xerox copies of educational qualification certificate and previous experience certification in respect of manufacturing and analytical chemists.
9. Full time employee declaration of manufacturing chemists and analytical chemists.
10. Letter of undertaking for the analysis of raw material and finished products.
11. Other declaration letter.
12. Specimen Labels, in triplicate.
13. Therapeutic justification, method of analysis

14. List of drugs to be permitted to manufacture, in quadruplicate
15. Original Licenses in Form 25 & 28.
16. Latest Renewal Certificate.
17. Dissolution Deed.
18. Original list of drugs permitted to be manufactured under Licenses in Form 25/28.
19. Director's / Partner's / Proprietor's address proof, specimen signature & photograph. with attestation.
20. Address proof & photograph of chemists.
21. Copy of latest Property Tax receipt.

For 25A & 28A, in addition to the above following documents to be submitted:
1. Copy of wholesale License
2. Consent letter from the manufacturer where they live to have the loan license

Note: Extra fees need to be paid for more than 10 products under each category
(tablets capsules, Liquid orals, external preparations, injectables)

c) Areas under zones of Tamilnadu State Drugs Control Offices

Zone - I

Parrys Corner	Tondiarpet	Burma Bazaar
Park Town	Royapuram	Mannadi
George Town	Flower Bazaar	
Chennai central	Thiruvottiyur Tollgate	

Zone II

Purasaiwalkam	Nelson Manickam Road	Kolathur
Kilpauk	Choolai	Kodungaiyur
Anna Nagar	Ayanavaram	Muthamil Nagar
Aminjikarai	ICF	Maga Kavi Bharathi Nagar
MMDA Colony	Villivakkam	Ponniamman Medu
Arumbakkam	Perambur	Egmore

Zone III

Anna Salai	Nandanam	Ashok Nagar
Triplicane	Saidapet	K. K. Nagar
Chindadripet	CIT Colony	Alwarthirunagar
MGR Nagar	Adyar	Mylapore
Royapettai	Besant Nagar	Vadapalani
Foreshore Estate	Taramani	Kodambakkam
Saligramam	Thiruvanmiyur	Greams road
Greeenways Road	Velachery	Virugambakkam
Ekkathuthangal	T. Nagar	Guindy
Teynampet	West Mambalam	Alwarpet

Zone IV

Tambaram	Chrompet	Navaloor
Pallavaram	Tambaram Sanatorium	Sholinganallur
Guindy	Maraimalai Nagar	Padur
Meenambakkam	Mahindra City	Neelangarai
St. Thomas Mount	Vandaloor	Vettuvankarai
Palavanthangal	Kelambakkam	Pallavakkam
Alathur	Guduvancherry	Echambakkam
Thiruporur	Urapakkam	Duraipakkam
Kancheepuram Dist	Pallikaranai	Kumananchavadi
Chengalpet Dist	Medavakkam	Perungudi

Source: Director of Drugs Control, Tamilnadu

d) Check-list of document to be submitted by the Pharma manufacturers for Certificate of Pharmaceutical Product (COPP) as per WHO Certification Scheme for use in international commerce

1. Application with a copy to CDSCO.
2. Copy of Site Master File (SMF) mentioning all details as prescribed in WHO Technical Report Series (TRS) 823.
3. Lay-out plan of the premises showing the classification and pressure differential of the respective area.
4. List of Products (Applied / Approved) along with license Copy.
5. Export details (if already COPP approved) For last two years.
6. List of equipment with numbers and capacity.
7. Schematic diagram of Heating, Ventilation and Air Condition (HVAC) with configuration of filters / pressure differential.
8. Schematic Diagram of Water System with Material of Construction (MOC), sampling points and validation reports.
9. Building Management System (BMS), if any
10. Labels for all the products.
11. Annual Product Review.
12. Trend analysis.
13. Stability Data (Real Time / Accelerated), as specified in WHO TRS 863.
14. Process validation.
15. For New Drugs / Fixed Dose Combinations (FDC) NOC from Drugs Controller General of India [DCG(I)]

Source: CDSCO (SZ), Chennai

e) Check List For Bioequivalence Study For Export

Application for BE NOC for export should enclose the following documents:-

1. Application in Form 44 as per Schedule Y of Drugs & Cosmetics Act 1945.
2. Treasury Challan for Rs. 15000/- in case of the drug which is approved for more than one year.
3. Treasury Challan for Rs. 25000/- if the drug is a new drug approved within one year.
4. Undertaking by the investigator/consent letter duly signed.
5. Name of the centre for clinical Facility to be utilized for the BE study.
6. Is the B/E Centre recognized by this Directorate? If so, Copy of the same.
7. Name of the sponsor.
8. Protocols for Study.
9. In case of unapproved drugs following documents to be furnished:-
10. Pre-clinical/Clinical Data on Safety & Efficacy.
11. Regulatory Status.
12. Package Insert of the product circulated in countries, where it is being marketed.
13. Name of the countries where it is being marketed
14. Certificate of Analysis for the Test Product and Reference Product.
15. Clearly indicating whether the proposed BE studies are being conducted for export purposes or for domestic marketing.

f) Check List For Test License Application

1. Application on Form 12 clearly indicating the name of country, manufacturer, Generic Name, composition of drug and Therapeutic class.
2. Separate application with requisite fees should be filled for import of same drug from more than one country.
3. Treasury Challan should be in the head of A/C viz. 0210 Medical & public Health. 04-Public Health. 104-Fees and Fines.

Note: The following documents are also required to submitted:-

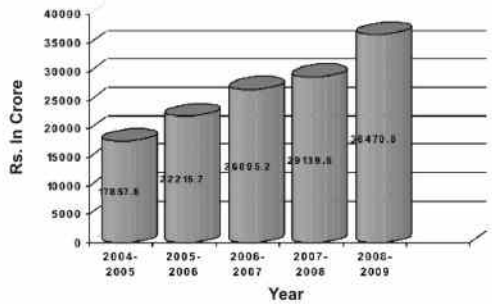
a) Copy of Manufacturing License / Form 29 issued by SLA / copy of Approval of the testing facility by the department of Sciences & Technology etc as applicable.
b) Purpose of import and detailed utilization indicating nature of test and quantity required for each test.
c) An undertaking that the drugs imported under test license would be used for tests & Analysis only should be enclosed.
d) Detailed information regarding import of same drug during last 3years along with certificate of destruction of unused drug from the competent regulatory Authority.
e) Application of Test License for import of drug for Be, studies should be submitted along with application for BE study approval only.
f) In case of Narcotic and Psychotropic drugs, the relevant Schedule of the NDPS act 1985 under which the drug falls is to be indicated.
g) No Test License will be issued in case of Banned Drugs.

Source: CDSCO website.

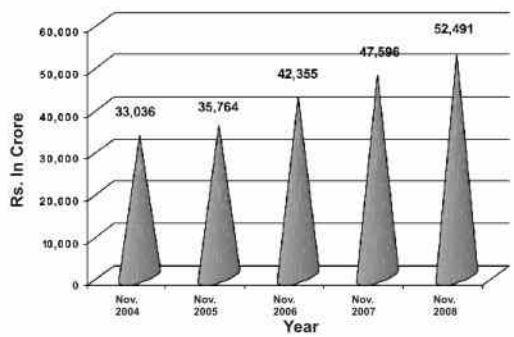
NEWS

(a) Statistical data of Pharmaceutical Products

Expanding Export of Indian Pharma Products to over 200 Countries



Expanding Domestic Pharma Market



Source: The Hindu, February 26, 2009

(b) Pharma Cos need to better quality: Panel

Pharma units, particularly those in the small scale sector, need to improve quality through proposed good manufacturing practices (Schedule M of Drugs and cosmetics Act) to fulfill the country's objective of creating a hub for drug manufacturing.

The amendments proposed in the Act are also important to protect interests of consumers, a committee headed by / Najma A Heptulla has said in a report submitted to parliament recently, adding that the government should support small scale by providing cheap institutional credit or interest subsidy. The report said support to small-scale pharma units becomes necessary, as "compliance with the amendments will require significant capital investment". Estimates suggest that it may involve investments of anywhere between Rs 20 Lakh to Rs. 2 Crore, to upgrade quality standards of these units. Amendments to Scheduled M were introduced in 2001, which led to closure of small units in certain states, while over half the industry claims to be Schedule M compliant.

Source: The Times of India, Chennai, Monday, March 9, 2009

(c) Domestic drug makers will not need WHO GMP Certificate

Domestic drug makers will no longer need a certificate of Good Manufacturing Practice (GMP) from the World Health Organisation (WHO) to sell their medicine within India. The Drug Controller General of India (DCGI) has asked the State Drug Controllers to let companies sell their brands in the country without the WHO's quality certificate, provided they comply with the quality norms set out in the Indian law.

COPP and WHO certification are compulsory if the company wants to export, a government official, who asked not to be named, said. The DCGI would not issue WHO-GMP certificate to any company from now on. "For marketing medicines within the country, only Schedule M certification under the Drugs and Cosmetics Act (DCA) is required. State regulators have been directed that they no longer need to insist for a WHO-GMP certificate from manufacturers while giving them marketing permission," the official said.

GMP is aimed at diminishing the risks inherent in pharmaceutical production. WHO-GMP Certificate is given based on certain guidelines laid down by WHO through which the regulator ensures that medicines and other medical products are consistently produced and controlled to the quality standards required for their best use.

The WHO-GMP certificate is a mandatory requirement in most global markets for companies to be able to sell their medicines. It is also required for specific drugs being supplied under the global disease control project to treat diseases like tuberculosis, malaria and AIDS>

However, the government claims that the Indian norms laid in the drug law are at par with the WHO-GMP guidelines and therefore there is no need to endorse the WHO norms. "We are also in talks with several international agencies in order to ensure that companies holding the COPP do not face problems in exports. It is important for the government as well to ensure that our own regulations find enough recognition in the international markets," the official said.

The drug regulator gives a COPP after conducting an inspection of the manufacturing plant. The certificate is valid for a period of two years. The Indian pharmaceutical market is estimated to be around Rs. 65,000 Crore. Out of this, export accounts for around Rs. 30,000 Crore.

Source: IDMA Bulletin, XL (7), 21st February 2009, page 39

(d) Government procurement of drugs and pharmaceuticals: IDMA Repn.

IDMA has submitted the following representation to the Secretary, Competition Commission of India, New Delhi on 30th December 2008

As you might be aware, different Central Government organizations have their own rules for their Drugs Tender. An important condition which is affecting our members is the turnover criterion for firms to be eligible to participate in the Tendor. The turnover criteria of some of the Central Government organizations are as follows:

SAIL (Particularly Bokaro Steels) (i) For Tablets for participation in tenders The company should be within 100 top ORG ranking manufacturers. (ii) For Injectables the Company should be within 200 top ORG ranking manufacturers.

Indian Railways (Kolkata) Purchase of medicine supplies only form manufactures having turnover of Rs. 50 Crore and above.

Directorate of Health Services, Government of Delhi the manufacturer should have an annual turnover of pharmaceutical products of Rs. 35 Crore or more per annum.

Because of such very high turnover criteria, most firms in the SME sector are virtually disqualified for participating in the tenders. We do realize that there has to be some minimum turnover criterion in any tender. But that has to be reasonable. A Rs 5 to 8 Crore threshold is acceptable but Rs. 35 and Rs. 50 Crore is grossly excessive and patently against the avowed Government policy of encouraging the SME sector but is also against the principles of competition.

We appreciate their anxiety for ensuring quality. However that can be taken care by more equitable methods. One such method is formulating criteria based upon quality certifications (as in Defence DGQA Certification) rather than turnover. It goes without saying that all participating firm must have a valid Schedule M Certificate from the Government.

Request: We request the Competition Commission to take notice of these anti-competitive practices and take action as deemed fit.

Thanking you in anticipation of your prompt and positive response.

(*Copy of the same has been submitted to joint Secretary, Shri Devendra Chaudhary, Department of Pharmaceuticals and Shri Madhav Lal, Development Commissioner, Ministry of MSME.)

Source: IDMA Bulletin, XL (1), 7th January 2009, page 6

(e) Delhi Pharmaceutical Trust's 13 minute Documentary Film "STORE WELL TO KEEP YOU WELL" CD is now available

Please send Rs. 300/- only per CD copy (including courier charges) by DD payable to Delhi Pharmaceutical Trust" and mail the envelope to

Dr. Manoj Dash
Delhi Pharmaceutical Trust,
C/o Multani Pharmaceutical Ltd.
C-100, Okhla Industrial Area, Phase I
New Delhi 110 020
Telefax - 011 23350063
Please allow 10 working days for you to receive the CD after the payment is received.

Source: IDMA Bulletin, XL (8), 28th February 2009, page 42

(f) Admission to M.S. (Pharm.); M.Pharm.; M.Tech. (Pharm); M.B.A. (Pharm.)

NIPER JOINT ENTRANCE EXAMINATION - 2009 (NIPER-JEE 2009)

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EVENTS

(a) Function - Release of "Pharma Web" first issue:-

The first issue of Pharma Web Newsletter of Tamilnadu Pharmaceutical Sciences Welfare Trust was released on 30th January 2009 at the meeting of Indian Pharmaceutical Association (TN Branch) in Chennai. The release was preceded by a technical lecture presented by Dr. D. Sampath Kumar Ph.D, General Manager R&D, Formulation Division, Shasun Chemicals and Drugs Ltd., Puducherry on the topic **Dissolution Method Development & Prediction of In-Vivo Performance -A Regulatory Perspective.**

Chief Guest Thiru. K. Sundara Swamy, Director of Drug Controll I/c, Tamilnadu, the then released the newsletter and Mr. S. S. Veerramani, Chairman and Managing Director, M/s. Fourrts (India) Laboratories Private Ltd., Chennai received the first copy.

The meeting was well attended by the members of IPA, industrialists, academicians and Chirman and Trustees of TMPSWT

(b) International Seminar at KMCH College of Pharmacy, Coimbatore

A one day international seminar on "Recent advances in LC/MS" was organized by KMCH College of Pharmacy, Coimbatore on Wednesday, 28th January 2009. LC/MS is one of the essential and advanced chromatographic techniques with mass spectrum used for the analysis and quantification of the drug. Dr. G. J. Samanathan, Advisor and Scientist-G, Department of Science and Technology, Ministry of Science and Technology, Govt. of India, New Delhi graced the occasion as Chief Guest. With a view to understand the fundamental concepts, techniques, method development and areas of application of LC / MS, the seminar included four brainstorming sessions. The seminar was attended by pharmaceutical professionals from industry, academia and research scholars from the various parts of the country and abroad.

The conference was presided over by Dr. Nalla G. Palaniswami, Chairman and Managing Director, KMCH; Felicitated by Dr. Thavamani D. Palaniswami, Managing Trustee, Kovai Medical Centre Research and Educational Trust and Dr. O. T. Buvaneswaran, Chief Executive Officer, Kovai Medical Centre Research and Educational Trust. Earlier Prof (Dr.) A. Rajasekaran, Principle KMCH College of Pharmacy had given the welcome address. Finally, Prof. J. Dharuman delivered the vote of thanks.

(c) Sri Ramachandra College - Continuing Education Programme

Sri Ramachandra College of Pharmacy, Sri Ramachandra University, organized a guest lecture as a part of Continuing Pharmacy education programme on 28/2/08 at Sri Ramachandra University. The programme was inaugurated by our Dean of Faculties, Professor Dr. K. V. Somasundram, Sri Ramachandra University. Our Principal, Professor. Dr. C. Uma Maheswara Reddy welcomed the gathering and Professor Dr. K. C. Chitra, Vice Principal, concluded the meeting with the vote of thatnks.

Professor Dr. James D Scott, from Western University of Health Sciences, California, USA, gave a lecture on **"Pharmacy Practice in HIV care".** He emphasized that adherence to therapy is crucial to the success of antiretroviral regimen and in the treatment and prophylaxis of opportunistic infections. The pharmacist plays a dominant and key role in improving patient compliance and prognosis of the patient.

Inaugural function of release of first issue of Pharma Web on 30th January 2009

Release of first issue of Pharma Web

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