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Pharma Web

Newsletter of Tamilnadu Pharmaceutical Sciences Welfare Trust

July - Aug. - Sep. 2012

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Tamilnadu Pharmaceutical
Sciences Welfare Trust

Pharma Web

Newsletter of Tamilnadu Pharmaceutical Sciences Welfare Trust

ISSUE : 15 July - Aug. - Sep. 2012

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EDITORIAL

Dear Readers,

We are happy to release 15th issue of **Pharma Web** for the period July-September 2012. This issue is sponsored by M/s Sri Ramachandra Medical Research Institute, Porur, Chennai. We are thankful to the management of Ramachandra University and Professor D Chamundeswari and Professor Uma Maheswar Reddy for accepting our request to sponsor this newsletter.

In this issue the profile and history of M/s Ramachandra University and Pharmacy courses conducted by them with details of their facilities and achievements are published. An article on the topic of **"Pharm D- A Perk To Pharmacy Profession"** written by faculties of pharmacy SRMC also published in this newsletter.

We have also published the third prized essay competition **on I am a Pharmacists- Why? By Ms Lilian Oigara,** Final year B Pharm, Periyar College of Pharmacy.

In order to benefit the Pharma industry we published Govt of India notification on the subject of Clinical trials, registration of Ethics Committee, Application and license forms for grant or renewal of loan license to manufacture Large volume Parenterals or Sera and Vaccine or Recombinant DNA derived drugs and allowing import of drugs through Bangalore and Goa Airports.

We are very glad to inform our readers that our trust office is renovated with modern facilities. A comfortable conference hall has been created with fully airconditioned and LCD projector etc. The conference hall can accommodate 20-25 persons for conducting any meeting. We hope the pharmaceutical manufacturers and the pharmacy college will utilize this conference hall for their meetings. There will be a very nominal rent for this hall. We are also providing back up electricity generator for continuous electricity.

One workshop was conducted for the benefit of pharmacy students on **"Professional Communication & Soft Skill Training"**. It was four days programme. About 17 pharmacy students participated in this training programme. Dr V Ravichandiran, Director, School of Pharmaceutical Sciences, Vels University and Mrs Pratima Mathur organised this programme.

We are thankful to M/s Delvin Pharmaceuticals, Chennai for conducting series of training programmes for their company employees in our renovated conference hall.

Our Trust office is acting as a Secretariat for the 64th Indian Pharmaceutical Congress to be held on 7-9 December 2012 at SRM University, Kattankulathur. We request all our Pharma professionals to take active part and also register as delegates for this congress.

We request our readers to give their views and comments about the contents and usefulness of **Pharma Web**. Your views will help us to improve the contents of our future Issues.

With best Regards,
R Narayana Swamy
Chief Editor

ARTICLES

PHARM D – A PERK TO PHARMACY PROFESSION

By
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Sri Ramachandra University, Porur, Chennai

Pharmacy profession in India has its way long back to the 18th century as in the United States. The seed of Pharmacy education was sown in 1860 at Madras Medical College, Madras, in the form of a training program to impart pharmaceutical skills for those intending to become chemists and druggists, which later became a two years Diploma course in Pharmacy. The first graduate course in pharmacy education in India originated in Benaras Hindu University in 1937 with the start of Bachelor in Pharmacy course. Since then, there has been a marked increase in the number of institutions in India offering the Diploma in Pharmacy, Bachelor in Pharmacy and the Master in Pharmacy programs.

Pharmacy has evolved into a clinical profession and the pharmacy education has become practice oriented in many developed countries since past few decades. But in India, the Pharmacy curriculum was more product oriented and focused to cater the needs of the Pharmaceutical industries rather than the patient community. Pharmacists graduated from Indian institutions as "drug experts" than as "health experts".

Over a period of time, there was tremendous need for the pharmacists' role in the Indian healthcare system, due to a grave shortage of medical professionals and an increase in the incidence of diseases and number of medications leading to irrational use of medications. These reasons have impelled the Pharmacy Council of India to start the Pharm D program in India in 2008, with an aim to groom the future Indian pharmacists with skills to provide better patient care by promoting safe, effective and appropriate use of medications.

Pharm D or Doctor of Pharmacy is a 6 year Degree course in Pharmacy designed to train the Pharmacy students to gain scientific knowledge and practical skills in a patient care set up, thus enabling them competent to their western counterparts, as Pharm D is the first professional degree and a prerequisite for licensing to practice Pharmacy profession in many of the developed countries. The Pharm D curriculum is devised into two phases consisting of first five years of academic and clinical training and one year of residency program in various specialty units of a hospital in the sixth year.

The Pharm D syllabus in India is oriented both towards industry and patient care. The subjects for the first three years of study is similar to that of B. Pharmacy course emphasising on Pharmaceutical analysis, Medicinal chemistry, Phytopharmaceuticals, Pharmacology and Pharmaceutics. Pharmacotherapeutics, Clinical, Hospital & Community Pharmacy, Clinical research, Pharmacokinetics and Therapeutic drug monitoring and Pharmacoeconomics are the subjects that are discussed in the fourth and fifth year of curriculum. In contrary to this, in Western countries the Pharm D curriculum is more patient focused and fully clinically oriented.

Pharm D graduates from India have diverse career opportunities in the fields of community and clinical practices by providing patient counselling, rendering health screening services, optimizing drug therapy and clinical outcomes, provide drug information services, in hospital pharmacy departments by involving in various activities like drug dispensing, drug therapy management and drug use evaluation. Pharm D graduates can also have a broad scope in pharma industries in

manufacturing, marketing and regulatory affairs. As the Pharm D graduates have knowledge related to drug development and therapeutics they can acquire unique positions to conduct clinical trials in various disease areas. The Pharm D graduates have career oppurtunities in the US to practice as Pharmacists for which they have to clear the licensure exams.

Though the Pharm D course was introduced in India with the approval of Government of India, to take the Indian Pharmacists to International standards in provision of patient care, the concept of clinical pharmacy practice and pharmaceutical care is still unaccustomed in India and the role of the pharmacists in clinical and hospital settings is not well recognised. The job opportunities for the Pharm D graduates in hospitals in India is unclear and even if jobs are assured the salary that they would get is unaccountable.

Pharm D graduates are best suited to potentially fill the gap created by the increase in population and shortage of doctors and nursing personnel in health facilities. This can be achieved through modifications in the health policies by the Central and the State governments to give considerable recognition for the Pharmacy profession and take initiatives to mandate the role of pharmacists in the health care setups, so as to better utilise their capabilities in the provision of better patient care. In doing so, the Pharmacy profession in India would be given a facelift among the medical fraternity and pharmacists would be accepted as a pivotal part of the interdisciplinary health care team.

Though Pharmacy council of India is taking necessary steps to strengthen the Pharmacy practice system in India, more emphasis should be given by the council to the Government of India to make necessary modifications in the health care policies of the government and give due recognition to the Pharm D graduates to start their career in academics and in Drug control departments.

Editorial Policy and Disclaimer

The objective of this newsletter is to impart current news to the readers and the newsletter is circulated free of cost. Description or reference to any information or publication does not implement endorsement by us.

Every effort has been made to ensure the timeliness and accuracy of information presented in this newsletter. The authors, editors and publisher will not in any way be held responsible for the timeliness of information, errors, omissions and inaccuracies in this publication. Users are advised to recheck the information with original resource material before applying to patient care or other purpose.

This issue of Pharma Web is also available online at the Trust website www.pictrust.com

I AM A PHARMACIST WHY?

By
Ms. Lilian Oigara – Final Year B.Pharm
Periyar College of Pharmacy, Trichy

A pharmacist is a health care professional prepared to formulate, dispense and provide clinical information on drugs or medications to health professionals and patients, through completion of a university program in pharmacy and passing state and federal license exam.

Pharmacist can work as an academic pharmacist to teach and do research in colleges and schools of pharmacy, ambulatory pharmacist to manage patients at risk of experiencing drug related problems, community pharmacist to give advice to customers on how to use prescribed medications, clinical pharmacists to provide variable drug information as well as monitoring drug interactions and drug therapy, as home care pharmacists to prepare injectables and deliver item to patients who are critically ill at home, as hospital pharmacists to dispense medications and advice the medical stuff on the selection and effects of drugs in hospitals and clinics, as industrial pharmacists to advance in marketing, sales research, quality control, production, packaging, as managed care pharmacists to work for health maintenance organization for managing and planning prescription drug use. as nuclear pharmacist to compound and dispense radioactive materials for use in nuclear procedures, as radio pharmacists to dispense radioactive pharmaceuticals used for patient diagnosis and therapy and as research pharmacist to develop new drugs and study the side effects of drugs.

For one to be called a pharmacist, he has to attain certain level of education, possess pharmacist's qualities and perform pharmacist's responsibilities. The level of education differs from one region top another. For example, in USA one has to attain Pharm D whereas in India a diploma or a degree in pharmacy is enough for one to be registered as a pharmacist.

Every person possesses qualities that qualify him to be what he is. On that note, pharmacists should have qualities that qualify them as pharmacists. These are; one, excellent communication skills to speak on professional level with peers and doctors and in layman's terms to the patient. Two, excellent interpersonal skills to deal with doctors, patients and other stall on daily basis. Three, leadership skill to supervise the work of technicians and assistants. Four, sharp analytical skills to reach conclusion based on information presented by patients, doctors and new research. Five, a good memory to easily recall drugs, side effects and interactions. Six. consciousness to pay close attention to detail in everything they do on the job- Seven, counseling skills to counsel patients on how their prescribed drugs work and what they expect after taking them. Eight, computer skills to use software programs to lake new orders, find drug information and manage inventory. Nine, they should he interested in continuing education opportunities for new research and development in industry. Ten, they should have a solid background in science including chemistry and biochemistry. In addition to possessing pharmacist qualities, a pharmacist has to perform various responsibilities without which he is useless. Among the various responsibilities are distribution of prescription drugs to individuals. They also advise their patients, as well as physicians and other health practitioners, on the selection, dosages, interactions, and side effects of medications.

Pharmacists monitor the health and progress of patients to ensure the safe and effective use of medication. Pharmacists in community pharmacies dispense medications, counsel patients on the use of prescription and over-the

-counter medications, and advise physicians about patients' medication therapy. They also advise patients about general health topics such as diet, exercise and stress management and provide information on products such as durable medical equipment or home health care supplies. In addition, they may complete third-part insurance forms and other paperwork. Those who own or manage community pharmacies may sell non-health-related merchandise, hire and supervise personnel and oversee the general operation of the pharmacy. Some community pharmacists provide specialized services to help patients with conditions such as diabetes, asthma, smoking cessation or high blood pressure. Others also are trained to administer vaccinations.

Pharmacists in health care facilities dispense medications and advise the medical staff on the selection and effects of drugs. They may make sterile solutions to be administered intravenously. They also plan, monitor and evaluate drug programs or regimens. They may counsel hospitalized patients on the use of drugs before the patients are discharged. Pharmacists who work in home health care monitor drug therapy and prepare infusions.

Most pharmacists keep confidential computerized records of patients' drug therapies to prevent harmful drug interactions. Pharmacists are responsible for the accuracy of every prescription that is filled, but they often rely upon Pharmacy technicians and pharmacy aides to assist them in the dispensing process. Thus, the pharmacist may delegate prescription-filling and administrative tasks and supervise their completion. Pharmacists also frequently oversee pharmacy students and train them in various aspects.

Increasingly, pharmacists are pursuing non-traditional pharmacy work. Some are involved in research for pharmaceutical manufacturers, developing new drugs and testing their effects. Others work in marketing or sales, providing clients with expertise on the use, effectiveness, and possible side effects of drugs. Some pharmacists work for health insurance companies, developing pharmacy benefit packages and carrying out cost-benefit analyses on certain drugs. Other pharmacists work for the government managed care organizations, public health care services, the armed services or pharmacy associations. Finally, some pharmacists are employed full time or part time as college faculty, teaching classes and performing research in a wide range of areas.

Indeed I am a pharmacist. Why? Because. I have attained the minimum qualification of a pharmacist. 1 possess the qualities of a pharmacist and perform the responsibilities of a pharmacist. Last but not least. I live and work according to the pharmacists oath to protect the health and safety of society. I am proud to be a pharmacist.

Note: The above article an extract of the Essay Competition on the subject of "I am a Pharmacist Why?" which was awarded Third Prize by TNPSWT

Recent Edition of WHO Technical Series books are available in our Trust Library

1) WHO Expert Committee on Biological Standardization Fifty-ninth report - WHO Technical Report Series 964, 2) Roadmap to prevent and combat drug-resistant tuberculosis, 3) WHO Expert Committee on Specifications for Pharmaceutical Preparations Forty-sixth report - WHO Technical Report Series 970, 4) The Selection and Use of Essential Medicines Report of the WHO Expert Committee, 2011-WHO Technical Report Series 965, 5) WHO Drug Information Volume 26, 2012, 6) The evolving threat of antimicrobial resistance - Options for action.

NOTIFICATIONS

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health)

NOTIFICATION

New Delhi, the 17th July, 2012

G.S.R. 572(E). - The following draft rules further to amend the Drugs and Cosmetics Rules, 1945, which the Central Government proposes to make, in exercise of the powers conferred by section 12 and section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), after consultation with the Drugs Technical Advisory Board, is hereby published for the information of all persons likely to be affected thereby, and the notice is hereby given that the said draft rules shall be taken into consideration on or after the expiry of a period of forty-five days from the date on which the copies of the Gazette of India containing these draft rules are made available to the public;

Any person interested in making any Objection or suggestion on the proposed draft rules may do so in writing for consideration of the Central Government within the period so specified through post to the Secretary, Ministry of Health and Family Welfare, Government of India, Nirman Bhawan, New Delhi - 110011.

DRAFT RULES

1. (1) These rules may be called the Drugs and Cosmetics (3rd Amendment) Rules, 2012.

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

2. In the Drugs and Cosmetics Rules, 1945, in Part X-A, after rules 122 DAB, the following rule shall be inserted, namely:-

   "122 DAC. (1). Permission to conduct Clinical Trial.- The licensing authority as defined in clause (b) of rule 21, after being satisfied that the data submitted along with the application in support of proposed Clinical trial is adequate, shall issue permission to conduct clinical trial subject to the following conditions, along with any other specific trial related condition(s) as

   (a) Clinical trial shall be conducted in compliance to the approved protocols, requirements of Schedule Y, 'Good Clinical Practice (GCP)' Guidelines for Clinical Trials in India and other applicable regulations.

   (b) Approval of the Ethics Committee shall be obtained before initiation of the study.

   (c) Ethical aspects of the clinical trial as described in the "Ethical Guidelines for Biomedical Research on Human Participants" published by Indian Council of Medical Research (ICMR), New Delhi shall be complied with.

   (d) Clinical trial shall be registered at Clinical Trials Registry - India (CTRI) before enrolling first patient in the study.

   (e) Annual status report on clinical trial viz. ongoing, completed or terminated shall be submitted to the licensing authority. In case the trial is terminated, the detailed reasons for the same shall be communicated to the said licensing Authority.

   (f) Any Suspected Unexpected Serious Adverse Reaction (SUSAR) occurring during clinical trial shall be communicated

within fourteen calendar days to Licensing Authority and to the other investigator(s) participating in the study, as per Appendix XI of Schedule Y.

(g) In case of study related inury or death, the applicant will provide complete medical care as well as compensation for the injury of death and statement to this effect shall be incorporated in the Informed Consent Document. Further, the details of compensation provided shall be intimated to the licensing authority.

(h) The premises of sponsor / Clinical Research Organization and clinical trial sites shall be open to inspection by the officer of Central Drugs Standard Control Organization, who may be accompanied by an officer of the concerned State Drug Control Authority, to verify compliance to the requirements of Schedule Y, Good Clinical Practices guidelines and other applicable regulation.

(i) The Sponsor/Clinical Research Organization, Investigators shall allow officer of Centra Drugs Standard Control Organization, who may be accompanied by an officer of the concerned State Drug Control Authority, to enter with or without prior notice, any premises of sponsor/ Clinical Research Organization, clinical trial site to inspect, search seize any record, data, document, books, Investigational drugs etc. related to clinical trials and provide adequate replies to any queries ralsed by the inspecting authority in relation to the conduct of clinical trial.

(2) If any sponsor/Clinical Research Organization, investigators conducting clinical trial fail to comply with any of the above condition the Licensing Authority may after giving an opportunity to show cause why such an order should not be passed, by an order in writing stating the reason thereof take following action:

(a) Issue warning letter giving details of deficiency found during the inspection, which might affect the right or well being of subject or the validity of the study conducted at the site.

(b) Recommendation that study may be rejected.

(c) Suspension / cancellation of clinical trial permission.

(d) Restriction of an Investigator, sponsor / Clinical Research Organization, to conduct future clinical trial.

(3) The sponsor / Clinical Research Organization, investigators against whom action as mentioned above has been taken by the licensing authority, may within ninety days of the receipt of the copy of the order by him prefer an appeal to the Central Government and the Central Government may after giving an opportunity of being heard, confirm, reverse or modify such order".

[F.No. X-11014/9/2011-DFQC]

ARUN K. PANDA, Jt. Secy.

Foot 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. 76(E) dated the 8th February, 2012.

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health)

NOTIFICATION

New Delhi, the 17th July, 2012

G.S.R. 573(E). - The following draft rules further to amend the Drugs and Cosmetics Rules, 1945, which the Central Government proposes to make, in exercise of the powers conferred by section 12 and section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), after consultation with the Drugs Technical Advisory Board, is hereby published for the information of all persons likely to be affected thereby, and the notice is hereby given that the said draft rules shall be taken into consideration on or after the expiry of a period of forty-five days from the date on which the copies of the Gazette of India containing these draft rules are made available to the public;

Any person interested in making any Objection or suggestion on the proposed draft rules may do so in writing for consideration of the Central Government within the period so specified through post to the Secretary, Ministry of Health and Family Welfare, Government of India, Nirman Bhawan, New Delhi - 110011.

DRAFT RULES

1. (1) These rules may be called the Drugs and Cosmetics (4rd Amendment) Rules, 2012.

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

2. In the Drugs and Cosmetics Rules, 1945, (hereinafter referred to as the said rules), after rule 122 DC, the following rule shall be inserted, namely:-

   "122 DD. Registration of Ethics Committee (EC).- (1) No Ethics Committee shall review and accord its approval to a clinical trial protocol without prior registration of the committee with the licensing authority as defined in clause (b) of rule 21.

(2) An application for registration of ethics committee shall be made to the licensing authority in accordance with the requirements prescribed in Schedule Y-I.

(3) The licensing authority after being satisfied that the requirements of the rules have been complied with and the conditions of the registration with be observed, may grant registration subject to the condition stated therein.

(4) The ethics committee will review and accord its approval to a clinical trial as per Schedule Y, the Good Clinical Practice Guidelines for Clinical Trials in India and other applicable regulatory requirements for safeguarding rights, safety and well being of the trial subjects.

(5) In case of clinical trial related injury or death, the ethics committee shall review the serious adverse event reports and recommend for providing compensation. The quantum of the compensation to be paid by the sponsor shall be decided by the ethics committee in accordance with the concurrence of Ministry of Health and Family Welfare for the purpose.

(6) The ethics committee shall allow inspectors / officials of Central Drugs Standard Control Organization to enter the premises of the committee to inspect any record data document etc. related to clinical trial and provide adequate replies to any queries raised by the inspecting authority in relation to the conduct of clinical trial.

(7) The registration, unless it is sooner suspended or cancelled, shall be valid for a period of five years from the date or issue.

(8) If the licensing authority is not satisfied, he shall reject the application and shall inform the applicant of the reasons for such rejection and the conditions which must be satisfied before the registration can be granted.

(9) If the ethics committee fails to comply with any of the conditions of registration, the licensing authority may after giving an opportunity to show cause why such an order should not be passed, by an order in writing stating the reasons therefor, suspend or cancel the registration of the ethic committee for such period as considered necessary.

(10) The ethics committee whose registration has been suspended or cancelled by the licensing authority, may within ninety days of the receipt of the copy of the order by him prefer an appeal to the Central Government and the Central Government may after giving an opportunity of being heard, confirm, reverse of modify such order.

Explanation:

For the purpose of this part an Ethics Committee is a committee comprising of medical / scientific and non-medical / non-scientific members, whose responsibility is to verify the protection of the rights, safety and well-being of human subjects involved in a clinical trial. Ethics Committees may be named as: (1) Institutional Review Board, (2) Ethics Review Board or (3) Independent Ethics Committees set up for the purpose outside the institute. The Ethics Committee shall be responsible for reviewing and approving the Protocol, the suitability of the investigator(s), facilities, methods and adequacy of information to be used for obtaining and documenting "Informed Consent" of the study subjects and adequacy of confidentiality safeguards".

(3) In the said rules, after Schedule Y, the following Schedule shall be inserted, namely:-

SCHEDULE Y
(See rule 122 DD)

Requirement and Guidelines for registration of Ethics Committee

1. Scope:

Ethics committee shall review every research proposal on human subjects and should evaluate the possible risks to the subjects, expected benefits and adequacy of documentation for ensuring privacy, confidentiality and justice. in case of clinical trial related injury or death the ethics committee should review and make recommendations for compensation to be paid by the sponsor in stipulated manner and time period.

These guidelines are not stand alone guidelines and are not in derogation of any other rules or guidelines applicable to the clinical trials.

2. Composition of Ethics Committee:

(a) Ethics committee should have at least seven members and should appoint from among its member a Chairperson (who is from outside the Institute) and a Member Secretary, other member should be mix of Medical / Scientific and nonmedical / Non Scientific members including lay public as specified in Appendix VIII of Schedule Y.

(b) The committee must include at least on member whose primary area of interest / specialization is non-Scientific and at least on member who is independent to institution.

(c) The Ethics committee should have as its members, individuals from other Institutions or Communities if required

(d) Members should be conversant with the provisions of clinical trials under the Schedule Y, Good Clinical Trial Practice Guidelines for clinical trials in India and other regulatory requirements to safeguard the rights, safety and well being of the trial subjects.

(e) The members representing as basic medical scientists and clinicians should have Post graduate qualification and adequate experience in their respective fields and aware of their role and responsibilities as committee members.

(f) Based on the requirement of research area e.g. HIV, Genetic disorder etc, specific patient group may also be included in the ethics committee as far as possible.

(g) There should be no conflict of interest. The members shall voluntarily withdraw from the ethics committee while making a decision on an application which evokes a conflict of interest which should be indicated in writing to the Chairperson prior to the review and should be recorded so in the minutes.

(h) Subject experts or other experts may be invited to the meetings for their advise but would not be having any voting rights.

3. Information required to be submitted by the applicant for registration of Ethics Committee:

(a) Name of the Ethics Committee

(b) Authority under which the ethics committee has been consitituted, membership requirements, the term of reference, conditions of appointment and the quorum required.

(c) The procedure for resignation, replacement or removal of members.

(d) Address of the office of the ethics committee.

(e) Name, address, qualification, organizational title, telephone number, fax number, e-mail, mailing address and brief profile of the Chairperson.

(f) Names, qualification(s), organizational title, telephone number, fax number, e-mail and mailing address of the members of ethics committee. The information should also include member's specialty (primary, scientific or non-scientific), member's affiliation with institution(s) and patient group representation, if any

(g) Details of the supporting staff.

(h) Type of research reviewed by the committee (e.g. pharmaceuticals, devices, epidemiological, retrospective, herbals etc.).

(i) Documents reviewed for every clinical trial protocol.

(j) Information in respect of number of meetings of the committee and documentation of the minutes of these committees concerning clinical trials.

(k) The information regarding review of serious adverse events reported during the conduct of the trial.

(l) The Standard Operative Procedures to be followed by the committee in general.

(m) Standard Operative Procedures followed by the committee for vulnerable population.

(n) Policy regarding training for new and existing committee members along with Standard Operative Procedures.

(o) Policy to monitor / prevent the conflict of interest along with Standard Operative Procedures.

(p) Has the committee been audited or inspected before? If yes, by whom.

(q) If the committee has been audited or inspected before, give details.

4. Maintenance of Record:

All documentation and communication of an ethics committee are to be dated, filed and preserved according to the Standard Operative Procedures. Strict confidentiality

is to be maintained during access and retrieval procedures. Records should be maintained for the following:-

1. The constitution and composition of the ethics committee members;
2. The curriculum vitae of all the committee members;
3. Standard Operating Procedures followed by the committee;
4. National and international guidelines;
5. Copies of the Protocol, data collection formats, Case Report Forms, investigational brochures etc. submitted for review;
6. All correspondence with committee members and investigators regarding application, decision and follow up;
7. Agenda of all ethics committee meetings;
8. Minutes of all ethics committee meetings with signature of the Chairperson;
9. Copies of decisions communicated to the applicants;
10. Record of all notification issued for premature termination of a study with a summary of the reasons;
11. Final report of the study including microfilms, Compact Disks and / or Video-recordings.

All records must be safely maintained after the completion / termination of the study for not less than five years from the date of completion or termination of the trial.

5. The Ethics committee shall be open for inspections by the officers of Central Drugs Standard Control Organization to verify compliance to the requirements of Schedule Y, Good Clinical Practices guidelines and other applicable regulations".

[F.No.X-11014/8/2011-DFQC]

ARUN K. PANDA, Jt. Secy.

Foot 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. 76(E), dated 8-2-2012.

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health)

NOTIFICATION

New Delhi, the 17th July, 2012

G.S.R. 574(E). - Whereas, a draft of certain rules further to amend the Drugs and Cosmetics Rules, 1945, was published, as required by Sections 12 and 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), vide notification of the Government of India in the Ministry of Health and Family Welfare (Department of Health), number G.S.R. 557(E), dated the 21st July, 2011 in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), dated the 21st July, 2011, inviting objections and suggestions from all persons likely to be affected thereby before the expiry of a period of forty five days from the date on which the copies of the Official Gazette in which this notifications is published are made available to the public;

And whereas, copies of the Gazette were made available to the public on the 2nd August, 2011;

And whereas, no comments or suggestions have been received from the public on the said draft rules or;

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

1. (1) These rules may be called the Drugs and Cosmetics (3rd Amendment) Rules, 2012.

   (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 75A, -

   (a) After sub-rule (1), the following sub-rule shall be inserted, namely:-

   "(1A) The application for grant or renewal of loan licence to manufacture for sale or distribution of drugs in 'Large Volume Parenterals', 'Sera and Vaccine' and 'Recombinant DNA(r-DNA) derived drugs' shall be made to the licensing authority appointed under this Part, in Form 27 DA and be made upto ten items for each category of drugs categorized in Schedule M and accompanied by a licence fee of six thousand rupees and an inspection fee of one thousand five hundred rupees for every inspection or for the purpose of renewal of licences :

   Provided theat if the application for renewal of a licence is made after its expiry but within six months of such expiry, the fee payable for renewal of the licence shall be six thousand rupees plus an additional fee of one thousand rupees per month or a part thereof in addition to the inspection fee of one thousand and five hundred rupees".

   (b) In sub-rule (2), the proviso shall be omitted.

3. In rule 76A of the said rules, for the heading and in the portion beginning with the words, "A loan licence to manufacture" and ending with the words "issued in Form 28 A, and the", the following words, letters, brackets and figures shall be substituted, namely:-

   "Forms of loan licences to manufacture for sale or for distribution drugs specified in Schedule C and C1 excluding drugs specified in Schedule X or of Large Volume Parenterals, Sera and Vaccine and recombinant DNA (r-DNA) derived drugs, and conditions for the grant or renewal of such licences, A loan licence to manufacture for sale or for distribution of drugs specified in Schedules C and C(1), excluding drugs specified in Schedule X, and Large Volume Parenterals, Sera and Vaccine and Recombinant DNA (r-DNA) derived drugs specified in Part X-B shall be issued in Form 28A and a loan licence to manufacture for sale or for distribution of Large Volume Parenterals, Sera and Vaccine and Recombinant DNA (r-DNA) derived drugs shall be issued in Form 28 DA, and the".

4. In rule 78A of the said rules,

   (a) in the heading and sub-rule (1), for the word, figures and letter "Form 28A", the words, figures and letters, "Form 28A or Form 28 DA", shall be substituted;

   (b) for the word and figures, "Form 28", the words, figures and letter, "Form 28 or Form 28D", shall be substituted.

5. In rule 83 A of the said rules, for the words, figures and letters, "Form 28A shall be issued in Form 26A", the words, figures and letters, "Form 28A or Form 28DA shall be issued in Form 26A or Form 26J respectively".

6. In rule 83AA of the said rules,-

   (a) for the word, figures and letter, "Form 28A", the words, figures and letters, "Form 28A or Form 28DA", shall be substituted;

   (b) for the word, figures and letter, "Form 26A" the words, figures and letters, "Form 26A or Form 26J" shall be substituted.

7. In Schedule A of the said rules,-

(a) after Form 26I, the following Form shall be inserted, namely:-

"Form 26J

[see rule 83 A and 83 AA]

Certificate of renewal of loan licence to manufacture for sale of Large Volume Parenterals or Sera and Vaccine or Recombinant DNA(r-DNA) derived drugs specified in Schedule C and C-1 excluding those specified in Schedule X.

1. Certified that Licence No. ..... granted on the ..... to .....for the manufacture of following Large Volume Parenterals or Sera and Vaccine or Recombinant DNA(r-DNA) derived drugs at the premises situated at ..... has been renewed from ..... to .....

2. Name(s) of drug(s) .....
(each item to be separately specified)

3. Name(s) of competent technical staff :

(a) responsible for manufacturing	(b) responsible for testing
1.	1.
2.	2.
3.	3.

Signature .....
Designation .....
Licensing Authority
.....
Central Licence Approving Authority

Date .....]",

(b) after Form 27D, the following Form shall be inserted, namely:-

"FORM 27 DA

(see rule 75A)

Application for grant or renewal of a loan licence to manufacture for sale or for distribution of Large Volume Parenterals/Sera and Vaccine/Recombinant DNA (r-DNA) derived drugs excluding those specified under Schedule X.

1. I/We* .....of # ..... hereby apply for the grant/renewal of a loan licence to manufacture on the premises situated at c/o @ ..... the under mentioned drugs being Large Volume Parenterals/Sera and Vaccine/Recombinant DNA (r-DNA) derived drugs specified in Schedules C, C(1), excluding those specified in Schedule X to the Drugs and Cosmetics Rule, 1945.

2. Name(s) of drugs .....

(each item to be separately specified)

3. The name(s), qualifications and experience of the competent technical staff responsible for the manufacture and testing of the above mentioned drugs,

(a) Name(s) of competent technical staff responsible for testing .....

(b) Name(s) of competent technical staff responsible for manufacture .....

4. I/We enclose:

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

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

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

5. A fee of rupees ..... has been credited to Government under the head of account .....

Date .....

Signature .....

Designation .....

* Enter her name of the proprietor, partner or Managing Director, as may be.

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

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

(c) after Form 28D, the following Form shall be inserted, namely:-

"FORM 28 DA

(see rule 76A, 78A, 83AA)

Loan licence to manufacture for sale or for distribution of Large Volume Parenterals/Sera and Vaccine/Recombinant DNA (r-DNA) derived drugs excluding those specified under Schedule X.

Number of licence ..... and date of issue .....

1. ..... of ..... is hereby granted a loan licence to manufacture on the premises situated at ..... c/o .....the following drugs being Large Volume Parenterals/Sera and Vaccine/Recombinant DNA (r-DNA) derived drugs specified in Schedules C, C(1), excluding those specified in Schedule X to the Drugs and Cosmetics Rules, 1945.

1. Name of drugs .....

2. Name(s) of competent technical staff .....

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

4. The licence authorizes the sale by way of wholesale dealing by the licensee and storage for sale by the licensee of the drugs manufactured under the licence subject to the conditions applicable to licence for sale.

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

Date .....

Signature .....

Designation .....

Licensing Authority

.....

Central Licence Approving Authority

Conditions of Licence

1. This licence and any certificate of renewal in force shall be kept on the approved premises and shall be produced at the request of an Inspector appointed under the Drugs and Cosmetics Act, 1940.

2. Any change in the competent technical staff shall be forthwith reported to the Licensing Authority and Central Licence Approving Authority.

3. If the licensee wants, during the currency of the licence, to manufacture for sale additional items of drugs not included above, he should apply to the Licensing Authority and/or Central Licence Approving Authority for the necessary endorsement as provided in the rules. This licence will be deemed to extent to the items so endorsed.

4. The licensee shall inform the Licensing Authority and/or Central Licence Approving Authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the licensing Authority and/or Central Licence Approving Authority in the name of the firm with the changed constitution".

[F.No. X-11014/3/2010-DFQC]

ARUN K. PANDA, Jt. Secy.

Foot note: The principal rules were published in the Official Gazette vide notification number F.28-10/45-H(I) dated the 21st December, 1945 and last amended vide notification number G.S.R. 76(E) dated the 8-2-2012.

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health)

NOTIFICATION

New Delhi, the 17th July, 2012

G.S.R. 575(E). Whereas certain draft rules further to amend the Drugs and Cosmetics Rules, 1945, were published, as required by sections 12 and 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), vide notification of the Government of India, Ministry of Health and Family Welfare (Department of Health), number GSR 853(E) dated the 1st December, 2011, in the Gazette of India, Extraodinary, Part II, Section 3, Sub-section (i), dated the 1st December, 2011, inviting objections and suggestions from all persons likely to be affected thereby before the expiry of a period of forty-five days from the date on which the copies of the Official Gazette containing the said notification were made available to the public;

G.S.R. 575(E). Whereas certain draft rules further to amend the Drugs and Cosmetics Rules, 1945, were published, as required by sections 12 and 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), vide notification of the Government of India, Ministry of Health and Family Welfare (Department of Health), number GSR 853(E) dated the 1st December, 2011, in the Gazette of India, Extraodinary, Part II, Section 3, Sub-section (i), dated the 1st December, 2011, inviting objections and suggestions from all persons likely to be affected thereby before the expiry of a period of forty-five days from the date on which the copies of the Official Gazette containing the said notification were made available to the public;

And whereas copies of the Gazette in which the said notification was published were made available to the public on the 7th December, 2011;

And whereas, objections and suggestions received in respect of the said draft rules have been considered by the Central Government;

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

1. (1) These rules may be called the Drugs and Cosmetics (4th Amendment) Rules, 2012.
   (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 43-A, for the words "Chennai, Kolkata, Mumbai, Cochin, Nhava Sheva, Kandla and Inland Container Depots at Tuglakabad and Patparganj, Delhi and Tuticorin in Tamil Nadu: in respect of drugs imported by sea into India. Chennai, Kolkata, Mumbai, Delhi, Ahmedabad and Hyderabad: in respect of drugs imported by air into India", the words "Chennai, Kolkata, Mumbai, Cochin, Nhava Sheva, Kandla, Inland Container Depots at Tuglakabad and Patparganj in Delhi, Tuticorin in Tamil Nadu and Marmugoa port in Goa: in respect of drugs imported by sea into India. Chennai, Kolkata, Mumbai, Delhi, Ahmedabad, Hyderabad, Goa and Bengaluru: in respect of drugs imported by air into India." shall be substituted.

[F.No.X-11014/4/2011-DFQC]
ARUN K.PANDA, Jt. Secy.

Foot Note: The principal rules were published in the Official Gazette vide notification No.F.28-10-45-H, dated 21st December, 1945 and last amended vide number G.S.R.76(E) dated the 8th February,2012.

Note: The above notification allows import of Drugs, Pharmaceuticals, Cosmetics and Medical devices through Bangalore and Goa Airports.

SRI RAMACHANDRA UNIVERSITY, CHENNAI
PROFILE & HISTORY

ABOUT SRI RAMACHANDRA UNIVERSITY

Sri Ramachandra University (SRU) was established in the year 1985 as a part of the Sri Ramachandra Education &Health Trust under the leadership of Shri N.P.V. Ramasamy Udayar. Over two decades, the institution has transformed into a full-fledged University with nine constituent colleges/faculties and around 100 courses in the health care sciences. More than 4300 students receive teaching and training within the University campus. SRU is committed to advancement in medical education, healthcare and research and is set to achieve a greater level of excellence in all these fields. The National Assessment and Accreditation Council (NAAC), an accrediting body of the UGC, has accredited SRU with 'A' grade with a CGPA of 3.52 on a four point scale, the highest to be awarded for a private medical University in India. The Joint Commission International (JCI) has accredited the University teaching hospital, the first teaching hospital in India to obtain such accreditation from JCI. The University established a Central Research Facility in 25,000 Sq.ft which houses high end sophisticated instruments to meet the needs of students, research scholars & faculties in the field of basic & applied research.

Faculty of Pharmacy, a constituent college of SRU, started in 1993, has taken rapid strides in the last one decade with the aim of providing a perfect ambience for the pursuit of excellence in pharmacy education and research. The institution offers B.Pharmacy, M.Pharmacy degree in six branches (Pharmacy Practice, Pharmaceutics, Quality Assurance, Pharmacognosy, Pharmaceutical analysis and Pharmacology), Pharm.D (Doctor of Pharmacy) and Pharm.D (Post Baccalaureate) programs. The B.Pharm, Pharm D and Pharm D (Post Baccalaureate) courses are approved by the Pharmacy Council of India (PCI), New Delhi, and the M. Pharmacy and B. Pharmacy courses are approved by the All India Council for Technical Education (AICTE), New Delhi. The B.Pharmacy course is accredited by National Board of Accreditation (NBA), AICTE, New Delhi for a period of three years (2011-2014). With committed 39 faculties, Faculty of Pharmacy is recognized as a research centre and it provides research facility leading to the award of Degree of Doctor of Philosophy (Ph.D). Socially relevant and community oriented funded major research projects are also in progress.

OUR STRENGTH

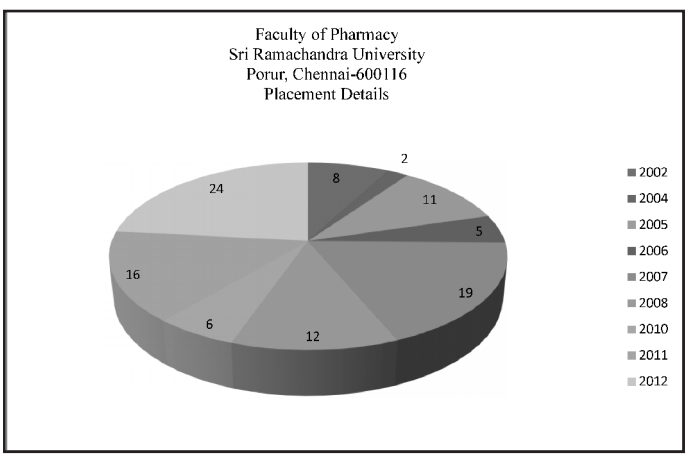
STUDENT DETAILS

The number of candidates so far enrolled in Faculty of Pharmacy is 1025 and number of passed out students since 1995 is given below:

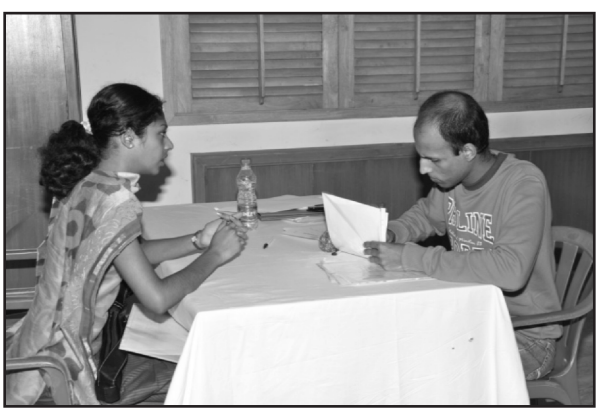
Sl.No.	Course	Number of candidates
1.	Ph.D	25
2.	M. Pharm Pharmacy Practice	79
3.	M. Pharm Pharmaceutics	60
4.	M. Pharm Quality Assurance	59
5.	M. Pharm Pharmacognosy	45
6.	Pharm.D (Post Baccalaureate)	20
7.	B.Pharmacy	669

PLACEMENT DETAILS

The Pharmacy College has an active Placement cell headed by Dr. P. Seenivasan, Professor, Department of Pharmaceutics as the Placement officer of the University. The placement cell signed MOU with industries for students training and placement. Totally 17 organizations/industries visited for campus placement and conducted campus interviews. To mention are Dr. Reddy's Laboratories Ltd., Hyderabad, Ordain Health Care Private Limited, Chennai, Wockhardt Limited, Bombay, Baxter India Limited, Haryana, Ranbaxy Laboratories Ltd., Chennai, Zydus Cadila, Chennai, Nestle India Limited, Chennai, Pfizer Limited, Chennai, Quintiles, Bangalore, ICON Clinical Research, Chennai, Orchid Healthcare, Chennai, Hospira Healthcare India Private Limited., Chennai, Spic Pharmaceuticals Chennai, Apollo Hospital Enterprises Ltd., Chennai, Arvind Remedies Ltd., Chennai, Eli Lilly Company (India) Pvt. Ltd., Chennai, Zydus Medica, Chennai. Recently in collaboration with IACP (Indian Association of Colleges of Pharmacy) the placement cell conducted a job fair on 27th July 2012, exclusively for Pharm.D students across the country. The year wise placement details are given in the following pie chart.



Students writing pretest during interview



Students interviewed by Quintiles Pharma

RESEARCH ACTIVITIES OF FACULTY OF PHARMACY

Albert Szent-Gyorgyi quotes "Research is to see what everybody else has seen and to think what nobody else has thought". Sri Ramachandra University strives to provide state-of-the-art equipment to its faculty, students and staff to facilitate cutting edge research in the frontier areas of science and technology. Research, together with teaching and service, is a major activity of the Faculty of Pharmacy at Sri Ramachandra University. Faculty, undergraduates, post graduate students and research scholars are extensively involved in the exciting process of discovery and dissemination of knowledge. Our research activities cover an extensive array of areas within the umbrella of the health sciences.

All 39 faculties are actively involved in research and our Principal Dr. D. Chamundeeswari, has received the young scientist award in the year 2007 from Department of Science and Technology. Faculties of our college have authored 130 national and 76 international publications in refered journals. Our faculty members and students have presented around 635 research findings in various national and international conferences, symposia, workshops and seminars. Approximately 92 undergraduate and 281 post graduate self funded projects from interdisciplinary programs have been carried out till date. The current strength of the Ph.D. scholars of the college is over 19 and 29 are in pipeline. 11 merit scholarships by students and 26 prestigious awards by our staff and students have been a matter of pride and pleasure for us. Our faculty has played a significant role in pushing the frontiers of knowledge and this has been duly recognized in the form of various awards and honors, including fellowships of professional societies and as reviewers of national and international journals.

The college has collaborations with various Academic and Research Institutes like Andhra University, Visakapattinam, Kakatiya University. Warangal, Central Leather Research Institute, Indian Institute of Technology, National Institute of Siddha, Captain Sreenivasa Murthy Research Institute for Siddha & Ayurveda, Madras Veterinary College, University of Madras, Centre for Advanced Studies in Botany, Anna University, Chennai, Mother Therasa Post Graduate Research Institute of Health Sciences, Pondicherry, Centre Animal Facility for Development Research & Toxicology, Central Research Facility, Sri Ramachandra Innovis and various departments of Sri Ramachandra University.

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1. The institution has the benefit of long and robust history of collaborations with leading industries like Tablets India Ltd., Fourrt's India Laboratories Pvt Ltd., apex Laboratories, Orchid Chemicals and Pharmaceuticals, Hospira Healthcare India Pvt. Ltd, Parr Formulations, Rumi Herbals, IMPCOPS, Retort Pharmaceuticals, Cholayil Pharma Pvt. Ltd., Amrutanjan Pvt. Ltd., Chennai, Laila Pharmaceuticals at Chennai and Vijayawada, Granules India Limited, Hetero Drugs Pvt. Limited, Natco Pharma Limited, Dr.Reddy's Laboratories Limited, Biological E Limited, Matrix Laboratories at Hyderabad, Syngene International Limited, Biocon Ltd, Medrich Pharma, Sami Labs at Bangalore, Cadila Pharmaceuticals, Wockhardt Pharmaceuticals at Ahmedabad, Cipla Pharmaceuticals, Alchem Laboratories and Pharmaceuticals Ltd, Mumbai, Vergo Pharma Research, Goa to impart latest technology among students.

Two of our faculty members namely Mr. R. Thirumalai Kumaran, Department of Pharmacognosy and Mrs. S. Ramalakshmi, Department of Pharmacy Practice have received GATE scholarship worth Rs.1,00,000/- for their project sponsored by Sri Ramachandra University to support excellence in research among

young faculties.

Four of our students projects have been awarded by Tamilnadu Pharmaceutical Sciences Welfare Trust with the cash prize of Rs.5,000/- each. Our undergraduate students are exposed to Research by a seed money of Rs.10,000/- for the best proposal under Chancellor's Summer Research Fellowship sponsored by Sri Ramachandra University during their summer vacation under the guidance of the Faculty. Our post graduate students are receiving stipend for carrying out their research projects from the collaborative industries.

Department of Pharmacognosy:

The department has received funds from various government agencies. Dr. D. Chamundeeswari, as a principal investigator completed three research projects at the amount of Rs.57,31,000/- from government agencies such as Department of Science & Technology, Central Council for Research in Ayurveda & Siddha, Defence Research Development Organization and as a co-investigator of a project worth Rs.1,15,20,000/- funded by Department of Science & Technology, as a principal investigator, in a project entitled "Development of preclinical evaluation of a polyherbal solid dosage formulation (chewable tablets) having anti-anxiety effect" worth Rs.19,10,200/- from Life Science Research Board and as a co-investigator for the project "Scientific evaluation of copper containing herbomineral formulations for the management of ulcers" worth Rs.1,07,56,557 funded by Department of Science & Technology which are in progress.

Thrust area of research is screening of herbal extracts/formulations/phytoconstituents for activities such as antioxidant, anti-inflammatory, hepatoprotective, anti-anxiety, anti-arthritic, anti-diabetic, wound healing, ulcer healing, anti-tumour and anticoagulant.

A separate research laboratory has been established in the department from the funds received from various government funding agencies for research. The department established a medicinal herbal garden in four acres and maintains about 75 species of medicinal plants. The department carries consultancy projects with various industries & institutions. Consultancy projects are utilized for the development of the department.

Department of Pharmacology:

The Department of Pharmacology actively conducts research on various pharmacological, toxicological experimental studies in collaboration with other departments of the Sri Ramachandra University. The current research areas of the department includes lead optimization, new drug discovery using CADD, QSAR, Combinatorial chemistry, Proteomics, Screening of new molecules from natural, synthetic and marine sources for their potential pharmacological effects such as anti analgesic, anti-inflammatory, anti-arthritic, anti-anxiety activities.

The Department has received fund grant worth Rs.19,10,200 from Life Science Research Board and Dr. C. Uma Maheswara Reddy is the co-investigator for the project entitled "Development of preclinical evaluation of a polyherbal solid dosage formulation (chewable tablets) having anti-anxiety effect"

Department of Pharmaceutics:

The research area of the department mainly focuses on Bioavailability enhancement studies, Formulation of solid oral dosage form, novel drug delivery systems such as collagen based drug delivery system for wound healing, in situ gels and Nanotechnology. Dr. S. Shanmuganathan, Professor, acquired Post doctoral fellowship from the United States Army of Institute of Surgical Research, Texas, USA in the area of wound healing and drug resistance.

The department is enriched with research activities in collaboration with other departments like Department of Pharmacology, Sri Ramachandra Medical College & Research Institute, Faculty of Dental Sciences.

Department of Pharmaceutical Chemistry:

Thrust areas of research is synthesis and characterization of Heterocyclics, In silico studies , Phytochemical and pharmacological studies of medicinal plants and marine species, Development, preclinical and standardization of a new herbal formulations, Biosynthesis of metal nanoparticles and biological evaluation, Analytical method development and validation of novel drugs in market. The department shares expertise in research with Sri Ramachandra Innovis under Consultancy services in the field of Analytical Chemistry and Docking studies.

Department of Pharmacy Practice:

Pharmacy practice as a part of multidisciplinary health care team is directed at achieving quality use of medicines for improving patients quality of life. The department focuses on the areas such as Therapeutic Drug Monitoring, Ward round participation, Patient counseling, Drug Utilisation Evaluation, Adverse drug reaction monitoring. It established drug information centre which provides drug related information to the doctors, community pharmacists and other health care providers. The current ongoing research are being carried out in the areas such as Cardiology, gynecology, nephrology, oncology & pulmonology targeting to solve various drug related problems and provide pharmaceutical care.

There are two ongoing projects in collaboration with Department of Clinical Pharmacology, Advanced Cancer Training Research & Education Centre, Mumbai in the area of Pharmacokinetics.

ANY OTHER SPECIAL INFORMATION

Faculty of Pharmacy has contributed its strength in organizing/ co-ordinating various conferences, seminars and workshops.

1. National Convention of Principals of Pharmacy Colleges was held on 27th January 2001 at Sri Ramachandra University, Chennai.

2. The Indian Pharmaceutical Association (IPA) – Education division organised a seminar on "Careers in Pharmacy" on 17.8.2002 at Sri Ramachandra University, Chennai.

3. AICTE Sponsored ISTE Programme on "Short Term Training Programme for Pharmacy

Teachers" (STTP) on Drug Development, ADR Management and Role of Clinical Pharmacist was held between 8th to 22nd October 2003 at Sri Ramachandra College of Pharmacy, Sri Ramachandra University, Chennai.

4. Honorable Dr. A. P. J. Abdul Kalam, The President of India, released "PHARMA VISION – 2020" during 55th Indian Pharmaceutical Congress in Sri Ramachandra University, Chennai on 17th December 2003.

5. 55th Indian Pharmaceutical Congress was held between 19th to 21st December 2003 at Sri Ramachandra University, Chennai.

6. "Career Prospects in Pharmacy Profession" was conducted by IPA (Education Division) & IPA (Tamil Nadu branch) on 26th March 2005 at Sri Ramachandra University, Chennai.

7. "Current Scenario in Pharmaceutical Industry – CHEMCON 2009" was organized and conducted by Department of Pharmaceutical Chemistry, Faculty of Pharmacy, Sri Ramachandra University, Chennai on 21st November 2009.

8. A National Conference on "Recent advances in Herbal Drug Processing, Development and Research – HERBOTECH 2010" was organised by Department of Pharmacognosy, Faculty of Pharmacy, Sri Ramachandra University on 21st January 2010.

9. Indian Pharmaceutical Association (IPA) convention was held between 14th & 15th March 2010 at Sri Ramachandra University, Chennai.

10. All India Council of Technical Education (AICTE) sponsored "National Seminar on Recent Advances in Herbal Drug Technology" was organized and conducted by Department of Pharmacognosy and Department of Pharmacology, Faculty of Pharmacy, Sri Ramachandra University, Chennai between 1st to 3rd July 2010.

11. "Practicum on HPLC" was organized by Department of Pharmaceutical Chemistry, Faculty of Pharmacy, Sri Ramachandra University, Chennai in collaboration with Spinco Biotech Pvt. Ltd, Chennai on 4th September 2010.

12. The Indo- American Pharmaceutical Regulatory Symposium was organized by Department of Pharmaceutics, Faculty of Pharmacy, Sri Ramachandra University, Chennai in collaboration with Northeastern University, Boston, USA; Annamalai University, Chidambaram; JSS University, Mysore & Indian Pharmaceutical Association, Tamil Nadu Branch, Chennai between 20th to 21st November 2010 at Sri Ramachandra University, Chennai.

13. Faculty Development Programme was organized by Education Unit of Faculty of Pharmacy, Sri Ramachandra University, Chennai between 9th to 11th March-2011for the junior faculties of Faculty of Pharmacy, Sri Ramachandra University, Chennai.

14. National conference on "Emerging Trends in Pharmacy Practice – PHARMAPRAC 2011" was organized and conducted by Department of Pharmacy Practice, Faculty of Pharmacy,

Sri Ramachandra University, Chennai between 10th & 11th November 2011.

15. Workshop on Molecular Docking Studies in Drug Discovery, Theme: Application of Software in Target Based Drug Discovery was organized and conducted by Department of Pharmaceutical Chemistry, Faculty of Pharmacy, Sri Ramachandra University, Chennai between 23rd & 24th February 2012.

16. Indian Council of Medical Research (ICMR), New Delhi sponsored National Seminar "Recent trends in novel drug delivery systems – NDDS 2012" was organized and conducted by Department of Pharmaceutics, Faculty of Pharmacy, Sri Ramachandra University, Chennai between 30th & 31st March 2012.

17. Indian Association of Colleges of Pharmacy (IACP) & Faculty of Pharmacy, Sri Ramachandra University, jointly organized Pharmacy Practice Module – Advanced Learning Series – II at Sri Ramachandra University, Chennai between 26th to 28th July 2012 for Pharm.D students and teachers.

18. Indian Association of Colleges of Pharmacy (IACP) & Faculty of Pharmacy, Sri Ramachandra University jointly organized "JOB FAIR – 2012 for Pharm.D Students" at Sri Ramachandra University, Chennai on 27th July 2012.

19. Memorandum of Understanding (MOU) by Faculty of Pharmacy, Sri Ramachandra University, Chennai with various Universities/ Pharma Industries/ Research Institutes includes Jamia Hamdard University, New Delhi; Central Leather Research Institute, Chennai & Vergo Pharma, Goa.

64th INDIAN PHARMACEUTICAL CONGRESS

The IPCA has decided to hold the 64th INDIAN PHARMACEUTICAL CONGRESS at Chennai. The Congress will be held from **7th to 9th Dec 2012.**

Venue: SRM University

For further details visit: www.64ipcchennai.com

SRI RAMACHANDRA UNIVERSITY

(Declared under section 3 of the UGC Act, 1956)

Accredited by NAAC with 'A' Grade

Porur, Chennai - 600116

FACULTY OF PHARMACY

COURSES OFFERED	BACHELOR OF PHARMACY (B. PHARM)	MASTER OF PHARMACY (M. PHARM)	DOCTOR OF PHARMACY (PHARM. D)	DOCTOR OF PHARMACY (PHARM. D) (Post Baccalaureate)	DOCTOR OF PHILOSOPHY (Ph.D)	
APPROVAL	All India Council for Technical Education (AICTE) Pharmacy Council of India (PCI) - New Delhi		Pharmacy Council of India (PCI) - New Delhi		Part Time	Full Time
ACCREDITATION	National board of Accreditation, New Delhi					
DURATION	4 years (8 Semesters)	2 years (4 Semesters)	6 years (5 years curriculum + l year internship)	3 years(2 years curriculum+ 1 year internship)	4 years	3 years
ELIGIBILITY	HSC/CBSE/ ISC	B. Pharm	HSC/CBSE/ ISC/ D. Pharm	B. Pharm	M. Pharm / Pharm. D	
INTAKE	60	Pharmaceutics - 10 Pharmacy Practice - 10 Pharmacognosy - 10 Quality Assurance - 10 Pharmacology - 18 Pharmacutical Analysis - 18	30	10		
RECOGNITION	National Assessment and Accreditation Council (NAAC) - Bangalore Joint Commission International (JCI) - U.S.A					
CAREER OPPORTUNITIES	Pharmacist Quality Control Analyst Production Chemist Professional Sales Service Retail Operations State & Central Drugs Inspector	Academicians State & Central Drugs Inspector Scientists in Drug Development Analytical R&D Formulation R&D Phytochemical Research Clinical Research Associates Regulatory Affairs Pharmacovigilance Community & Hospital Pharmacist (In Abroad)	Community & Hospital Pharmacist (In Abroad) Clinical Services Clinical Research Associate Regulatory Affairs Pharmacovigilance Academicians Data Management		Academicians State & Central Drugs Inspector Scientists in Drug Development Analytical R&D Formulation R&D Phytochemical Research Clinical Research Associates Regulatory Affairs Pharmacovigilance Community & Hospital Pharmacist (In Abroad)		

SRI RAMACHANDRA UNIVERSITY
(Declared under Section 3 of the UGC Act, 1956)
Porur, Chennai - 600 116.

UNIVERSITY OF MIAMI

CITI Collaborative Institutional Training Initiative

"A web-based Research Ethics Education Program on Protection of human research subjects and welfare of laboratory animals"

Training in ethical conduct of research is essential for all those involved in research using human subjects / laboratory animals. In this context an online program for research ethics education has been developed by CITI (Collaborative Institutional Training Initiative) of University of Miami, USA since the year 2000 and is made available in more than 10 different countries all over the world with 1130 participating institutions.

On 24th November 2009 an MOU was signed between CITI of University of Miami, USA and Sri Ramachandra University, Chennai, India to further develop the program and make it available for researchers in India and neighbouring countries as "CITI-India program".

This program was officially launched on 20th September 2010 by the Honourable Minister for Shipping, Shri. G.K.Vasan during the silver jubilee celebrations of Sri Ramachandra University. The program is now available for institutions and individuals in India and neighbouring countries for a nominal registration fee.

The program comprises of different modular courses and will be useful to anyone interested in doing research related to human subjects (clinical, social & behavioural) and research using laboratory animals. The modules have been

developed by experts in the field of ethics and the content is updated periodically. The modules have been developed in simple language and is easy to understand. As the course is online the user has the flexibility to do the course at any convenient time.

The CITI-India Program provides 25 different modular courses in the Protection of Human Research Subjects and in the welfare of laboratory animals.

Each course comprises of several modules. At the end of each module, the researcher will have to answer objective type of questions. To complete the course, the researcher has to get a minimum score. A certificate would be automatically generated online after completion of each course, which can be printed by the user for his/her record.

The courses which are currently made available are based on the modules developed by the CITI, University of Miami, USA, which are to a great extent applicable to India and research done in India using human beings as study subjects and in research done using laboratory animals. Courses specific for the Indian setting are in the process of development. The training program though not-for-profit would be chargeable to institutions/ individuals at a nominal cost towards logistics of offering the CITI-India program.

The CITI-India program offers two kinds of subscription: Institutional & Individual subscription.

Institutional subscription: An institutional subscription enables unlimited number of individuals of the institution to take up any of the courses. The subscription fee for the institute would be Rs. 50,000/- per year.

Individual subscription: Individuals who are not attached to any institution or whose institution is not subscribed with CITI-India can take up the course(s) with a payment of Rs.1000/-, which will be valid for one year.

Apart from the automatically generated online certificate, if the individual user wants to obtain a printer certificate duly signed by signatories of CITI (University of Miami and Sri Ramachandra University), the individual user would need to pay Rs.100/- per course.

Payment options:
Payment can be made by a crossed cheque (Rs.50/- to be added to the subscription towards bank charges for outstation cheques) or demand draft drawn in favour of **"Sri Ramachandra University CITI-India Account"** payable at Chennai and sent to the address given below.

Individual users are requested to fill the registration form attached with this brochure and enclose it with the demand draft/cheque. After realization of the cheque/demand draft, a username and password will be sent by email.

Organizations/Colleges/Universities who are interested to take up Institutional subscription are requested to contact the CITI-India Program Office given below.

ADDRESS FOR CORRESPONDENCE:
Pro-Chancellor (Research)
CITI-India Program
Central Research Facility
Sri Ramachandra University
No. 1, Sri Ramachandra Nagar,
Porur, Chennai - 600 116,
Tamil Nadu, INDIA
Phone : +91-44-24765512 Ext : 665
Fax : +91-44-24765514
email : citi.india2009@gmail.com

For more information please click on the CITI-India link on the homepage of Sri Ramachandra University at : **www.sriramachandra.edu.in**

Signing of MOU
24.11.2009

Launch of CITI-India Program
20.09.2010

Registration form for individual users

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Name : _____

Age (in yrs) : _____ Sex : M / F

Qualification: _____

Designation : _____

College/
University : _____

Address : _____

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Phone : _____

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Amount (Rs.) : _____

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Name of Bank : _____

Branch : _____

Note : Demand Drraft/Cheque to be drawn in favour of **"Sri Ramachandra University CITI-India Account".** Please add Rs.50/- for outstation cheque. after realization of cheque a username and password would sent to your email address.

ADDRESS FOR COMMUNICATION:

Pro-Chancellor (Research)
CITI-India Program
Central Research Facility
Sri Ramachandra University
No. 1, Sri Ramachandra Nagar,
Porur, Chennai – 600 116
Tamil Nadu, INDIA
Phone : +91-44-2476 5512 Ext : 665

INFORMATION

M. Pharm Scholarship 2011-2012

Profile of 3rd Rank Projects

PHARMACEUTICS

Name : Mr Prashant Kumar Hingarh

Project Title: Nano –Structured Lipid Carrier (NlC): A Novel Particulate System For Enhancing The Oral Bioavailability Of Olanzapine

College: J S S College Of Pharmacy, Ooty

Guide's Name: Mr. N. Jawahar

Name : Ms A Gokila

Project Title: Formulation and Optimization of Ramipril Niosomes

College: Madurai Medical College, Madurai

Guide's Name: Prof. A Abdul Hasan Sathalt

PHARMACEUTICAL CHEMISTRY

Name: Ms Rajeswari.R

Project Title: QSAR Studies And Synthesis of Certain Pyrazoline And Azetidinones Of Quinoline Carboxylic Acid Derivatives And Evaluation of Their Possible Biological Activities

College: Sri Ramakrishna Institute of Paramedical Sciences, Coimbatore

Guide's Name: Dr. T.K.Ravi, M.Pharm, Ph.D,

PHARMACEUTICAL ANALYSIS

Name: Ms Geetha Talgalla

Project Title: An analytical method for the developed Nanoparticles of Gefitinib, its validation and Bio-distribution in rats

College: J S S College Of Pharmacy, Ooty

Guide's Name: D. Nagasamy Venkatesh

PHARMACOLOGY

Name: Ms. R.T.D. Isravanya

Project Title: A Pharmacogenetic Analysis of Atorvastatin Efficacy and Safety

College: Madras Medical College, Madras

Guide's Name: Dr.R.Nandini ,

PHARMACOGNOSY

Name: Ms Seema Talreja

Project Title: "Development .Optimization of Novel Anti-diabetic Herbal Formulation"

College: J.S.S. College of Pharmacy, Ooty

Guide's Name: Dr. B. Duraiswamy

Name: Ms S. Dhanalakshmi

Project Title: Studies on leaves and its volatile Oil of Citrus aurantium L – A Promising anti infective with antiplasmid, innate immunity Stimulation agent by using Bombyx mori model

College: Madurai Medical College, Madurai.

Guide's Name: Dr. Mr. K. Periyanayagam.

BIOTECHNOLOGY

Name: Ms Monica Mishra

Project Title: "In Vitro Investigation on the Anti-Tumour and Antioxidant Activity of Selected Biophytum Sentivium"

College: JSS College of Pharmacy,Ooty

Guide's Name: Dr. P.Vijayan

PHARMACY PRACTICE

Name: Mr T.Vigneswaran

Project Title: "Evaluation of Antibiotic use in a Private Corporate Hospital"

College: Sri Ramakrishna Institute of paramedical Sciences, Coimbatore.

Guide's Name: Mr. B. Rajalingam, M.Pharm, (Ph.D)

EVENTS

WORKSHOP ON PROFESSIONAL COMMUNICATION & SOFT SKILL TRAINING

Tamilnadu Pharmaceutical Sciences Welfare Trust had organised a "Professional Communication and Soft Skill Training" programme for students of Pharmacy in the conference Hall of the Trust office. The four-day training programme was conducted on 25th & 26th of August and 1st & 2nd of September 2012. The workshop was organised by Dr. V. Ravichandran & Mrs. Pratima Mathur, the workshop was inaugurated by Mr. R. Thiruvengadam, Joint Managing Director, M/s. Tablets (India) Limited, Chennai. The resource person for the programme was Ms. R.Padma who is a soft-skill trainer and a behavioral analyst, with a vast experience in this field and also in mentoring, motivating and supporting the students in their quest to bridge the gap between college & corporate.

Aim and objective of the Training:
The Final year Pharmacy students, in particular are at the verge of facing the real world scenario and embracing the corporate world in the near future. The training sessions were aimed at imparting good interpersonal and communication skills, developing self-confidence, highlighting the importance of grooming, etiquette, presentation skills in a business scenario, and the essence of team work, etc.

Various topics such as team work, Barriers of Communication, being assertive, the importance of listening in communication, how to be assertive, why it is important to probe to get more information, self confidence, self-esteem, Success, Presentation skills: covered in the programme, writing skills, reading skills, Case studies, Group Discussions, Writing of Resume etc. were covered.

17 students of second, third and final year B.Pharm from College of Pharmacy, Vels University participated in the training programme. On the last day Dr. K. Chinnaswamy, awarded course-completion certificates to all the participants.

PERIYAR COLLEGE OF PHARMACEUTICAL SCIENCES, TRICHY

Periyar College of Pharmaceutical sciences, Tiruchirappalli organized a One Day Refresher Course on **"Knowledge Updating for the Community and Hospital Pharmacist"**, sponsored by the Tamil Nadu Pharmacy Council, Chennai on 1st July, 2012. **Thiru. T. Ilango,** Registrar. Tamil Nadu Pharmacy Council, Chennai inaugurated the function Special address delivered by **Prof. Dr. V. Ravichandran,** Vice President, Tamil Nadu Pharmacy Council, Chennai. Welcome address by **Prof. Dr. R. Senthamarai,** Principal, Periyar College of Pharmaceutical Sciences, Trichy and **Thiru. Gnana Sebastian,** Correspondent, Periyar College of Pharmaceutical Sciences Trichy, presided over it

MMC, ALUMINI MEET, HELD ON 15TH AUGUST 2012

NEWS

Blood Tests to Diagnose TB Banned

Blood tests, commonly used in India to detect tuberculosis (TB), have been banned.

The Union health ministry has banned the import of sero-diagnostic kits, saying it is giving inconsistent and imprecise results leading to wrong diagnosis of the deadly air-borne disease.

The official gazette notification says, "Their use is likely to involve risk to human beings", and safer alternatives are available. Experts say these blood tests more often test positive when the patient does not have TB (false positive) and test negative when the patient actually has TB (false negative).

The World Health Organization, in its first-ever negative policy recommendation, recently called on governments to immediately ban blood tests prescribed and used to detect TB, mainly in the private sector.

Despite the evidence against blood tests to detect TB, experts say 15 lakh TB serological tests are estimated to be done in India, with patients spending an estimated Rs 75 crore ($15 million) annually on such tests.

Joint secretary in the ministry Arun Panda says in the notification, "In exercise of the powers conferred by section 10A of the Drugs and Cosmetics Act, 1940, the Central government hereby makes the following amendment."

A published study in 2010 estimated that in India $47.5 million (out of patients' pockets) are spent on serological tests, most of which miss many TB cases.

Source: *The Times of India, 20th June 2012*

Cos eye $ 1 bn Generic Play

Top Drugs go Off-Patent In US/Re Slide Adds to Upside

It's literally a billion-dollar opportunity. In the wake of patent expiries on three blockbuster drugs over the last six-seven months, an opportunity worth nearly $1.3 billion is up for grabs for domestic generic players.

With three drugs - Lipitor, Zyprexa and more recently Plavix - going off-patent, along with a sharp rupee depreciation, a significant revenue upside has emerged for players like Ranbaxy, Dr Reddy's and others. Of this, Ranbaxy is believed to have mopped up an estimated $600-million revenue already from generic Lipitor since it was launched in December last year, analysts say.

This assumes significance as Lipitor sold by Pfizer and Plavix sold by Sanofi and Bristol-Myers Squibb, which are top-selling drugs with multibillion dollar sales over the last decade or so, fell off the branded radar, with the US Food and Drug Administration clearing their generic versions.

Ranbaxy recently said that it has garnered 47% share in the Lipitor market till mid-April. The company holds the highly lucrative first-to-file rights, which ensures 180-day market exclusivity on the drug. The company will share around half of the proceeds with generic biggie Teva.

Ranbaxy's sales in North America more than doubled to Rs 2,093 crore during the first quarter ended March, the first full quarter after the generic Lipitor (atorvastatin) launch. The US business grew mainly on account of two exclusivities - atorvastatin and amlodipine+ atorvastatin, according to a Ranbaxy official.

But more recently, the patent expiry of cardiac blockbuster Plavix, which mopped up US sales of $6.8 billion, has opened up a huge opportunity for domestic generic players including Sun Pharma, Torrent and Aurobindo for the 75 milligram dose. While Dr Reddy's along with Teva, Mylan and Gate Pharmaceuticals, has received the approval to sell 300-milligram dose of Plavix (clopidogrel), with Mylan getting a 180-day exclusivity for being the first across the approval finish line. Sales of generic Plavix will only be known over the next few months, but it is estimated to mop up around $500 million.

Says Ranjit Kapadia, senior VP, Centrum, "These blockbuster expiries have opened up significant avenues for generic companies. Majority of domestic companies are integrated players, which have approved facilities, and can garner good sales and profits from these opportunities. The sharp depreciation in the rupee will also be beneficial".

Analysts say the US will continue to be a good growth driver for the pharma sector since nearly $60 billion worth of drugs will go off patent from 2012-15, with nearly $30 billion in 2012 alone. Domestic companies have scaled up their R&D facilities over the last few years to take advantage of the patent cliff.

Source : *The Times of India, 14th June 2012*

Where the outlook is healthy

Contrasting conditions

Countries	Expenditure on health as % of GDP		Hospital beds	Nurses	Physicians
	Government	Private			
Germany	7.8	2.7	82	108	35
UK	7.2	1.5	34	103	21
USA	7.3	7.9	31	98	27
Japan	6.7	1.6	138	41	21
Russia	3.1	1.7	97	85	43
Brazil	3.7	4.7	24	65	17
South Africa	3.3	4.9	28	41	8
Thailand	3.0	1.1	22	15	3
China	2.0	2.3	41	14	14
Vietnam	2.8	4.4	29	10	12
India	1.4	2.8	9	13	6
Global Median	5.0	3.3	24	28	12

Source: World Health Statistics (2008)

The size of the Indian healthcare delivery market was Rs.2.6 lakh crore in 2011-12. We expect it to almost double to Rs.4.7 lakh crore in 2016-17. The private sector plays a vibrant role, as evidenced by the fact that some of the large corporates in the healthcare delivery industry have clocked an annual average revenue growth of around 20-25 per cent during the last five years. We believe that the market has immense potential in the long-term due to a combination of factors.

First, a shift in demographics, fuelled by an increase in population and the rise in life expectancy, will necessitate greater coverage of healthcare. Second, higher purchasing power due to rising income levels, coupled with rising literacy levels, will boost awareness on preventive and curative healthcare and, in turn, increase the hospitalization rate (the number of times an individual visits a hospital).

On the negative side, however, the stresses and strains of modern day living will continue to result in rapid increase in lifestyle-related ailments such as cardiac diseases, oncology (cancer) and diabetes. In value terms, cardiac ailments account for around 22-25 per cent of the overall market (in 2011-12), and we expect this to go up steadily in the next five years. Likewise, oncology, at present, accounts for around 4-5 per cent of the overall market, and is likely to grow to 5-7 per cent in the next five years. This rise in lifestyle-related ailments will concomitantly increase the demand for healthcare services associated with these diseases such as diagnostic facilities.

Another driver will be the sustained expansion of healthcare insurance coverage. As per the World Health Organisation's (WHO) world health statistics, around 74 per cent (as of 2008) of India's private healthcare expenditure now takes place in the form of out-of-pocket expenditure. As health insurance coverage widens, hospitalisation rates are also likely to go up.

Because healthcare costs are extremely competitive in India compared to the developed countries and other nations in Asia, the country is also an attractive destination for medical tourism. According to industry sources, nearly 6-8 lakh patients visit India from abroad for treatment. We believe that this number is likely to increase substantially in the years ahead.

On the flip side, however, the challenges are daunting, despite the fact that India has made great strides in healthcare since independence. While average life expectancy has nearly doubled to around 64 years since independence, infant mortality rate (IMR) and the maternal mortality ratio (MMR) have fallen significantly, the overall access and quality of healthcare for a vast majority of Indian remain sub-par. As compared to other countries, including developing ones such as China, Thailand, and Vietnam, India fares poorly on almost every key health indicator.

Two key factors responsible for this are the low share of government in total healthcare expenditure, and the lack of skilled human resources. In India, government healthcare expenditure as a percentage of gross domestic product (GDP) (1.4 per cent), too, is far lower than the global median (5 per cent). Not only is the government healthcare spend/GDP ratio close to 6 per cent or above for most developed western countries, even BRICS (Brazil, Russia, India, China, South Africa) nations such as Brazil and South Africa are far superior to India on this score. It is evident that even if public spending increases further in the next few years, a lot more resources will need to be raised through other avenues, including private sector, to bridge this gap.

Over the next five years, we believe that India will require investments of Rs.6 lakh crore if it has to attain the global median of 24 beds per 10,000 persons (now, this number is nine beds per 10,000 persons). In addition, opportunities exist for

diversification into allied industries such as medical equipment and medicine. It is evident that the demand prospects for healthcare delivery are bright in the medium-to-long-term, which presents an attractive opportunity for the private sector.

Source: *The Hindu, 2nd July 2012*

Govt. to Set Up Rs.2,000-Crore Venture Fund for R&D in Pharma

Scientists work inside a laboratory of the Research and Development Centre of a pharma company in Hyderabad. —FILE PHOTO

The Central Government has decided to set up a venture capital fund of Rs.2,000 crore which will promote research and development (R&D) in the pharmaceutical sector.

Addressing a press conference here on Tuesday, Commerce and Industry Minister Anand Sharma said the government was in talks with Exim Bank for setting up this fund.

The government's contribution would be worked out accordingly, he added. Earlier in the day, he reviewed the pharmaceutical sector with the stakeholders and officials of various Ministries.
During the meeting , industry representatives raised issues such as problems in getting approvals from the Health and Family Welfare Ministry. Mr. Sharma said that a Committee of Secretaries (CoS) would be set up to address the concerns of the industry. The CoS would have the Commerce Secretary, the Secretary DIPP and DCGI. "We are mindful of the challenges of the sector with regard to financing of R&D, credit costs and duration, and we are going to address these issues soon," he added.

India is the third largest producer of pharma products by volume, and the industry is growing at 15-20 per cent annually. The domestic pharmaceutical industry is pegged at $20 billion. It is expected to touch $75 billion by the end of this decade.

India's pharmaceutical exports stood at $13 billion last year. Officials said the venture capital fund would be established under the public-private partnership (PPP) mode and would help in discovery of new medicines.

The National Institute of Public Finance and Policy is advising the Department of Pharmaceuticals in the process of selecting an agency to design the fund with the aim to make affordable bio-pharmaceutical products by 2020.

At present, there is no dedicated private equity or venture capital fund available in India for research activities in the pharmaceutical sector. The idea of the fund will be to offer financial incentives to companies focussing on research in neglected diseases prevalent in developing countries.

Source: *The Hindu, 4th July 2012*

Post-vaccination deaths spark debate on side-effects

The Tamil Nadu health department does not appear to be following the post- convulsions, collapsed or cried incessantly.

Doctors say this is plain impossible. "While we can't quote numbers, mild side-effects like fever, swelling and pain are common, which is why we always prescribe a paracetamol when we send them back home," says Meena Thiagarajan vaccination protocol of making visits to homes of children administered the pentavalent vaccine. Officials claim that not one of the 2.9 lakh children vaccinated in the state till July has suffered any adverse reactions.

According to the 'operational guidelines on surveillance and response to AEFI (adverse effects from immunisation)' of the Union health ministry, there must be around 600 adverse reactions per million vaccinations. In reply to an RTI query from a Delhi-based paediatrician Dr Jacob Puliyel, the TN health department said none of the children vaccinated in the state since December had fever, experienced, a paediatrician with Apollo Children's Hospital. The practice is followed in all government health centres.

The pentavalent vaccine protects children from diphtheria, pertussis, tetanus (DPT), hepatitis B and HIB (Haemophilus influenzae type B), by combining five drugs each with side-effects of their own. According to the World Health Organisation website, DPT alone causes high fever in one of every 330 vaccinations and convulsions in one of every 1,750 children vaccinated within 48 hours. Other side-effects include swelling, redness, pain which causes incessant or inconsolable crying for more than three hours. Effects like collapse, anaphylaxis and seizures also occur but rarely.

This, experts say, points to a trend of children not being followed up and defeats the purpose of the national technical advisory group for immunization (NTAGI) creating a trial period of one year.

The pentavalent vaccine was in the news recently when a three-month-old girl died in Chennai hours after being administered the injection. This is the sixth death in the country suspected to be caused by adverse effects of the vaccine. Though the cause of death has been proved in only one case, WHO guidelines state that any death occurring within 48 hours of being vaccinated, has to be suspected to have been caused by the vaccine.

Source : *Times of India, 15th July 2012*

Sharma to Review Pharma Sector Today

Amid slowdown in exports, Commerce and Industry Minister Anand Sharma will hold discussions on with pharmaceutical industry players on ways to enhance shipments and promote 'Brand India' in the world market.

In the first meeting of the consultative group on exports of pharmaceutical products here, Mr. Sharma will review the sector, an official release said.

The group would discuss providing support to research and development in the sector.

It will also deliberate on "steps taken to emphasize commitment to quality, safety and efficacy of Indian medicines, ways to promote 'Brand India Pharma' in important markets and the manner in which India can attain a leadership position in the world in exports.''

Besides Mr. Sharma, secretaries of commerce department, industrial policy and promotion, health & family welfare, pharmaceuticals, Secretary (Economic Relations) and Drug Controller General of India would participate in the meeting.

India is the third largest producer of pharma products by volume and the industry is growing at a rate of 15-20 per cent annually. — PTI

Source: *The Hindu, 3rd July 2012*

Drug Trials Claim Over 2,000 Lives in Four Years

In the last four years, 2,031 people died in India as a result of Serious Adverse Events (SAEs) caused during drug trials but only about 1 per cent cases received any compensation, information disclosed by the office of the Drug Controller-General of India has revealed.

The figures of SAE-related deaths for 2008, 2009, 2010 and 2011 are 288, 637, 668 and 438. However, compensation was provided only in 22 cases of deaths and that too only in 2010, according to information available with the DCG (I).

No compensation was paid for 2008 and 2009 and the data for 2011 has yet to be compiled.

The information was provided by the DCG (I) in response to a Right to Information query filed by Indore-based medical rights activist Anand Rai.

The reason for such a small number of cases receiving compensation is simple: Pharma companies conducting clinical trials pay compensation only in cases where it is established that the death was caused as a result of the trials and not merely during the trial.

"But it is the companies themselves that decide whether a death was caused due to the trials or not. So there is a conflict of interest there as the companies want to pay compensation in the lowest possible number of cases," says Dr. Rai, who founded the Clinical Trial Victim Association of Madhya Pradesh.

"We believe all cases of SAE-related deaths should receive compensation. We have filed a petition in the Supreme Court on the matter," says Dr. Rai.

Dr. Rai also asked for the SAE-related death figures for the year 2012 and for details of the trial sites/hospitals where the 2,031 deaths occurred and

their State-wise location, but the DCG (I) said it did not maintain such data.

However, on an appeal by the petitioner, the CIC on Friday directed the DCG (I) to provide the State-wise trial site details by August 15, 2012.

The CIC also directed the DCG(I) to provide the petitioner with figures for SAE-related deaths till January 2012. The DCG(I) told the Commission the data up to January 2012 had not been compiled as it was compiled four to six months after the end of the calendar years.

On this, Information Commissioner Shailesh Gandhi said data should be available on a monthly basis.

Source : *The Hindu, 1st July 2012*

Coonoor Lab Releases Vaccine After 4 Yrs

After a gap of four years,the Pasteur Institute of India (PII) in Coonoor released a batch of 15 lakh doses of DPT vaccine for the Universal Immunization Programme (UIP) on Tuesday.

The Centre had suspended the manufacturing licence of the 100-year-old institutes vaccine manufacturing plant in January 2008 citing that it didnt follow the norms prescribed for the production of vaccines.Three years later,PII resumed production when the government revoked the suspension.

On Tuesday,the first batch of DPT vaccine was released by S K Rao,joint secretary to the Union ministry of health,at a function organized in Coonoor.These were released after standardization of production procedure,final testing and certification by the Central Drug Laboratory, Kasauli. The release of vaccine after a gap of four years is a significant achievement in the history of the institute .Also, the government has sanctioned 150 crore for the expansion of the institute as per Good Manufacturing Practices (GMP) standards, Rao said.PII proposes to supply 300 lakh doses of DPT vaccine to the government during 2012-13.The resumption of commercial production of DPT vaccine at PII will enhance the vaccine security of the country to a great extent,he said. Rao also outlined the ministrys plan to upgrade tissue culture anti-rabies vaccine manufacturing facility at the institute as per GMP standards.This,he said,would enhance the production capacity of the institute from the current 2 lakh doses of anti-rabies vaccine per annum to 10 lakh doses.The 150-crore expansion work is expected to start shortly and will be completed in three years.

At its peak,PII supplied up to 60% of DPT vaccine that the country needed.

Source : *The Times of India, 27th June 2012*

Bitter Pill: Abortion Kit Sales Plunge by 65% in Mumbai

While one of the Food and Drug Administration's (FDA) strategies to fight female feticide is to crack down on chemists illegally selling the abortion pill, the ham-handed manner in which the FDA has acted has led to an undesired effect. Chemists in the city are afraid to even legally stock the pill, making it scarce.

Experts say this could lead to an unhealthy situation. "If the pill is not available or there are too many restrictions, there is a fear that abortions will go underground," said Dr Suchitra Dalvie of the Asia Safe Abortion Partnership.

The Medical Termination of Pregnancy (MTP) kit, whose sales have dropped 65% in Mumbai, is one of the safest ways to end an unwanted pregnancy. Noting the danger in its non-availability, health minister Suresh Shetty ordered action against stores not stocking the kit even as the crackdown continues on selling it without proper prescriptions and paperwork.

But on Friday, a day after the Maharashtra government said it would act against retailers not stocking the pill, chemists remained reluctant to stock it. "The FDA reports us directly to the police for not keeping paperwork. Isn't this extreme?" said a city retailer.

The current scarcity can be blamed as much on the illegal use of MTP kits as on the state's crackdown on chemists, said experts.

Dalvie said there has been rampant illegal use of MTP kits, especially in sex-selective abortions. Dr Rekha Daver, who heads JJ Hospital's gynaecology department, said, "The pill is recommended only for pregnancies of not more than 63 days, that too on a prescription written by a gynaecologist certified to carry out abortions. But in practice, the drug was being dispensed by homoeopaths, MBBS doctors, quacks and chemists themselves."

However, by not stocking the pill the chemists are protesting against what they say is the government's move to link the pill to female foeticide. "The sex of the unborn child is known only after 12 weeks (84 days). So, how can we be blamed for female foeticide?" asked Dilip Mehta of the Maharashtra State Chemists & Druggists Association.

Times View

Something as essential to public health as abortion pills going off chemists' shelves shows how misdirected the FDA campaign has been. Abortion pills, if dispensed legally and properly, don't lead to female foeticide; they help women escape unwanted pregnancies. Pushing women to opt for unsafe abortions is actually pushing them a generation back. More thought needs to be applied and better brains need to be engaged before embarking on campaigns as important as the present one to end female foeticide.

Source: *Times of India, 8th July 2012*

Code to Bar Pharma Cos from Bribing Docs
Govt Calls Meeting on July 18 To Discuss New Marketing Practices For Drug-Makers

NEW DELHI: The Centre is likely to bring a mandatory code to bar the pharmaceutical industry from inducing doctors with gifts and hospitality.

The move seeks to end the skewed legal regime in which a mandatory code makes it illegal for doctors to accept "favours" from the pharmaceuticals industry but there is no such deterrent for drug makers from offering inducements to medical practitioners.

According to sources, the department of pharmaceuticals in the chemicals and fertilizers ministry has called the industry, health ministry and revenue department on July 18 to discuss the marketing practices to be enjoined upon drug-makers.

While a "voluntary code of marketing practices for Indian pharma industry" has been in discussion for some time, sources said the move appeared drifting towards mandatory "don'ts" at par with the ones for doctors.

The parliamentary standing committee on health in 2010 had expressed concern that the "evil practice" of inducement of doctors continued because the Medical Council of India had no jurisdiction over the pharma industry and it could not enforce the code of ethics on it.

The government has been spurred into action by Congress MP Jyoti Mirdha who sent a bunch of air tickets to Prime Minister Manmohan Singh to claim that doctors and their families were beating the scorching Indian summer with a trip to England and Scotland, courtesy a pharmaceutical company.

As many as 30 family members of 11 doctors from all over the country reportedly enjoyed the industry's hospitality.

The letter and the air tickets, which Mirdha said was evidence of junketeering, spurred the PMO into seeking action.

Department of pharmaceuticals' decision to rope in the revenue department under finance ministry has triggered speculation if they are to help in devising methods to link the money trail to offending companies.

The continuing tryst with code of ethics in the health industry is blamed on the mismatch in the "dos and don'ts" for doctors and the industry.

The MCI, in December 2009, had notified a mandatory code which prevents doctors from accepting gifts, hospitality, travel grants, funds and endorsing commercial products. But the code does not deter the industry which is the other half of the violation.

Source : *The Times of India, 9th July 2012*

விதி மீறிய ரத்த வங்கியின் உரிமம் ரத்து

மதுரையில் விதிமீறி மாணவர்களிடம் ரத்தம் உறிஞ்சிய ரத்த வங்கி குறித்து, மருந்து கட்டுப்பாட்டு அதிகாரிகள் சோதனை நடத்தி, அறிக்கை தாக்கல் செய்துள்ளனர். சம்பந்தப்பட்ட வங்கி உரிமத்தை, ரத்து செய்ய நடவடிக்கை எடுக்கப்பட்டு வருகிறது.

பாக்கெட் மணி

பள்ளி மாணவர்களிடம், பாக்கெட் மணி ஆசை காட்டி, உயிர் காக்கும் ரத்தத்தை, 250 ரூபாய் கொடுத்து உறிஞ்சி, அந்த ரத்தத்தை, 2,000 ரூபாய் வரை விற்பதாக, மதுரை தனியார் ரத்த வங்கி மீது புகார் எழுந்தது.

இது தொடர்பாக, தினமலர் நாளிதழில் செய்தி வெளியானது. இதுபற்றி மாவட்ட மருந்து கட்டுப்பாட்டு அதிகாரிகள் குழு விசாரித்தது.

விசாரணை முடிவு குறித்து, சென்னையில் உள்ள மருந்து கட்டுபாட்டு இயக்குனருக்கு அறிக்கை தாக்கல் செய்யப்பட்டது.

இது குறித்து மருந்து கட்டுப்பாட்டு துறை உயர் அதிகாரி ஒருவர் கூறியதாவது:

ஆவணங்கள் மாயம்

மதுரையில் புகாருக்குள்ளான ரத்த வங்கியில், மருந்து கட்டுப்பாட்டு அலுவலர்கள் சோதனை நடத்தியதில், மொத்த ரத்த இருப்புக்கான ஆவணங்கள் இல்லை.

மேலும், ரத்தம் பெறப்படும் டோனர்கள் பெயர்களில் குளறுபடி, அடித்தல் திருத்தலும் இருந்தன. டோனர்களின் ரத்த பேக்குகளுக்கும், ஆவணங்களுக்கும் வித்தியாசம் இருந்தது.

இதன் மூலம் அந்த ரத்த வங்கியில் முறைகேடாக ரத்தம் பெறப்பட்டது தெரியவந்தது. இதுகுறித்த அறிக்கை, அரசின் கவனத்துக்கு கொண்டு செல்லப்பட்டது. அந்த ரத்த வங்கி உரிமையாளர் மீதும், வங்கியின் உரிமத்தை ரத்து செய்யவும் ஓரிரு நாட்களில் நடவடிக்கை எடுக்கப்படும்.

இவ்வாறு அவர் தெரிவித்தார்.

Source: *Dinamalar, Chennai, 12th July 2012*

Fake Pharma Unit Raided, Tablets Seized

Police unearthed a fake pharmaceutical marketing unit and seized carton loads of tablets in Madurai, on Friday.

The tablets were packaged and marketed under the names of popular brands. One person has been detained from the unit, while the owner managed to run away. While police said that about 43 cartons containing strips of tablets to the tune of several hundreds were seized, they were yet to ascertain if all the tablets are fake.

Police said that they received a tip-off about the fake tablet racket going on in Jaihindpuram and raided the house of Mariselvam in Bharathiar Road.

As soon as the police landed at the spot, Tamaraiselvan, reported to be the owner of the fake tablet unit, fled from the house. However, the police caught Anand, an employee and are interrogating him. Police added that they found many cartons of paracetomol and amoxilin tablets labelled after popular medicine brands.

We are inquiring about Tamaraiselvan and for how long he was running the unit. He might have been selling the tablets under popular brands for quite some time, a police officer said.

They also said that they are inquiring if there is a bigger gang involved in the racket, They have decided to seek assistance from experts to find out the raw materials used in the manufacturing of the tablets. Police have also seized documents from the house and are studying them to find if they provide clues regarding the source of the tablets and the trade network.

We have launched a hunt for Tamaraiselvan. Interrogating him would throw light on the entire network, the police officer said.

Source: *The Times of India, 18th August 2012*

Bid to Rein in Patented Drug Prices

Govt's Move to Make Medicines Affordable May Irk Global Pharma Biggies

The government may soon bring in a mechanism to control prices of exorbitantly-priced patented medicines to make them more affordable.

Though the move has been discussed for over six years now, not much headway has been made on it. Now, a committee set up to decide the mechanism for reining in prices has submitted its recommendations, Dilsher Singh Kalha, secretary department of pharmaceuticals, told reporters on the sidelines of an industry conference, here on Friday.

"We will be putting out the recommendations in the public domain over the next month or so," he said. "There could be reference pricing system (for patented drugs) or maybe fixed-pricing, but a final decision has not been taken," Kalha said.

The government has been making attempts to bring in an effective price control mechanism in place for drugs which are patented, imported or expected to hit the market soon. Such a mechanism is required in the country, where the cost of treatment is borne by the patient (private) with practically no contribution from the government, and in cases, where the healthcare bill may run up to a few lakhs of rupees.

At present, patented drugs, many of which are imported into the country, are free of price controls. Patented drugs are mostly imported by drug multinationals, and used to treat diseases like cancer, HIV and heart ailments. The committee is understood to have looked at options like reference pricing mechanism and the negotiated pricing model.

Under the reference pricing mechanism, data from other countries and emerging markets, will serve as a reference for deciding the prices. Experts say that the mechanism under which prices are negotiated with pharma biggies may not work very well.

Internationally, a system of reference pricing for medicines exists across developed markets such as the United States and Europe.

The move is almost certain to draw the ire of global drugmakers like Pfizer, GlaxoSmithKline and Merck, which spend billions of dollars researching new treatments and are hoping for huge growth for branded medicines in emerging economies such as India.

The step would be the latest by India to make medicines more affordable after it announced earlier this month it would implement a $5.4 billion plan to provide free generic medicines to its people. Currently, there are restrictions on the prices of 348 so-called "essential" drugs. The medicines are beyond the reach of most of India's 1.2 billion people, 40% of whom live below the poverty line of $1.25 a day. For example, Nexavar, a cancer drug developed by Germany's Bayer, costs Rs 280,000 per monthly dose.

Early this year, Bayer lost a landmark drug ruling in India and was forced to grant a compulsory licence for Nexavar to Natco Pharma, a local generics maker, which sells it for Rs 8,880, a price later undercut by Cipla.

With inputs from Reuters.

Source : *The Times of India, 28th July 2012*

Teva to Foray into India via JV with P&G

P & G Teva to invest Rs250 crore to set up OTC drug manufacturing facility at Sanand.

AHMEDABAD: Global pharma giant, Teva Pharmaceutical Industries (TPI) shall foray into India through ajoint venture with US based Proctor & Gamble (P&G) and will set up its first manufacturing facility at Sanandin Gujarat, a top state official said here.

"TPI and P&G joint venture P&G Teva would set up over the counter (OTC) drug manufacturing facility at Sanand with an initial investment of Rs 250 crore," Gujarat's Commissioner Food and Drug Control Administration (FDCA) H G Kohsia said.

A formal announcement is likely to be made after signing of MoU with the state goverment during the Vibrant Gujarat Global Summit-2013 scheduled for January next year, official sources said.

"The facility to come up on 15 acres of land is proposed to have two seperate lines, one for manufacturing Ayurvedic drugs and another for allopathic medicines," he said.

A joint delegation of P&G Teva recently visited Gujarat and evinced interest in setting up a manufacturing facility here.

"A four member delegation led by Vice President Corporate Quality of Teva Karin Baer met us and sought details of setting up a facility to manufacture OTC products like cough syrups, inhalers.... amongst others," Koshia said.

Assistant Vice President Teva Rajiv Palliwal, Senior Director OTC operations Teva Haresh Gill and Seema Sundereshan, a senior scientist from P&G were part of the delegation, he said.

The proposed facility at Sanand would have state-of-the-art equipment and adhering to good manufacuring practices (GMP) norms to make products both for Indian and overseas market, Koshia said.

A lot of global companies have evinced interest in setting up their facilities in Gujarat, an established hub for pharmaceutical companies, especially SMEs.

NYSE listed, Teva Pharmaceutical is number one global generic company, having a portfolio of 1,480 molecules with operations in 60 countries and distribution network in around 100 countries.

Source: *The Economic Times, 26 th July 2012*

Lupin to Challenge US Court Order on Pfizer's Nerve Pain Drug

Pharma firm Lupin Limited says it will challenge a US court order that prevents it from selling a low-cost generic version of Pfizer's nerve pain drugpregabalin for six years.

A court in the US state of Delaware had last week allowed Pfizer to retain the marketing monopoly of its two patents for pregabalin, sold under the brand Lyrica, until December 2018.

The order threatens to derail Lupin's plan to tap pregabalin's fast growing market in the US.

"We are reviewing the judgment and will appeal in due course," a Lupin spokesman told ET.

Pfizer's Lyrica had notched sales of $1.8 billion last fiscal in the US. If Pfizer had lost the case, Lupin would have got permission to start selling its drug by October next year.

By virtue of being the first to challenge the patent,

the Indian firm would have also got an exclusive six-month marketing advantage during which no other generic drug maker would have been allowed to sell its products.

Although Lupin has not disclosed the revenue potential from the drug, Deutsche Bank's pharma analyst Abhay Shanbhag says Lupin would have made about $110 million during the 180-day exclusivity period.

"While the generic companies will appeal against the verdict, we believe that the opportunity is largely lost," Shanbhag said in a July 20 note to clients.

Pfizer and the Northwestern University, which owns the patents for Lyrica, sued a group of drug makers that included Lupin, Teva, Sun Pharma and Mylan. These drug makers had sought the US Food and Drugs Administration's (FDA) approval to sell their low-cost version of the drug in the US.

Earlier this month, Lupin got the FDA's approval, the first among the generic companies, raising expectations among analysts that the Mumbai-based company may launch its drug by October 2013.

The generic companies, led by Lupin, had challenged three patents of Lyrica. The court upheld the validity of the patents protecting the medicine until 2013 and 2018, while rejecting one that was also valid until 2018.

People close to Lupin say the legal setback will not impede the company's growth as sales figures from this opportunity were not factored in by Lupin in its forecast.

Source : *The Economic Times, 24th July 2012*

Sun Pharma May be Looking to Buy German Stada

Sun has sought to raise about $ 1 billion for a European deal, a source said

Bloomberg, Paris, London

Sun Pharmaceutical Industries Ltd, India's largest drug maker by market value, is looking for acquisitions in Europe, including a possible takeover of German generic drug maker Stada Arzneimittel AG, people familiar with the matter said.

Sun has sought to, raise about $1 billion for a European deal,said one person familiar with the matter, who asked not to be identified as the process is private.

Company executives recently toured Europe to meet with potential targets, another person said. Stada, based in Bad Violbel, Germany, has a market value of about e1.4 billion ($R1.7 billion). Stada shares dropped as much as 5.7% on Thursday to e24.11, the biggest intraday decline since April 13, after Deutsche Bank cut its stock-price prediction to e 32.5% from e34.

Sun fell 0.6 per cent to Rs 656 in Mumbai trading on Thursday, valuing the company at Rs 67,500 crore ($12 billion). The stock has climbed 32 per cent this year, compared with the 12 per cent return on the 17-company BSE India Healthcare Index.

A spokesman for Sun said the company wasn't in talks to buy Stada. A spokesman for Stada declined to comment on a potential deal.
Sun, controlled by billionaire Dilip Shanghvi, has about $927 million of cash reserves and may seek acquisitions to broaden its geographic breadth or enhance its presence in the US, Nomura Holdings Inc said in a May 31 report.

Source : *The Economic Times, 3rd August 2012*

Hetero to Make New HIV Drugs

Hyderabad-based Hetero Drugs has recently signed an agreement with UNITAID promoted Medicines Patent Pool, to make HIV medicines for developing countries.

As per the agreement, Hetero can make four medicines, originally developed by U.S. pharma giant Gilead Sciences: cobicistat, emtricitabine, elvitegravir and a combination (including these three drugs), and tenofovir in a single pill, called, the "Quad". These were licensed to the Medicines Patent Pool by Gilead last year.

Speaking to this correspondent, company Director (Marketing) Srinivas Reddy said, "These are all new molecules in various stages of clinical trials, being conducted by Gilead. We will have to pay royalty as part of the agreement. This process is more desirable as otherwise the compulsory licence granted by countries is a long and laborious process and not all countries agree to it.''

Hetero is, in fact, the fourth Indian company to obtain a licence from the Medicines Patent Pool; the others being Mylan Labs, Ranbaxy Laboratories and Strides Arcolab. The Indian manufacturers can make medicines based on emtricitabine and tenofovir.

Under the agreement, Gilead will provide technology as well as funding to help in process improvement to reduce costs.

"A lot depends on the outcome of the trials — the acceptability of the product, the patient response to the treatment and the like.. Based on their success, these could translate into a market size of at least $25 million. For Hetero, it would mean sales of around $10 million. However, the medicines would be launched after 2013-14 only and would be sold at a fraction (about 5 per cent) of the U.S .market price," Mr. Reddy said.

While Hetero can sell tenofovir in several countries where it is now not under patent, cobicistat, elvitegravir and the Quad are new drugs, which are being developed now. With a licence through the Pool, they can be sold much faster in developing countries after regulatory approval.

Source: *The Hindu, 11th August 2012*

'Chemical in lipsticks can cause heart ailments'

A chemical commonly used in lipsticks, handwashes and other personal care products may cause heart problems and muscle impairment, a new study has claimed.

Scientists at the University of California have found that triclosan, which is used in hundreds of household products, can hinder the process by which muscles, including the heart, receive signals from the brain.

In tests on mice, they noted a 'dramatic' 25 per cent reduction in heart function within 20 minutes of exposure, and warned there is 'strong evidence' it could affect human health.

However regulators and other experts insist triclosan levels in products are safe, and that the doses injected into the mice were higher than those to which humans would ever be exposed.

Previous studies have found that triclosan may have links to thyroid and fertility problems, this is the first time its effects have been tested on muscles.

Scientists had thought that the chemical — which was devised to prevent bacterial infections in hospitals — was metabolised quickly by the body without harmful effects.

However, the researchers at the University of California say it may remain active and be transported to organs, causing damage.

"Triclosan is found in virtually everyone's home and is pervasive in the environment," said professor Isaac Pessah, who led the study, published in the Proceedings of the National Academy of Sciences.

"These findings provide strong evidence that it is of concern to both human and environmental health,"

Source: *The Times of India, 15th August 2012*

Health Activists Oppose Clinical Trial Compensation Guidelines

Health activists have strongly opposed the draft guidelines brought out by the Central Drugs Standard Control Organisation (CDSCO) on the quantum of financial compensation to be paid in case of clinical trial-related injury or death, saying age and income could not be the lone criteria for calculating the amount.

The draft guidelines, put up on the CDSCO website for comments, say that for assessing compensation, the age and income of the deceased and the seriousness and severity of the disease the subject was suffering from at the time of his or her participation in the trial should be taken into consideration. It has also suggested a formula for calculating the amount.

Also, the subject shall be entitled to financial compensation as per the recommendations of the Ethics Committee.

Reacting to the guidelines, S. Srinivasan of LOCOST, a rights-based non-governmental organisation, said it appeared that the old would get lesser compensation than the young; the financially better-off would get more compensation than the poor and that the formula provided lesser compensation to the seriously ill and those suffering disability as a result of the trial, than to the healthy persons who are affected. "Much would also depend on how neutral the Ethics Committees are, that normally is not the case," he said.

Mr. Srinivasan said the guidelines were unfair to subjects below the age of 16 or housewives who had no income. Also, there was no clarity on the procedure to decide the percentage of disability. He said it appeared that healthy subjects would get more compensation than those suffering from some ailment at the time of their agreeing to the trial.

N. Sarojini of Sama said: "For me this notion of income is extremely problematic. What about those who are not working, like children, young students or old people? How do we calculate their stream of income? Similarly, the income can also be flexible; it may increase or decrease, particularly in the context of unorganised sector."

Pointing out how the principle of compensation could be misused, she said: "The formulae in the guidelines are delinked from responsibility. The compensation, either for injury or death, should be multiple times in cases where the agency conducting the trial is held guilty of misguiding or misinforming people. In situations where the negative intent is established, the compensation principle has to be different. Otherwise, the principle of compensation encourages irresponsible trials."

The compensation should not be restricted to direct short-term injury during the trial. In many cases, the injury to the research participants is not immediate. At present, there is no specific provision under the Drugs and Cosmetics Rules for payment of compensation in case of clinical trial-related injury or death. However, the Good Clinical Practice (GCP) Guidelines for Clinical Trials of India state that the research subject who suffers physical injury as a result of his participation in clinical trials is entitled to financial or other assistance to compensate him equitably for any temporary or permanent impairment or disability, subject to confirmation from the Ethics Committee. In case of death, the subject's dependents are entitled to compensation.

Source : *The Hindu, 14th August 2012*

Most Substandard drugs in Maha, TN

Almost one in three drugs (36%) found "not of standard quality" from across India last year were from Maharashtra (23%) and Tamil Nadu (13%) alone.

Around 9.2% of the rest of the sub-standard quality drugs were from Kerala, Gujarat (8.5%), Karnataka (7.2%), Uttar Pradesh (6.9%), Jammu & Kashmir (6.08%) and Rajasthan (5.8%).Union health minister Ghulam Nabi Azad said on Tuesday that of the 48, 082 drug samples tested by state drug controllers between 2011 and 2012 (till October); 2,186 samples, or around 4.5% failed the quality test.

In comparison, 4.9% of the samples tested in 2009-10 and 4.7% in 2011-11 were sub-standard. Of these, around 133 samples — almost 6% — were found to be spurious or adulterated, the minister said.

The maximum number of samples tested were from Maharashtra (6,928), followed by Karnataka (5268), Andhra Pradesh (4,758), Tamil Nadu (4,110), Kerala (3,904), Punjab (3,031) and Gujarat (2,874).

A very few samples were tested in Delhi (283) of which only 13 samples — around 4.5% — were found to be sub-standard.

Source : *The Times of India, 22nd August 2012*

Staff Shortage Hampering Fight Against Fake Drugs'

Almost one in three drugs (36%) found not of standard quality from across India last year were from Maharashtra (23%) and Tamil Nadu (13%) alone.

As far as spurious or adulterated drugs are concerned, which has no active ingredient or is an expired drug that has been re-labeled and sold, Gujarat recorded the highest number of such samples at 64,followed by Maharashtra (19),UP (11) and Delhi (9).Union health ministry officials say there are more than 10,000 drug manufacturers and more than six lakh outlets that sell fake drugs.

Experts say acute shortage of drug inspectors (DI) is hampering the nations fight against spurious and fake drugs. The Central Drug Standard Control Organization, which lays down standards of drugs, estimates that the nation requires 3,200 DIs for its six lakh chemists, but only about 1,000 DIs are available.

The Union health ministry had earlier formulated a whistleblower policy to handsomely reward both public and officers who help seize spurious, adulterated and misbranded drugs, cosmetics and medical devices. The policy stipulated a reward of maximum of 20% of the total cost of consignments seized as payable to the informer that wo'nt exceed Rs 25 lakh for a case. However, the policy fell flat.

Although many labs have facilities for testing of drugs (quality),they aren't equipped to test contaminated substance in drugs, it said. It has also suggested setting up of a state-of-the-art pharmaceutical research laboratory to carry out analysis of drugs at a cost of Rs 50 crore.

Drug Controller General of India estimated that about 46 banned fixed dose combination drugs continue to be marketed irrespective of the ban.TNN

Source : *The Times of India, 22nd August 2012*

Information about Augmentation of Drugs Inspectorate Staff and Drug Testing Analyst in Directorate of Drugs Control Department , Govt of Tamilnadu,

Mr. Selvaraj M.Pharm
Director of Drugs Control, Tamilnadu

The Chief Editor of Pharma Web, Shri. R. Narayana Swamy discussed with Mr. Selvaraj ,Director of Drugs Control of Govt of Tamilnadu on the recent selection of huge numbers of Drugs Inspectors and Drug testing Analysts. Mr. Selvaraj briefed us the following.

There are one Director & Joint Director and 3 Deputy Directors in the Head quarters at Chennai whoare overseeing the functions of their Drugs Control Dept.

There are 15 numbers of Asst Directors heading 4 Zonal offices in around Chennai as well as 11 other zonal offices in Districts like Coimbatore, Kanchipuram, Madurai(2 ADS), Thanjavur, Trichy, Thirunelveli, Thiruvallur, Salem, Vellore, and Virudhunagar. 90 numbers of Drugs Inspectors are recently recruited through Tamilnadu Public Service Commission in addition to the existing staff of 20 to 30 inspectors. These new inspectors are posted in various Districts in order to improve the enforcement of Drugs Cosmetics Act & Rules thereunder .The present strength of Inspectorate Staff will be sufficient for strict enforcement of the Act as told by the Director. There are 800 Drug manufacturing units & 40,000 Chemists & Druggist sales outlets in Tamilnadu. The Department is getting new office space in Chengalpet,Villupuram, and Kanyakumari. Most of the new Drugs Inspectors are (70%) Post graduate in Pharmacy and some are even Doctorate in Pharmacy. Thus highly educated & Knowledgeable Pharmacists are selected by TNPSC for the new posts as Drug Inspectors.

Like wise Drug testing Laboratory under the Drugs Control Department of Tamilnadu also expanded inorder to test more samples of Drugs & Cosmetics drawn by the inspectors in timely manner.23 numbers of Drug Analysts were recruited recently by TNPSC. Govt is planning to establish new lab for testing of Schedule C&C1Drugs which includes Antibiotics, Vitamins and Injectable preparation etc. 6000 samples in a year can be tested in future.

Govt. Analyst DRUGS CONTROL ADMINISTRATION (TN)
DATA OF SAMPLES (STATUTORY SAMPLES)

Year	SAMPLES RECEIVED	SAMPLES ANALYSED	STANDARD QUALITY	NOT OT QUALITY	% OF NSQ
2004 - 05	3532	3607	3210	386	10.701
2005 - 06	3461	3389	2699	261	7.701
2006 - 07	2983	3141	2945	196	6.240
2007 - 08	2691	2427	2131	296	12.196
2008 - 09	2864	2534	2124	419	16.77
2009 - 10	2861	3664	3250	403	10.99
2010 - 11	3565	3873	3596	277	7.152
2011 - 12	3457	3321	3063	258	7.769

Conference Hall Available

The office of Tamilnadu Pharmaceutical Sciences Welfare Trust at Little Mount, Chennai renovated with modern facilities. The air-conditioned conference hall with LCD projector, screen with comfortable seating for 20 to 25 peoples are available for conference, workshop, interview, meetings etc.,

All pharma manufacturers and pharmacy colleges and others are requested to avail above facility for their meetings.

For further details contact:
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View of the Conference Hall

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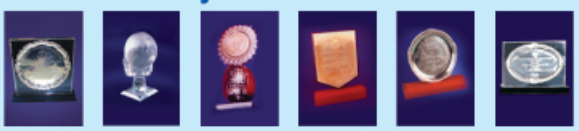

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