Jan.- Feb. - Mar. 2014

Pharma Web

Newsletter of
Tamilnadu Pharmaceutical
Sciences Welfare Trust

ISSUE No. 21

Tamilnadu Pharmaceutical
Sciences Welfare Trust

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ISSUE : 21 **Jan.-Feb.- Mar. 2014**

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TAMILNADU PHARMACEUTICAL SCIENCES WELFARE TRUST
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EDITORIAL

Dear Readers,

In the absence of your editor Mr. Narayana Swamy, I have been given the privilege of editing the 21st issue of Pharma Web News Letter for the months January-March 2014.

In this edition of the News Letter we have included two articles viz: 1. Accreditation and Quality Assurance in Pharmacy Education, Challenges in Privatization and Globalization in Pharma Education By Dr. Bhushan Patwardhan and 2. Roles and Responsibilities of Ethics Committees by Shri. Rakesh Kumar Rishi. The award winning essays on Ethics in Pharmacy Practice and Pharmacists Role in Safety of Medicine for Welfare of Common Man conducted by the Trust are also included. In the information section. The profile of first rank projects of M. Pharm & Pharm D Scholarships 2013 - 14 awarded by TNPSWT find place.

Dr. S. Manivannan has taken charge as Deputy Drugs Control India (CDSCO), South Zone at Chennai from 4th February 2014. A very warm welcome to him. Pharma Web wishes him all the best in his new assignment. We also congratulate Mr. M. M. Yousuf (Retd. Jt. Director, Drugs Control Admin, Tamilnadu), President, IPA (Tamilnadu) and the Jt. Secretary of TNPSWT for being elected as a non academic member to the Madras University for the years 2014-2016.

"Pharma Knowledge & Training Institute- Finishing School" is starting their first Training Program on **"Industrial orientation Training for Quality Management Personnel"** from 12th May 2014 to 9th June 2014 at Tamilnadu Pharmaceutical Sciences Welfare Trust, Block AB- Basement, Baid Metha Complex, 16, Anna Salai, Little Mount, Saidapet, Chennai - 600015. This Training Programme is open to B. Pharm and M. Pharm students who have completed their course and also for those who will be taking their final examination in the month of April 2014.

With Best Regards,

K. Prafulla Chandra
Associate Editor.

ARTICLES

ACCREDITATION AND QUALITY ASSURANCE IN PHARMACY EDUCATION CHALLENGES IN PRIVATIZATION AND GLOBALIZATION IN PHARMA EDUCATION

By

Dr. Bhushan Patwardhan

Professor & Director, Inter disciplinary School of Health Sciences,

University of Pune, Pune

Lecture Delivered at 64th IPC Chennai, on 9th December 2012

Prime Ministers Speak

- Indian Universities are falling behind their peers elsewhere in the world in terms of both personnel and infrastructure. There is a need to make India's institutions of high education and research world-class.

…Manmohan Singh,

- Education is a liberating force, and in our age it is also a democratising force, cutting across the barriers of caste and class, smoothing out inequalities imposed by birth and other circumstances.

…..Indira Gandhi

Higher Education Challenges: Pharmacy is no exception

- Scarce finances,
- Lack of innovation and freedom,
- Poor germane content
- Balance Equality and Excellence
- Growing importance to Knowledge
- Globalization -- New Economy

We need to change to meet these challenges

How long can we resist?

Change is the only constant

It is not the strongest of the species that survive, nor the most intelligent, but the one most responsive to change…

……Charles Darwin

Like in business and in the jungle ultimately it will be the survival of the fittest.

Indian Universities

- Based on the British model of affiliating.
- Consist of a large number of colleges.
- Pharmacy is still finding its own place…..
- Governance has been very bureaucratic and rigid.
- Multiple controls at local, state and central level.
- Poor mechanism for effective quality assurance and lacks adequate accountability.
- The approach of the Government has been more of a 'Controller' than a 'Developer.'

Overview: India

- Near 500 Universities
- Over 40,000 colleges (Government and Private)
- Over 7,000,000 students.
- 34,000 graduates and 30,000 skilled technocrats migrate every year to the US…75% Do not return.
- Estimated fees paid to institutions abroad by Indian students is over $500 million every year.

Pharmacy

- Degree colleges 748
- Diploma 666
- Pharm D 119

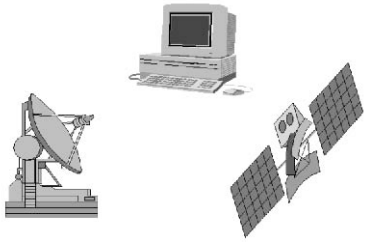
The Old and New Paradigms

- Linear, sequential college curriculum
- Very rigid and compartmentalized
- Student mobility across Pharmacy discipline is difficult
- Inter and Interdisciplinary environment needs strengthening
- Based on lectures to passive students
- Modular, Credit based
- Very flexible for students
- Interdisciplinary and open
- More practical
- Larger involvement of Industry

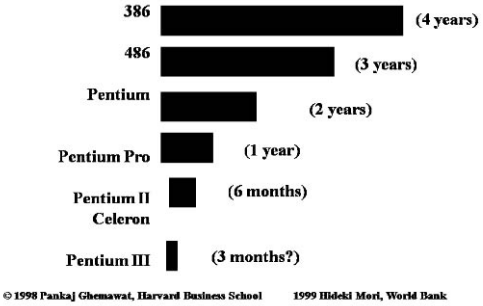
Some Facts of Today

- 50% of economic growth is driven by knowledge based new technology.
- 90% of new jobs require college-level education.
- Most important factor in determining personal income is the level of one's education.
- Corporate leaders estimate that the "high-performance workplace" will require that 20% of a worker's time will be spent in formal education.
- In an age of knowledge, learning must be a lifetime commitment. Hence they will seek employment where they are provided with the richest set of learning opportunities.

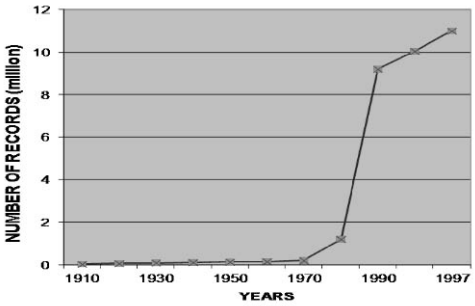
Economic development is increasingly linked to a nation's ability to acquire and apply knowledge



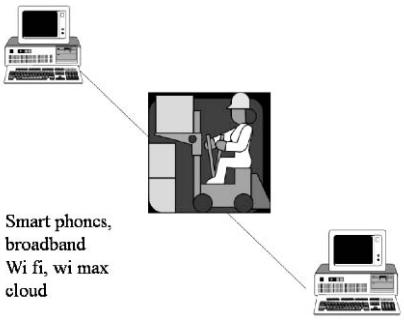
Duration of Intel domination



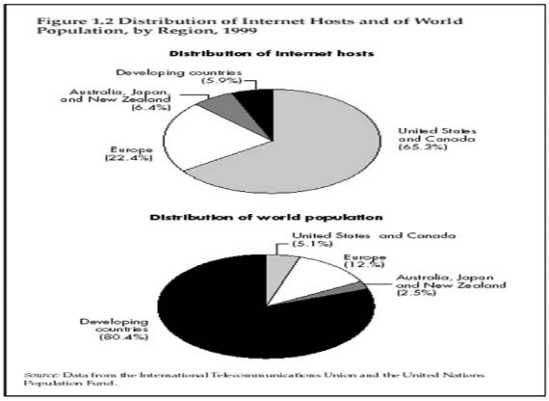
Growth of the Chemical Abstracts database



1990 -2012 Internet Revolution



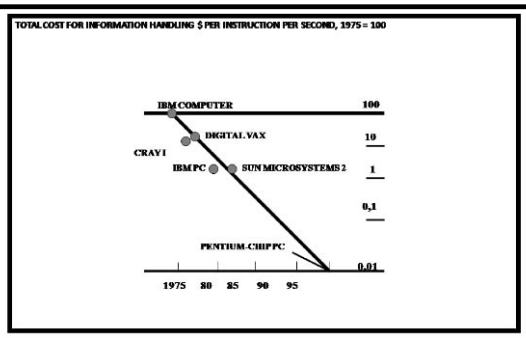
Smart phones,
broadband
Wi fi, wi max
cloud



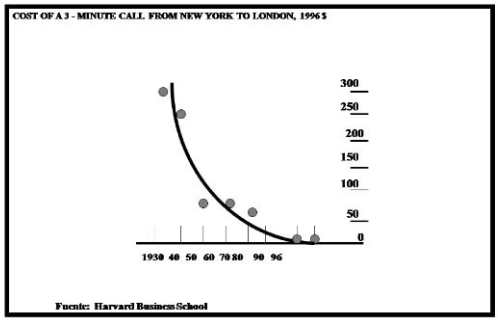
Information and Communication Technology

- Expansion of computing power
- Falling cost of transmitting information
- Convergence of computing and telecommunications

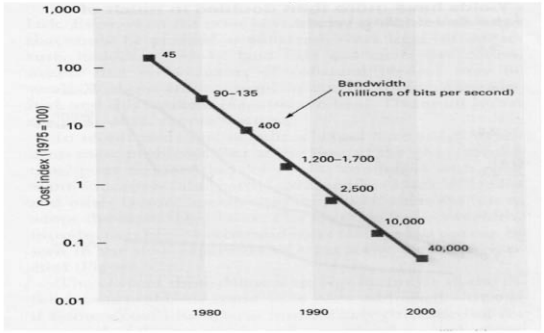
Evolution of computers...



Long-distance Telephoning



Cost of sending information...

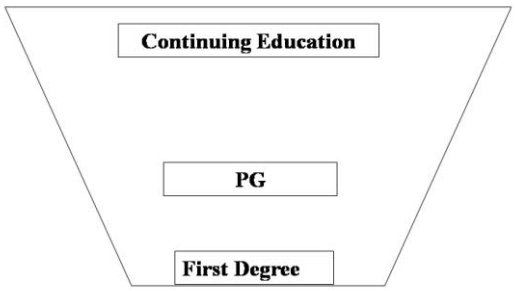


Traditional Structure

PG | Continuing Education

First Degree

University of the Future



1450-1990

"Thirty years from now the big university campuses will be relics. Universities won't survive. It is as large a change as when we first got the printed book."

–Peter Drucker

Education: Inclusive or Profit ?

- Privatization of education is not a very new process in India.
- Private coaching has become a big business.
- Capitation fees or donations.
- Many private companies have broken the traditional barrier and monopoly of Universities to impart higher and specialized education.
- Most of such institutes functioning as *de facto*

Competition: From Charity to Business

- Aggressive Marketing Efforts
- Private For-Profit Ventures
- Professional Management
- Education ... Next in the pipeline after
  - Consumer products, Automobile, Post and Telegraph, Communication, Energy, Health Care....

Monopolies would dwindle and Excellence should emerge

From Takshseela to Chattisgad ?

Indian Higher Education at Cross-Roads

Over 500 Universities

(INIs, Central, State, Deemed, Private) and

40, 000 Colleges

(autonomous, affiliated)

No place in Global Ranking of Top 100 Universities!!

Need more world class Pharmacy Institutions
Accreditation beyond physical measures

TQM: Teachers Quality Management

Teachers should become the Change Managers

Capacity building

- Strengthen connection between education and research
- Use of technology in education
- Develop soft skills
- Continuing education
- Role of Alumni

The Visionaries Guiding Force

- "Education is not the amount of information that is put into your brain and runs riot there, undigested, all your life. We must have life-building, man-making character-making, assimilation of ideas. If education were identical with information, the libraries would be the greatest sages of the world and encyclopedias the rishis". -
  – .....Swami Vivekananda
- *"I do not want my house to be walled in all sides and my windows to be stuffed. I want the culture of all lands to be blown about my house as freely as possible, but I refuse to be blown of my feet by any"*

  Mahatma Gandhi.... Young India, June 1, 1921

Change is the only constant

- *It is not the strongest of the species that survive, nor the most intelligent, but the one most responsive to change…*
  – .....Charles Darwin

Like in business and in the jungle ultimately it will be the survival of the fittest.

"I wonder at times if we are not like the dinosaurs, looking up at the sky at the approaching comet and wondering whether it has an implication for our future." – *Frank Rhodes*

Organizations like IPC will play an important role during this process of change in Indian Pharmacy Education

Thank you!

ROLES AND RESPONSIBILITIES OF ETHICS COMMITTEES

By

Shri. Rakesh Kumar Rishi

Government Analyst, Central Drugs Laboratory, Kolkata

Ethical Principles

The principle of Ethics is the foundation of clinical research. Every clinical trial (single case studies, randomized clinical trials, observational studies, etc.) needs to adhere to ethical aspects of respect, beneficence and justice. Respecting individual subjects in clinical trials by treating them as independent subjects, conducting clinical research that intends well-being and thereby ensuring beneficence, and planning clinical research in such a way that the associated benefits and burdens are clearly accounted for need to be adhered to. The principle of transparency mandates researchers to be factual about the planning, conduct and reporting of clinical trial. Reporting of clinical trial starts with proper planning and continues with proper conduct of the experiment. The principle of transparency ensures that each step during the planning, conduct and reporting is taken only after due thought process that has gone into justifying the particular step that was taken. Transparency creates confidence in the public at large about the clinical research. Another ethical principle of scientific un-bias is based on scientific and communication excellence which is achieved by evaluating the clinical research process in a holistic approach. That means, the final interpretation is based on internal validity of the clinical research to ensure that clinical researcher and consumers of this research are closer to the truth.

These ethical principles are universal. Statistical principles like hypotheses testing, confidence intervals, sample size, randomization and blinding, bias and bias reduction, design of experiments, statistical interpretation of data and meta-analyses can be applied to make the clinical research ethical, transparent and scientifically unbiased.

Background

The first official guideline for the formation of ethics committees was issued by Indian Council of Medical Research (ICMR) in February 1980. Now, it has been more than three decades since the establishment of ethics committees in India. These guidelines stipulated requirements for membership criteria and ethical standards for review, which later became the foundation for the establishment of ethics committees in India. This was followed by release of the ICMR guidelines in bioethics in year 2000, which was a guidance document for research in medical, epidemiology, and public health and was further revised in 2006. The Schedule Y to Drugs and Cosmetics Rules came in existence in 1988, revised in 2005, and further revision took place in 2013. Revised Schedule Y provides clarity on the composition, function, roles and regulatory responsibilities as well as registration process of ethics committees.

The Medical Council of India Code of Ethics Regulations, 2002 mentions that research involving patients or volunteers must be undertaken as per provided ethical considerations described in the ICMR guidelines. It is clearly stated that violation of the existing ICMR guidelines would constitute misconduct. Further, if informed consent is not taken as per the guidelines from a trial participant, this shall also be construed as misconduct.

Definition of Ethics Committee

Ethics Committee (EC) is defined in rule 122-DD as "*For the purpose of this rule an Ethics Committee is a committee comprising of medical, scientific, non-medical and non-scientific members, whose responsibility is to ensure the protection of the rights, safety and well-being of human subject involved in a clinical trial and it shall be responsible for reviewing and approving the protocol, the suitability of the investigators, facilities, methods and adequacy of information to be used for obtaining and documenting informed consent of the study subjects and adequacy of confidentiality safeguards".* EC is also known as Independent Review Board (IRB) or Independent Ethics Committee (IEC).

Regulatory Status

Para 2 (1) (i) of Schedule Y states that clinical trial on a new drug shall be initiated only after the permission has been granted by the licensing authority and the approval obtained from respective ethics committee(s). Rule 122-DD (1) further states that no Ethics Committee shall review and accord its approval to a clinical trial protocol without prior registration with the Licensing Authority as defined in clause (b) of rule 21. From this, it is clear that no clinical trial can be conducted in the country unless it is approved both from the Drugs Controller General of India (i.e., licensing authority) as well as EC. Therefore, sponsor and/or investigator should get the opinion of an EC regarding suitability of the p*rotocol*, methods and documents to be used in recruitment of s*ubjects* and obtaining their i*nformed consent* including adequacy of the information being provided to the study subjects.

Composition of EC

The composition of EC should be multidisciplinary and multi-sectorial. The independence and competence are two hallmarks of an EC. ***Appendix VIII to Schedule Y and Rule 122-DD describes composition of EC. It states that*** number of persons in an EC should be at least seven including a chairperson (who is from outside the institution) and a member secretary. Other members should be a mix of medical/non-medical, scientific and non-scientific persons, including lay public, to reflect the different viewpoints.

For review of each protocol the quorum of Ethics Committee should be at least 5 members with the following representations:

(a) basic medical scientists (preferably one pharmacologist)

(b) clinicians

(c) legal expert

(d) social scientist/representative of non-governmental voluntary agency / philosopher / ethicist / theologian or a similar person

(e) lay person from the community

The quorum is the count of the number of members present in the EC meeting and if number present falls below the required number, the quorum fails. If any member of EC defined in Schedule Y is absent, the requirement of quorum will not be met. It is also important to mention here that if an investigator is part of the quorum of five members, and if he is unable to vote for his own study, the quorum will fail.

The EC must include at least one member whose primary area of interest or specialization is nonscientific and at least one member who is independent of the institution/trial site. Besides, there also should be appropriate age, gender, and community representation. If required, subject experts may be invited to offer their views. Further, based on the requirement of research area, e.g. HIV/AIDS, genetic disorders etc. specific patient groups may also be represented in the EC as far as possible. Only those members who are independent of the clinical trial and the sponsor of the trial should vote/provide opinion in matters related to the study.

Training of EC Members

The members of EC should be well acquainted with the national and international developments in the clinical research especially in the area of ethics. Whenever appropriate, the members of EC should get trained in ethical aspects of the biomedical research. Such training includes statutory requirements, ethical codes, GCP guidelines, clinical research, risk benefit analysis, responsibilities of EC, EC review process etc. Members should also be trained on recruitment of vulnerable population, conflict of interest, placebo-controlled trials, etc.

Application to EC

The researcher submits an application to the EC along with the clinical trial protocol at least three weeks in advance. As per the requirements of Indian GCP guidelines (para 2.4.2.5), the protocol should include the following information:

1. Clear research objectives and rationale for undertaking the investigation in human subjects in the light of existing knowledge.
2. Recent curriculum vitae of the Investigators indicating qualification and experience.
3. Subject recruitment procedures.
4. Inclusion and exclusion criteria for entry of subjects in the study.
5. Precise description of methodology of the proposed research, including intended dosages and routes of administration of drugs, planned duration of treatment and details of invasive procedures if any.

6. A description of plans to withdraw or withhold standard therapies in the course of research.
7. The plans for statistical analysis of the study.
8. Procedure for seeking and obtaining informed consent with sample of patient information sheet and informed consent forms in English and vernacular languages.
9. Safety of proposed intervention and any drug or vaccine to be tested, including results of relevant laboratory and animal research.
10. For research carrying more than minimal risk, an account of plans to provide medical therapy for such risk or injury or toxicity due to over-dosage should be included.
11. Proposed compensation and reimbursement of incidental expenses.
12. Storage and maintenance of all data collected during the trial.
13. Plans for publication of results - positive or negative - while maintaining the privacy and confidentiality of the study participants.
14. A statement on probable ethical issues and steps taken to tackle the same.
15. All other relevant documents related to the study protocol including regulatory clearances.
16. Agreement to comply with national and international GCP protocols for clinical trials.
17. Details of Funding agency / Sponsors and fund allocation for the proposed work.

Responsibilities

Free from any bias and influence, EC reviews (from scientific and ethical angle) and accords its approval to a trial protocol to safeguard the dignity, rights, safety and well being of all trial subjects. EC has to ensure that universal ethical values and international scientific standards are expressed in terms of local community values and customs. EC meets periodically at frequent intervals to review new proposals, evaluate annual progress of ongoing ones and assess final reports of all research activities involving human beings through a previously scheduled agenda, amended wherever appropriate.

EC exercises particular care to protect the rights, safety and well being of all vulnerable subjects participating in the study, e.g., members of a group with hierarchical structure (e.g. prisoners, armed forces personnel, staff and students of medical, nursing and pharmacy academic institutions), patients with incurable diseases, unemployed or impoverished persons, patients in emergency situation, ethnic minority groups, homeless persons, nomads, refugees, minors or others incapable of personally giving consent. All the procedures of EC are properly documented and SOPs are maintained.

The EC evaluates the possible risks to the subjects with proper justification, the expected benefits and adequacy of documentation for ensuring privacy, confidentiality and justice issues. Any change in the trial procedure should be brought to the notice of the EC with proper justification for evaluation of the risk-benefit analysis. At appropriate intervals, EC reviews the ongoing trial to recommend changes in the study if

required. If EC revokes its approval, it must be recorded with reasons and information should be communicated to the investigator(s) as well as the licensing authority.

The ECs are entrusted not only with the initial review of the proposed research protocols prior to initiation of the trial, but also have a continuing responsibility of regular monitoring for the compliance of the ethical aspects and other regulations till the trial is completed. Such an ongoing review is in accordance with the Declaration of Helsinki and all the national and international guidelines for biomedical research. The EC should make it a practice to monitor informed consent process by having one of its members observing and verifying the adequacy of consent process. During the continuing review, the EC should focus on protocol deviations, safety reporting, progress reports etc. and seek additional information from the investigator.

Reporting of Serious Adverse Event of Death

As per the newly inserted clause 5(iv) in Schedule Y, the Ethics Committee shall forward it's report on the serious adverse event of death of subject during clinical trial, after due analysis, along with its opinion on the financial compensation, if any, to be paid by the Sponsor or his representative, to the Chairman of the Expert Committee constituted by the Licensing Authority with a copy of the report to the Licensing Authority within twenty one calendar days of the occurrence of the serious adverse event of death. In case of serious adverse event other than death occurring to the clinical trial subject, the Ethics Committee shall forward its report on the serious adverse event, after due analysis, along with its opinion on the financial compensation, if any, to be paid by the Sponsor or his representative, to the Licensing Authority within twenty one calendar days of the occurrence of the serious adverse event.

Terms of references

The members of EC should be made aware of their role and responsibilities as committee members. Confidentiality should be maintained and any conflict of interest should be disclosed in advance. A member must voluntarily withdraw from the EC 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. If any member has his own proposal, he should not participate in the proceedings.

The members of EC should be aware of all national and international developments relating to clinical research. The statement on policy, tenure of the EC, and its quorum should be included in the terms of references. Other issues such as the duration of the term of membership, policy for removal, replacement and resignation procedure etc. should also be pointed out. Each EC should have its own set of SOPs that should be made available to each member.

Record Keeping

Rule 122-DD mandates that all documentation and communication of an EC are dated, filed and preserved according to SOPs. Strict confidentiality is maintained during access and retrieval procedures. Records are maintained for the following:

1. Constitution and composition of the EC
2. Curriculum vitae of all members
3. SOPs
4. Copies of national and international guidelines, appropriate legislations, copies of the protocol, data collection formats, CRFs, investigational brochures etc., correspondence with EC and investigator(s), agenda, minutes, and decisions made on the proposals
5. Notifications issued for premature termination of a study with a summary of the reasons
6. Final report of the study
7. Registration letter from Licensing Authority

It is recommended that all records must be safely maintained after the completion / termination of the study for at least a period of 5 years if it is not possible to maintain the same permanently.

Role of Pharmacist in Ethics Committee

Although there is no regulatory requirement, pharmacist should be co-opted as a member of the ethics committee. A professionally qualified and experienced pharmacist can participate in the ethics committee and can look into the ethical aspects of the trial. By virtue of his vast knowledge in chemistry and formulation aspects of pharmaceutical products, pharmacist can provide an expert opinion on the pharmaceutical aspects of the investigational product undergoing ethical review. Pharmacist may also give valuable opinion on study design and methodology, choice of investigational product and comparator, blinding issues, formulation, administration, contraindications, side effects and interactions of the investigational product. Pharmacist can check whether product has been manufactured under Good Manufacturing Practice (GMP), whether labelling is appropriate, and whether sponsor has provided adequate information on handling, storage, dispensing and disposal of investigational product before considering approval of a clinical trial by the ethics committee.

The pharmacist must be aware of, and where appropriate, must declare any possible conflict of interest between her/his role on the ethics committee and involvement in providing pharmacy clinical trials services or in the clinical trial as a researcher/investigator.

Format for Approval of Ethics Committee

There is a format prescribed in Appendix VIII para III of Schedule Y for granting approval of a clinical trial. This format is reproduced as under:

To

Dr.

Dear Dr. _____

The Institutional Ethics Committee / Independent Ethics Committee (state name of the committee, as appropriate) reviewed and discussed your application to conduct the clinical trial entitled "……" on …….(date).

The following documents were reviewed:

a. Trial Protocol (including protocol amendments), dated_____ Version no(s) ____.
b. Patient Information Sheet and Informed Consent Form (including updates if any) in English and/or vernacular language.
c. Investigator's Brochure, dated_____, Version no._____.
d. Proposed methods for patient accrual including advertisement(s) etc. proposed to be used for the purpose.
e. Principal Investigator's current CV.
f. Insurance Policy / Compensation for participation and for serious adverse events occurring during the study participation.
g. Investigator's Agreement with the Sponsor.
h. Investigator's Undertaking (Appendix VII).

The following members of the Ethics Committee were present at the meeting held on (date, time, place).

_____ Chairman of the Ethics Committee
_____ Member secretary of the Ethics Committee
_____ Name of each member with designation

We approve the trial to be conducted in its presented form.

The Institutional Ethics Committee / Independent Ethics Committee expects to be informed about the progress of the study, any SAE occurring in the course of the study, any changes in the protocol and patient information/informed consent and asks to be provided a copy of the final report.

Yours sincerely,

Member Secretary, Ethics Committee.

Registration of Ethics Committee

It is now mandatory for the Ethics Committee to get the registration from the Licensing Authority as per the requirements of Rule-122 DD of Drugs and Cosmetics Rules and as per the provision laid down in revised Appendix VIII of Schedule Y.

Ethics in Pharmacy Practice and Pharmacists' Role in Safety of Medicine for Welfare of Common Man

By

Mr. M. Muthuraman, Kamalakshi Pandurangan College of Pharmacy, Tiruvanamalai

Note: This article was awarded First Prize in the Essay Competition conducted by our Trust.

Introduction

Ethics are the code of moral principles or the branch of philosophy concerned with the human character and conduct. For the practice of pharmacy, the code of ethics are framed by the Pharmacy Council of India, which guides them how he should conduct himself, his patrons, colleagues and general public, members of the medical and other health professionals. Pharmacists, the health care professionals play their valuable role in managing overall healthcare. Though patients receive care from multiple health professionals in several locations, only the Pharmacists plays a vital role through their actions as a link in communication and safety oversight among all the members of the health care team. They render services in Pharmacy and help in preparation of pharmaceuticals, provide drug information, monitor drug therapy, manage medicine supply as well as in patient- centered care with counseling.

Ethical Responsibilities

The code of ethics is intended to capture the philosophical foundation of pharmacy practice and to express the responsibilities and professional values that are fundamental and inherent to the pharmacy profession.

Overall Being a Pharmacist, they must

- Make the health and well being of the patient. Promote patient's self-determination, respect patient's rights, autonomy & freedom of choice. Use the professional judgement in the interests of patients and the public and promote family and community health. Should exercise their duties with professionalism.

- Actively seek and apply contemporary pharmacy knowledge and skills to ensure a high standard of professional competence. Act in a manner that promotes public trust and confidence in pharmacists and enhances the reputation of the profession. Practise in a manner that does not compromise professional independence, judgement or integrity or that of other pharmacist role.

Role of Pharmacists In Medication Safety

Pharmacists have an important role in medication safety & they do much more than count out pills and pour liquids to fill prescriptions. They perform several duties like,

- Help prescribers to make medication decisions and catch errors (like incorrect drug & dose or the wrong instructions) before the medication makes it to the patient.

- Directly coordinate with patients and assist with medication adherence. Resolve patient questions especially when the patient is unsure what time to take the medication. Help to find an affordable alternative for the patient, in case of expensive drug.

Checking Prescriptions

Pharmacists are the medication experts, check each prescription, help to ensure that the information provided by the prescriber is complete, there is no interaction, the medication and dosage are safe with any medical conditions that they are aware what the patient may have.

Patient Education And Counseling

It is the key role of pharmacists to educate patient with the complete details of their therapy and medications. With the medication profile of the patient, Pharmacist can warn the patients of possible harmful drug interactions or allergies. Tell them about potential side effects. Advise them on foods, drinks or activities to avoid while taking a certain medication or on what to do if they miss a dose.

By giving information about a medication's ability to impair driving, pharmacists may be able to decrease the likelihood that their patients will be involved in a motor vehicle crash. They warn the patients about complications on driving performance and help to recognize the signs of impaired driving. Pharmacists should collaborate with physicians to change drug therapy for patients to lessen the risk for potentially driver-impairing effect and can recommend a medication schedule that may lessen driving risk.

Clinical Responsibilities

An important clinical responsibility of the pharmacist is the early detection of ADRs and other drug-related problems as well as monitoring of the effectiveness of medicines. The pharmacist's expertise is vital to the application of the safety profile of a medicine to the needs of a particular patient.

Drug - Interaction Factors

With today's technology, drug interactions would be rare, but in fact, they are still quite common. This is extinct for patients with chronic conditions, and today's patients are shunted from specialist to specialist. So to prevent such interactions, Pharmacists and other healthcare providers can follow a number of best practices. One such is medical reconciliation.

Medical Reconciliation

- Process of creating and maintaining the most accurate list possible of all medications a patient is taking and using that list to guide the assessment of therapy.
- Decreases hospital utilization and prevent readmissions.
- Begins when the patient is admitted, continues whenever the patient transitions to another level or setting of care and occurs again when the patient is discharged.
- The goal is to provide correct medications to the patient at all transition points within the hospital and is completed only when each drug, the patient is taking has been actively continued, discontinued, held or modified at each transition point.

Conclusion

Pharmacists play a key role in the partnership for patients, aim to reduce ADR events and improve care transitions. By taking an active role in the health of their customers, Pharmacists can really make a difference in their health. Whether it is a community pharmacist partnering with community organizations or a clinical pharmacist partnering with physicians and others in a hospital to provide vital team-based care, they play a vital role to improve patient safety and decrease readmissions. However busy pharmacies, lack of time and communication problems are some of the obstacles that pharmacists face when trying to provide effective medication counseling to patients. No matter whatever the barriers to counseling are, pharmacists have a professional and in some case a legal responsibility to ensure that they incorporate appropriate patient counseling into their practice.

Ethics in Pharmacy Practice and Pharmacists Role in Safety of Medicine for Welfare of Common Man

By
Ms. S. Sharmila Banu, Vels University, Chennai

Note: This article was awarded Second Prize in the Essay Competition conducted by our Trust.

SYNOPSIS:

- **INTRODUCTION**
- **MISSION OF PHARMACY PRACTICE**
- **ETHICS IN PHARMACY PRACTICE**
- **GOOD PHARMACY PRACTICE**
- **CODE OF ETHICS FOR PHARMACIST**
- **ROLE OF PHARMACIST IN SAFETY USE OF MEDICINE**

INTRODUCTION

The health of the public is fundamental to the happiness and welfare of all people. Barriers to good health include poor access to quality medical products, lack of access to trained health professionals and care, an inadequate health workforce, unaffordable cost of care and poor standards of education of health-care professionals. Medicines are an essential and critical part of health-care services in all cultures and societies.

Pharmacist: Pharmacists are health professionals who assist individuals in making the best use of medications.

Ethics in pharmacy practice:

Ethics and responsibility are expressions that should characterize professional practice in many sectors of society. Pharmacy, being a high technology activity, is just an example of a field where (responsible) decisions about medicines and health care are closely connected to private and public life.

Mission of pharmacy practice:

The mission of pharmacy practice is to contribute to health improvement and to help patients with health problems to make the best use of their medicines.

- Being readily available to patients with or without an appointment, identifying and managing or triaging health-related problems;

- Health promotion;
- Assuring effectiveness of medicines;
- Preventing harm from medicines; and
- Making responsible use of limited health-care resources.

Good Pharmacy Practice:

The aim of pharmacy practice is defined as to **"contribute to health improvement and to help patients with health problems to make the best use of their medicines."**

GPP is defined as" the practice of pharmacy that responds to the needs of the people who use the pharmacists' services to provide optimal, evidence-based care. To support this practice it is essential that there be an established national framework of quality standards and guidelines".

Code of ethics for pharmacist:

- **A pharmacist respects the covenantal relationship between the patient and pharmacist.** A pharmacist promises to help individuals achieve optimum benefit from their medications, to be committed to their welfare, and to maintain their trust.
- **A pharmacist promotes the good of every patient in a caring, compassionate, and confidential manner.** A pharmacist is dedicated to protecting the dignity of the patient. With a caring attitude and a compassionate spirit, a pharmacist focuses on serving the patient in a private and confidential manner.
- **A pharmacist maintains professional competence.** A pharmacist has a duty to maintain knowledge and abilities as new medications, devices and technologies become available and as health information advances.
- A pharmacist respects the autonomy and dignity of each patient.
- A pharmacist acts with honesty and integrity in professional relationships
- A pharmacist maintains professional competence.

Role of pharmacists in safety use of medicines:-

Pharmacists play a key role in reducing adverse drug events and improving patient safety during transitions in healthcare. Pharmacists are one of the most accessible healthcare providers, and are among the best trained to help patients use their medication. Collaboration with other health professionals to implement and evaluate system-wide improvement measures is critical to promoting quality and safety and reducing healthcare costs.

Patient safety:- Patient safety is a high-priority issue for all professionals – like pharmacist – who care for the health and general well-being of people. Patient safety is defined as ***the prevention of harm to patients, including through errors of commission and omission.***

For centuries, pharmacists have been the guardians/safeguards against "poisons" those substances which could cause harm to the public. Now more than ever pharmacists are charged with the responsibility to ensure that when a patient receives a medicine, it will not cause harm.

The involvement of pharmacists in patient safety can be as early at the prescribing phase and up to the administration of the medicines.

Medicines play a crucial role in saving lives, restoring health and preventing, diseases and epidemics. However, what generally is not realized that for a human body, medicines are essentially foreign substances and therefore, if not used with care they can do more harm than good.

Patient medication counseling:

Patient counseling is an interpersonal communication between the pharmacist and the patient/patient party regarding the disease, medication and lifestyle modifications. It deals with providing information, advice and assistance about medication and therapy either orally or in written form to the patients or to their representatives.

Rational use of drugs:

In current scenario, the rational use of medicines is an utmost issue. WHO defines it as "rational use of drugs requires that patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirement for an adequate period of time, at the lowest cost to them and their community. A pharmacist is one of the inevitable members of healthcare team who can help in achieving the goal of rational use of drugs by following good pharmacy practices.

Specialist in preventing drug/medicine abuse:

Medicines have confined not only immense benefits but also number of harms to mankind. Abuse of medicines is a serious global issue. **Pharmacist can play a key role in preventing drug abuse by providing clear information and advices about the adverse effects of medications.** Drug abuse may arise due to one of the following reasons such as wrong diagnosis, inappropriate drug selection, and wrong dosage schedule, situations where indications are not specified, unwarranted prophylactic use, poly pharmacy and drug interaction, drug nutrient interaction, self medication with OTC/prescription drugs, lack of facilities in rural/poverty areas.

Hence, it is the prime responsibility of a **pharmacist to take an active role in helping the drug abusers to avoid abuse of drugs.** Pharmacist can also play an integral role in instructing drug abuse counselor and

other health care professionals about pharmacology and mechanism of action of abused substances and of medication used to treat substance use disorders.

Role in self care and self medication:

Self medication is the selection and use of medicines by individuals to treat their self recognized illness or symptoms. It is an accepted fact that self care is the primary source of drug abuse in the healthcare system. The need of the hour is that, pharmacist accept these challenges boldly and courageously to ensure safe use of medicines even during self care and self medication. He cannot be a helpless spectator.

Preventing drug interactions:

Some medicines can interact with other medicines, foods and dietary supplements. As a result, they don't show their expected effects or may cause unpleasant and adverse reactions. To prevent drug interactions, there should be a healthcare management which must be followed by a pharmacist.

- Patient profile should be reviewed thoroughly including drug history and patient risk factors.
- Complex therapeutic regiments should be avoided.
- Probability of a clinically significant drug interaction should be determined.
- Patient profile should be re-evaluated when changing drug therapy.

Conclusion

Proper role and involvement of pharmacist in medicine management and overall healthcare programmed, therefore, becomes very crucial. Wide range of drugs and healthcare products need to be properly stored and distributed by a qualified pharmacist so that they can be appropriately used by a patient. In the emerging scenario, it is logical that society would be happy to rely upon pharmacist to enhance the quality of drug therapy by identifying inappropriate prescribing, pharmaceutical delivery, patient compliance, patient idiosyncrasy and appropriate monitoring of drug therapy. However, pharmacist will have to develop their pharmaceutical expertise and facilities in order to deliver high-tech and individually-tailored medicines in the primary care settings. Hence, if pharmacists do not rise to the occasion and accept these challenges to serve mankind by ensuring safe use of medicines, they will be blamed forever for the disastrous results.

There are four main roles where pharmacists' involvement or supervision is expected by society and the individuals they serve:

- Prepare, obtain, store, secure, distribute, administer, dispense and dispose of medical products.
- Provide effective medication therapy management.
- Maintain and improve professional performance.
- Contribute to improve effectiveness of the health-care system and
- Public health.

NOTIFICATIONS

MINISTRY OF HEALTH & FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 17th January 2014

G.S.R 29(E) – Whereas the Central Government is satisfied that the drug Oxytocin has a definite therapeutic use in certain medical conditions;

And whereas, the Central Government is satisfied that it is necessary and expedient to regulate and restrict the manufacture, sale and distribution of the said drug in the country to prevent its misuse in public interest.

Now therefore, in exercise of the powers conferred by section 26A of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government hereby directs that the drug oxytocin shall be manufactured for sale or for distribution or sold in the manner specified below, in addition to the provisions contained in the said Act and Rules made thereunder, namely:-

1) The manufacturers of bulk oxytocin drug shall supply the active pharmaceutical drug only to the manufacturers licensed under the Drugs and Cosmetics Rules 1945, for manufacturer of formulations of the said drug.

2) The formulations meant for veterinary use shall be sold to the veterinary hospitals only.
The order shall come into force on the date of its publication in the official Gazette.

[F.No.18-11/2013-DC/DFQC]
ARUN K PANDA, Jt. Secy

CONGRATULATIONS

The Madras University elected Jt. Secretary of our Trust, Mr.M.M.Yousuf, Joint Director, Drugs Control Administration, Tamilnadu (R), President, Indian Pharmaceutical Association –TN Branch, as a non-Academic member to the University, for period of three years, from **1st January 2014 to 31st December 2016**. Pharma Web congratulates him for his success in his new assignment.

INFORMATION

M.Pharm & Pharm D Scholarship 2013 - 14 awarded by TNPSWT
Profile of First Rank Projects

PHARMACEUTICS

Name: Mr. S. Karthik

Project Title: Development of solid lipid nanoparticles for enhanced oral bioavailability of Tetr-Hydrocurcumin (THC) and Assessment of Pharmacokinetic parameters.

College: PSG College of Pharmacy, Coimbatore

Guide's Name: Mr. S. M. Habibur Rahman

PHARMACEUTICAL CHEMISTRY

Name: Mr. U. Jayaram

Project Title: "Design and synthesis of dna gyrase(gyrb) and topoisomerase iv (par e) dual inhibitors as robust antibacterial agents".

College: JSS College of Pharmacy, Ooty

Guide's Name: Dr. Md. Afzal Azam

PHARMACEUTICAL ANALYSIS

Name: Mr. M. Preetham Reddy

•**Project Title:** "Enantiomeric separation of Guaifenesin by using chiral Stationary Phase"

College: JSS College of Pharmacy, Ooty

Guide's Name: Mr. M. R. Jeya Prakash

PHARMACOLOGY

Name: Mr. J. Sivaraman

Project Title: "A study on the clinical profile and pharmacogenetics of Methotrexate (MTX) treatment in patients with Rheumatoid Arthritis"

College: Madras Medical College, Chennai

Guide's Name: **Dr. R. Nandini**

PHARMACOGNOSY

Name: Ms. S. R. Nandhini

Project Title: The Green synthesis of silver nanoparticles from the ethanolic extract of leaves of *Costus pictus* D.Don for enhancing the oral bio-availability.

College: Madurai Medical College, Madurai

Guide's Name: **Dr. Ajithadas Aruna**

PHARMACY PRACTICE

Name: Ms. Megha Gupta

Project Title: A Study on Monitoring & Detection of Adverse Drug Reactions using Laboratory Signals

College: JSS College of Pharmacy, Ooty

Guide's Name: Dr. S. Ponnusankar

PHARM D – PHARMACY PRACTICE

Name: Mr.K.Ganesamuthy, Mr.Hithesh, Ms.Keerthi Chaitanya, Mr.M.Venkata Saicharanteja

Project Title: Patient Satisfaction with Proton Pump Inhibitors in a Tertiary Care Teaching Hospital

College: Sri Ramachandra University, Chennai

Guide's Name: Ms. K.Kousalya

PHARM D- CLINICAL PHARMACY

Name: Ms. Esther Mary Soman, Ms.Merlin Jose, Ms.Renu Elizabeth Markose, Ms.Susanna K Sam

Project Title: Population Pharmacokinetics of Gentamicin in South Indian Pediatric Population

College: JSS College of Pharmacy, Ooty

Guide's Name: Mr. Arun K P

"Training Program For Quality Management Personnel"

"Pharma Knowledge & Training Institute- Finishing School" wish to inform that the first Training Program on **"Industrial orientation Training for Quality Management Personnel"** would be held from **12th May 2014 to 9th June 2014** at Tamilnadu Pharmaceutical Sciences Welfare Trust, Block AB- Basement, Baid Metha Complex, 16, Anna Salai, Little Mount, Saidapet, Chennai - 600015.

This Training Programme is open to B. Pharm and M. Pharm students who have completed their course and also for those who will be taking their Final examination in the month of April 2014. Those interested to join the Training Programme should register themselves by payment of Rs. 5,000 /- as Advance Registration Fee (balance amount to be paid on or before 12th May 2014). The total number of seats is only 20. Registration will be closed once the 20 seats are filled. The course fee has been reduced to Rs. 7,000/- from Rs. 10,000/- for the first programme.

The Demand Draft for Rs. 5,000/- drawn in favour of "Tamil Nadu Pharmaceutical Sciences Welfare Trust", payable at Chennai should be sent to the following address, giving their Biodata, Contact number and Email I.D.

The Chairman, Pharma Knowledge and Training Institute
Tamilnadu Pharmaceutical Sciences Welfare Trust
Block AB- Basement, Baid Metha Complex
16, Anna Salai, Little Mount, Saidapet
Chennai - 600015.
(Contact Nos.: 044-22300992, 22200854, Fax: 044-22355864, E-Mail: pictrust@hotmail.com)

NEW ADDITION TO TRUST LIBRARY

The following new Reference books are added to our library for the year 2014

1) USP 2014 - 37th Edition
2) British Pharmacopeia - 2014
3) Indian Pharmacopeia - 2014

EVENTS

FELICITATION FUNCTION
to
SHRI. S. V. VEERRAMANI
PRESIDENT, INDIAN DRUG MANUFACTURERS' ASSOCIATION

Shri. S. V. Veerramani, Chairman & Managing Director, M/s. Fourrts (India) Laboratories Pvt. Ltd. Chennai has become the National President of INDIAN DRUG MANUFACTURERS' ASSOCIATION and has taken charge as The President on 4th January, 2014 on the Annual Day of IDMA celebrated at The Lalit Hotel, Mumbai.

It was decided by the various Pharma Associations in Tamil Nadu to felicitate Shri. S. V. Veerramani immediately and the programme was conducted on 9th January, 2014 at Hablis Hotel, Guindy, Chennai.

Officers from State and Central Drugs Control Department, Heads of various organizations, members of all the associations took part and greeted him for his successful & purposeful tenure, for more years.

Shri. Ashwini Kumar, Ex DCGI, ,Shri. M. Rajarathinam, Chairman, IDMA, TNPSB, Shri. .B Sethuraman, President, PMA TN, Shri. M.M. Yousuf, President, IPA TN, Shri. C. V. Ramaiah, President, Retd. Drug Controllers' Association and office bearers of these Associations, Heads of most of the Pharmaceutical companies and educational institutions who were present felicitated. Shri S V Veerramani.

While thanking the participants for their whole-hearted support to him, Shri. Veerramani assured that he will continue to work for the welfare of the Pharmaceutical community in the country.

Shri S. V. Veerramani headed various Associations as The President of The Pharmaceutical Manufacturers' Association of Tamilnadu, The Chairman of Indian Drug Manufacturers' Association of Tamilnadu State, President - Rotary Club of Adyar, District Rotary Foundation Chairman – Rotary International District 3230, etc.

He was the Chairman of Local Organizing Committee of the 64th IPC at Chennai during December 2012.

He is the Chairman of Tamilnadu Pharmaceutical Sciences Welfare Trust, Chennai.

Shri Veerramani has been working with passion for the upliftment of Pharmaceutical Industry, especially the SMEs.

The meeting concluded with vote of thanks.

NATIONAL ELOCUTION COMPETITION – 2013 - REPORT

The Education Division of Indian Pharmaceutical Association (IPA) is regularly organizing the National Elocution Competition since 1989 for developing the Intellectual and elocution skills of Pharmacy students. For the past several years, the participation from the students has been very encouraging and highly appreciated by our professionals. This type of competition will certainly boost the morale & confidence of our young talented students and also improve the professional and competitive spirit in them. Prof. Dr. B. Jayakar, Co-Chairman of Education Division was appointed as National Convener for the year 2013.

To conduct the Elocution Competition for the year 2013, Dr. Jayakar nominated the state coordinators for 23 states, to conduct the preliminary round in the Pharmacy Colleges of the respective state before 20th November 2013.

The topic for the preliminary round was **"Pharmacist – Challenges in Drug Discovery and Development".** The first and second place winners from each state were eligible to contest in the semifinal round.

The semifinal round was conducted at Auditorium of Vivekananda College of Pharmacy, Bangalore on 11th December 2013. Dr. Ramesh, Syndicate member Rajiv Gandhi University for Health Sciences, Bangalore, the special guest for the function, inaugurated the competition. Prof. T. V. Narayana welcomed the gathering.

The topic for the semifinal round was **"Pharmacists – Better Clinical Care"**. Among them, six candidates were selected for the final round. In semifinal round, 1st prize winner Ms. Priyanka Maddirala, II. M. Pharm, Lalitha College of Pharmacy from Andhra Pradesh received a cash award of Rs.5,000/-, 2nd prize winner Ms. Deepthi Merin Raju, IV. B. Pharm, J.S.S. College of Pharmacy, Ooty from Tamilnadu received Rs.3,000/- and 3rd prize winner Ms. Linda Jacob, V. Pharm. D, Vinayaka Mission's College of Pharmacy, Salem from Tamilnadu received Rs. 2,000/- as cash award with a memento and certificate. All the other participants received the participation certificates and a memento.

The final round was conducted on the second day of 65th Indian Pharmaceutical Congress held at Amity University, Noida, New Delhi on 21.12.2013. Mr. J.A.S. Giri, President, IPA, Mumbai was the Chief Guest and inaugurated the competition, Dr. T. V. Narayana, President, IPA - Education Division, presided over the function, Mr. S. D. Joag, General Secretary, IPA, and Mr. C. Gopalakrishnamoorthy, Former President of IPA were the guests of honour. Dr. S. M. Mudda, Executive Director - Technical Operation, Micro Labs Ltd, Bangalore, was the special guest and distributed the prizes. Dr. B. Jayakar welcomed the gathering. The judges for final round of elocution competition 2013 were Mr. Krishna Dev, Former Deputy Drug Controller India, CDSCO, Dr. Vijayarathinam, Professor, Department of Pharmaceutics, Andhra University, Dr. Vadalamudi Rao, Director, St. Peter Institute of Pharmaceutical Sciences, Warangal, Andhra Pradesh, Dr. Roop K. Khar, Principal, Anoog Pooria, Institute of Pharmacy, Hariyana. Dr. P. Jay Sekhar, Ph.D., Prof & Chair, Department of Pharmacy, Omen Medical College, Muscut, Sultanate of Omen.

The topic for the final round was **"Pharmacists for Safe & Effective Medication"**. Ms. Deepthi Merin Raju, IV .B. Pharm, J.S.S. College of Pharmacy, Ooty, Tamilnadu, won the first prize and received a cash award of Rs.20,000/-, Ms. Alanta Maria Raj, IV. B. Pharm, St. James College of Pharmaceutical Sciences, Kerala won the second prize and received a cash award of Rs.10,000/-. The third prize was won by Ms. Linda Jacob, V. Pharm. D Vinayaka Mission's College of Pharmacy, Salem, Tamil Nadu and received a cash award of Rs.5,000/-

The awards were sponsored by Dr. M. Venkateswarlu (Former Drug Controller General of India) Memorial Trust, created by Andhra University Pharmacy Alumni Association, Vishakapatnam.

CONGRATULATIONS TO Dr. S. MANIVANNAN

Dr. S. Manivannan has taken charge as Deputy Drugs Controller India, (CDSCO, Ministry of Health & Family Welfare, Govt of India) South Zone at Chennai from 4th February 2014, Dr. S. Manivannan was born in a village called K.R Thoppur in Salem District in the year 1966. He did his D-Pharm followed by B-Pharm at Annamalai University, Chidambaram and passed out in the year 1989.

After the completion of degree, he worked in the Pharmaceutical Industry at Mumbai and Chennai in Quality Assurance Department for 7 years.

In the year 1998, he joined as Drugs Inspector, CDSCO, Govt. of India, Ministry of Health and Family Welfare at Chennai.

In the year 2006, as a service candidate, he joined, M. Pharm (Pharmaceutics) in Madras Medical College, Chennai and passed out in the year 2008. Immediately he registered for his Ph. D in “The Tamil Nadu Dr. M.G.R. Medical University”, under the guidance of Dr. V. Ravichandiran, Director, Vel's University and completed his Ph. D in June 2013.

In the year 2009, he was given an assignment of setting up a new office of CDSCO at Bangalore as ADC (I) In-Charge.

In the year 2010, he was promoted as Assistant Drugs Controller India and transferred to Mumbai for handling both Sea and Airport for controlling export and import of Drugs and Cosmetics.

In the year 2011, he was directly selected through UPSC as Deputy Drugs Controller India, CDSCO and transferred to New Delhi. In September 2012 he was transferred to Bangalore as Head of the office for the State of Karnataka.

In 2013 May, he visited China as a member of the team of officers for inspection of manufacturing facilities. The above scheme was introduce for first time in India by Ministry of Health and Family Welfare for overseas inspection of manufacturing facility who supply pharmaceuticals / APIs to Indian market.

He is trained by USFDA for Clinical Trial Inspection. As a Drug Inspector he carried out many joint inspections of Pharmaceutical Manufacturing Units for WHO Certification,Blood Bank, LVP Manufacturing Units, Vaccine Manufacturing Units, Medical Devices, etc. for licensing purpose, approval / renewal of testing laboratories & clinical trial sites.

Tamilnadu Pharmaceutical Sciences Welfare Trust welcomes him and wishes him all the success in his new posting.

INDIAN CONGRESS OF PHARMACY PRACTICE2014
&
INAUGURAL CONVENTION OF THE
INDIAN ASSOCIATION OF COLLEGES OF PHARMACY

The Inaugural Convention was held on 21st & 22nd February 2014 at Hotel Sheraton, Bangalore-Karnataka. Dr. Wayne A.I. Frederick, President, Howard University, Washington, USA inaugurated the convention.

The other guests of honor at the convention were Dr. Jagadish Prasad, Director General of Health Services, Govt. of India, New Delhi, Dr. Premkumar Rajagopal, Vice Chancellor, AIMST University, Malaysia, Dr. B Suresh, President, Pharmacy Council of India, New Delhi and Vice Chancellor, JSS University, Mysore, Dr. S. Manivannan, Deputy Drugs Controller (India), Chennai and Dr. Raghuram Bhandary, Drugs Controller of Karnataka,

More than 1360 delegates attended the convention from India and abroad. The conference deliberated on how pharmacists can play a leadership role in safe use of medicines. The Congress had 8 sessions with 31 speakers.

Besides the inaugural event, the congress also showcased the 1st batch of Pharm D students who will graduate in June 2014. Some of the highlights of the Convention include;

Scientific Sessions:

1. Advancing Pharmacy Practice in India: The Next Generation Pharmacist
2. Practicing Pharmacists: Global Experiences and Challenges.
3. Pharm.D.Education: Global Experiences and Challenges.

Symposia:

1. Symposium on International Accreditation
2. Symposium on Specialty Practice

Panel Discussion:

1. Pharm. D. Programme- Challenges and Opportunities
   Poster presentations on various Research topics were also held.

IACP has invited leaders in pharmacy practice and education, and also leaders in the healthcare sector – to interact with the new breed of pharmacists who will radically change India's healthcare delivery. More than 25 leaders in pharmacy practice and education from USA, Australia, UK, Southeast Asia, Middle East and Europe participated in the conference.

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

Faculty of Pharmacy Sri Ramachandra University, Chennai

Faculty of Pharmacy, Sri Ramachandra University conducted the "1st International Congress on the Society for Ethnopharmacology" in association with the School of Natural Product Studies, Jadavpur University, Kolkata with the theme "Globalizing Traditional Medicine – Present and Future Prospects"' from 7th to 9th March 2014. On 7th, the preconference workshop on the theme "Publishing your research in impact journals" was held at Dental auditorium. Prof. Michael Heinrich, Review Editor, Journal of Ethnopharmacology, Dr. Rudolf Bauer, Editor, Planta Medica, Dr. Gail B. Mahady, Associate Professor, Univ. of Illinois, Chicago, Dr. T. K. Mukherjee, Ex-Editor, Indian Journal of Traditional Knowledge CSIR-NISCAIR, New Delhi were the speakers.

At 2:30 pm, on 7th, the inaugural of program ICSE-2014was held at the University auditorium. Prof. H. Devaraj, Vice Chairman, UGC, inaugurated the conference and Shri. Shekhar Dutt, Honorable Governor of Chattisgarh was the special guest of honor and released the book "Traditional Medicines and Globalization - the Future of Ancient Systems of Medicine". Dr. Pratim Banerji, President, Society for Ethnopharmacology, Dr. S. Datta, Pro-Vice Chancellor, Jadavpur University, were the special guests and Dr. Anna K. Jager, President, International Society for Ethnopharmacology gave the presidential address and distributed the annual awards of the Society for Ethnopharmacology. Dr. S. P. Thyagarajan, Professor of Eminence & Dean (Research), received Merit of excellence award, and Dr. D. Chamundeeswari, Principal, Faculty of Pharmacy, SRU, received "Outstanding Service Award". Three awards of recognition were instituted by the Faculty of Pharmacy, SRU, and the awards were distributed by Thiru. V. R. Venkataachalam, Chancellor, SRU.

The second day of the Program started with GCIM oration by Dr. S. Ramasamy, Director General, Central Research Institute for Siddha, Arumbakkam. Totally 33 speakers from USA, UK, Germany, Bangladesh, Nigeria, Brazil, London and 600 delegates from 44 institutes attended the conference.

An intercollegiate cultural event was held at 6:30 p.m. on 8/3/2014 with Kala Master, Dance Master and Choreographer, as the Chief guest.

The valedictory function was held on 9/3/2014 at 3:00 p.m. Prof. B. Suresh, President, Pharmacy Council of India, New Delhi & Vice Chancellor, J.S. S. University, Mysore was the chief guest and delivered the valedictory address. Prof. B. Suresh distributed the recognition awards and also the prizes of scientific Oral and Poster presentations given by SFE.

INDIAN PHARMACEUTICAL ASSOCIATION (TAMILNADU) AGM

The Annual General Meeting of The Indian Pharmaceutical Association, Tamilnadu was held on Saturday, the 8th February, 2014 at 5.30pm at Hotel Hablis, Chennai.

Shri. S. V. Veeramani, President – IDMA , spoke on **"Current Trends in the Indian Pharmaceutical Industry",** This was followed by the lecture on **"Inspection Compliance - Latest Scenario" by Shri. Sanjay Das Mohapatra, President, Technical & Operations, Medopharm.**
About 100 members attended the meeting.

NEWS

IDMA to Present New Proposals in Pharma Vision - 2014: Veeramani

With a view to fetch larger fortunes for small and medium scale pharma enterprises, including bulk drug manufacturing units, through exports, the Indian Drug Manufacturers Association (IDMA) will present new proposals in the Pharma Vision-2014 to be submitted to the government next month. Plans to avail technology upgradation fund scheme for SMEs are the most significant suggestions, according to S V Veerramani, President, IDMA.

While delivering a lecture on "Current Trends in Indian Pharmaceutical Industry", organised by TN IPA, Veerramani pointed out that the ongoing technology upgradation scheme was not adequate and it has to be increased and updated in all the areas. If updated technology and skilled workers are employed, these units can enter into contract manufacturing business with big players and thereby to increase exports.

He said drugs worth US$ 40 billion in USA and US$ 25 billion in Europe will be going out of patent shortly. Out of this, India is likely to take up 30 per cent of the market valuing around US$ 19. 5 billion. Further, chances are there in US market as Obama Care in the USA is going to increase the demand for generics shortly. So, the chances of SME sector are tremendous to earn more through exports provided complying with market regulations.

"We have more than 7000 SME units which are all engaged in contract manufacturing business. The process of technology upgradation is going on, but more of it is required. For obtaining contract manufacturing from national and multi-national companies, these units have to intensify the GMP training. IDMA has requested the government for financial support to help these units," he said.

Although India manufactures around 500 APIs, it depends on China for around 50 per cent of its requirements for bulk drugs. India's bulk industry is growing at a rate of 17 per cent and it is hoped that India would replace Italy as second largest producer in the world. Government has also plans to push up the API industry. Now, IDMA is asking for capital subsidy, power subsidy, fund for cluster development and common effluent treatment plant (ETP) for the development of SME sector in order to compete with China.

"Compared to world pharma companies, India is spending very low on R&D because of lack of resources and margins. Recently big Indian companies have started spending more than 10 per cent of their sales on R&D, mainly on new drug delivery systems. More spending on research and development, increased GMP training and upgradation of technology are required for the survival of small scale pharma units in our country. For this, the IDMA will seek the support of the government," he added.

IPA Tamil Nadu unit president, MM Yousuf presided over the meeting, secretary J Jayaseelan presented the report and welcomed the audience.

welcomed the audience.

Source: *Pharmabiz, 11th February 2014.*

Intellectual Property Rights: US Set to Punish India

It's not looking good between New Delhi and Washington. Tensions over the Khobragade episode are yet to fully dissipate, but the two sides are locking horns again over intellectual property rights. The Obama administration is scheduled to announce unspecified "trade enforcement action" against India on Monday evening (Tuesday am IST) Washington time.

United States trade representative (USTR) Michael Froman and general counsel Timothy Reif will hold a news conference to announce action related to India, the USTR said earlier in the day in a head's up to journalists.

The Indian embassy in Washington DC too scheduled a briefing by its economic and commerce wings soon after the expected US action. All this comes ahead of a re-scheduled visit to New Delhi of US energy secretary Ernesto Munoz, which was postponed from January because of the Khobragade row.

At the heart of the latest ongoing dispute is the perception in US quarters, particularly among its business and industry in sectors like Pharma, that India's poor intellectual property rights protection is undermining them (and according to Indian critics, undercutting their avaricious profit taking). The two countries are also sparring over everything from export of shrimps that pit the fishermen of Kerala versus fisherman of Louisiana, to the import of steel pipes.

Last week, the US chamber of commerce called for measures to reprimand India over IPR, in an effort to prevent Indian drug companies from producing cheap generic versions of medicines still under patent protection. Organizations such as Doctors Without Borders have supported India in its effort to produce cheap medicines for the world's poor with modest improvements in IPR, but Big Pharma isn't impressed by the rapid strides made by India's generic drug industry, which they feel threatens western advances.

Incidentally, the head of the US Food and Drug Administration, Margaret Hamburg, is on a ten-day visit to India even as Washington has cracked down on India-based Pharma majors such as Ranbaxy for sloppy production procedures among other things. There are murmurs in the Indian industry and in the corridors of the government that India companies are being singled out because they threaten the runaway profits made by western drug companies.

On Monday, the Global Intellectual Property Centre (GIPC), an organization ostensibly aimed at advancing US industry interests, pressed the USTR designate India a "Priority Foreign Country" under its Special 301 report "in order to strengthen engagement with India to address the rapidly deteriorating intellectual property environment in this market." The GIPC believes that USTR's Special 301 Report provides an important tool to assess those countries that fail to abide by their IP rights obligations as outlined in trade agreements and international rules, the center said.

USTR honchos appeared prepared to wield the stick against India although a hearing on the matter is scheduled on February 24 as part of the administration's annual review of IPR rules and practices impacting US businesses worldwide. The office releases a Special 301 report at the end of the process.

Source: *The Economic Times, 10th February 2014*

India-US Seek to Better Drug Making Process

US Food and Drug Administration and its Indian counterpart on Monday decided to collaborate on inspection of drug units for good manufacturing practices (GMP) compliance and seamless sharing of regulatory information between them. The move, both sides reckon, will ease tensions between Indian drug companies and the US regulator which have escalated recently.

This comes even as the US trade representative was slated to announce later in the day a trade enforcement action against India for its disgruntlement over India planning to issue a clutch of "compulsory licenses" to local firms sidestepping some patents the US values.

Margaret Hamburg, commissioner of the US FDA, as part of her first, week-long visit to India, inked an agreement with Union health minister Ghulam Nabi Azad under which the two countries will exchange "information relevant to lack of compliance with accepted good manufacturing practices, good clinical practices, or good laboratory practices, as appropriate, by manufacturers and sponsors of medical products".

Drug companies that have faced adverse regulatory action by the FDA in recent months include Ranbaxy Laboratories, Wockhardt and Strides Acrolab. On January 23, the FDA banned the import of products manufactured by Ranbaxy at its plant at Toansa, the company's fourth plant to face regulatory action from the FDA, after its Mohali, Paonta Sahib and Dewas plants.

Analysts see the agreement as a sign of the two countries appreciating the mutual benefits of pharmaceutical trade between them - India with its 530 FDA-approved plants is keen to sustain and enhance its exports to the US while the Obama administration's healthcare plan relies significantly on cheaper generic drugs from countries like India.

India's pharma exports increased 10% to $14.6 billion during 2012-13, with shipments to the US accounting for about 26% of that. The country's pharma exports are soon to surpass domestic drug sales in value.

Curiously, USTR Michael Froman was expected to discuss the trade action against India at a news conference in Washington at 2 p.m. local time (1900 GMT), in what is seen as yet another sign of the mounting US pressure on India to make its patenting regime "more liberal." India's patent law

Source: *Financial Express, 10th February 2014.*

Low Standards of India's Aviation and Drug Regulators Pose Danger Primarily to Indian Consumers

In January two US regulators, Federal Aviation Administration (FAA) and Food and Drug Administration (FDA), penalized India's aviation regulator and drug manufacturer Ranbaxy Laboratories for falling short of their standards. Consequently, India`s aviation companies and the drug company are restricted from pursuing business opportunities in US. Coming on the heels of India`s diplomatic spat with US, there is a tendency to view these incidents through the prism of jingoism. That would be an incorrect way to approach the issue. January`s developments beg questions of Indian regulators in aviation and drugs. The question that should be asked is whether low standards among these regulators put Indian consumers at risk.

FAA has lowered India's aviation safety ranking after it found domestic regulator, Directorate General of Civil Aviation, did not exercise adequate regulatory oversight. The downgrade will hurt the aviation industries, including Air India's commercial interests in US. But what should worry us most is that DGCA seems ill-prepared to protect domestic fliers, even as it is intent on ensuring that 'royal' treatment is accorded to MPs at Indian airports.

Similarly, India's drug regulator, Drug Controller General of India (DCGI), was quick to point out society and economy here are different from US. DCGI's attitude is troubling because more than one Indian drug company had a problem with US FDA. The charges against them are serious, primarily ones dealing with falsifying data to make a drug seem more pure than it is. The issue is not about differences in manufacturing standards. It is about ethical standards and we should worry about whether all companies are accurately meeting domestic regulatory requirements. DCGI has no reason to be sanguine.

Source: *The Times of India, 4th February 2014*

Now, Indian Regulators to Inspect Ranbaxy's Plants

Watchdog Drug Controller General of India (DCGI) will soon begin inspecting Ranbaxy Laboratories' plants in India to test these for manufacturing practices and hygiene norms in the latest string of run-ins with regulators faced by the generic pharmaceuticals company.

The DCGI's scrutiny is crucial for Indian companies as violations can lead to cancellation of manufacturing licenses that can potentially shut the door on selling drugs even in India.

"We will scan Ranbaxy and Wockhardt thoroughly as the allegations leveled by US FDA are alarming," G N Singh, drug controller general of India told HT.

"In case of any violation, we will suspend their manufacturing activity."

The DCGI's move comes less than a week after the USFDA blacklisted Ranbaxy Laboratories' Toansa plant- the generic drug makers' fourth factory to face such an import ban, effectively ruling out exports from its Indian plants.

Singh confirmed that DCGI will be sending a team of officials to inspect Ranbaxy's Toansa plant shortly. "We have ordered strict inspection for Toansa facility. And for other plants at Dewas, Poanta Sahib we have sent a notice to the company."

Last year, US and British drug regulators had warned Wockhardt, for violations at its manufacturing facility in Maharashtra. Both Ranbaxy and Wockhardt did not respond to HT's mails. Experts, however, said that the chances of a USFDA-type of blacklisting by DCGI of Indian Pharma plants were remote because of different product standarisation rules and tolerance thresholds on purity.

Indian purity standards ask for only 99.9% whereas USFDA thresholds are more, he said.

Source: *The Hindustan Times, 29th January 2014*

Biocon Launches Cheaper Breast Cancer Drug

The biotechnology major will start selling 'CANMAb', a 25% cheaper breast cancer drug developed jointly with US-based Mylan.

Biotechnology company Biocon on Saturday launched a new and cheaper drug to treat 'metastatic' breast cancer that aggressively spreads to other parts of the body.

The company said its product, CANMAb, the world's first 'biosimilar' or remake of Swiss multinational Roche's original drug Trastuzumab, would cost about 25 per cent less than the original.

Roche sells the drug in India as Herceptin, which generated 2012 sales worth around Rs.130 crore. Globally, it was around $6.4 billion.

Biocon's tumour-targeting product is slated to enter the market in the first week of February.

It will make breast cancer treatment more affordable and accessible to many Indian patients who test positive for the cancer-indicating HER2 (short for human epidermal growth factor), Chairman and Managing Director Kiran Mazumdar-Shaw told a news conference.

She said, "Biocon intends to make a significant difference in the treatment paradigm for HER2-positive breast cancer in India by enhancing access to more affordable treatment with CANMAb. [It] offers the same level of safety and efficacy as the reference product [Herceptin.]"

The local version costs Rs.19,500 for a 50 mg budget vial and around Rs.57,000 for 400 mg. The original rival comes in a single 400 mg offer and costs around Rs.75,000-80,000, according to company officials.

Patients need to take at least three intravenous drug cycles lasting around three months before any change in tumour can be noticed. In India, breast cancer is the No. 2 cancer striking women and roughly 1.5 lakh new cases are detected each year. At least a quarter of them or nearly 40,000 test positive for the HER2 and can benefit from CANMAb.

Biocon co-developed the new product with U.S. Pharma major Mylan; their 2009 partnership covers four more products and a shared market.

Source: *The Hindu, 18th January 2014*

Indigenous Diabetes-Screening Strips to Cost Rs 4, Says Ghulam Nabi Azad

Union health minister Ghulam Nabi Azad said that his ministry will be launching indigenously developed diabetes-testing strips that will cost just Rs 4.

"This strip will make diabetes screening affordable in the country. This indigenous strip is very cheap. It will cost just Rs 4 and will replace the strips that are currently costing Rs 35 in the market. One week later I will be launching these strip," Azad said while addressing NRI doctors at a summit organised by American Association of Physicians of Indian Origin (AAPI) at Ahmedabad on Saturday.

Source: *The Financial Express, 17th January 2014*

Regulator Mulls Changes in Labeling Norms for Drugs

India's drug regulator is considering changes in the norms for labeling medicine packs after some state drug controllers raised concerns that consumers may be getting misled by the way marketing companies are displaying their names on packs.

Officials at the Drug Controller General of India (DCGI) said the changes in the norms will ensure that consumers do not mistake the marketing firm to be the manufacturer of the drug.

"We are considering different options on labeling norms, including different sized fonts for the marketing firms and manufacturers, so that while buying the drug, people can make an informed decision about who is the manufacturer of the drug and who is marketing it," an official at the DCGI told ET. The official, who requested anonymity, said stakeholders will be consulted on the feasibility of various options before a final decision is taken on the matter.

State drug regulators had recently raised concerns on the varied formats of labeling on drug packs.

At a recent meeting of the drug consultative committee, the drug regulator of Andhra Pradesh said it has come across several instances where large pharma companies, which are only marketing products manufactured by smaller and lesser known firms, print their own names in bold fonts, giving the impression that the drugs have been manufactured by them. Drug regulators of several other states supported this contention.

At present, rules under the Drugs and Cosmetics Act do not explicitly bar the marketing company from printing its name in any way along with the original manufacturer.

Members of the drug consultative committee, which is an advisory body on drug regulations, "recommended that a provision may be made in the rules that the label of the drug formulation should not contain any other information except for what is required under the Drugs and Cosmetics Act and rules, or is required to be given in compliance to any other Act in force", according to the minutes of the meeting.

"If the proposal on differentiated fonts is mandated, it will work to the advantage of the smaller players over a period of time, by creating familiarity with the names of their companies in trade channels and among consumers," said Amit Chander, partner, healthcare, Baring Private Equity Partners, India.

Source: *The Economic Times, 17th January 2014.*

DCGI wants Mandatory Recordings of Clinical Trial Consent

The Drug Controller General of India (DCGI) has released draft guidelines that make it mandatory for clinical research organisations to conduct an audiovisual recording of the trial patients informing them about each and every risk involved while undergoing the trial. The measure, introduced in addition to the existing written consent forms, could bring in greater transparency and clarity in clinical trials.

According to the draft guidelines issued by the drug controller in response to a Supreme Court directive, this norm will also apply to the global trials conducted in India. In case the trial patient is not able to give informed consent, the investigators have to take the consent of a legally representative person.

"All clinical trials in addition to the requirement of obtaining written informed consent, audiovisual recording of the informed consent process of each trial subject, including the procedure of proving information to the subject and his/her understanding on such consent is required to be done while adhering to the principles of confidentiality. Such audiovisual recording and related documentation would be preserved," the drug controller said in its draft guideline.

The apex court had issued this directive so that any uninformed or false consent from patients enrolling into trials could be avoided. The directive came after the court heard a public interest litigation filed by the organisation Swasthiya Adhikar Manch, which alleged that the government was granting clinical trial approvals without following proper norms, as a result of which many patients were enrolled in trials without giving their consent. The measure will also apply to the new trials that got approval in the past one year.

"I think this is a welcome move. Those who have been conducting trials ethically are already recording the statements of the patients; this is a good documentary procedure," said Arun Bhatt, managing director of Clinvent, a clinical research company. This move will also help provide evidence against the patients who turn back on their consent after signing up for a trial, Bhatt added.

However, some fear that the additional requirement could be tedious and impractical. "Companies can record consent. However, spelling out each and every detail of the trial procedure might scare off the patients who might decide to withdraw their participation in the trial. I think this guideline is impractical," said RK Shanghvi, chairman of the medical sub-committee of industry body Indian Drugs Manufacturers' Association.

The approval of clinical trials in India has become an emotive issue, with health activists claiming that pharma companies are unethically enrolling candidates for their research. The Supreme Court had last September halted the approval of more than a hundred trials in the country because it suspected they were not being conducted according to the norms.

Source: *The Economic Times, 16th January 2014*

NPPA to keep Time-Release Medicines under Price Control

India's drug price regulator has decided to ignore the health ministry's suggestion and stick to its plan of keeping essential time-release drugs under price control.

The National Pharma Pricing Authority (NPPA) had originally included this set of drugs while fixing price caps last year, implying they fell under the price net. But the ministry last month told the authority that time-release set of drugs should be kept out of the essential drugs' list, meaning they could be excluded from the price net, an advice the regulator has chosen to turn down.

"We believe that within the latest drug price control order, there is a special category for exemption, which has to be applied to this class of drugs on a case-to-case basis," said the official, requesting anonymity.

These drugs release medicine at a measured pace to improve efficacy and compliance of patients and involves different forms of releases: modified, sustained, extended, controlled and delayed release therapies. Usually priced at a premium to plain drugs, time-release drugs constitute over 3,000 crore of the domestic drug market, which is estimated at 72,000 crore by Aiocd Awacs, a pharma market research company.

The drug pricing order says that if a new drug uses a new delivery system (to which time-release class of drugs belongs) and is developed through indigenous research and development, it can claim exemption from price regulation for five years from the date it gets approval for marketing in India.

Had the policy originally intended to exclude this entire class of drugs, it would not have incorporated separate exemption clauses for some of them, the official said. "The health ministry's view is more of a clarification and that cannot override an existing statutory order," he added.

Prices of 348 drugs enlisted by the government as essential are currently being lowered, under a new pharma pricing policy, which has come after a gap of 18 years.

Domestic drugmakers are strongly opposed to the NPPA's stand and may even challenge it. "Clubbing these drugs with other price-controlled drugs would be contrary to what the policy stood for in letter and spirit and a big blow to innovation," said DG Shah, secretary general, Indian Pharma Alliance, a grouping of leading domestic drugmakers.

The drug price regulator fears that if prices in this category are not capped, drugmakers may use it as a window to flee the price net by launching under this category more drugs, many of which may not add any significant therapeutic value. "There is no foolproof mechanism in the pricing policy to avert a possible mass migration to this category of drugs," the NPPA official said.

After the last drug pricing order, several pharma companies had launched new combination drugs, allegedly to bypass it. A parliamentary standing committee had noted last year that many of these drugs had not been tested for safety and efficacy. However, drugmakers say fears over mass migration to time-release drugs are misplaced.

Source: *The Economic Times, 15th January 2014*

Medicines Made in India Set off Safety Worries in US

Ranbaxy, one of India's biggest drug manufacturers, pleaded guilty to felony charges and paid a $500 million fine last year, the largest ever levied against a generic company.

India, the second-largest exporter of over-the-counter and prescription drugs to the United States, is coming under increased scrutiny by American regulators for safety lapses, falsified drug test results and selling fake medicines.

Dr. Margaret A. Hamburg, the commissioner of the United States Food and Drug Administration, arrived in India this week to express her growing unease with the safety of Indian medicines because of "recent lapses in quality at a handful of pharmaceutical firms."

India's pharmaceutical industry supplies 40 percent of over-the-counter and generic prescription drugs consumed in the United States, so the increased scrutiny could have profound implications for American consumers.

FDA investigators are blitzing Indian drug plants, financing the inspections with some of the roughly $300 million in annual fees from generic drug makers collected as part of a 2012 law requiring increased scrutiny of overseas plants. The agency inspected 160 Indian drug plants last year, three times as many as in 2009. The increased scrutiny has led to a flood of new penalties, including half of the warning letters the agency issued last year to drug makers.

Dr. Hamburg was met by Indian officials and executives who, shocked by recent FDA export bans of generic versions of popular medicines - such as the acne drug Accutane, the pain drug Neurontin and the antibiotic Cipro - that the FDA determined were adulterated suspect she is just protecting a domestic industry from cheaper imports.

"There are some people who take a very sinister view of the FDA inspections," Keshav Desiraju, India's health secretary until this week, said in a recent interview.

The FDA's increased enforcement has already cost Indian companies dearly - Ranbaxy, one of India's biggest drug manufacturers, pleaded guilty to felony charges and paid a $500 million fine last year, the largest ever levied against a generic company. And many worry that worse is in store.

"If I have to follow U.S. standards in inspecting facilities supplying to the Indian market," G. N. Singh, India's top drug regulator, said in a recent interview with an Indian newspaper, "we will have to shut almost all of those."

The unease culminated Tuesday when a top executive at Ranbaxy - which has repeatedly been caught lying to the FDA and found to have conditions such as flies "too numerous to count" in critical plant areas - pleaded with Dr Hamburg at a private meeting with other drug executives to allow his products into the United States so that the company could more easily pay for fixes. She politely declined.

India's drug industry is one of the country's most important economic engines, exporting $15 billion in products annually, and some of its factories are world-class, virtually undistinguishable from their counterparts in the West. But others suffer from serious quality control problems. The World Health

Organization estimated that one in five drugs made in India are fakes. A 2010 survey of Delhi pharmacies found that 12 percent of sampled drugs were spurious.

In one recent example, counterfeit medicines at a pediatric hospital in Kashmir are now suspected of playing a role in hundreds of infant deaths there in recent years.

One widely used antibiotic was found to contain no active ingredient after being randomly tested in a government lab. The test was kept secret for nearly a year while some 100,000 useless pills continued to be dispensed.

More tests of hospital medicines found dozens more that were substandard, including a crucial intravenous antibiotic used in sick infants.

"Some of the fake tablets were used by pregnant women in the post-surgical prevention of infections," said Dr. M. Ishaq Geer, senior assistant professor of pharmacology at Kashmir University. "That's very serious."

Investigations of the deaths are continuing, but convictions of drug counterfeiters in India are extremely rare.

Satish Reddy, president of the Indian Pharmaceutical Alliance, said Indian drug manufacturers are better than the FDA now contends. "More rigorous enforcement is needed, for sure, but this impression that India is overrun with counterfeits is unjustified," Mr. Reddy said.

But Heather Bresch, chief executive of Mylan, which has plants in the United States and India, said regulatory scrutiny outside of the United States was long overdue. "If there were no cops around, would everyone drive the speed limit?" Ms. Bresch asked. "You get careless, start taking risks. Our government has enabled this."

For Dr. Hamburg, the trip is part of a long-running effort to create a global network of drug and food regulators to help scrutinize the growing flood of products coming into the United States, including 80 percent of the seafood consumed in the United States, 50 percent of the fresh fruit, 20 percent of the vegetables and the vast majority of drugs.

She has gone to conclaves of regulators from Europe and elsewhere to coordinate policing, but Indian officials have so far not attended such meetings.

Many of India's drug manufacturing facilities are of top quality. Cipla, one of the industry's giants, has 40 plants across the country that together can produce more than 21 billion tablets and capsules annually, and one of its plants in Goa appeared just as sterile, automated and high tech on a recent tour as those in the United States.

Cipla follows FDA guidelines at every plant and on every manufacturing line, and the company exports more than 55 percent of its production, said Yusuf Hamied, the company chairman.

But Benjamin Mwesige, a pharmacist at the Uganda Cancer Institute in Kampala, said in an interview in July that the institute had stopped buying cancer drugs from India in 2011 because it had received shipments of drugs that turned out to be counterfeit and inactive, with Cipla labels that Mr. Mwesige believed were forged.

He became suspicious when doctors began seeing chemotherapy patients whose cancer showed none of the expected responses to the drugs - and who also had none of the usual side effects. The drugs that had been prescribed were among the

mainstays of cancer treatment - methotrexate, docetaxel and vincristine. Laboratory tests confirmed that the drugs were bogus, and Mr. Mwesige estimated that in 2011 about 20 percent of the drugs that the institute bought were counterfeit.

Enforcement of regulations over all is very weak, analysts say, and India's government does a poor job policing many of its industries. Last month, the United States Federal Aviation Administration downgraded India's aviation safety ranking because the country's air safety regulator is understaffed, and a global safety group found that many of India's best-selling small cars are unsafe.

India's Central Drugs Standard Control Organization, the country's drug regulator, has a staff of 323, about 2 percent the size of the FDA's, and its authority is limited to new drugs. The making of medicines that have been on the market at least four years is overseen by state health departments, many of which are corrupt or lack the expertise to oversee a sophisticated industry. Despite the flood of counterfeit drugs, Mr. Singh, India's top drug regulator, warned in meetings with the FDA of the risk of overregulation.

This absence of oversight, however, is a central reason India's pharmaceutical industry has been so profitable. Drug manufacturers estimate that routine FDA inspections add about 25 percent to overall costs. In the wake of the 2012 law that requires the FDA for the first time to equalize oversight of domestic and foreign plants, India's cost advantage could shrink significantly.

Some top manufacturers are already warning that they may leave, tough medicine for an already slowing economy.

"I'm a great nationalist, an Indian first and last," Dr. Hamied said. "But companies like Cipla are looking to expand their businesses abroad and not in India."

American businesses and F.D.A. officials are just as concerned about the quality of drugs coming out of China, but the F.D.A.'s efforts to increase inspections there have so far been frustrated by the Chinese government.

"China is the source of some of the largest counterfeit manufacturing operations that we find globally," said John P. Clark, Pfizer's chief security officer, who added that Chinese authorities were cooperative.

Using its new revenues, the F.D.A. tried to bolster its staff in China in February 2012. But the Chinese government has so far failed to provide the necessary visas despite an announced agreement in December 2013 during a visit by Vice President Joseph R. Biden Jr., said Erica Jefferson, an FDA spokeswoman.

The United States has become so dependent on Chinese imports, however, that the FDA may not be able to do much about the Chinese refusal. The crucial ingredients for nearly all antibiotics, steroids and many other lifesaving drugs are now made exclusively in China.

Denise Grady contributed reporting from Kampala, Uganda, and Hari Kumar from Srinagar, Kashmir.

Source: *The Times of India, 15th February 2014*

India Raises Concerns over FDA Actions on Local Drug Cos

To submit informal note to US for discussing sensitive issues and their resolution

India will issue an informal note to the US in which it will protest against the "disproportionate" action targeting Indian pharmaceutical companies, commerce and industry minister Anand Sharma said after his meeting with visiting US Food and Drug Administration (US FDA) chief Margaret Hamburg. Known in diplomatic terms as a 'nonpaper', the informal document is used to discuss sensitive issues without taking them to a formal level. "We are going to give a non-paper overall on some of our concerns. Some of it relates to duration (delays) in the registration process for the filing (of drug applications). But it will be general, the paper, which I have suggested we will give them," Sharma told reporters. Officials privy to the discussion between Sharma and Hamburg said the minister brought to her attention the recent increase in FDA audits and inspections at Indian drugmaking sites, saying that "most of the time, audit inspections were not followed by a discussion with the companies and if clarifications were sought (by USFDA) in some cases, harsh decisions were taken even before clarifications were given". Attention was also drawn to disproportionate penalties imposed in some cases, without specifically referring to the $500-million fine slapped on Ranbaxy Labs in May 2013. India-based drugmaking sites have received over half of warning letters USFDA's drug safety office has sent out in 2013. Union health minister Ghulam Nabi Azad, who met Hamburg in the morning, told her that "developing countries such as India, which have a growing pharma industry, should be allowed to grow". He added that Indian drugs are affordable but that doesn't make them "spurious". "Efficacy of Indian drugs should not be judged on the basis of their cost, as the input cost in India is much less than that in developing countries due to the less-expensive human resources," the health minister said. Hamburg told Azad that there is huge expectation and dependence of public on the regulator to ensure the quality of what the people consume through drugs and food. India and the US signed on Monday a statement of intent, through which the two countries promised to facilitate better coordination between the two drug regulators. As part of that, the US would work towards informing the 'regulatory authorities' here before it conducts inspections at Indian manufacturing sites, so that officials here can join as observers. Intelligence sharing between the two regulators is also on the cards. "Sharing of information relevant to lack of compliance with accepted current good manufacturing practices, good clinical practices, or good laboratory practices, as appropriate, by manufactures and sponsors of medical products and manufacturers of cosmetics, in one another's country, or any other information as mutually decided upon," said a health ministry statement.

Hamburg held over an hour-long meeting with her Indian counterpart, Drug Controller General of India, GN Singh, in the evening. "We hope to start inspecting sites overseas from which India is importing drugs. Being an observer during US inspection will sharpen the skills of our inspectors," Singh said.

Besides issues related to the pharma sector, the commerce minister discussed market access issues for rice, pomegranate and mango, urging the US to remove what India considers 'non-tariff barriers'. In the context of various agro chemicals, India insisted that they should not be set by default but fixed on the basis of regular health risks.

Hamburg will be meeting CEOs of Indian pharma companies on Tuesday.

Source: *The Times of India, 11th February 2014*

Drug Cos, IP Experts Question US Index Ranking

Intellectual Property experts and generic drug firms in India have questioned the methodology and even the motive behind the US Chamber of Commerce s Global Intellectual Property Centre (GIPC) index in which the nation has been ranked the lowest among 25 countries. The ranking calls those IP regimes strong which, unlike that in India, continue to promote weak and trivial inventions, patent experts argued while trashing the index that yet again placed the country the lowest in its second edition released last week. Underlying this report is a major paradox that protecting weak patents makes the IP regime a strong one, IP expert Shamnad Basheer told ET. Countries such as India that have stood up for genuine innovation and refused to protect trivial inventions have been accused of having weak IP regimes while it should have been the other way round. In its report which ranked the US, UK and France as the top upholders of intellectual property rights, the GIPC said, India continues to have the weakest IP environment of all countries included in the Index. Despite the 2010 declaration by the then-president of India that the next 10 years will be India's Decade of Innovation, the continued use of compulsory licenses, patent revocations and weak legislative and enforcement mechanisms raise serious concerns about India's commitment to promote innovation and protect creators. Experts pointed out that the charge of continued use of compulsory licenses notwithstanding, India had granted only one such license to domestic drug maker Natco Pharma in 2012 to make a generic version of Bayer s expensive cancer drug Nexavar. Although the government has been considering compulsory licenses for a few other expensive drugs,it is yet to take a final decision in any other case. Industry body Indian Pharma Alliance (IPA) has alleged that this index is a tool to push the interests of American companies in India. The report was commissioned by the US Chamber of Commerce was drafted by a boutique consultancy Pugatch Consilium.

Source: *The Times of India, 3rd February 2014*

Natco Wins Indian Patent Dispute Case

Natco Pharmaceuticals, the Hyderabad-based drug manufacturer, has won a patent case against Teva Pharmaceuticals of Israel.

The New Delhi High Court, on February 28, dismissed Teva's suit seeking an injunction over the marketing of a generic version of multiple sclerosis drug, copaxone (glatiramer acetate) in the U.S. While Teva does not have a patent on the drug in India, the injunction sought to prevent Natco exporting it.

The decision could allow Natco to launch generic version of Teva's Copaxone in the U.S., subject to approval from the U.S. Food & Drug Administration (USFDA).

The patent on the $4 billion sales drug, expires in the U.S. on May 24, 2014.

"We are still awaiting USFDA approval, and our plans in the U.S. depend on that," M. Adi Narayana, Company Secretary & Vice President-Legal & Corporate Affairs, Natco Pharma, told The Hindu.

Natco has been selling it in India since 2007, and plans to market it with partner U.S.-based pharma giant Mylan with whom it has a global marketing alliance since 2008.

Teva sued Natco, seeking an injunction as it alleged Natco's move infringed on its process patent. Mr. Narayana said, "We are very pleased with the decision by the New Delhi High Court to dismiss and take no action in this matter. We continue to believe that the sole Indian process patent is invalid, as reinforced by the outcomes of numerous other legal proceedings. We are also pursuing other challenges against this patent". Natco took on big global pharma in the past having won a case against Novartis for its blood cancer drug, Glivec last year and also receiving India's first compulsory license (CL) on the kidney cancer drug Nexavar made by Bayer.

Mr. Narayana said Natco successfully completed a preferential issue to CX Securities for Rs.153 crore to retire old debt and had shareholder approval to raise capital to set up a facility in Mehbubnagar, Andhra Pradesh, to cater to Mylan's requirements.

Source: *The Hindu, 3rd March 2014*

Indian Drug Firms May Lose Out as US Pharma Supply Chain Consolidates

Consolidation in the pharmaceuticals supply chain in the US will weigh on the bargaining power of Indian drug firms in that market, top Indian players apprehend. A spate of acquisitions and joint ventures - 16 in 2012 and 10 in 2013 - has resulted in fewer suppliers of prescription drugs, which might work against the interests of Indian firms.

Lupin CEO Vinita Gupta acknowledged there will be pricing pressure because of the mergers in the supply chain space. Speaking to analysts after the Q3FY14 results announcement, Gupta observed, "The challenges arising from the consolidation of our customers are significant and there is a lot of pressure on pricing. But the Walgreen consolidation happened well before the CVS-Cardinal (deal) and so far, we have survived it. We've been able to manage pretty well."

Abhijit Mukherjee, president and head of global generics segment, Dr Reddy's Laboratories, also agreed, on a call with analysts, that there could be some impact of the changes in the US supply chain environment. "There have been some mergers between wholesalers and retailers and depending on how many customers a company has in each segment, there will be an impact," Mukherjee said, adding that his firm had factored the changes into its plans. "While there will be an impact, it's a part of the erosion in the generics business," he said.

Sun Pharmaceutical Industries CEO Dilip Shanghvi recently said it was clearly becoming increasingly difficult to find a way to negotiate effectively. "There would be increasing pressure on manufacturers," Shanghvi noted.

In a recent report, HSBC Global Research said the CVS-Caremark, Medco-Express Scripts and Walgreen-Alliance Boots mergers have increased the purchasing power of distributors and retailers.

"The higher power of PBMs (pharmacy benefit managers) may result in downward pressure on drug prices and consequently hurt margins of most drug companies in the US market," the HSBC Global Research note highlighted.

"Indian companies have indicated some volume-price trade-off given the product mix and given that

they are the top suppliers of several products. Large generics players believe they are better placed given their relationships with global supply chains and the capacity to meet large volumes," JPMorgan analyst Neha Manpuria said.

The pharma supply space has seen a fair bit of consolidation in 2012 with 16 deals in the drug supply chain. In 2013, there were 10 acquisitions and in November. CVS Caremark - the largest supplier of prescription drugs in the US - bought Coram, a specialty infusion service provider, for $2.1 billion. In December 2013, CVS Caremark and its peer Cardinal Health decided to create a joint venture to source generic drugs for the US market. Scheduled to take off in July, the venture will procure generics worth $11 billion to $12 billion. The deal was announced nine months after US distributor AmerisourceBergen announced an agreement with retail drugstore operators Walgreen and Alliance Boots in March 2013, signalling a tie-up in the retailer-wholesaler chain. Another US distributor, McKesson, announced it will buy a majority stake in German drugs wholesaler Celesio for about $5.4 billion, adding the German market to its portfolio. Already, in 2014, two deals have been announced.

Analysts say the segment has not seen the last of consolidation. Charles Rhyee at New York-based brokerage Cowen and Co recently observed, "We have now seen some of the largest generic purchasers combine to form partnerships, and we expect the trend to continue. In addition, we think other large direct purchasers of generics may look to join the various coalitions."

In the US, distributors also referred to as PBMs such as CVS Caremark, Cardinal Health, AmerisourceBergen, McKesson, Express Scripts purchase drugs from manufacturers that are then sold to operators of retail drugstore chains like Walgreen, Alliance Boots, Rite Aid and Shoppers Drug Mart.

HSBC analysts tracking the pharmaceutical market said the share of Indian companies in the generic US prescription market rose from approximately 12% in 2008 to about 26% in 2013, while generic drug penetration has jumped to more than 85% over the last five years mainly due to significant patent expiries, which hints at the potential market Indian generic drug companies can take advantage of.

Source: *The Financial Express, 3rd March 2014*

Stethoscopes Major Cause of Spread of Infections

Although healthcare workers' hands are the main source of bacterial transmission in hospitals, physician's stethoscopes have now been found to actually play a major role in spreading deadly infections. Researchers at the University of Geneva hospitals assessed the level of bacterial contamination on physician's hands and stethoscopes following a single physical examination.

"Considering that stethoscopes are used repeatedly over the course of a day, come directly into contact with patient's skin and may harbour several thousands of bacteria (including MRSA) or drug resistant ones collected during a previous physical examination, we consider them as potentially significant vectors of transmission," said lead investigator Didier Pittet. "From infection control and patient safety perspectives, the stethoscope should be regarded as an extension of

the physician's hands and be disinfected after every patient contact." Researchers examined 71 patients who were checked by one of three physicians using sterile gloves and a sterile stethoscope.

After they completed the examination, two parts of the stethoscope (the tube and diaphragm) and four regions of the physician's hands (back, fingertips, and thenar and hypothenar eminences) were measured for the total number of bacteria present. The stethoscope's diaphragm was more contaminated than all regions of the physician's hand except the fingertips. Further, the tube of the stethoscope was more heavily contaminated than the back of the physician's hand. Similar results were observed when contamination was due to methicillin-resistant Saureus (MRSA) after examining MRSA-colonized patients. "This work is the first to compare directly the level of contamination of physician's hands and stethoscopes. Stethoscope contamination is not trivial and is comparable to the contamination of healthcare worker's fingertips," the research said.

Source: *The Times of India, 1st March 2014*

Govt Cautious on Cancer Drug Patent Regimes

Amid heightened scrutiny of the intellectual property regime, the government has decided to tread with caution on a compulsory licence for a cancer drug to ensure that its decision is in line with the legal provisions.

While compulsory licencing, which entails waiver of patent under extreme situations, for three cancerdrugs was being pushed by the health ministry, the issue is now limited to Dasatinib, a medicine to treat a type of cancer of the white blood cells, for which Bristol-Myers Squibb (BMS) holds a patent.

Sources said that the commerce and industry ministry recently wrote to the health ministry, rejecting the plea that the government should issue a compulsory licence under section 92 of the Patents Act. Using this provision, the government can only waive the BMS's patent rights in case of a national emergency or a circumstance of extreme urgency, which was not the case at the moment.

There is a third possibility as well, which is to suspend the rights for public non-commercial use in special circumstances, including public health crisis. In fact, the Patents Act has listed AIDS, HIV, tuberculosis, malaria and other epidemics as examples.

Sources said that in case of Dasatinib, this provision may be used but then the health ministry has to clearly show that it has the budget to procure the medicine and supply it under a plan for cancer patients.

"You can't expect a manufacturer to sell the medicine below cost," said a source.

Sources said that the commerce & industry ministry has pointed out that availability of patented drugs at affordable prices, which is being cited by the health ministry for granting a patent waiver, should not be dealt by the government. In fact, the health ministry was recently told that section 84 of the Patents Act clearly stipulates that compulsory licence can be issued if a "patented invention is not available to thepublic at a reasonably affordable price".

But the government does not have powers under the law to suspend patent rights on the grounds of affordability. The law only allows the Patent Office, which is an independent agency, to issue a compulsory licence. Last October, the Patent Office had rejected an application from BDR Pharma to

make a generic version of BMS's Dasatinib, which is sold under the Sprycel brand. The proposal was rejected on the grounds that the Indian company did not make enough efforts to obtain a voluntary licence for the anti-cancer drug.

Source: *The Times of India, 1st March 2014*

Indian Institute of Chemical Technology Signs Mou for Research on New Cancer Drug

The Indian Institute of Chemical Technology (CSIR-IICT) has signed an MoU with Dortmund University, North Rhine-Westphalia, Germany for research in cancer drugs.

The MoU will help in developing cancer drugs, said IICT chief scientist Dr S Chandrasekhar.Dortmund university is said to closely work with the Max-Planck's Drug Discovery and Development Centre, Germany in stem cell research. "The new chemicals that we discover in our lab from raw materials will be transferred to strengthen the cancer drug research programme," Chandrasekhar said.

Chandrasekhar spoke to the media on the sidelines of the CSIR-IICT's 70th year celebrations. An international symposium on 'Nature inspired initiatives in chemical trends' is being organized to mark the occasion. The symposium was inaugurated by Prof Goverdhan Mehta, national professor, University of Hyderabad and was presided by Dr M Lakshmi Kantam, director, CSIR-IICT. Nearly 600 delegates from USA, France, Germany, Switzerland, Japan, China and South Korea are participating in the event.

According to IICT scientists, nature assembles complex bioactive structures, which inspires the chemist to synthesize these molecules in the laboratory. The compounds become handy tools to understand the modulation of biological pathways, they said.

It was found that neem could also help treat renal cancer, said Rao. Mayo Clinic, Rochester, US is already working on drugs for renal cancer, he added. The average life expectancy had gone up from 47 years before independence to 67 years in India, mainly to the drugs made available, Rao said.

The drug Galantamine for Alzheimer's disease, common among the aged, was derived from natural sources, he said. Since India has a long coastline, scientists would look for new fish at a depth of 1,000 meters to find chemicals that could be used to cure disease, Rao said.

Source: *The Times of India, 4th March 2014*

Novartis May Be Fined for Submitting 'Fake' Document to Drug Controller General of India

Swiss drug innovator firm Novartis may face penalties in India for submitting 'fake' document to the Drug Controller General of India (DCGI) for a veterinary medicine. The Indian arm of Novartis has admitted before the DCGI that it had submitted a document that was later found to be 'fake' with regard to its site of manufacturing for Tiamulin Hydrogen Fumarate (80% granule).

Top officials of Novartis India BSE -0.18 %, who appeared during a hearing in the drug regulator's office last week, have 'tendered an unconditional apology for the commission of the act', according to an order passed by the DCGI and reviewed by ET.

The drug regulator has cancelled the import licence and registration for the drug used for respiratory problems in animals and ordered its immediate recall from the market, said the order. The matter of furnishing a fake certificate to get registration of a drug has been forwarded by the watchdog to the health ministry for further 'legal action'.

A Novartis spokesperson told ET that its application for the re-registration of the drug has been rejected by the DCGI.

"While we will reapply for the registration, Novartis had already stopped further marketing and distribution of the product," she said, adding that the company has a "strong code of conduct with zero tolerance for deviations".

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The drug regulator has also identified another 26 of Novartis' imported products, documents of which are being assessed for their authenticity at present.

The DCGI may follow up the investigation with inspection at some of the company's European manufacturing sites, according to another order of the drug regulator reviewed by ET.

The development comes at a time when manufacturing facilities of many Indian pharma companies have also been hauled up by the US drug regulator for 'data integrity' violations that has resulted in import ban on a number of plants. Novartis has annual sales of $58 billion globally while its Indian arm, a listed entity, earns Rs 900 crore yearly.

The Indian drug regulator became suspicious of the document that claimed the drug was manufactured in one of its Austrian facility at Tyrol after it spotted another application of the company displaying an identical certificate number, but citing a different manufacturing site at Trento, Italy.

Subsequently on the drug regulator's request, director, European Directorate of Quality Medicine, Council of Europe, confirmed its suspicion and said that the certificate of Novartis claiming that the drug was manufactured at its Austrian site was 'fake'.

A DCGI team of four officials headed by deputy drug controller K Bangarurajan conducted an inspection at Novartis India's office in Mumbai for four days towards the end of January to get to the bottom of the matter. The mail from the headquarters said that the company is requesting EDQM for a fresh certificate for the drug now.

Source: *The Economic Times, 4th March 2014*