Pharmacy in India

In the service of proper use of medicines
Foreword

Dr. C. Gopalakrishna Murty
President
Indian Pharmaceutical Association-India,

Dear All Readers,

Friends, you may all feel disappointed that the session of Pharmacy in India in this 71st International Congress of FIP has to be unfortunately cancelled due to tactical reasons but I have made every effort to fill the void thus created, by giving this publication for the benefit of all the delegates.

I would like to bring to your information that this book “Pharmacy in India” has earlier been published in 2005. However, as there is not much perceptible change about Pharmacy in India since then, I felt it prudent to make a reprint for the benefit of the Community Pharmacy Section delegates attending the 71st International Congress of FIP & World Congress of Pharmacy and Pharmaceutical Sciences, 2011 being jointly organized by Indian Pharmaceutical Association and FIP from 3-8 September, 2011 in India at Hyderabad. It is expected that this publication will certainly give a good real insight of Pharmacy in India to all the delegates.

Indian Pharmaceutical Association feels very happy to extend a very hearty and warm welcome to all the delegates attending the 71st International Congress of FIP and hope you all will carry home the happy memories of this Congress.

Thanking you all,
Yours sincerely,

[Signature]

Dr. C. Gopalakrishna Murty.
Learning from the West

The release of the first edition of "Pharmacy in India in the service of Proper Use of Medicines" coincides with an important event for the Indian pharmacists: the First Indo-French Medical and Pharmaceutical Day Conference in Delhi on November 19, 2005. This international exchange of experiences will offer an excellent opportunity to profit from another country's systems and ideas. Learning from the west is precisely what we can do at the Indo-French Medical and Pharmaceutical day and is indispensable, especially in such a sensitive field as healthcare. There is hardly any other area where quality of products and services is of comparable importance.

This document contains a large number of articles, which bring out the current status of pharmacy profession in India and demonstrate pharmacists' role in medicine management and health care activities. These articles are contributed by renowned experts in the field of pharmacy and pharmaceutical sciences. We, at the Indian Pharmaceutical Association, always endeavor to follow the example of the best in the world. Our priorities are education and training of pharmacists and pharmaceutical scientists for developing their competence and fulfillment of service in managing access and ensuring proper use of medicines.

Pharmaceutical industry in India has made a remarkable progress and we look forward to also offering our know-how, products and services to others.

November 9, 2005

Prafull D. Sheth
Immediate Past President, IPA
Winds of change

India is becoming an important contributor to the health of the global population. In the era of escalating costs, advances in technology, fierce competition and vast generic opportunity, Profession of Pharmacy in India is undergoing a change. The regulations, quality standards are being harmonized with the rest of the world. This will necessarily bring in changes in Pharmacy Practice, Pharmacy Education.

Indian Pharmaceutical Association strives to upgrade the status of Pharmacy Profession in India. We are in process of building bridges with rest of the Pharmacists community in the world. Through regular interactions, meetings, seminars and training programmes, we shall try to achieve our objective of catering to the needs of the profession.

This book on “Pharmacy in India” gives updated information on all the facets of the profession, which surprisingly was not available in one document till today.

I hope that this book will create awareness of the status of the Pharmacy Profession in India.

November 9, 2005

Subodh Priolkar
President, IPA
MESSAGE

The President of India, Dr. A.P.J. Abdul Kalam, is happy to know that the Indian Pharmaceutical Association is organising the Franco-Indian Pharmaceutical Day Conference on the theme “Healthcare Policies in India and in France” on the occasion of the inauguration of the 44th Indian National Pharmacy Week on November 19, 2005 at New Delhi.

The President extends his warm greetings and felicitations to the organisers and the participants from India and abroad and wishes the events all success.

PRESS SECRETARY TO THE PRESIDENT
MESSAGE

I am happy to learn that the ‘Indo-French Medical and Pharmaceutical Day’ and Inauguration of the 44th Indian National Pharmacy Week are being organized on 19th November 2005 at New Delhi and that a special publication “Pharmacy in India - for proper use of medicines” is also being brought out on the occasion.

Since independence, India has made great strides in research and we live today in extremely dynamic and exciting times as India is emerging as one of the largest suppliers of pharmaceuticals to the world. In this context, I hope this occasion will only provide for a greater bond to be established between our two countries in this sector. The scientific program on the Healthcare Policies in India and in France should also provide a platform for experience sharing in Healthcare systems, social protection and new product approvals in the pharmacy sector.

I am sure the Event will provide a unique opportunity to healthcare personnel to achieve better understanding of the health care scenarios of both India and France.

I wish the Event and release of publication all success

(Dr. Anbumani Ramadoss)

Shri Prafull D. Sheth,
Immediate Past President,
Indian Pharmaceutical Association,
E-256 (FF), Greater Kailash -1,
New Delhi- 110 048.
Message

Dr Samlee Plianbangchang, Regional Director,
World Health Organization, South-East Asia Region

I am very happy to extend my greetings and good wishes to the Indo-French Medical and Pharmaceutical Day and the Inauguration of the 44th Indian National Pharmacy Week on 19th November. The synergies that can be achieved through Indo-French cooperation are significant and are useful for health developments in the future. The key role of the Indian Pharmaceutical Association (IPA), the professional association of pharmacists in India, in these activities ensures wide national dissemination.

The themes that have been covered in the previous annual “National Pharmacy Weeks” are at the centre of WHO’s activities. The Essential Medicines Concept is at the core of the WHO Medicines Strategy; Rational Use of Drugs was the debated and a Resolution adopted by the World Health Assembly in May 2005. The “Guiding Principles for Pharmacists in HIV/AIDS in India” usefully complement WHO’s “3 by 5” initiative. The Tobacco Free Future activities of IPA are a useful adjunct to the WHO activities related to the Framework Convention for Tobacco Control. Some of these topics will be discussed on the 19th during the current events and should contribute to achieving a better understanding of the issues involved, and in addressing them.

The scientific programme of “Healthcare Policies in India and France” will allow a fruitful comparison of different national strategies. As India’s health care advances to cover an increasing proportion of the population, issues of financing, access and equity need to be addressed; France’s experience in comprehensive health care will form a useful basis for discussion.

The Indian Pharmaceutical Association is a founding member of the South-East Asia Pharmaceutical Forum (SEARPharm). As the South-East Asia organisation of the International Pharmaceutical Federation, SEARPharm Forum has participated in the global activities and contributed to the advancement of the pharmacy profession in the Region.

I wish the Indo-French Medical and Pharmaceutical Day and the Indian National Pharmacy Week all success.
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PHARMACY IN COLONIAL INDIA

The earliest traditional systems of medicine practiced in India have been Ayurveda and Siddha. The Unani, Greco-Arabic medical system, came from West Asia. The European colonizers brought the western system of medicine to the country. During the colonial period, this new system got firmly established. It held sway and came to have controlling influence on health care. On the country attaining independence, there was no going back.

Today, though the traditional systems of medicine continue to be practiced in India with sufficient state support, but the mainstay of the official public health care setup is the internationally recognized system of medical treatment, which is termed in India as allopathic or modern. Consequently the meaning of pharmacy as viewed in India is no different from what it implies the world over.

The medical personnel in the employ of the East India Company and later the British Crown were instrumental in the introduction and development of the western system of medicine. The Indian Medical Service (I.M.S.) in particular played a dominant role. The Service was essentially a military service, though a large proportion of its members were generally in civil employment. The members of the Indian Medical Service served the Indian troops; the officers of the Royal Army Medical Corps who were temporarily stationed in India served the British troops in the country.

The western medical education in India owes its origin, almost entirely to the I.M.S. The instructions in the western medical system were first introduced in the beginning of the nineteenth century. The Medical College at Calcutta and the Medical School, later designated as College, at Madras were established in 1835. The Grant Medical College at Bombay came up in 1845. Close to the independence of the country there were 19 medical colleges giving instructions leading to medical degrees. At the time there were also 19 medical schools training licentiates.

During the nineteenth century there were subordinate classes of apothecaries and hospital assistants, who had medico-pharmaceutical functions. The apothecary class consisted of trained boys of European or Eurasian extraction; they carried out duties with European troops, hospitals and depots. The hospital assistants were invariably natives; they worked with native troops and army hospitals.

The western materia medica was strengthened through provision of pharmacopoeias of British origin. The drugs required to keep the new medical system going were generally not available in India. The drugs and related items had to be imported from overseas to sustain the new system, which had been successfully introduced. The drug industry in India was at a rudimentary stage. All types of medicinal, pharmaceutical and biological products were imported into British India. The focus of imports was more on finished products, prepared from the active drugs of foreign origin. The retail and wholesale drug trade continued to be mainly dependent on imports. The most valuable was the business in proprietary and patent medicines, which largely originated abroad.

On introduction of the new medical system in India, there naturally followed the emergence of pharmacy houses, to meet the requirements for western drugs and other supplies. The European establishments, generally managed by the British started appearing from the early nineteenth century. In the British Empire, India was a place for doing lucrative business. It is understandable that European pharmacists and druggists also found this land promising for practicing their profession. They were attracted to the locations where the population of the British was large enough to provide good returns. The British population was mostly concentrated in the big metropolitan towns and cantonment locations. As years passed several of other smaller towns also saw European pharmacies. Delhi received attention after the capital shifted there from Calcutta in 1911. The summer
resorts too were reached for business harvest. The main hill stations frequented by the Europeans were Simla, Mussorie, Nainital and Darjeeling in the Himalayas, Ootacamund and Conoor in theNilgiris, and Mahableshwar in the Bombay Presidency. The civil and military service personnel and their families constituted the main clientele, whose pharmaceutical needs were catered by the European druggists’ establishments. The number of drug purchasing patients patronizing the European establishments was small, and they were from the rich native gentry. The common people could not afford to pay the 'Europe prices.'

The European chemists and druggists also added other profitable lines to their business. The chemists proved to be successful businessmen. Nearly all of them were manufacturers of aerated waters, the demand for which was enormous. The chemists spread their business net fairly wide. Some of them also entered field of manufacturing. The supply of photographic apparatuses, surgical instruments, hospital furnishings, toilet requisites, and wines and liquors were other fields of interest. A few even had printing presses. One drug house even had its own weekly newspaper. Another had an auction mart. In general, the European drug houses developed into merchandise and departmental stores. Pharmacy owners felt that more varied were their stocks, the more would be the returns from their enterprise. So, as it was, the prescription pharmacy practice was generally combined with dealing in general merchandise. In certain of the establishments the dispensing may have constituted a small part of the whole business.

The European business buildings were imposing and palatial. Several retail and drug establishments were much larger than any in England. The pharmacies in Bombay and Calcutta were splendid places. Looking at an establishment of an English pharmacist in India and comparing it with an ordinary pharmacy in England, brought to mind contrast between a mansion and a villa. The photos of some of the colonial period pharmacies reproduced here have been obtained through the Wellcome Library, London.

The European chemists and druggists were a prosperous community. The establishments made princely earnings. The business was good, particularly in the second half of the nineteenth century. By turn of the century, the turnover came down. In later years certain of the European establishments came under Indian ownership. There were also many standard firms all over the country which started through Indian ownership and maintained ethics. It may be mentioned that in colonial India there were all sorts of conditions of chemists’ shops. Since there were no drugs or pharmacy laws in the country, there were hardly any restrictions on opening of drug shops. Some of the druggists were doing legitimate business and there were also small-time drug dealers trying to make a living.

Notwithstanding the existence of some standard pharmacies, the overall situation with regard to drugs and practice of pharmacy remained of grave concern. To say it again there were no relevant legal restrictions for control of drugs and practice of pharmacy. There were malpractices in import and sale of drugs. The absence of adequately qualified pharmaceutical personnel compounded the sad state of affairs. The public-spirited people were perturbed by the situation, as it existed. The media of the time raised its voice against prevailing scenario. The pressure kept on building up providing control of adequate. The volume of the opinion generated, professional commercial and lay, reached a crescendo and the Government could no more be deaf to the rising pitch of criticism. The Government of India was compelled to appoint the Drugs Enquiry Committee in 1930 to study the issues and recommend measures for correcting the prevailing conditions. The Drugs Enquiry Committee (1930-31) made several worthwhile recommendations. The Committee recommended that there should be Central Legislation to control drugs and pharmacy. The legislation proposed was for a combined drugs and pharmacy act, or a separate drugs act and a separate pharmacy act.

Sadly, the Government of India did not feel the urgency to implement the recommendations of the Drugs Enquiry Committee for drugs and pharmacy legislations. It was a long
wait of nine years of receipt of the Report by the Government that the Drugs Act 1940 was enacted. Five years later the Drug Rules 1945 under the Act got ready. The Pharmacy Act 1946 became a reality, after a waiting period of seventeen years, subsequent to the publication of the Report. The Government decided to implement the Drugs Act 1940 from 1 April 1947. If the drugs and pharmacy statutes had been enacted simultaneously the contents of both vis-a-vis each other could have been more realistic. The legislative incongruity still stands.

During the colonial period no serious governmental effort was made to produce pharmaceutical manpower of adequate quality. There was a Chemist and Druggists class run in Madras presidency. This was the only course of its kind and standing in colonial India, which was geared to provide qualified manpower for modern pharmacy practice. This class was not popular and it attracted only a few students. For want of statutory support the students coming out did not have in view any assured jobs. There was a class of compounders, who were largely ill-trained and were low-level practitioners of pharmacy. They were despaired and disparaged as professionals.

There were two pharmacy degree-awarding institutions. The Banaras Hindu University and the Panjab University instituted B.Pharm. courses in 1937 and 1944, with a yearly intake of 20 and 5, respectively. The pharmacy graduates looked for jobs in the drug industry.

The Health Survey and Development Committee (1943-45) of the Government of India brought out that at the time the number of doctors available was 47,500 (for population of 300 million, giving ratio of 1 to 6,000), and there were only 75 qualified pharmacists (1 to 4,000,000 ratio to the population) in the country. Apparently, the compounders, whose total number was probably close to 27,000, were considered inadequately qualified to be counted as pharmacists.

Broadly, the above was the state of pharmaceutical affairs in the country during the colonial period. Since India attaining independence in 1947 there have been tremendous developments. That gives us some satisfaction but we have to keep the concerted efforts on for further progress and consolidation to get considered to be at par with the western world in the realm of western, now international, pharmacy.
THE WONDERFUL WORLD OF THE COMMUNITY PHARMACIST OF INDIA

In every country, quality health personnel has evolved in course of last few years, and sometimes it has taken couple of centuries. The training of physicians or nurses in the U.S. is different than in other countries of Europe, Asia and Africa. The differences are many more than the commonalities. So is the case of the community pharmacist.

I have had the opportunity to visit the pharmacies of countries, so far apart from one another, i.e., Mexico to Indonesia and from U.S. and Canada to Soviet Union to China and Japan. In the last few months, I saw the pharmacies in China, most of whom have a division each of Chinese medicine and modern medicine (sometimes on a separate floor).

Where Do we stand?

Our community pharmacist in India, unlike in the west, is a Diploma holder and not a University degree holder and we have almost 500,000 of them serving all over the country. His pharmacy, in most cases, is not more than 300 Sq Ft. (30 metres) in area. Patients/their relatives form a beeline from early in morning and he serves them speedily, unlike in the U.S. or Canada where he asks the customer to come after a couple of hours in which he fills the prescription. The pharmacy nearest to my home ‘Om Pharmacy’ is owned and catered by “Madho” (full name, Mahadev Prasad Sharma) who begin work at 9:00 A.M.

10 minutes (7 Customers) with Madho

A young girl (14) wants a cough remedy for her 10 yrs old brother. Madho gave Syrup Corex for Rs. 40 to be taken one tea spoon TDS and the customer instructs the customer to avoid cold water or cold drinks, and take only hot food.

Next patient is an old man of 70 who asks for a purgative. He is given “Bisacodyl” and charged Rs. 2 for a 3 days course to be taken at bedtime.

Mala (24) a young woman comes with a child sick with diarrhoea. She goes back with a sachet of ORS and is told to give two tea spoons in half a glass of water as often as the child could take and is also asked to visit a doctor if improvement does not take place by the evening.

The next visitor bring a doctor’s prescription for Tab. Glibenclamide ½ tablet per day before breakfast, to be gradually increased to 2 tablets in the next 2 weeks. The strength of the tablet is not mentioned. Madho gives him 5 mg tablets for 2 weeks and charges Rs. 20.

Then comes a mother with her son (10) who had itching red eyes. Conjunctivitis is rampant in the season. He has given a 5 ml vial of Tobramycin 0.3% eye drops for Rs. 23.

Next comes a 30 year old man, a labourer with high fever. He is given Crocin (Paracetamol) 500 mg tablet 1 TDS, and charged Rs. 12.

Then comes a 60 year old asks for some “Takat Ka Dawa” a sex stimulant and is given one Tablet of “Caverta” (Sildenafil) 25 mg for Rs. 9.

What Wrongs he did?

Where did Madho exploit, erred or deviated from his duties?
To (1) he gave the most expensive cough depressant.
According to the rules, he should have given a non-addictive cough syrup but he provided immediate relief. For (4) he dispensed Gilbencimide 5 mg without checking with the physician. This is available 2.5, 5 and 10 mg. It was more of an omission by the doctor and he could have referred it back. He gave 5 mg tablets that is most commonly used. For the (5) he gave Tobramycin without authority but if he referred it to a doctor, it would mean an extra expense of Rs. 25-50 which the patient can never afford. In 9 out of 10 cases what he gave was the best for the patient. For the (6) he guessed that he was suffering from a viral fever (then prevalent) and not malaria or typhoid. In 9 out of 10 cases he would be right. For (7) he again went beyond his authority. In India, Sildenafil can be prescribed by a urologist only. If (7) had gone to one, he would be required to sell out Rs. 100-200. This customer was, perhaps, used to the preparation and the dose both. He would have never gone for it if he had to go the medical specialist.

He is fulfilling Who’s objectives

The WHO has evaluated and that only 35% of the population in India gets modern drugs while the rest are deprived of these because of ignorance / poverty. The aim of WHO is to increase the availability which would serve a useful purpose. The WHO feels that the community pharmacist in India should make more and more drugs available to the needy patient. The aim is to spread the use of drugs and make them available to all sectors of the society at an affordable price and of good quality. The Drug Rules in India have classified 90% (much more than in other countries) of the drugs and the doses as "Physician prescribed". Looking to the need of a large number of poorer sections of the society only 20% need to be classified in the category. In India a visit to the doctor is very expensive (Rs. 25 to 100) and if Madho, the neighbourhood pharmacist had gone by the book he would have sent 3 out of 7 patients, described above without a medicine. He, by bending the rules in favour of the patient definitely did a positive service to the community.

Why not bear with him for some more time

Today, the Indian Pharmacist may not be advising the patient on drug-drug or drug-food interactions but makes available standard drugs at a very affordable price. He is highly courteous and friendly.

He cautions the patients on major side effects and does not charge extra for any of these services. It is true that he should provide more professional guidance. He thinks it will be coming slowly but surely. Let us not forget that until 20 years back the Pharmaceutical Industry in India was in infancy.

Today, it is the fourth largest selling in the world. Indian Pharmaceutical Education in the country was also not of a high standard until 15 yrs back. Now some of our colleges and institutes are of international standard. These achievements have taken place without any support of the government but because of competition.

Where the Indian Pharmacist Exceels

Most community pharmacists in India are like Madho who is highly resourceful, pleasing and accommodating, yet decisive. He keeps his eyes and ears wide open and catches your point promptly and provides immediate service. This is the way he served 7 patients in 10 minutes i.e., in record time. The Indian pharmacist excels over all others in prompt service.
The Indian Pharmaceutical Association

The Indian Pharmaceutical Association (IPA), which is the National professional body of pharmacists, was founded way back in 1939 and has today evolved into a well-recognized professional organization in its own right. With a well-defined constitution, and objectives, that set out a path for professionalism, the IPA began its crusade to promote the science and arts of Pharmacy. A major emphasis was given to impart suitable education and training to Pharmacists and curriculums were designed to meet the future challenges.

The membership criteria for the Association is strictly adhered to, to ensure that the standards of the profession are upheld. A vibrant organization with over 12,000 strong membership today, IPA constantly strives to promote the highest professional and ethical standards of the pharmacy profession. It has its headquarters in Mumbai and has 18 active state branches all over the country.

It's mission is: "The Indian Pharmaceutical Association (IPA) is the national professional body of pharmacists engaged in various facets of the profession of pharmacy. It is committed to promote the highest standard of pharmacy, focus the image of pharmacists as competent healthcare professionals, sensitize the community, government and others on vital professional issues and support pharmaceutical education and sciences in all aspect".

The tasks that it has set out to achieve are numerous, but the main ones are:

1. To impart suitable education and training to the members preparing for the profession of pharmacy or to those already engaged in the profession.
2. To undertake, carry on or promote scientific and technical research in pharmaceutical and allied sciences.
3. To edit and publish journals, books, magazines, documents and other publications for promoting the causes of the profession of Pharmacy.
4. To urge or represent on any legislation and other measures, and to procure change of law and practice in the interests of the profession of Pharmacy in India.

In the first few decades of its existence, emphasis had been more on education and industrial pharmacy. This had spectacular results in producing pharmacists of international standards and creating industries that could compete worldwide.

The pharmaceutical industry of India is now the fourth largest producer by volume. Most essential drugs are indigenously available at competitive cost. The vision of Indian industry now is to become a global player. It is also poised to be the preferred global destination for drug development research as well as clinical research. Pharmacy professionals therefore, are getting geared up to meet global challenges, and the Indian Pharmaceutical Association is sparing no effort to upgrade the knowledge and skills of the members of the profession to meet these challenges. It organizes conventions, conferences and training programmes to provide updated information to fellow pharmacists and to provide a platform to interact with the other members of the profession, Industry and the international community.

The challenges for the pharmacists to serve our own country are daunting too. The per capita consumption of drugs still being among the lowest in the world, the issue of
Pharmacists have the information you need...
...To make the best choices for your health

Your Pharmacist...
...a Patient-oriented Professional

Antibiotics don’t work on most colds! They are potent medicines; have to be prescribed by a doctor depending on the type of infection.
affordability continues to plague the industry. Judicious use of the available medicines needs to be ensured. The Government of India is taking interest in putting an effective healthcare system in place. The Indian Pharmaceutical Association is also taking steps to position the pharmacist as an important link in the healthcare system whose practice, based on his unique knowledge and skills about drug therapy, ensures optimal patient outcomes. It is therefore now making special efforts to develop the community pharmacist and hospital pharmacist in the country.

To be able to pay attention to the activities of the various areas of specialization of Pharmacy, the Indian Pharmaceutical Association now has 5 divisions with their divisional heads working to develop these areas. These are:

1. The Industrial Pharmacy Division.
2. The Regulatory Division
3. The Community Pharmacy Division
4. The Hospital Pharmacy Division
5. Education Division

The Indian Pharmaceutical Association is in constant touch with other professional bodies within the pharmaceutical system as well as the allied healthcare system such as the Pharmacy Council of India, the Indian Drug Manufacturers Association, The Organisation of Pharmaceutical Producers of India, The Retail Druggists and Chemists Association, The Pharmaceutical Teachers Associations. The Education Division also mentors Student activities.

Jointly with these associations, the IPA celebrates the National Pharmacy Week, wherein awareness is created among the general public for different issues related to pharmacy and health.

The IPA also plays an active role in relation to other international pharmaceutical bodies such as The Federation International Pharmaceutique (FIP), The AAPS (The American association of pharmaceutical Scientists), The Commonwealth Pharmaceutical Association (CPA), SEARPheum Forum (FIP: WHO Forum of National pharmaceutical Associations of SouthEast Asia), Federation of Asian Pharmaceutical Association (FAPA) and International Pharmacy Students Federation (IPSF).

It also participates in international conferences and represents the important issues in the country.

The IPA has taken a number of initiatives such as creating “Good Pharmacy Practice Guidelines” for community pharmacists in the country, collaborating with WHO in conducting specific studies in relation to diseases haunting our country like tuberculosis and AIDS.

And finally, the Indian Pharmaceutical Association recognizes the efforts of eminent personnel in the field of Pharmacy who have contributed to this profession significantly by conferring various awards. The crusade thus continues.

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**National Drug Authority: A new agency**

**Historical Background**

The recommendation for setting up a statutory body called the National Drug Authority (NDA) started with the Hathi Committee report submitted in 1975. The Government of India, at that time, did not accept this recommendation but the concept was included in the Policy Document of 1986, which stated that a machinery called the National Drug and Pharmaceutical Authority (NDPA) would be established at the central level. However, no action was taken by the Government to create this machinery. The Drug Policy announced in 1994 once again envisaged setting up of an Independent body called NDA for providing a more efficient mechanism to ensure quality control and rational use of medicines. Some efforts were made by the Ministry of Health and Family Welfare to take this concept forward but no real progress could be made due to lack of clarity on many issues.

The Pharmaceutical Policy of 2002 once again stated that the Ministry of Health and Family Welfare would “set up a world class Central Drug Control Organization (CDSCO) by modernizing, restructuring and reforming the existing system and establish an effective network of drug standards enforcement administrations in the States with the CDSCO as a nodal center, to ensure high standards of quality, safety and efficacy of drugs and pharmaceuticals”.

In 2003, Government of India constituted an Expert Committee led by Dr. R. A. Mashelkar with terms of reference that included among others, to examine and recommend a new structure for the Drug Regulatory System in the country including the setting up of the National Drug Authority (NDA). The Committee examined all aspects and concluded that there were several complex operational, legal, constitutional and political issues involved in setting up NDA. The Committee emphasized that the existing infrastructure at the Centre and states was not adequate to perform the assigned functions efficiently and speedily. Creating another authority such as NDA will not solve the problem at hand. The Committee reiterated the policy decision of the Government, enunciated in the 2002 Pharmaceutical Policy and recommended a strong, well empowered, independent and professionally managed Central Drug Administration (CDA) reporting directly to Ministry of Health and Family Welfare. It was recommended that CDA, under a single authority would also perform the functions of licensing of all drug-manufacturing units in the country.

**Current Drug Regulatory System In India**

The Drugs and Cosmetics Act, enacted in 1940, is a central legislation which regulates the import, manufacture, distribution and sale of drugs and cosmetics in the country. The main objective of the Act is to ensure that the drugs available to the people are safe and efficacious and conform to prescribed quality standards and the cosmetics marketed are safe for use.

Under the Constitution of India, ‘Drugs’ being a concurrent subject, the responsibility of enforcing the Drugs and
Cosmetics Act vests with the Central Government and the State/UT governments. Under the Act, the Central and State/union territories Governments have different responsibilities and these are well defined.

The main functions of the Central Government are:

a. Approval of new drugs to be introduced in the country;

b. Permission to conduct clinical trials;

c. Registration and control on the quality of imported drugs;

d. Laying down regulatory measures and amendments of the Act and Rules;

e. Laying down the standards for drugs, cosmetics, diagnostics and devices and updating the Indian Pharmacopoeia;

f. Approval of licenses as the Central License Approving Authority for manufacture of large volume parenterals, vaccines and biotechnology products and operation of blood banks and also of such other drugs as may be notified from time to time; and

g. Coordinating the activities of the States and advising them on matters relating to uniform administration of the Act and Rules in the country.

The State/union territories Governments are responsible for:

a. Licensing of manufacturing establishments and sales premises;

b. Carrying out inspections of licensed premises for ensuring compliance to conditions of licenses;

c. Drawing samples for tests and monitoring the quality of drugs and cosmetics available in the states;

d. Taking appropriate actions like suspension/cancellation of licenses;

e. Surveillance over sale of spurious/adulterated drugs and cosmetics;

f. Instituting legal action, wherever needed, as provided in the Act and Rules; and

g. To monitor objectionable advertisements pertaining to drugs.

Issues

The licensing and control of manufacturing units by different authorities in the 32 states and union territories has resulted in non-uniformity of enforcement of the Act and Rules framed thereunder. Even after 58 years, the level of enforcement in many states has been far from satisfactory. The non-uniformity in the interpretation of the provisions of laws and their implementation and the varying levels of competence of regulatory officials in the states are the main reasons for this less than satisfactory performance.

The problems in the regulatory system in the country are mainly due to:

- Inadequate and weak drug control infrastructure at the Center and in the States
- Non-uniformity of enforcement
- Shortage of Drug Inspectors
- Inadequate drug testing facilities
- Lack of specially trained cadres for specific regulatory areas
- Non existence of data bank and non availability of accurate information

What is needed:

As recommended by Mashelkar Committee, a strong, well empowered, independent and professionally managed Central Drug Administration (CDA) in the Ministry of Health and Family Welfare would be created. A single authority will take up the responsibility of licensing and control on the manufacture of drugs in the whole country for uniform enforcement of the Act and Rules.

Structure of CDA

The present CDSCO would be restructured as CDA with a number of adequate Divisions at the headquarters manned by qualified and properly trained professionals. The restructured CDA would perform all the existing functions of the Drug Controller General (India) and also take over the functions of licensing of all drug manufacturing companies in the country which at present is the responsibility of state drug controllers.

A strong CDA would require significant and adequately qualified and skilled manpower. It would, of course, need creation of additional posts at the headquarters and at the field offices. For performing the function of licensing of all manufacturing units in the country, the CDA would need to be restructured and set up offices region-wise and state-wise depending upon the concentration of drug manufacturers. It would involve enhanced deployment of technical and administrative manpower in the proposed CDA and also the commitment of the Central Government for additional funds and infrastructure.

The CDA will have a well established infrastructure and qualified pharmaceutical and pharmacological scientists, legal and other competent officers at the headquarters, at the regional/zonal offices and for the drug testing laboratories to perform their functions more effectively and expeditiously. The functions of CDA, being multi-disciplinary in nature, it would be necessary to have considerable sourcing of expertise from external experts and institutions and this would require provision of sufficient funds at the disposal of the head of CDA, i.e. the Drugs Controller General (India).

Once the licensing of all drug-manufacturing units in the country is taken up by the CDA, the state drug regulatory
authorities can then concentrate on the sale and distribution of drugs and monitor the quality of drugs marketed in their states by regular sampling and testing. The states would need to establish effective intelligence cells to tackle the problem of spurious/counterfeit drugs in their states. The states can also then enforce the provisions of Drug Price (Control) Order as well as of Drugs and Magic Remedies (Objectionable Advertisement) Act more effectively.

Indian Pharmacopoeia Commission testing and evaluation of drugs

The first Pharmacopoeia of India was published in 1868 when India was still under the British rule; and for various reasons, it soon went into oblivion. After independence, an Indian Pharmacopoeia Committee was constituted in 1948, which prepared the Indian Pharmacopoeia 1955. The subsequent editions of 1966, 1985 and 1996 with one or two Addenda or Supplements in between got published under similar arrangements. This irregular production is a source of considerable anxiety to the profession and the industry. The Drugs Technical Advisory Board (DTAB), a statutory body under the Drugs and Cosmetics Act 1940 initiated action in 1982 for creation of an autonomous body to publish the Indian Pharmacopoeia on a regular basis. Ultimately, the Government of India, Ministry of Health and Family Welfare issued its Order on 22 March 2005 for setting up an Indian Pharmacopoeia Commission as a registered Society under the Societies Registration Act, 1880.

India had practically no pharmaceutical industry when the country got its independence in 1947. Over the years, it has grown phenomenally so much so that the country has become practically self-sufficient in most drugs. Many manufacturers from the organized sector are presently capable of manufacturing drugs meeting the stringent quality requirements of advanced countries like the USA, the UK, EU, Australia, South Africa, etc. Some of the Indian pharmaceutical companies like Dr Reddy’s Lab, Ranbaxy and Cipla have started manufacture in a number of countries outside India. While this is one end of the spectrum, the bulk of the pharmaceutical industry continues to be in the small scale and medium scale sectors that have not yet been able to upgrade their facilities adequately. It is, therefore, imperative that the standards to be applied to such units need to be compatible with the ground realities without sacrificing the basic need of purity, safety and efficacy of drugs.

As the technology for manufacture and testing of drugs in different countries is not uniform and is influenced by the available financial resources and technical expertise, standards to be applied in different countries need to be looked at from a practical angle. Consequently, most countries or groups of countries have their national or International Pharmacopoeia.

The Government of India consists almost entirely of ex-officio members with little expertise in subjects of relevance to pharmacopeial standards. For the constitution of the Scientific Body, a Search Committee formed by the Government has recommended various names. It is hoped that the recommendations are implemented at the earliest. But this body will be able to perform well only if its work is not interfered with by the predominantly non-technical members of the Governing Body and the General Body of the I P Commission.

There is need for harmonization of the Indian Pharmacopoeia with other international pharmacopoeias. The IP procedures have to be upgraded to meet the international Conference on Harmonization (ICH) guidelines if India has to attain a global status. Many such procedures ready for inclusion in the Addendum to IP 1996 due for publication in 2004 have yet to become official.

The IP Commission will also take up some new tasks in the coming years with the changed industrial environment because of the patent laws and upgradation of the regulatory requirements. The inclusion of fixed dose combinations particularly for treatment of tuberculosis and AIDS in the IP also needs to be quickly decided upon. I P has already a number of anti-retroviral drugs included in Addendum 2002 but more are necessary.

The IP Commission should be an autonomous body with a whole-time Scientific Director-cum-Secretary with full administrative, financial and scientific freedom to carry out its functions in accordance with rules and procedures approved by the Governing Body. The General Body, the Governing Body and the Scientific Body of the IP Commission should be headed by an eminent scientist in the field of pharmaceutical and allied sciences so that the work of the Commission proceeds on scientific lines with speed. A world class laboratory service with assured credibility will be essential for building and sustaining the image and authority of the Commission.

As the funds for the work of the IP Commission will be provided by the Government of India, it would be appropriate to have the financial adviser to the Ministry of Health as a member of the Governing Body to act as a watch dog on proper utilization of funds. Similarly, the Drugs Controller General of India, being the chief technical adviser to the Government on matters pharmaceutical, can also be there as a member of the Governing Body. The Director of the National Institute of Pharmaceutical Education and Research (NIPER), an institute that has already started earning an international image for the quality of its work in the short time of its existence, can also be there to provide quality inputs to the Commission. As the work of the IP Commission is essentially scientific and technical in nature, there is no alternative but to have a majority of the members from the scientific community on the Governing Body. The manner in which the Governing Body is constituted presently gives an impression that the scientific community, which has to do the actual job, is not trusted by the powers that be.
The quality improvement attained in IP 1996 was possible mainly because the Working Group specially constituted for the purpose consisted exclusively of scientists with experience in implementation of pharmaceutical standards. It is very essential that the work of the IP Commission is transparent. Let all the proposals for amendments and additions, etc., be published in a monthly publication that could be named as "Indian Pharmacopeial Forum" or "Indian Pharmacopeial Gazetteer", or any other suitable name in which proposals and comments on various issues concerning the IP and its standards are publicly debated before they become part of the I P. We must also ensure regularity in publication of the IP. A new edition every 5 years and an Addendum every year should be our immediate aim.

All the constituent bodies of the Commission must ideally have majority of scientific and technical persons. If, however, it is difficult to scrap the system proposed under the Government Order, the following suggestions should be given serious consideration:

(i) The Chairman of the Scientific Body must be Co-Chairman of the Governing Body.

(ii) At least 3 additional scientists of repute with long experience in pharmacopeial work must be made members of the Governing Body.

(iii) In addition to the position of the Chairman of the Scientific Body of the IP Commission, a position of Vice-Chairman may be provided to take care of the work in the absence of the Chairman from meetings because of his busy schedules.

This is by no means a detailed modus operandi for the IP Commission. These are some stray thoughts for making it work efficiently and to take account of the problems likely to be encountered.

**Fostering Pharmaceutical Sciences and Practice of Pharmacy in India**

The National Institute of Pharmaceutical Education and Research (NIPER), established in 1994, is an autonomous body set up under the aegis of Ministry of Chemicals and Fertilizers, Government of India. It is the first national level institute in pharmaceutical sciences with a proclaimed objective of becoming a centre of excellence for advanced studies and research in pharmaceutical sciences. The Institute is conceived to provide leadership in pharmaceutical sciences and related areas not only within the country, but also to the countries in South East Asia, South Asia and Africa.

The main objectives of NIPER are:

1. Toning up the level of pharmaceutical education and research by training the future teachers, research scientists and managers for the industry and profession.

2. Offering Continuing education programmes

3. Creation of National Centres to cater to the needs of pharmaceutical industries and other research and teaching institutes

4. Collaboration with Indian industries to meet the global challenges

5. National/international collaborative research

6. Curriculum and media development

7. Study of sociological aspects of drug 'use and abuse', and rural pharmacy, etc.

8. Conducting programmes on drug surveillance, community pharmacy and pharmaceutical management

Ever since its establishment, NIPER has been consistently inching its way towards the objectives laid. The objectives are achieved through teaching, research and training to the postgraduates of pharmaceutical sciences and the professionals in various sectors. The educational programmes are offered by nine different departments viz; Pharmaceutics, Pharmacology and Toxicology, Pharmaceutical Technology, Pharmaceutical Management, Pharmaceutical Analysis, Biotechnology, Medicinal chemistry, Natural products and Pharmacy Practice. In addition, the institute offers a two-year course in Pharmacoinformatics.

The initiation of six departments at the beginning and subsequent introduction of courses only reflects that the growth of each department is well-nurtured and the foundation is rock-solid. In the year 2002, the department of pharmaceutical management and the department of pharmacy practice were established. This was followed by the introduction of the emerging discipline of pharmacoinformatics, a year later. As of August 2004, 321 students have successfully completed the Master’s program in various disciplines and 45 have obtained doctoral degree. Without exception, all the graduates have been very well received by the pharmaceutical industry & academia, both within and outside the country. The contribution of NIPER in providing quality manpower ready to take up the responsibilities at job has been recognized worldwide.

In order to facilitate learning, NIPER research laboratories are accessible round-the-clock to the faculty members and the researchers. This would not have been possible but for the idea of having everyone on campus. Two separate hostels accommodate as many as 325 students. This is not restricted to the students and staff; all the essential staff lives on the beautiful 135 acres campus in the peaceful and small township of Mohali (S A S Nagar).

NIPER’s location in Mohali (S A S Nagar) offers exceptional synergy with public institutions like Institute of Microbial Technology (IMTECH), Postgraduate Institute of Medical Education & Research (PGIMER), Central Scientific Instruments Organization (CSIO), National Institute of Technical Teachers’ Training & Research (NITTTR), Punjab University, Government Medical College and Hospital (GMCH).
all in Chandigarh- and private institutions like Fortis Heart and Multispeciality Centre in Mohali.

At the back of the success of this young institute is its philosophy of achieving excellence in its initiatives. The founders of NIPER had envisaged the requirement of quality manpower in the area of pharmaceutical sciences and in a very short period of time, NIPER has become a brand. The Institute derives its strength from three quarters the students, who are selected through an all-India competitive examination, the experienced and competent faculty members and the leadership's determination to excel. Each faculty member is provided with start-up funds, depending upon the requirement and the research activities with application to the industry are highly encouraged. This facilitates the interaction of the pharmaceutical industry with the Institute. The Institute has a facility for an advanced state-of-the art instrumentation (Central Instrumentation Laboratory; CIL) that caters to the increasing needs of the industries not only in the region but also the country. The CIL is equipped with LC-MS/MS, GC-MS, NMR, XRD and MALDITOF-TOF. These are not only utilized to train young students under the supervision of competent personnel but also to meet the industrial needs.

**Fostering Pharmaceutical Sciences**

NIPER sees its activities in two major domains viz. capacity building activity, offering technical consultancy & undertaking contract research assignments with clearly defined objectives. The capacity building project is funded through the World Bank and the regulatory personnel, production staff and analytical staff from all parts of the country attend the customized training programmes offered at NIPER campus. This five-year project started in January 2004 and as of date 20 training programmes and a two-day workshop for senior government analysts (Nov 2004) have been successfully conducted with 993 participants.

Realizing the potential of the Institute and the availability of competent manpower, several pharmaceutical industries have been assigning their research projects to NIPER, especially in the areas of formulation development, Impurity profiling, pharmacological screening, toxicological evaluation and BA/BE studies. The establishment of the National Bioavailability Centre (second in the world), National Pharmacoinformatics Centre, GLP-compliant Toxicological Laboratory at NIPER only underlines the confidence the funding agencies have reposed in the capabilities of the Institute. As of date, over 150 sponsored projects (both, industry & govt) have been successfully completed while many more are in progress. In the past few years, the prestigious Dr. SS Bhattacharjee Award to a faculty member, Ranbaxy Research Award to two, Chopra Memorial Award to one and OPPI Award to two faculty members do deserve a mention.

NIPER also provides the pharmaceutical industry with trained managers with a strong footing in pharmaceutical sciences. In the 2-year sectorial MBA (Pharmaceutical Management) course, pharmacy graduates are provided education and training in managerial skills thus meeting a long felt demand by the industry.

**Fostering the Practice of Pharmacy**

The department of pharmacy practice at NIPER was established in 2002 when NIPER recruited the faculty and staff and decided to send two of them to the School of Pharmacy, University of London for a 21-days intensive real time training in clinical pharmacy practice. Simultaneously, arrangements for the clinical training of the students were finalized at the Fortis Heart and Multispeciality Centre. Subsequently, a similar interface was established at the Postgraduate Institute of Medical Education & Research (PGIMER). NIPER was awarded a “Higher Education Link” programme, managed by the British Council, for the development of this department.

Understanding the needs of the practicing pharmacists and matching the mandate of NIPER, the department initiated a series of Continuing Education Programmes which became increasingly acceptable among the practicing pharmacists. As many as six such programmes have been successfully organized in less than three years. These programmes have provided a very good interface with the practicing pharmacists and they do not feel alienated. The spectrum of these programmes has been strengthening of the skills of the hospital pharmacists to sensitization on themes of pharmacovigilance and medicine information.

Secondly, the Medicine Information Centre established under the aegis of the Higher Education Link programme of the British Council is the only one in the country with staff trained for six-weeks in UK. The Medicine Information Centre at NIPER, which is currently accessible through the e-mail or personal visit, provides technical support to the clinicians and nurses in the region on all drug-related issues. In two years, the centre has earned a name for itself through the handouts it circulates on the e-group PharmacyPracticeIndia and also for circulation within the city. The counselling support to the patients suffering from diabetes is only the beginning of a patient-centered pharmaceutical care process.

The students of pharmacy practice receive real-time clinical training in two hospitals while they assist the clinicians in a third hospital on providing clinical pharmacy services and resolving drug-related problems. With over 800 hours of training at the hospitals and 200 hours at experience at a community/ hospital setting(s), the students are equipped to take the professional responsibilities effectively. In fact, of late, the corporate hospitals have approached NIPER to hire clinical pharmacists. At the time of writing this note, one of the pharmacy practice graduates had joined as clinical pharmacist in a corporate hospital in New Delhi. It is not only the hospital administrators but also the CROs who have identified the skills of the graduates of pharmacy practice of NIPER and several of them have been hired by CROs as well.

Finally, the Institute which was established to provide leadership and foster the discipline of pharmaceutical sciences - in its short 10 year life- has been effectively pursuing its purpose of establishment.
PHARMACY EDUCATION IN INDIA

A History

In India, Pharmacy Institutions came into existence first, even before the Constitution of Regulatory Authorities. The origin of pharmacy institutions in India dates back to 1899 when the first institution for training the pharmacists was started in Madras. It was followed by State Medical Faculty of Bengal in 1928, Banaras Hindu University in 1932, Andhra University, Waltair in 1937, Madras University in 1938, Bombay University in 1943, Punjab University in 1944 and L.M. College at Ahmedabad in 1947.

B Statutory Regulation of Pharmacy institutions

- On 23.12.87, All India Council for Technical Education Act, 1987 was enacted and 'Pharmacy' was included under the definition of "Technical Education" u/s 2(g) of the said Act.

Presently, pharmacy institutions in India are regulated by two statutory bodies, namely, PCI and AICTE working under two different Ministries. This has resulted in dichotomy in regulation of pharmacy education in the country.

| Levels of Pharmacy Education Imparted by Pharmacy Institutions in India |
|-----------------------------|-------------------|-----------------------------|
| Level | Duration of Course | Admission Qualification |
| D.Pharm | 2 years and 3 months practical training | 10+2 (science academic stream) |
| B.Pharm | 4 years course | 10+2 (science academic stream) or Pass in D.Pharm direct admission to IInd year B.Pharm under lateral entry system |
| M.Pharm (Specialisation) | 2 years course | B.Pharm |
| Ph.D | Variable | M.Pharm |

Pharmacy Institutions in India

- Pharmacy institutions in India are either run by the State Govt. funded by the State Govt. (aided) or self-financing institutions.

- Most of the Pharmacy Institutions in India are co-educational. However, some institutions are exclusively for Giris also.
PHARMACY COUNCIL OF INDIA
NEW DELHI

(Constituted under the Pharmacy Act, 1948)
Combined Councils' Building, Temple Lane, Kotla Road
Aiwan-E-Ghalib Marg, Post Box No. 7020, New Delhi-110 002
Telegram: ‘Farmcouncil’ Telephone: 23239184, 23231348 Fax: 11-23239184
Email: pci@ndb.vsnl.net.in ● Website: www.pci.nic.in

STATUS
Statutory autonomous body working under Govt. Of India,
Ministry of Health & Family Welfare

ORIGIN
Pharmacy Act, 1948 passed by Indian Parliament

DATE OF ENACTMENT OF PHARMACY ACT
4th March, 1948

PREAMBLE
"An Act to regulate the Profession of Pharmacy"

DATE OF CONSTITUTION OF PCI UNDER THE PHARMACY ACT
9th March, 1949

PRIMARY FUNCTIONS
Regulation of the Pharmacy Education in the country for the purpose of registration
as a pharmacist under the Pharmacy Act
Regulation of Profession and Practice of Pharmacy

President
Prof. B. Suresh

Vice President
Sri Sher Singh Thakur

Registrar-cum-Secretary
Smt. Archna Mudgal
No. of Pharmacy Institutions in India*

Pharmacy Institutions (624)

Diploma Institutions (383)
- Co-educational (360)
  - Intake capacity (22013)
- For Women only (23)
  - Intake capacity (915)

Degree Institutions (241)
- Co-educational (236)
  - Intake capacity (13140)
- For Women only (5)
  - Intake capacity (260)

*As on June, 2005

Statewise concentration of Pharmacy Institutions in India*

Approved Diploma Pharmacy Institutions

<table>
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<tr>
<th>States</th>
<th>Institutions</th>
<th>Intake</th>
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<td>Tripura</td>
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<tr>
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<tr>
<td>Jammu &amp; Kashmir</td>
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<td><strong>Total</strong></td>
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<td><strong>22,928</strong></td>
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*As on June, 2005

Approved Degree Pharmacy Institutions

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<tr>
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<td>Haryana</td>
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<td>Orissa</td>
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<td>Pondicherry</td>
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<td>Punjab</td>
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<td>Tamil Nadu</td>
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<td>Uttar Pradesh</td>
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<tr>
<td>Uttarakhand</td>
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<td>180</td>
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<tr>
<td>West Bengal</td>
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<tr>
<td><strong>Total</strong></td>
<td><strong>241</strong></td>
<td><strong>13,400</strong></td>
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*As on June, 2005
**Growth of Pharmacy Institutions in India**

From a handful of pharmacy institutions in India about 50 years back, there has been a manifold increase in the number of diploma & degree pharmacy institutions all over the country.

**Diploma Pharmacy Institutions**

- **1950 to 1980**: Steady increase from 2 to 72 institutions.
- **1980 to 1985**: 154.16% increase
- **1985 to 1990**: 25.13% increase
- **1990 to 1995**: 26.63% increase
- **1995 to 2000**: 18.27% increase
- **2000 to 2005**: 11.66% increase

**Degree Pharmacy Institutions**

- **1945-1950 to 1990-1995**: Steady increase from 3 institutions to 62 institutions.
- **1990-1995 to 1995-2000**: 130.64% increase
- **1995-2000 to 2000-2005**: 68.53% increase

*As on June, 2005.*
Problems faced by Pharmacy Institutions in India

- Dual Regulation by PCI and AICTE is resulting in
- Dual standards of norms and monitoring mechanisms on institutions.
- Litigations due to variation in decisions.
- Wastage of manpower, time and financial and human resources as both the statutory Councils are performing similar function of promoting pharmacy education.
- Multiplicity of Regulation at State level causes hardship in implementation process by the State Governments and Examining Authorities.
- AICTE has caused without any need or manpower requirement assessment, sudden increase in the number of pharmacy Institutions in States like Maharashtra, Andhra Pradesh, Karnataka, Orissa and Punjab leading to
  - Dilution of educational standards due to
    - Shortage of qualified and experienced teaching staff as per statutory requirements.
    - Insufficient training centers for imparting practical training to students as a part of pharmacy curriculum.
    - Compromise on infrastructural requirements
  - Economic viability of running institutions at stake.
- Unemployment problems may arise due to disturbance in demand and supply balance.

Need

- Scientific and technological advancement in pharmaceutical sector has resulted in rapid growth of Health Care System and Pharmaceutical Industry which has-
  - Led to increase in demand for clinically as well as technologically trained pharmacy professionals with aptitude for research.
  - Challenged the pharmacy profession to become a part of the Public Health Infrastructure and provide required health care delivery.

- Shifted the focus of practicing pharmacist towards counselling of the patients and prescriber (Doctors) about drugs.
- The new Indian Patent Act is applicable from 2005 as a result of which there will be a stiff competition.
- In moving from current scenario towards WTO environment, several changes will have to be made at various fronts like-
  - regulation of pharmacy institutions at all levels be entrusted fully to Pharmacy Council of India.
  - redesign the pharmacy education to produce competent pharmacists who are well equipped to face the challenges of evolving global Health Care scenario.
  - stress on Continuing Education Programmes in line with global standards to introduce basic competency in pharmacists to ensure better Health Care.
- to ensure good pharmacy practices by making provisions for-
  - practice of profession at all levels by qualified registered pharmacists.
  - quality assurance of both practicing pharmacists and practice.
  - stringent penal provisions for defaulters violating the Pharmacy Act thereby making pharmacist accountable to society.
  - pharmacists to charge professional fees.
  - curbing the commercialization of pharmacy education.
  - standards of professional conduct & etiquette and a Code of Ethics for pharmacists.

- to introduce provision for Mutual Recognition Agreement (MRA) with other countries to ensure that the manpower entering the country is sufficiently qualified to practice the pharmacy profession in India and ensure that pharmacists do not have to undergo additional equivalence examination for practicing in country which is signatory to MRA.
CONTINUING EDUCATION IN PHARMACY: AN OVERVIEW

Pharmacy and Pharmaceutical Sciences & Technology are considered knowledge based frontiers. A medicine which is deemed as life saving today, may be banned tomorrow due to emergence of serious adverse effects/toxic effects or it may be outdated due to introduction of a better alternative. Pharmaceutical technology which is considered current today, gets outdated tomorrow due to development of newer, more sophisticated high-end, effective technology. Even frequent changes in regulations lead to altering of many dimensions in the field of Pharmacy. To cope with this situation, a pharmacist requires continuous updating of knowledge, and knowledge management.

Pharmacist teachers

Pharmacists involved in teaching have several opportunities for continuous education provided by the University Grants Commission (UGC), All India Council for Technical Education (AICTE) etc. They are also required to go through certain categories of training for promotion. AICTE has established centres for improving the quality of in-service teachers, for upgrading qualification as well as Continuing Education programme. It has also some other programmes like Travel Grant, Seminar Grant, Career Award for Young Teachers, Emeritus Professorship, Visiting Professorship, Early Induction Programme, Staff Development programme etc. for encouraging teachers. AICTE also has a programme through which they provide financial grant to Professional Societies/Bodies etc. for updating their members. There are some opportunities offered by Dept. of Biotechnology (DBT), Indian Council for Medical Research (ICMR), Council for Scientific & Industrial Research (CSIR), IPA- Shri Ramanbhai Patel Education, travel grants etc.

Pharmacists in regulatory

Central Drugs Standards Control Organization (CDSCO) organizes training for Drugs Control Officers in collaboration with the WHO. Recently the training is being conducted by National Institute of Pharmaceutical Education & Research (NIPER). The Homeopathic Pharmacopoeia Laboratory organizes training on different aspects of homeopathic medicines like, quality control, manufacturing, and GMP etc. Central Research Institute (CRI) conducts training for Drugs Control Officers and personnel engaged in Drug Testing Laboratory. CDSCO recently launched National Pharmacovigilance programme involving different health professionals including pharmacists to generate data on ADR and to educate all concerned about its significance.

Industrial Pharmacists

Generally the industries have their own training modules and concerted programmes for updating their employees, but sometimes, institutions like, CDSCO, NIPER, CRI arrange some training for industrial pharmacists. Different professional organizations like the Indian Pharmaceutical Association (IPA) and industrial organizations like IDMA, OPPI etc., organize several seminars, workshops on different emerging topics to educate the large number of industrial pharmacists.

Hospital & Community Pharmacists

There are rapid changes in this field with quick obsolescence of medicines. The expectations of patients are also in tune with global changes. Pharmaceutical education in India was
for a long time industry-oriented but recently changes have been initiated to make it more patient oriented. Several Universities have already started postgraduate courses on Clinical Pharmacy, Pharmacy Practice etc., but the pharmacists need continuing education in the new fields like Pharmacoconomics, Pharmacovigilance, Clinical Pharmacy, Rational Pharmaceutical Management, Rational Use of Medicines etc. Though such training courses are being arranged by some professional associations, NGOs, and Universities, no formal mechanisms exist for updating the practicing pharmacists. Recently Pharmacy Council of India (PCI) has floated a proposal that a registered pharmacist is required to go through some training for renewal of registration. This may be the first mandatory training in this field.

PCI has conducted refresher courses for pharmacists in the year of 1998 throughout the country, but it covered a meager percentage of working pharmacists. PCI needs to continue such training courses, or else they can approve courses offered by other agencies and allot credit points per course on the basis of standard, course content and duration.

A project on “Good Pharmacy Practice” sponsored by DCGI-WHO India office is being implemented by Indian Pharmaceutical Association (IPA) throughout the country.

Another project on “Rational Drug Management” sponsored by WHO is also under process by IPA. A project on training for Community Pharmacists on HIV/AIDS has already been implemented in some states like Maharashtra, Karnataka etc. by SEARPharm Forum in collaboration of IPA. Recently West Bengal Govt. has formed a Task Force involving representatives from Govt. and organizations like SEARPharm Forum, IPA, West Bengal Pharmacy Council (WBPC) etc. for imparting training on guiding principles for pharmacists in HIV/AIDS. A few state Govts. have organized training for pharmacists working in Govt. Hospitals and Health Centres. One such initiative was taken jointly by Govt. of West Bengal and West Bengal Pharmacy Council during last two years, where a six-day training module on “Rational Drug Management” was implemented and about 240 pharmacists from 152 Hospitals and Health Centres undergone this training. In order to cater the societal need the course curriculum needs to be redesigned. IPA has framed a course for B.Pharm. “Pharmacy Practice” involving the emergent areas like, Patient Counseling, Drug information, Rational Use of Drugs etc. and pursuing the concerned authorities like Pharmacy Council of India (PCI), All India Council for Technical Education (AICTE) etc. for implementation of the newly framed course curriculum.
Industrial pharmacists

Industrial pharmacy in India has made phenomenal progress in academia, industry, regulatory affairs, marketing, R&D, distribution, and exports of drugs and pharmaceuticals over a period of last six decades. Visionary approach of some of the professionally dedicated pharmacists, who were associated with academia, industry, regulatory agencies, research and development, made significant impact in perceiving and creating the present status of industrial pharmacy a profession of choice for industrial pharmacist in India with global recognition.

From teaching and practice of industrial pharmacy covering galenicals - essentially dealing with liquid extracts, tinctures, spirits, powders etc. As per the pharmacopoeial monographs, specialization has made significant progress in last six decades to cater requirements of all types of dosage forms including new drug delivery systems besides pharma-biotech derived active materials and their dosage forms (Bio Generics).

Extemporaneous preparations - classical dispensing practice has been significantly replaced by safe, stable, efficacious and elegant drug delivery systems for patient care.

Industrial pharmacy made a remarkable contribution in achieving a turn over of the industry of about USD 7 billion for drugs and pharmaceuticals and pharma-biotech (bio generics) turn over of about USD 1 billion.

Curricula and teaching methodology have been oriented to specialization in industrial pharmacy (pharmaceutics) at post-graduate level is offered by number of pharmaceutical educational institutions in India.

There are more than 50 Indian pharmaceutical manufacturing units in the country, approved by US - FDA, UK - MHRA, EU - EDQM, Canada - HPB, Australia - TGA, South Africa - MCC, exporting active materials and formulations to developed countries.

Collaborative research activities of academia, industry, government research laboratories have improved the outcome of multi-disciplinary research.

Course content of the specialization is periodically updated to include current requirements of cGMP, GLP, GAP, GEP, GDP and GCP (rapidly developing area) in progressive institutions to meet international standards.

In view of available trained qualified manpower, facilities and expertise, India has become preferred destination, with linked economic operations, for contracted services in the following areas:

- Manufacturing of active materials and dosage forms
- Research and Development - NDDS
  - New Drug Development
  - Formulation Development
  - Custom synthesis
  - Specialty chemicals
- Clinical studies besides Bio-availability and Bio-equivalance
- Product and process development
• Consultancy services
• Knowledge sharing and
• Human Resource

Academia is gearing up to meet challenging opportunities in the field of pharmaceutical-biotechnology (active materials bio generics and formulations).

Thrust is on pharmaceutical engineering and regulatory compliant systems to meet international regulatory requirements. Role of professional bodies like Indian Pharmaceutical Association (IPA) and International Society of Pharmaceutical Engineering (ISPE-INDIA) and others has been loudable in achieving professional excellence.

Community Pharmacists

Community Pharmacy in India is slowly awakening. With steady efforts of the Indian Pharmaceutical Association, and the constant infusion of ideas and encouragement of many senior professionals over the past few years, the concept of professional pharmacy practice is slowly being realized by many pharmacists. The need seen by the Pharmacy Council of India to strengthen and upgrade curricula of pharmacy schools, and to make continuing education compulsory will further add to the awakening.

From small family owned pharmacy shops scantily scattered in the cities many decades ago, a transformation has taken place, with rapid proliferation of pharmacies in every nook and corner. Today, close to half a million pharmacies/medical stores/chemists and druggists all over the country, make medicines available to the public. Unfortunately, the proliferation is skewed, with the major concentrations in the urban areas, and the rural pockets continue to be sparsely represented.

In India, ownership of a pharmacy is not the exclusive domain of the pharmacist alone, as is in many European countries. Such shortcomings in the laws have permitted just simply anybody (regardless of qualification and background in pharmacy) to open up pharmacies, and either look after them themselves, or hand them over to someone (not necessarily pharmacists) to be managed! Pharmacy, in India is more often seen as a mere business, than a profession and a mission.

We do have many owners of pharmacies, who are pharmacists themselves, and dedicate themselves to serving the profession and the public in the proper use of medicines. Unfortunately, they often feel let down because they do not have backing of the law making and enforcement agencies:

• Too many pharmacies allowed to open in close proximity to one another results in these pharmacists losing out business to aggressive "medicine sellers".
• Other pharmacies selling prescription medicines without a prescription (and going unpunished), often makes them more popular amongst the public, than the pharmacist who remains strict and insists on a doctor's prescription.
• Other pharmacies operating without the presence of a pharmacist often go unpunished.

Due to such aberrations of reality, some pharmacists often end up being tempted to do illegal/wrong things like the others to cope up with competition. Or, they remain frustrated, often helpless, and on the losing side. It is often said that a pharmacy strictly insisting on a prescription for every prescription medicine, may in all probability today, end up having to close down shop sooner or later!

Sadly, most of our pharmacists have remained mere 'dispensers', a task which could be well accomplished by technicians. Some pharmacists do attempt to educate clients on their medicines, but the numbers are small.

The concept and art of compounding prescriptions has almost been wiped out over the past 3 decades, with no more than 1% prescriptions likely to be compounded today. This has made the domain of pharmacy open to almost anybody, and the pharmacist has lost his importance in the public eye, as public often see 'dispensing' as an ordinary job akin to selling! There is an urgent need to constantly highlight the presence and crucial role of the pharmacist in the health care system.

The pharmacist is most often the first health care professional whom clients seek for their health needs. The pharmacist is also the last link with the patient when he dispenses the medicines. These are two sound reasons why the pharmacists' potential needs to be tapped in the interest of health of the people. The community pharmacist can prove to be a key component in the health care team, and lot of planning and effort needs to be put together to make this a reality.

Pharmacists need to be guided, educated and trained on a continuous basis into performing a more professional role at the community pharmacy, and thus go beyond just “selling” medicines for the labelled price!

Pharmacists spend long hours of the day in the pharmacy, often having to make sacrifices in family life, making medicines available to clients. Open at odd hours of the day.
and at times at night, often regardless of holidays, to make maximum business, faced with the tough competition of clusters of pharmacies in the neighbourhood, the pharmacist goes on and on stuck to his routine, with little time for anything else.

A pharmacy today has to accept the reality of the more than 60,000 formulations/brands marketed in the country, and face the big dilemma, as to which brands to stock, with terrible space constraints, and economic difficulties. It would be of great help if he had lesser brands or even generics to remember, allowing him to use his memory and time in grasping details of limited number of drugs.

It is very much essential to empower today's pharmacists by training them in the proper use of the array of OTC medicines, and also providing an additional category of 'Pharmacist Only Medicines' which only Pharmacists can use with their discretion.

Upgrading the Curriculum, ensuring good quality Education and providing effective Training in practicing community pharmacy needs urgent attention, and then implementation. The present system (Diploma or Degree education) is not adequate to equip the pharmacist to efficiently practice pharmacy in the community. A strong training component, followed by a pre-registration examination will ensure that pharmacists are specifically equipped to safeguard the well being of the public.

The IPA has adopted Good Pharmacy Practice Guidelines, and followed it up with a Training Manual for Community Pharmacists, with support from the WHO-India Country Office and the Drugs Controller General of India. The training of pharmacists has just begun, but to reach out to around 450,000 pharmacists in the country, the task is gigantic, and will take a long time.

Whilst the training of every practicing pharmacist may not be a feasible task, steps have to be urgently taken to at least initiate the process. To summarise, the few areas which are very important for community pharmacy in the country to be effectively practised are:

I - Curriculum - Education - Training

II - Creating conducive environment to practice pharmacy -
- Law making Pharmacy for pharmacists, sufficient breathing space around existing pharmacies, disband doctor's dispensing.
- Implementation of law that pharmacist to be present all the time during open hours of the pharmacy, sale of medicines strictly against a prescription.
- Public education Advocating Role and Importance of a Pharmacist, and need to strictly use and buy medicines against a valid prescription of a 'qualified' doctor.

Hospital pharmacists

Hospital pharmacy is a fascinating area as it allows practice of pharmacy in a hospital setup. The practice of pharmacy includes, hospital pharmacy, clinical pharmacy and community pharmacy. The minimum educational qualifications, as laid down in the Pharmacy Act (1948), for the hospital pharmacists is Diploma in pharmacy of two years duration after schooling of 10+2. The hospital pharmacists have to get themselves registered with the State Pharmacy Councils. The minimum qualification is likely to be soon upgraded to degree in pharmacy, which is four years course after 10+2. At present the number of registered pharmacists with the Pharmacy Council of India is 559,000 in India. India has an intake capacity of 22,928 students at 383 diploma institutions and 13,400 students at 241 degree institutions.

These statistics are as on June 2005.

It may be interesting to note that courses to get master degree in hospital pharmacy and in pharmacy practice, are available in about 12 institutions which are attached to hospitals. They have been successful in setting up department of pharmacy practice in hospitals which undertake the activities like, drug information, counselling, clinical pharmacy, pharmacists interaction with the inpatient along with doctor's visit in addition to other normal activities of hospital pharmacy.

In all, the government and other hospitals, diploma holders are actively involved with purchase, storage and distribution of drugs. The drugs are purchased from government medical depots to ensure the quality of drugs for distribution in and out patients free of cost. The drugs not available from medical store depots are purchased from the market by inviting quotations by the hospital authorities. The drugs not supplied by the hospitals are purchased from the chemist shops around the vicinity of the hospital. Some of the hospitals have got private chemist shop in their premises which sell the drugs round the clock. The compounding activity has been limited since most of the drugs are manufactured by the pharmaceutical industries and are readily available in the market. The pharmacists are mostly busy in distributing medicines to a large number of out-patients. The patient counselling is limited only to inform the dose and mode of administration of the drugs. The proper
labelling and counselling is not possible due to very poor ratio of pharmacists as related to patients. Some of the major hospitals have hospital formularies of their own while some of the formularies are available at state level. These publications are helpful to the physicians to prescribe drugs more rationally and to the pharmacists for his giving information to the patients about the drugs. The National Formulary of India exists, but it is not being revised periodically as per the pattern of the British National Formulary. The use of National Formulary of India is therefore, limited.

The drugs supplied by the hospital or dispensary maintained or supported by government or local body or exempted from the provisions of Chapter IV of the Drugs and Cosmetics Act and the Rule thereunder which require them to be covered by a sale license, subject to the following conditions:

i. The dispensing and supply of drugs shall be carried out by or under the supervision of a registered pharmacist;

ii. The premises where drugs are supplied or stocked shall be open to inspection by an inspector appointed under the Drugs and Cosmetics Act who can, if necessary, take samples for test;

iii. The drugs shall be stored under proper storage conditions.

There is a need for more legislative control on hospital pharmacy, in terms of staff, equipment and space requirements and also by incorporating good pharmacy practices so as to ensure efficient pharmaceutical services. The Central Government and State Government servants are covered under central General Health Scheme and employees State Insurance Schemes. Under these schemes the employees get free medical services on nominal contribution every month. They have got their own separate hospitals and dispensaries for providing medical care to the beneficiaries. The masses have, however, not adopted health insurance schemes. However, lately the said schemes are being patronized by the sections of society who are above poverty line and can afford the premium for the same. The pharmaceutical services shall improve once the health insurance schemes become popular and are adopted by most of the people.

It may be worthwhile to note that there exists professional association for hospital pharmacists at National level, namely, the Indian Hospital Pharmacists Association which has been publishing bi-monthly publication entitled "The Indian Journal of Hospital Pharmacy" to keep the knowledge of the practicing hospital pharmacists up to date.

The hospital pharmacy is a very important area of pharmaceutical services since 90% of the patients, visiting hospitals, do avail the pharmacy services in one way or the other. In addition as much as 30% of the hospital budget is spent on drugs. There is a bright future of hospital pharmacy in India in time to come with minimum educational qualification to degree in pharmacy. The total number of hospitals in India is 5479 with bed strength of 380,993 as on 01.01.2004 which are being catered by the registered pharmacists.

Present status (education and employment)

Up to nineties, only diploma holders use to go for hospitals as there was no choice except dispensing in a hospital counter or to open a chemist shop, at the most as medical sales representative in small companies. Now B.Pharm is the minimum qualification of practicing pharmacy in India (yet to implement) and many graduates are opting for hospital pharmacy, pharmacy practice, clinical pharmacy etc. as their specialization of choice in post graduate courses and joining private/cooperative/government hospitals as a professional. In eighties, only college of pharmacy Delhi was promoting post graduate course in hospital and clinical pharmacy, now at least 8-10 in institutions are offering the same and many more students are opting a career in hospital pharmacy by "Choice of specialization Not by Chance". Hospital and Clinical Pharmacy in India is now a specialization subject in all levels of studies. So the corporates and specialization player in the field like Aditya group, Max group, Action Balaji, Fortis, etc. are employing only those persons. Previously only mission hospitals were proudly employing those specialist of hospitals and clinical pharmacy. A vast area of working are, non sterile and sterile manufacturing, patient counseling, ADR monitoring, providing teaching and training to diploma, degree and post graduate students and other paramedicals, In drug information/poison information centres as Convenor, participating in analysis and clinical trials in big hospital. Helping total computerization of the pharmacy department and some even doing I.V. admixing, eye drops and other sterile solutions manufacturing (e.g. dialysis etc.). Even the pharmacists are prescribing medicines in absence of any doctor at the district health centre or CHS's and it is with official permission of DGHS of Himachal Pradesh. Of course, the basic job of hospital pharmacist remain the same and common to all, that is procurement, purchase, storage, sale, distribution, pricing, dispensing and compounding. The better and advanced knowledge of the pharmacist is now necessary and legal obligation for both public and private hospitals. Now the licensing of all hospital pharmacy is compulsory (for all private nursing home or hospitals) under the act, previously license as well as bulk compounding was exempted for this institution. So this is a positive change in qualitative and quantitative upgrading of the profession in general. Further all surgical disposals including sutures legatures, vulve, health accessories equipments, CSSD and blood bank is under the preview of the pharmacist by law and are slowly taking up by those specialized professionals. So the scenario of the hospital pharmacy is changing very fast and it is the need of the hour.

Very big hospitals like St. Stephen's, CMC Vellore, CMC Ludhiana, JSS Hospital at Mysore, JJ Hospital at Mumbai, Madras Medical College & Hospital, Trivandum Government Hospital & Medical College or any other hospitals connected or associated with their medical colleges are having above branches of hospital pharmacy with more or less same infrastructure. Many more changes, development, upgradation and modernization is unavoidable, as many more knowledgeable and highly educated professionals are joining in this sector. There is greater scope of consultant pharmacist in India.
Clinical pharmacists

Clinical Pharmacists in India are concerned with the promotion of effective, safe and economical drug therapy. Clinical Pharmacy has its origin in hospital pharmacy but in some countries clinical activities, which in the beginning were restricted to hospitals, are now well-developed in the community setting.

Drug use is a complex process and there are many drug related problems at various levels involving prescribers, patients, pharmacists, the pharma industry and the government. Clinical Pharmacists whose number is increasing annually, are addressing all drug related issues.

Hospital pharmacists manage drug inventory, drug dispensing at OPD dispensaries and record keeping. With appropriate education and training graduate pharmacists can help to improve medication use, by providing services such as drug therapy monitoring, patient counselling, drug information services, ward round participation and adverse drug reaction (ADR) reporting and monitoring.

Patient counselling, unbiased drug information services, ADR reporting and monitoring, Drugs therapy monitoring, case note reviews and joint ward rounds with health care professional have improved patient medication adherence, brought in rational prescribing and minimized ADR's. Patient focused clinical pharmacy teaching have provided students with opportunities to provide pharmaceutical care services.

Excellent relationship with the medical profession is needed to ensure the progress of clinical pharmacy.

Clinical pharmacy is a rewarding career path with opportunities to contribute to improved medication use through employment in hospitals, teaching, drug information, pharmacovigilance, clinical research and medical information.

Pharmacists in drug distribution system

India’s economic march in recent times has received worldwide acclaim. Besides IT, the pharmaceutical industry is the most buoyant sector. The glamour functions in the drug industry are Research & Development, Quality Assurance, Exports, Marketing & Finance and to some extent Production. Among the glitter, the toil & turmoil and sweat & blood of distribution goes largely unheralded because it is not a visible function. The “seminarians” and the media focus their attention largely on the technical, legal and commercial issues and the consuming public is interested in the flaws and the gaffes of the drug makers, besides the cure of course.

Admittedly, it is important to discover drugs, formulate them, create awareness through marketing efforts and use them on the aililing and the needy. It is perhaps as important, if not more, to make these drugs available in every nook and corner of the country. This successful march of the drugs is a tribute to the tireless and silent functioning of the Indian Drug Distribution System (IDDS). To make a comparison, it is like the circulatory system, the failure of which would cripple the entire body of the drug industry.

Not surprisingly, the function of distribution is saddled with multifarious problems. Detailing these problems would provide enough fodder for the wailing seminarians who would smack their lips gleefully if the Pandora’s box is opened for them. The following listing should provide pointers to the serious minded well-wishers of the Indian pharmaceutical industry.

Regulatory issues
- Laws and amendments do not keep pace with the rate of development.
- Licensing of warehouses and distribution vehicles is largely based on the legality of ownership than any pharmaceutical value-concept.
- Doctors and hospitals are exempt from drug laws pertaining to storage and distribution of drugs.
- Qualification of personnel is not a priority for regulators when dealing with distributors.
Manufacturing Interface
- The number of manufacturers keeps increasing by the day. It is estimated that there are about 10,000 licensed manufacturers in the country.
- The number of products, both branded and generic, keeps bludgeoning. The current estimate pegs at about 60,000 formulations with new products waiting to flood the already teeming market.
- Mergers and acquisitions add to the burden on the distributors. Ownership, cut-off points, documentation, commercial settlements become additional issues to keep track of.
- “Intelligent” manufacturing practices (IMP) like subsidiary manufacturing, loan-licensing, contract manufacturing, third-party manufacturing, leasing, “manufactured by-marketed by” type of arrangements with multiple licenses makes it difficult for distributors to keep track of the supply chain. While these arrangements may help exploit the loopholes in commercial laws like Central Excise, Income Tax and Sales Tax, it does make brand ownership hazy.
- Year-end dumping by marketing managers to show enhanced sales is another headache as it involves documentation, storage, handling and associated evils.

Storage and handling
- New Drug Delivery Systems (NDDS) and innovative packaging call for innovative storage and handling.
- Hiring versus owning warehouses is an economic decision where pharmaceutical considerations come second.
- Short-expiry, outdated, non-moving products add to a distributor’s woes.
- The responsibility of a distributor can also increase with the market economy situation in parts of the country. This is especially true when heat-sensitive products are handled. Moreover, in a large country like India with tremendous climatic diversity, the chances of product spoilage in the possession of a distributor, either during storage or in transit, are significant.

Transportation
- This transport industry is not yet managed professionally. The “personalized” management, ill of pilferage and highway looting has forced some companies to factor these as “normal losses” in their “standard yield” reports.
- The transporting vehicle, though licensed by the authorities, is not subject to qualification under any set of pharmaceutical guiding principles.
- The loading/unloading of the vehicle is at the mercy of the owner and/or labourer.
- Most loading patterns are governed by schedules, product mixes and other commercial aspects like excise-duty. There are no pharmaceutical guidelines which the transporter has to follow as a matter of check-list.
- Cost of transportation is directly related to the cost of fuel and spares. Prices of both are sky-rocketing.

Personnel
- Personnel working in a distribution setup are largely categorized as:
  - Office staff: computer and finance proficient
  - Sales staff: sales oriented
  - Delivery staff: drivers, helpers and bookies
  - Labour loaders/unloaders

A pharmacist is not on the priority list of employment with a distributor. This is largely because the law does not enforce it.
- Qualified staff is easier to obtain in urban than in rural areas. But cost of employment is significantly higher in the urban area.

Investments
- Capital investments can be astronomical in metros.
- Growing population, growing number of retail outlets means growing need for transportation and storage. Hence growing investment.
- Since market forces rule, fierce competition forces higher investment because of credit policies, stock dumping (more space), obsolescence, returns, insurance and taxation.
- Considerations have become part and parcel of trade and commerce. The government-trade interface is fringed with considerations and most Chartered Accountants call it consultation fees. It is part of the ‘working’ capital of an organization.

Trade associations
- While unions take care of the interest of their members, uninhibited power can corrupt some union officials and this can lead to unhealthy practices like blocking markets, favouring companies, arm-twisting for better margins and striking.
- By and large trade associations have been responsible and co-operative.

The narrative above can be called ‘flirting’ with the issue. A serious ‘involvement’ would consume larger resources and for that the ‘commitment’ of the concerned parties is paramount. We are quite far from ‘tying the knot’ as far as drug industry in India is concerned. So we shall stay content with tickling the problems knotting the drug distribution system of India.
Indian Pharmaceutical Industry: Overview of growth and innovation

Currently, Indian Pharmaceutical Industry ranks 4th in volume and 13th in value (mainly owing to very low prices) in the total world pharmaceutical market. The industry is highly fragmented with about 9,000 plus registered manufacturing units out of which about 300 constitute the organized sector.

Emergence of pharmaceutical sector in India
Earlier to 1970, pharmaceutical industry in India was underdeveloped. Later with the implementation of Drug Price Control Order (DPCO) 1970, and The Indian Patent Act (IPA) 1970, it started to grow constantly and rapidly. Regulations due to DPCO and IPA resulted in many Indian Pharmaceutical Companies producing active pharmaceutical ingredients (APIs) and finished formulations at a controlled but lower price compared to that of the innovator. Due to DPCO even multinational corporations have to cut down the prices of drugs and pharmaceuticals, if they wish to market in India. Thus process patents and market exclusivity for a duration of 7 years became the growth drivers for Indian Industry, which currently manages to meet more than 95% of country’s pharmaceutical requirements.

For many years the industry concentrated on process patents and reverse engineering and made APIs and formulations. Since India has the abundance of manpower resources with sound technical skills, the industry could generate pharmaceutical products at costs that are many fold lower than those in developed countries like US, Japan, or UK.

Many drug formulations (over 100,000 which include mostly vitamins, antibiotics, antibacterials and cardiovascular drugs) and APIs (over 400) are produced in India. Amongst the formulations, about 80% of the manufacturers contribute for sales less than Rs. 100 Cr. The organized sector contributes for the rest of the sales of which top 20 players control about 78% of the market share.

The Indian pharmaceutical market grew from Rs. 400 crores (US $ 300 million) in 1970 to Rs. 29 000 crores (US $ 6 billion) in 2003 at a CAGR of 13.5 per cent. Presently the market size is estimated to be Rs. 37 000 crores (US $ 8 billion) in March, 2005 (Cygnus Research). According to Akinsey, a management consulting firm, Indian Pharmaceuticals market would grow to US $ 25 billion by 2010.
Global Presence of Indian Pharmaceutical Industry

Indian industries have mastered the art of abbreviated new drug applications (ANDAs) submissions. Indian Pharmaceutical giants like Cipla, Dr. Reddy's, Ranbaxy and Sun Pharmaceuticals are constantly eyeing to increase their global market share by entering into generic market. With about US $ 40 billion worth of drugs going off patent over the next four to five years, the opportunity for Indian companies to get a larger share of the global market is bound to increase further.

Exports of pharmaceuticals consist of APIs, drug-intermediates and finished formulations. India's pharmaceutical exports were worth about US $ 2.5 billion in 2002 and could reach US $ 6 billion by 2010. The industry thus is a net foreign exchange earner for the country.

Since exports demand, Indian companies have adopted global standards in all sections. There are 61 US FDA approved plants in India, which is the largest outside the USA. Indian companies topped in DMF filing (119) and also filed 73 ANDAs in 2003, which is about 30 per cent of the total DMFs and 20 per cent of the total ANDAs filed with the US FDA.

Pharmaceutical Research and Development In India

Since India became a signatory to GATT and a WTO member since 1995, it has to ensure IPR and comply with TRIPS from 1st January, 2005. The period, 1995-2005 was the transition period during which the Indian companies should transform and comply with provisions under TRIPS. This means introducing product patents in India for pharmaceuticals for a uniform duration of 20 years.

To meet the global regulatory compliance post 2005, and to sustain the pharmaceutical business, Indian companies started investing more in R&D. Earlier to 1995, Indian companies invested about 3 per cent of their revenue in R&D. Currently, the major pharma players in India have increased their R&D investments up to 10 per cent. Though, Indian companies started to invest in drug discovery still the major share of R&D expenditure goes to generic formulations.

Indian Pharmaceutical Industry and Outsourcing

One of the main revenue earning avenues for Indian companies is contract manufacturing of APIs and API-intermediates. Many companies have adopted the contract research and manufacturing services (CRAMS) model as a growth driver. Currently, many multinational corporations are establishing divisions in India for pharmaceutical manufacturing and outsourcing, marketing, conducting clinical trials and research and development in order to speed up the drug development process and make it cost efficient. Many contract research organizations (CROs) have set up shops in India in the last few years.
PHARMACISTS AND THE LAW

Pharmaceutical advertisement

In India, an act was enacted in 1954 to control advertisements of drugs in certain cases, namely, the Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954. The preamble of the act states,

"An act to control the advertisements of drugs in certain cases, to prohibit the advertisement for certain purposes of remedies alleged to possess magic qualities and to provide for matters connected therewith."

The object of this act is to prohibit advertisement for prevention, mitigation or cure for certain diseases or disorders by drugs and magic remedies like "Tantra", "Mantra" etc. Disease and disorders for which prevention, mitigation or cure cannot be advertised are prescribed under section 3 and the schedule to the Act and the rules framed under it.

The definition of an advertisement under the act includes any notice, circular, label, wrapper or other document and any announcement made orally or by any means of producing or transmitting light, sound or smoke.

Section 4 of the Act has a wide scope. It states that no person shall take any part in the publication of any advertisement relating to a drug if the advertisement contains any matter which

a) directly or indirectly gives a false impression regarding the true character of the drug; or
b) makes a false claim for the drug; or
c) is otherwise false or misleading in any material particular.

In India, generally the non-prescription drugs are advertised for common ailments like pain, cough/cold, indigestion, skin infection etc. There is no specified agency in India to regulate advertisement of drugs. However, offences under the Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954 are investigated by the State regulatory authorities and offenders are proceeded against.

The Drugs and Magic Remedies (Objectionable Advertisement) Rules, 1955 prescribe manner in which advertisements may be sent confidentially to registered medical practitioner (RMP) or pharmacist. Rules provide that all documents containing advertisements relating to drugs should be sent by post to a registered medical practitioner or wholesaler or retail chemist. Such documents should be at top, printed in indelible ink in a conspicuous manner, the words "For the use only of Registered Medical Practitioner or a hospital or a laboratory".

A provision similar to section 3 of the Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954 appears under Rule 106 of the Drugs and Cosmetics Rules procure or may convey to the intending user any idea that it may procure or assist to procure miscarriage in women. It has also been provided that no drug may purport or claim to prevent or use or may convey to the intending user any idea that it may prevent or cure one or more diseases or ailments specified in schedule J to the Drugs and Cosmetics Rules, 1945.

From the foregoing account, it may be seen that there is prohibition of advertisement in respect of claim for prevention, mitigation and cure of specified diseases, disorders or ailments limiting the scope of regulation on advertisement. There is need for a legislation which should make it mandatory for the advertiser to give the following information.

- benefits of drug product
- precautions, if any
- normal duration of use
- adverse effects
The advertisement must be balanced by highlighting benefit/risk ratio.

**The Indian Patent Act**

The Changes were made to the Patents (Amendment) Act 2002 by the Patents (Amendment) Act 2005 (the Amended Act), which has since received the assent of the President of India primarily focuses on the pharmaceuticals and agrochemicals industry.

The Patents (Amendment) Act 2005 has been given a retrospective operation with effect from January 1, 2005.

**What constitutes an inventive step**

Inventive step has now been defined by the amending Act to mean a feature of an invention that involves technical innovations as compared to the existing knowledge or having economic significance or both and makes the invention not obvious to a person skilled in the art.

This definition is accepted internationally and in all probability the term economic significance will be interpreted as being synonymous to industrial application.

**What is a novel invention**

New invention or novelty for securing the grant of a patent has now been restricted in scope from being relative novelty to absolute novelty. Thus, for any invention to be considered novel, it should not have been anticipated by publication in any document anywhere in the world, or used anywhere in the world before the date of filing of the patent application.

The legislature has set two ways of assessing novelty. First being an absolute novelty test, and the second being the relative novelty test for determining anticipation of the patent grant, which can invalidate the grant of a patent at any one of the three stages: pre-grant opposition, post-grant opposition, and revocation proceedings. Further, under the pre-grant, post-grant or revocation proceedings, novelty by virtue of publication in any document is assessed from the priority date as opposed to the filing date of the complete specification.

**Pharmaceutical substance**

The Patent Act has for the first time defined pharmaceutical substance to mean a new entity involving one or more inventive steps. This appears to attempt to ensure that only new chemical entities are granted a patent.

**Measures to prevent Evergreening of Patents**

The legislature has also taken special measures to prevent evergreening of a patent, especially in the Indian pharmaceutical industry. The Ordinance prohibits the grant of a patent to an invention which is mere discovery of any new property or "mere" use of a known substance. The addition of the word "mere" before the term "new" might have entitled the grant of a patent for a "second medical use" or new physical forms, isomers, and polymers.

As such, this part of the Act was further revised by the Amended Act:

"Section 3: the following are not inventions within the meaning of this Act:

(d): the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.

Explanation to Section 3 (d): "Salts, ester, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations, and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy".

Note that the word "mere" was included by virtue of Patent Ordinance, effective from 1st January, 2005.

A closer reading of section (d) seems to suggest that what is not allowed is "a mere discovery of a new form of a known substance, which does not result in the enhancement of a known efficacy of that substance".

However, if the new form that is discovered is a form that "results in the enhancement of the known efficacy of that substance," then it might be considered for the grant of a patent.

The explanation provided to this Section does not rule out the grant of patent to derivatives, complexes, combinations, isomers and so on, if an industrial application in terms of its efficacy as a consequence of its properties can be shown.

It is, however, pertinent to note that "efficacy" is something that the Patent Office is not competent or may be not equipped to determine. It will be now up to the Applicants/Inventor and their Patent Attorney as to what all they would like to disclose in the Patent Application.

**What is a Provisional protection**

The 2004 Ordinance provided for provisional protection in respect of applications for patents on and from the date of publication of the application and until the date of grant of a patent.

This provision has been retained in the amended Act. However, this provision is subject to three conditions, namely:

a) A suit for infringement can be instituted only after the date of publication of grant of a patent:

b) In cases filed before January 1, 2005 in respect of mail box applications under section 5(2) for pharmaceuticals and agrochemicals, the rights of the patentee will accrue from the date of the patent grant as opposed to other cases, where the rights of a patentee will accrue from the date of publication of application under Section 11A; and

c) An additional provision which has been added in the amended Act states that if any company (for example, a generic drugs maker) has made significant investment and is producing and marketing a product prior to January 1, 2005 for which an application has been filed under Section 5(2), then the enterprise is permitted to continue such manufacture and marketing even after the patent grant. In such cases, the patentee will only be entitled to receive a reasonable royalty in return.
Therefore, patentees will have to live with generic Indian companies that were making pharmaceutical products before January 1, 2005, though the patent owner will receive a reasonable royalty. The problem here is what constitutes reasonable royalty which the Patents Act has not defined. The courts will have to see to this:

- The nature of the invention and its scope;
- The amount of expenditure incurred by the patentee in making and developing the invention and obtaining a patent and keeping it in force;
- Public interest considerations (specifically applicable in India);
- The prevailing margin of profit in the pharmaceutical industry;
- The risk posed to the patentee's business by the third party products.

Provisions of Compulsory Licence

There has been substantial changes in the provision relating to compulsory licences.

The "reasonable period" in which an applicant for a compulsory licence has made efforts to obtain license from the patentee has now been defined by the amended Act as being a period not ordinarily exceeding six months.

The Ordinance marked the first time that India implemented paragraph 6 of the Doha Agreement. According to Section 92A introduced by the Patents (Amendment) Act, 2005, a compulsory licence shall be available for manufacture and export of patented pharmaceutical products to any country especially least developed countries having in sufficient or no manufacturing capacity in the pharmaceutical sector for the concerned pharmaceutical product to address public health problems provided compulsory licence has been granted by such country has, by notification or otherwise, allowed importation of the patented pharmaceutical products from India.

The provision which deals with the terms and conditions for grant with compulsory licence has been further broadened by the amended Act to grant a permit to the licensee to export the patented product with a predominant purpose of supplying the Indian market. This provision was earlier of a limited nature, which permitted the licensee to export the patented product only in respect of patented pharmaceutical products.

Also under the amended Act, effective from 1 January, 2005 may be granted a license is permitted to export patented products to remedy an anticompetitive practice, as determined by a judicial or administrative process.

It was realized that most of the least developed countries might not have a patent system in place to allow obtaining a compulsory licence from another country for importing the patented pharmaceutical product. Therefore, the expression 'by notification or otherwise' was included by the amended Act to permit the import of the patented products by such a country. The amended act has also further defined "pharmaceutical products".

Parallel Imports

The 2002 Act also permitted the import of patented products by any person from a person who is duly authorized by the patentee to produce and sell or distribute to product.

The provision was further broadened by the Ordinance to permit the import of the patented product from a person who is duly authorized under the law to produce, sell or distribute the product. This provision remains unchanged by the amended Act.

Bolar provision

The Bolar provision (Section 107A) introduced by the Patents (Amendment) Act 2002 has also been revised by the Amended Act to include the act of importing in addition to using and selling for the purposes of obtaining regulatory approvals as not constituting infringement of a patent right.

Ever more stringent control in manufacturing - Schedule M

In the year 1988 for the first time requirements for Good Manufacturing Practices (GMPs) were notified by the Ministry of Health and Family Planning, Government of India, under Schedule M to the Indian Drugs & Cosmetics Rules (1945). In keeping with the trends of upgradation taken place in the Pharma Industry during past two decades, and accepting need to update the 1988 requirements essentially on the lines of GMP guidelines published by WHO and other international regulatory authorities, the Central Government published a Notification on December 11, 2001 to amend the Drugs & Cosmetics (8th Amendment) Rules 2001 whereby the Schedule M was substituted with 'revised' Schedule M with title reading: 'Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products'. It directs that to achieve the given objectives listed under the Schedule, each licensed manufacturer of pharmaceutical (medicinal) products shall evolve appropriate methodology, systems and procedures which shall be documented and maintained for inspection and reference. The 'revised' GMP requirements came into force on the day of the Gazette Notification. However, the rules were not applicable to the manufacturers holding Mfg. License prior to 11th December 2001 for period up to 31st December 2003. Subsequent notification extended the period up to 30th June 2005.

PART 1 of the Schedule gives General Requirements covering factory locations, its design and construction. Emphasis given is to avoid the risk of mix-ups between different categories of drugs or with raw materials, intermediates and in-process materials, and also to minimize risk of contamination and cross contamination by providing effective HVAC, Dust Control and AHU systems. Segregated areas for Warehousing, Production, Quality Control and Ancillary operations are recommended. Separated dedicated facilities are required to be provided for the production of highly sensitizing products like B-lactams, sex hormones, Cyto-toxic substances, biological preparations with live organisms.

Water system is well defined. Microbiological specifications are specified for Potable Water, Purified Water and Water for Injection. Their usage, storage and distribution system
within the operational areas are suggested.

The Schedule M spells out requirements for documentation at every stage of production and testing. Validation of processes and equipment, SOPs, training of personnel, self-inspection and audit procedures for assessment of all or part of the Quality Assurance System are some of the other areas covered under the Schedule. QA and QC systems are well defined. What should be included is Site Master File, Master Formula Records, Batch Processing Records, Batch Packaging Records, Analytical Records and Batch Distribution Records are now well stipulated. The manufacturer is required to have a SOP for effective recall of product(s)/product batch at level of each distribution channel. Its effectiveness has to be evaluated from time to time.

Specific Requirements for manufacture of various dosage forms, such as Sterile Products, Oral Solid Dosage forms, Oral Liquids, Topical Products, Metered Dose Inhalers are laid down. Also GMP requirements for Active Pharmaceutical Ingredients (APIs), are stipulated.

Air Borne Particulate Classifications for manufacture of Sterile Products (SVPs/LVPs/Ophthalmic preparations) are given. It demands AHU System fitted with appropriate filters/HEPA filters to provide Grades A, B, C and D classified areas for carrying out various types of operations.

For manufacture of Tablets and Capsules where processing of dry materials creates problems of dust control and cross-contamination, effective dust-extraction/dust control systems, as also AHU systems are required to be installed.

At least 5 micron filtered air is required to be supplied to the area where Oral Liquids are filled/sealed in primary packs. The area where topical products (Creams, Ointments, lotions etc.) are manufactured the air is required to be filtered thro’ at least 20 micron filter.

Products not prepared under aseptic conditions are required to be free from pathogens like Salmonella, E-coli, Pyocyanea.

PART II of the Schedule gives Requirements of Plant and Equipment. For various categories of dosage forms, a list of recommended equipment needed for manufacture of product preparations is provided. Minimum area for basic installation for manufacture of each of the product dosage form has been recommended.

Required up gradation of water system, installation of AHU systems provided with air-conditioning and humidity control units, to meet with the specified environmental conditions prescribed for various dosage forms as also for selected operational areas to avoid risk of contamination/cross-contamination, required major investment. To provide separate dedicated and self-contained facilities to manufacture sensitizing products required major changes in structural design of the existing units or creating an entirely new facility. After due consideration of the representation of the industry further extension of time for compliance of the Schedule M was granted and provisions of the revised Schedule M is now made applicable with effect from 1st July 2005.

The objective of the stringent requirements now made under the amended Schedule M is to ensure that the Indian Pharmaceutical Industry enhance its image and credibility and harmonize the GMP requirements with guidelines recommended by agencies like WHO and ICH. Non-compliance with the given requirements under the Schedule attracts cancellation or suspension of drug manufacturing license by the State Licensing Authority or the Central Licensing Approving Authority.

Ever more stringent control in clinical research - Schedule Y

The Clinical trials were initiated some where in 1537, but it came to lime light when James Lind in 1747, first introduced control groups in a study of scurvy. Later he went on to become the father of clinical trials. The clinical trials starting flourishing from 1800, the focus of studies use to be on study design. From 1863 onwards the scientists started using Placebos. The randomized studies were initiated in 1923 and from 1945, the focus moved to ethical aspect of clinical trial. Since then the clinical research underwent major changes with close monitoring of trials by the Regulatory bodies.

The global clinical research market has been steadily growing over the years and it is expected to be worth US$ 26 billion by 2007. India was quite slow in tapping this ever growing market. Just about US$ 100 Million was the share India could get in 2004. It is assumed that India is expected to reach a turnover of about US$300 by 2010. It is just an assumption of the market leaders of clinical research. Whatever said and done, the turnover we are expecting in clinical research is far below our capacity. India can do better and why not look for a better global share.

The move India has made by entering into the WTO Patent Regime by revising the Schedule Y of the Drugs and Cosmetics Rules, 1945 in 2005 is very positive and is in the direction of converting India as a global destination for clinical research. The major change India has brought in the Schedule Y is by introducing the requirements and guidelines for permission to conduct clinical trials.

The guidelines are on par with that of any developed country covering various requirements like prior approval for clinical trial, responsibilities of sponsor, investigator, ethics committee, informed consent, human pharmacology (PhaseI), Therapeutic Exploratory trials (Phase II), Therapeutic confirmatory trials (Phase III), Post Marketing Trials (Phase IV), studies in special populations like elderly, pediatrics and pregnant women. It also includes Post Marketing Surveillance, Bio-Availability, Bio-Equivalence studies. The guidelines cover GCP, GLP and GMP.

One good thing to be well appreciated is before the amendment was made, the Govt. of India has already started initiating the process of asking the companies to follow most
PHARMACISTS AND THE LAW

of the guidelines prescribed in Schedule Y now. The Indian Pharma Industry as well the global pharma giants have appreciated the move made by the Indian government since the future clinical trials made in India can be well accepted to be published in the leading medical journals.

This positive move has paved the way for many of the multinationals to start phase I to phase IV multi centered clinical trials of their research molecules in India. This will not only make India has a global destination for clinical trials but also generate employment at various levels. There is no doubt India has presence of huge knowledge base with abundance supply of intellectual man power. With the steady growth of clinical research organizations that are providing world class facilities and infrastructure, speedy trials, English speaking patients, India is bound to become a favorite destination of multinationals for clinical trials.

Another positive note to be considered is the easier availability of new drugs because of speedy trials. Bio-Equivalence Studies industry is already flourishing well in India catering to multinationals and the leading Indian multinationals. We would be witnessing lot of happenings in the pharma industry like setting up of CRO’s, R&D labs, takeovers, joint ventures, tie-ups, co-marketing, etc.

The Indian Council for Medical Research has been in the front providing all the assistance to the pharma industry in terms of clinical research and conducting regular workshops and training programs to the professionals involved in clinical trials. Many of the leading pharmaceutical organizations have started conducting international workshops for the Indian professionals by bringing in internationally reputed experts of clinical research. Clinical Research Educational Institutions have started coming up to train and provide the required manpower to the upcoming CRO’s.

There is lot of positive wind of clinical research moving throughout India. Today the question we will have to ask ourselves is whether we are on right track or still there is a long way to get into the right track. The Govt. has done its job of bringing in guidelines to follow to perform ethical clinical trials. But the Govt. does not have the required man power to monitor each and every clinical trial in India.
Clinical Research Organizations (CRO) in India are fairly in the playing fields of clinical research worldwide. However, with many inherent strengths and country specific advantages, they have quickly established themselves and have potential to become a strong global player. India is currently leading the world in the knowledge revolution. With a large workforce that is young, highly educated and English speaking on its side India Inc. is on the fast track. Clinical research organizations in India exist either as departments of large pharmaceutical companies or independently as contract research organizations. A lot of international contract research organizations have subsidiary branches in India, either independently or in collaboration with Indian companies. On the other hand, many of India’s premier CRO’s are wholly owned Indian companies, such as Ahmedabad based Lambda Therapeutic Research.

Business
Majority of research being done across the world today is sponsored by the pharmaceutical industry, regulated by strict regulations and guideline, applicable in various countries as well as India. The research undertaken by most of the clinical research organizations in India is outsourced projects from some of the major international pharmaceutical companies or studies on drugs developed by Indian companies and being marketed internationally. In recent times, there is also an increased thrust on research to study drugs developed indigenously, for specific Indian conditions. The CRO industry in India is currently estimated to earn 100 to 300 million USD projected to grow at a phenomenal rate (Centrewatch 2003). These are very encouraging figures and it would be worth the while to examine the strengths that make India CRO’s the current hotbed for clinical research.

Capabilities
Most of the clinical research organizations offer varied services in clinical research. The services span from undertaking of clinical studies from Phase 1 to Phase 4. Technical services like feasibility studies, protocol development, CRF designing, report writing, monitoring, bio-analytical services, quality assurance and data management are variedly providing by these organizations, with few providing a full service spectrum. There are CRO’s offering niche services like conduct of bioavailability studies, data management for global trials, monitoring and site management of Phase 3 trials.

Strengths
The clinical research organizations in India are fairly young organizations, staffed with highly skilled workforce most of them armed with varied advanced technical qualifications. Clinicians, pharmacologists, post-doctorates, pharmacists, toxicologists, chemists, analysts are among the few technical staff that are available in most of these organizations, a few very well trained. The understanding and awareness of various regulatory guidelines and issues is sound and the infrastructure is usually state of the art. Most of the premier facilities comply with applicable GXP’s and quite few have been audited by various international regulatory agencies. The unique advantage with which the clinical research organizations in India operate is their lower operating costs and an extremely fast turnaround time for...
execution for most projects. The organizations structures in these companies are usually lean and system driven, which ensures fast and consistent decision making and project execution capabilities. The quality standards in a lot of these are at par with that seen in most of the reputed international CRO's.

**Regulatory support**
The clinical research industry is quite dependent upon the outlook of the regulatory body of any country. The Indian regulatory agencies have also recognised the opportunity that India has in terms of growing demand for clinical research conducted in India and is undertaking many new initiatives in the regulations to address some of the unmet concerns of the pharmaceutical industry in India and abroad. The new regulations, Schedule Y, have been in force since this year and include the Indian GCP guidelines. Newer initiatives are afoot, such as registration and training of ethics committees, revision of the ICMR guidelines on ethics in biomedical research, issues regarding Intellectual Property Rights and data protection etc.

**Challenges**
Considering the delicate nature of the business, conducting drug trials on humans, the industry needs to ensure a strict code of conduct. Considering the demand for trained investigators and other study personnel, the government and the industry needs to explore newer avenues to generate more awareness and create training opportunities in this field. Clinical research in India is here to stay and grow.
MARKETING MEDICINES AT AFFORDABLE PRICES:
National Pharmaceutical Pricing Authority

The Indian government has promulgated DPCO 1995 by taking into consideration the various certain announced in the Drug Policy of 1994. Accordingly, only those drugs which have mass consumption with insufficient market competition and drugs under monopolistic situation as existed in 1991 had come under price control. All other drugs are outside price control and the government / National Pharmaceutical Pricing Authority (NPPA) is expected to intervene in the prices of these drugs only when it has been established that the price of a particular medicine had adversely affected public interest. In the absence of any specific paragraph regarding monitoring mechanism under DPCO 1995/ guidelines from the government, NPPA has evolved its own procedure over the years for monitoring of prices of non-scheduled formulations and has been taking action.

The overall position with respect to the prices of medicines and the role of NPPA can be summarized as below:

A. Schedules Formulations
A consolidated list of scheduled drugs is available and the drugs covered are well defined. The mechanism of price fixation is clearly stipulated under the provisions of DPCO 1995 and NPPA has been able to fix / revise the prices regularly.

As regards implementation of prices fixed/revised by NPPA suitable measures are taken to ensure that information is made available to all the concerned agencies like individual manufacturers, State Drugs Controllers and industry associations through various means like press release, posting on website, of the NPPA, individual communications etc. NPPA do not have its own work force for inspections and the responsibilities wholly lies with the State Drugs Control agencies for enforcing the prices fixed by violations action is taken for recovery of overcharged amounts. Due to lack of delegated authority and inadequate manpower / posts, NPPA has so far not initiated action for launching prosecutions against the defaulting companies. However, some state governments launch prosecutions as per the only power available to them for taking action under the DPCO 1995 Essential Commodities Act, 1995.

The government has given exemption from price control for scheduled formulations manufactured by small-scale sector units provided such formulation (pack) is not covered by a ceiling pricing notified by NPPA and subject to compliance of certain conditions stipulated in the notification. These conditions relate to independent existence of the unit / self ownership of brand name and own marketing of the product etc. It has been the observation of NPPA that some organized sector units who are otherwise not eligible for exemption are taking advantage of this provision to circumvent price control mechanism. An effective, full proof notification making available the benefit of price exemption only to the genuine small scale units / companies having non significant sales and not to organized sector units is considered necessary at the earliest.

In the fast changing environment rigid price control systems, particularly, cost based pricing mechanisms are not desirable.

B. Non schedule formulations
During the monitoring of prices of non-scheduled formulations NPPA has noted the following aberrations from
the prices of drugs covered under scheduled category.
i. Generally, the manufacturers fix the retail prices as per prevailing market conditions and not based on cost of production and the MAPE / MARK UP availed over cost of production is higher than 100% A (which is being allowed in scheduled formulations).

ii. While the prices of scheduled formulations marketed by different manufacturers are uniform / closer, large variation in prices is noted with respect to non scheduled formulations, the variation in some cases being as high as 500% to 1000%.

iii. The price changes (increase/decrease) are effected periodically based on market conditions.

iv. Fall in prices of bulk drugs (which constitute the major component of cost in most cases) is not generally / discounts and bonus schemes etc, instead of offering the medicine at low prices to the patient / consumer.

v. The manufacture prefer to offer a considerable amount of profit margin to trade in the form of trade margins/discounts and bonus schemes etc. Instead of offering the medicine at low price to the patient/consumer.

vi. Aggressive marketing costs involving incentives to medical profession also add significantly to the total cost of sale of the medicine and this plays a major role in the fixation of price by the manufacturer.

As could be seen from the above, several factors play a role in the prices charged by the manufacturers for non-scheduled formulations. While there are several thousand non-scheduled formulations marketed by small / big pharma companies, NPPA with its very limited staff monitors the change in prices of about 4000 formulations (packs) which have considerable sale sins in the trade channels. They constitute about 80% of total pharma market in trade channel. The data reported by various reputed agencies like ORG MARG and IMS Health is used in monitoring this activity.
Public Health - What Does it Mean to Pharmacists

Pharmaceutical Care: The Way Ahead for Community Pharmacists

The pharmacy profession in India has been full of contrast. On one side is the pharmaceutical industry which is successful on par with the world; on the other side, pharmacy practice has remained much behind time. A country with more than 500,000 pharmacies is yet to see the concept of Pharmaceutical Care being put into practice. The pharmacist is still not a true health professional but is more of a "shopkeeper." For years together, retail pharmacy has been dominated by the business attitude rather than a professional approach. The mushrooming of pharmacies giving rise to tough competition, the unethical marketing tactics of pharmaceutical companies, weak implementation of existing laws are some probable reasons for this 'product' oriented trade practices to maintain the profits. Lack of relevant skills & knowledge, workforce issues, time constraints further obscure the development of professional retail pharmacy practice.

Time to Change...

But, slowly, as professional pharmacy advances in other parts of the world, and globalization sets in, it is realized by the retail chemist associations, other national pharmacists associations and regulatory authorities that there is a "urgent need to change". They are coming together on a common platform to work towards this distant goal. This is best exemplified by collaboration of the Drug Controller General of India with the Indian Pharmaceutical Association (IPA) and the WHO to develop Good Pharmacy Practices for Indian Community Pharmacies. Think globally & act locally is the 'mantra' for the impending change.

Pharmacy educationists have now realized that there is need to bring in changes in the pharmacy curriculum to produce future generations of competent pharmacists. Due to continuing education programmes, and the emphasis given by visionary leaders as well as increasing expectations of educated consumers, the pharmacists themselves are realizing the need of patient focused services. They realize that it is for the benefit of society, in addition to establishing the image as a true professional rather than being merely a 'drug vendor'. The provision that professional services will eventually help to grow the business, leading to a "win-win" situation is also recognized. Thus, the groundwork for the journey of the traders towards the transformation to health professionals has just begun.

Changing Mindsets, Evolving Pharmaceutical Care

Pharmaceutical care is the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life. It involves the process through which a pharmacist cooperates with a patient and other professionals in designing, implementing, and monitoring a therapeutic plan that will produce specific therapeutic outcomes for the patient. Central to the concept of Care is the one to one relationship that is established between a patient & a pharmacist. New generation pharmacists are getting geared up for this change & are willing to absorb new ideas. This changing mindset of the pharmacists is an asset to progress towards Pharmaceutical Care. Computerization of pharmacies is being done on a priority, making maintenance of patient records easier. There is great interest to attend the continuing education programmes & implement the learnings in practice, partially or in the full sense. The participation of pharmacists in projects such as TB Fact Card (project of IPA with Commonwealth Pharmaceutical Association and International Pharmaceutical Students Federation) indicates a new era is beginning in the history of Indian pharmacy. The counseling offered, treatment
SEARPharm Forum is FIP Forum of National Pharmaceutical Organisations in collaboration with WHO Regional Office for South East Asia. Its secretariat is based in Delhi.

**Our Objective** is to encourage and support a dialogue and collaboration among national and regional pharmaceutical associations in the South-East Asia region of WHO and WHO SEARO by:

- Improving health in the South-East Asian region by development and enhancement of pharmacy practice (Good Pharmacy Practice)
- Encouraging the implementation of pharmacy service and pharmacy practice projects by national pharmaceutical associations
- Supporting WHO-policies and goals
- Integrating appropriate WHO policies into undergraduate, postgraduate, and continuing education programmes in pharmacy
- Formulating policy statements on health issues
- Combating the production and distribution of counterfeit medicine and sale of medicine by people who are not qualified.

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monitoring & creation of awareness about TB among the community by information dissemination, encompasses all aspects of pharmaceutical care by the pharmacists. There is a healthy partnership which is getting established with the physicians through such work.

Involvement of pharmacists as ‘DOTS’ Providers in near future will be a major breakthrough & an ideal way of contributing to the public health. Even though the number of such pharmacists is limited at present, this type of project is breaking the barriers & giving a lot of confidence & inspiration to the pharmacists as well as to their leaders.

Pharmacist’s Role: Tremendous Scope

Widespread infectious diseases plus lifestyle disorders & millions of formulations in the market make the Pharmacist’s role more significant. The pharmacists can effectively contribute in counseling for health promotion, minor illnesses, & disease management. The pharmacists are getting ready for the management of diseases such as diabetes, cardiac disorders & HIV/AIDS. Use of computers will facilitate the therapeutic follow up of patients with chronic ailments. Simple clinical measurements such as body weight & B.P. measurements are starting in the pharmacies. Providing patient information cards/leaflets is emerging as one feasible way of patient counseling in addition to the brief verbal counseling. With such patient education, there will be a great improvement in the correct use of medicines by the community which will certainly contribute to the rational drug use. Free health check up camps are being organized in rising numbers.

The fact that the country still has high illiteracy & poverty further demands the pharmacist’s services. The pharmacists in rural areas are already the friendly health advisors to the rural community which is deprived of the medical facilities. Now, with the right education these pharmacists can acquire technical know how for the patient services.

With the recent spate of natural disasters striking the country, the role of pharmacists in disaster management is also being seriously thought over & IPA has initiated discussion and framing strategies for this.

Long Way to go...........

The amendments to the laws are awaited in the near future and soon continuing education will be compulsory for the pharmacists. Attempt as well is being made to make a provision for remuneration for professional services of pharmacists. The implementation of Good Pharmacy practices, amendments to the law & constant efforts of the associations will further ensure that pharmacy practice is on the right track & moves slowly but definitely towards Pharmaceutical care. It is true that it is going to be a slow evolution & not a revolution. It will evolve little by little in response to many constraints. But the Indian pharmacist has made the small beginning with positive attitude which will go a long way in establishing the Pharmaceutical Care.

Pharmacists Fight against HIV/AIDS in India

India’s National Health Policy (NHP) is based on Indian civilization’s universal agenda in the form of ancient vedic hymn ‘Sarve Santu Niramaya’ that is ‘May All be Happy’. India’s first National Health Policy document in 1983 hoped to provide Health for All by 2000 A.D. The NHP was reformulated in 2002 on the basis of realistic considerations of capacity. India has ambitious plans to achieve zero level growth of HIV/AIDS by 2007. India’s AIDS crisis is huge and growing. As on mid 2005, there are up to 5.13 million HIV positive cases and 111,608 confirmed AIDS cases in 1997. In this context, proper role and involvement of pharmacists in medicine management and overall healthcare programme becomes crucial.

The World Health Organization has signed a joint declaration with International Pharmaceutical Federation (FIP) on the role of the pharmacist in the fight against HIV/AIDS pandemic. The Indian Pharmaceutical Association (IPA) in its countywide initiative undertook sensitization of pharmacists during National Pharmacy Week Campaign in the year 2000. FIP appointed a community pharmacy section observer from 2000-2004 with a specific aim for development of Guiding Principles for Pharmacists to deal with HIV/AIDS in India. The efforts were supported by CPS and FIP Foundations for Education and Research. The Guiding Principles document was prepared with the help of a working group and they are now used for training the trainers and in-service pharmacists. So far, over 400 pharmacists from Delhi, 150 pharmacists from Mysore and 25 pharmacists from Kolkata have been trained.

The training objectives are to motivate pharmacists to feel responsible for promoting the message of protection against AIDS; explain about the safe use of disposable needles and condoms; inform the HIV/AIDS patients about proper use of drugs, diet and lifestyle changes; encourage and counsel the kith and kin of AIDS patients; and offer moral support for leading a smooth life. The six hour training module deals with the role of pharmacist in prevention and information, pathophysiology, mode of transmission and therapeutics of AIDS, safe blood and blood products, diagnostic screening tests, and perils of injectable drug use.

Due to the vast geography and huge number of pharmacists, it is desirable to intensify the training process by joining consortium of like-minded organizations for global funding and unleashing proper use of anti-retrovirals.
Pharmacists for future free of tobacco

"Four million unnecessary deaths per year, 11,000 every day. It is rare if not impossible to find examples in history that match tobacco's programmed trail of death and destruction. I use the word programmed carefully. A cigarette is the only consumer product which when used as directed kills its consumer" says Dr Gro Harlem Brundtland, Director-General Emeritus, World Health Organization. Currently, there are an estimated 1.3 billion smokers in the world. The death toll from tobacco consumption is now 4.9 million people a year; if present consumption trends continue, the number of deaths will increase to 10 million by the year 2020, 70% of which will occur in developing countries.

The government of India both at Center and States has new legislations to deal with smoking in public places. Besides smoking, addictions to tobacco chewing and snuffing are highly prevalent. Certain products containing tobacco flakes in beetle nut powder are already banned. The Drug Technical Advisory Board has amended Schedule K to exempt from sale licence nicotine gum as nicotine replacement therapy (NRT) to help in tobacco cessation and avoid tobacco dependence.

The Indian Pharmaceutical Association conducted a survey on Indian pharmacists and smoking to know their perceptions and attitude. 429 respondents who participated in the survey conducted between 8 and 25 July 2003 included 107 community pharmacists, 88 pharmacists working in other disciplines (industry, regulatory, teaching etc) and 234 students from Delhi, Mumbai and Gwalior. The respondents were mainly male population. The results of the survey are summarized below:

- Almost 25% of pharmacists said they have ever used smoke or smokeless tobacco
- Almost 15% pharmacists and 11% students have used smoke or smokeless tobacco daily for 6 months or more
- Almost 11% currently use smoke or smokeless tobacco. As per the National Tobacco Information Online System (NATIONS) data, 45% of general population currently use smoke or smokeless tobacco, clearly indicating that the pharmacists as a health care personnel are conscious about well being.

- The major reasons amongst pharmacists for not smoking are:
  - Health protection
  - Avoiding unpleasant symptoms
  - Pressure from colleague, family and friends was not an important factor
  - The desire to save money was least important to all pharmacists but important for students
  - More than 75% pharmacists felt that their knowledge about smoking is sufficient
  - Almost 90% pharmacists felt that smoking in drug stores should be completely banned

- Almost 86% of the pharmacists felt that they should be trained to assist patient/customer who wish to stop smoking
- Almost 90% pharmacists felt that smoking prevention and cessation should be included in normal training programmes for pharmacists
- Almost 75% pharmacists said they knew the legislative actions taken by State/Center
- Almost 45% of pharmacists felt that legislative actions taken in the country/state are sufficient
- Almost 78% community pharmacists said they advise patient/customers to stop smoking
- Only 25% community pharmacists volunteer written information on smoking cessation to patient/customers
- Only 40% of community pharmacists volunteer information about smoking cessation courses to patient/customers who want to stop smoking
- Only 38% of community pharmacists actively promote Nicotine Replacement Therapy (NRT)
- However, almost 95% community pharmacists felt that they have a role to play in fight for future free of tobacco

The survey clearly brought out that pharmacist need education and training for promoting smoking prevention and cessation; they should be equipped to volunteer information on the use of tobacco to patients/customers who want to stop smoking. They should actively promote NRT through their drug stores.

At the global level, the initiatives taken by International Pharmaceutical Federation (FIP) in tobacco cessation activities are indeed commendable. FIP launched a call for the adoption of a ban on the sale and use of tobacco products on their premises, to “ensure that all staff and customers can enjoy a smoke-free working environment”. Such an initiative is prophetic and exemplary for other institutions to follow. We have to be role models ourselves if we want to bring a change in the society’s attitude. In the same initiative, FIP stated that “It supports legislation that eliminates the sale of cigarettes from all licensed health-care facilities. They pointed out that pharmacists are health professionals committed to improving the health of their customers, and that individual pharmacists should provide leadership by being free of tobacco themselves. To this effect, FIP during the 64th FIP Congress also issued a press release entitled “FIP calls for ban on tobacco sales and smoking in pharmacies”. Such initiatives are appreciable and praise-worthy. We have good regulations; what needs to be tested is the execution and implementation of the existing regulations. Under the circumstances it is heartening that Indian chemists do not stock tobacco containing products in their premises.

Tobacco use is a global pandemic; which needs to be addressed in a holistic manner. We need to combine all forces to combat this greatest addiction on mankind. The initiatives taken at various individual associations and organizations need to be combined, if we are really looking for a viable and effective solution for combating this epidemic. The World Health Organization (2005) very rightly says “There is only one way to combat this epidemic, and that is by implementing a comprehensive, continuous, sustainable and adequately funded tobacco control strategy”.
A time has come when we need to synergize our efforts and fight unitedly to uproot this epidemic. Only then can we give our future generations a “Future Free of Tobacco”....

Pharmacist in promoting access to essential medicines and rational use of medicines

The pharmaceutical industry in India has made a remarkable progress and today, Internationally India is the largest pharmaceutical producing country by volume. Almost all essential medicines are indigenously available at most competitive prices. Prices offered by the Indian Pharmaceutical Industry have influenced the global pharmaceutical scenario to the extent that almost all leading pharmaceutical producers have to revise their pricing policies to meet the Indian challenge. This has facilitated affordable access to medicines that were totally out of reach to a large section suffering masses in the world, especially HIV/AIDS epidemic areas in Sub-Saharan region. However, the chasm between the affordability and availability continues to trouble our conscious, the chasm between affordability and rational use is a challenge to all of us. Nearly 70% of the population of India is deprived of essential medicines for a variety of reasons including poverty, illiteracy and apathy towards one’s own health, non-availability or inequitable distribution of health professionals in different regions of the country and inadequate facilities for providing proper professional advice about usage of drugs. Essential Medicines are those that satisfy the priority health care needs of the population. These are selected keeping in mind public health relevance, efficacy, safety and cost and should be available in a health system at all times and in adequate amount at a price that community can afford. Pharmacists and retail pharmacy outlets (medical stores) are crucial focal point for the community, as nearly 80% of population has to bear the expenses on medicines and health care “out of their own pocket”. Most often, these outlets are the first-point-of-call (as primary health care) for the community. As pharmacists can communicate with the community in a language that is understandable and dialects, his outreach is tremendous for discussing their health problems and helping them to find solution to their problems.

In order to inspire, encourage and empower the pharmacist to find a meaningful role and recognition in the society in India by acquiring required key competencies, a modest attempt was made at Jaipur on 17th February 2002 at the time of conclusion of a WHO sponsored 2 week International Course on Pharmacoeconomics (in which the author was a facilitator and Organizing Secretary), utilizing the presence of international WHO resource persons. The meeting was chaired by Prof. Roy Chaudhury, Coordinator, WHO-India Essential Medicines Programme and co-chaired by Dr. Hans Hogerzeil (now, the Director, Essential drugs and Medicines, WHO, Geneva). Leading pharmaceutical professionals having shown concern for the Community Pharmacy were invited to attend this brain storming session. Summing up the session Prof. Roy Chaudhury and Dr. Hans Hogerzeil welcomed this effort in identifying the role of Community Pharmacist towards Enhancing the Access to Essential Drugs and collaboration with medical profession. In pursuance thereof, a joint declaration with the name as “The JAIPUR DECLARATION” was issued along with the Guiding Principles.

Pharmacist and consumer friendly storage of medicines

India has seen a phenomenal growth of finished medicines production of high quality. However enough attention has not been given to aspects related to distribution, storage and labelling of medicines.

Delhi Pharmaceutical Trust (DPT) a beneficiary of IPA surveyed 100 retail outlets in Delhi storing and selling pharmaceuticals. The results of the survey was so damning that no professional magazine was willing to publish. The study revealed need for improvement all around. While industry needed to change the way text was given related to storage on the labels to make them both Pharmacy friendly (easily understood by retail chemists so that they keep the medicines in proper places in their outlets) and Consumer friendly (consumers to keep medicines at home properly). The drug laws and the monographs in the Indian Pharmacopoeia also need major changes. Massive training and awareness programmes are the need of the hour to highlight the importance of good storage practices. DPT then set out to achieve the first step and brought out a document entitled Good Storage Practices (GSP) for Pharmaceutical Products at a Retail Pharmacy- a Guide for Retail Pharmacists.

India being a vast nation with widely varying climatic conditions it is really a challenge to ensure proper storage of medicines. The temperature and humidity across the country vary considerably and seasonality adds another dimension. Temperatures can be as high as 47 degrees for almost a week in certain parts of North India, generally hovering above 40 degrees for 2-3 months in a year and going as low as 0 degree....
in other parts of the country. Humidity can change and go as high as 95% RH in several parts for more than 3 months averaging to above 60% RH throughout the year in coastal areas. There is lack of ground level data regarding storage at wholesale depots, C&F agents’ warehouses and godowns. Transportation and distribution from the manufacturer till the medicines reach the retail pharmacy outlet involves a range of transportation methodologies-involving trucks, tempos, trains, small vehicles many of them with open roof tops and involving multiple stages of trans-shipment, exposing the packed medicine shippers to excursions of high temperature, direct sunlight and humidity the total duration of which is not known. At the other end from intermediate stockists sales assistants and officers are seen to carry small stocks kept in large bags hung onto bicycles for delivery to individual chemist outlets. The law and the situation related to ensuring proper storage of medicines across this chain of transportation and distribution needs to be looked into by all concerned.

The survey also brought out the need for rationalisation of the language used on the label to clearly convey how a particular product is to be stored.

<table>
<thead>
<tr>
<th>S.No</th>
<th>Storage texts on the label</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Keep in a cool dry place</td>
<td>To be stored in refrigerator (from +2°C to +8°C)</td>
</tr>
<tr>
<td>2</td>
<td>Protect from heat and light</td>
<td>To be stored at room temp. (from +2°C to +30°C)</td>
</tr>
<tr>
<td>3</td>
<td>Store below 25°C</td>
<td>To be kept in refrigerator (from +2°C to +8°C), not in freezer chamber</td>
</tr>
<tr>
<td>4</td>
<td>Store between 15°C-25°C</td>
<td>To be stored in normal humidity at room temperature (RH less than 60%); to be provided by the manufacturer in a moisture resistant container.</td>
</tr>
<tr>
<td>5</td>
<td>Store in dark at 2°C-8°C</td>
<td>Protect from light</td>
</tr>
<tr>
<td>6</td>
<td>Do not store above 25°C</td>
<td>To be stored in a light resistant cupboard/drawer; to be provided by the manufacturer in a light resistant container or pack.</td>
</tr>
<tr>
<td>7</td>
<td>Store at room temperature</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Keep in a cool place (do not freeze)</td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>Keep in a dry place (not more than 30°C)</td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>Cool place protect from frost</td>
<td></td>
</tr>
</tbody>
</table>

Typical examples of current labelling seen on wide variety of medicines

DPT has recommended to the government to change Pharmaceutical products labelling guidelines and asks the manufacturers to restrict to the following text to make them both Pharmacy friendly and Consumer friendly.

The above would cover only the tip of the iceberg. Massive efforts are needed to bring high level of awareness and action amongst the stakeholders. Industry need to proactively ensure that their products are stored properly till it reached the consumer and the Pharmacists be it the wholesaler or the retailer need to play a greater role in ensuring the same. Good Storage Practices need to be implemented not only in this chain but also at hospitals and dispensaries run by the government.

Consumer habits in India are not friendly to protect the medicines they buy till they use it. Consumers in at least metro towns are seen to store vegetables, fruit juices, soft drinks in refrigerators or proper places. They take great pains to keep even their cosmetics properly, however they don’t seem to take the same care when it comes to their medicines. They leave their medicines in dashboards or boots of cars and motorcycles, keep medicines in kitchen and bathrooms and many time keep them on the window panels only to see them melt, crack and change consistencies or undergo deterioration. Habit of tightly closing lids after each use of medicine bottles is not high.

Lastly but not least the consumers have to be educated on do’s and don’ts for the medicines they buy. They need to be told to keep the medicines well to keep themselves well. Harnessing today’s technology of mass communication through net, CDs and DVDs using effective short films would be one approach. Industry and chemist associations should pool in resources to produce such infomercials, as it is their professional obligation.
Indian pharmaceutical market is the world’s 13th largest in terms of value and 4th largest in terms of volume. The total market size is Rs. 25,000 crores (Ref: IMS Health) that includes all the pharmaceutical products, fast moving healthcare products and some fast moving consumer goods (FMCG) products sold through the chemists across the country. While all the formats of retailing have changed, be it apparel retailing, grocery retailing, fuel retailing, jewellery retailing, somehow pharma retailing has not undergone changes. Though all this has continued for more than 55 years but changes are imminent in the next 2-5 years. The changes in the next 5 years in this business will be more than what has happened in the past 55 years. Earlier, shopping was considered a headache involving running from pillar to post. Now retailing has changed and become leisure and pleasure trip & it’s become more of an outing for the entire family.

Pharmacy retailing has seen consolidation the world over. Five pharmacy chains control 40% of the sales in the US. Seven pharmacy chains control more than 60% of the market in UK. A similar situation prevails is there in most developed nations around the world.

In India, there are more than 800,000 independent chemists. With so many chemists there is a demand supply imbalance and as there is almost no differentiation, the shakeout is inevitable. The pharmacists in India will have to change and the trade has to become organized.

Better need driven business and every pharma relating family requires medicines / health related goods. So the scope of educated people getting into the same is higher. Margins are decent and returns are good. Medical men are getting into this business. An average family spends almost 20% of monthly budget spend on health care, up from 10% in 1985.

Storage conditions of pharmaceutical goods is becoming a public issue. Majority of the medicines needs to be stored under cool conditions (Below 35°C) And the day time temperatures in many parts in India cross above 40 °C thus making the efficacy of the medicines questionable. So pharmacists will have to air condition their outlets to maintain the efficacy and shelf life of the medicines. In fact, most of the state governments are in the process of making Air conditioning of the retail outlets mandatory for the license. So this will be a single most important reason for change. This will also reduce the number of chemists as some of them are so small that they cannot store properly.

The FDA authorities of all states are tightening the implementation of law and have been closing down chemists who “rent” pharmacies.

Third Party Administrators (TPAs) have to empanel chemists for the cashless facility. They would have to bank on pharmacists who are system driven and on a common platform to monitor the payouts. This will again be a market requirement that will go in favour of chains.

Expensive biotech drugs will have to be stored, air conditions, non-computerized pharmacies. No manufacturer would like to gamble with the lives of patients by selling their expensive products through people who do not follow the international storage guidelines. Fear of substandard and spurious drugs drives customers towards more trusted names.

India will become a major centre of medical tourism destination and retail medicine business cannot remain unaffected. It has to change and adopt global standards. While India can be considered as a developed country for IT, in health care and pharmcare looked upon as underdeveloped.
How will the change happen?
The organized pharma retailing is growing at 100% per year. Last year, chains like Medicine Shoppee grew 100%. With internet being used at a much lower level in India, internet pharmacies may be the order of the day 5-10 years from now. This is going to bring about a big change in the customer's perception of cost and service levels in pharma retailing.

Corporate and organized pharmacies will drive the change: Apollo hospital group, Dial for Health - Zydus group, AIICOI, Guardian, 98.4, CRS Wellbeing, Life Springs are trying and finally as it happens in retailing, the international retailers may dominate the scene. The future of pharma retailing is in for a big shakeout from all the three parties; manufacturers, retailers and customers. Since all are looking at a better value for saving time, costs and delivering a better value with fast and relevant information, there could not be a better time for the changes in pharma retail.
India is a country of immense proportions. Its 3287590 sq. km. area, 1060 million population, 16 official languages and 35 states & union territories (several of which are larger than many European countries) don't lend themselves to conventional logistics. More than half a million qualified Doctors cater to the healthcare needs of our vast nation, supported by 6, 24000 beds in more than 15000 hospitals. Gigantic number of drugs are produced and consumed in India, which is the fourth largest producer of pharmaceuticals in the world.

Clearly aware of the enormity of the task and determined to establish a vibrant, sustainable and credible adverse drug reaction monitoring programme in the country, the central drugs regulatory authority - the Central Drugs Standard Control Organization (CDSCO) - has initiated a well structured and highly participative National Pharmacovigilance Programme.

The National Pharmacovigilance Programme is largely based on the recommendations made in the WHO document titled "Safety Monitoring of Medicinal Products: Guidelines for Setting Up and Running a Pharmacovigilance Centre". The Programme aims to foster the culture of ADE notification in its first year of operation and subsequently aims to:

- generate broad based Adverse Drug Reactions (ADR) data on the Indian population and share the information with global health-care community through WHO-UMC
- ensure optimum safety of drug products in the Indian market
- provide technical expertise for evaluating statutory Adverse Effects (AE) reports furnished by sponsors conducting clinical trials in India

Even though India started participating in the WHO Pharmacovigilance programme many years ago and has several professionals who have organized many pharmacovigilance workshops, adverse drug reaction monitoring in India is still in its infancy.

An objective analysis of the earlier ADR monitoring attempts in India pointed towards deficiencies in attitude, expertise and management that included lack of reporting culture among physicians, lack of appropriate monitoring and supervision facility, lack of trained clinical pharmacists and nurses, as major factors. Further, health care professionals were not clear about what to report, how to report or where to report.

Over the last three years, CDSCO engaged various stakeholders (Doctors, pharmacy professionals from hospitals, pharmaceutical industry, clinical research organizations as well as academicians from related fields) to discuss pharmacovigilance in Indian context and elicit suggestions for conceptualizing a robust nation-wide pharmacovigilance programme for generating, collating, analyzing and evaluating the data.

Two extensively participated discussion meetings culminated in a workshop organized in March 2003, where a National Pharmacovigilance Protocol and Standard Operating Procedures were documented, which now form the bed-rock of the National Pharmacovigilance Programme in India.

To effectively deal with the expected scale of operations in the country, National Pharmacovigilance Programme envisages several Peripheral Pharmacovigilance Centers pooling their data at five Regional Pharmacovigilance Centers which in turn funnel their data to the two Zonal Pharmacovigilance Centers.

Zonal Pharmacovigilance Centers are expected to analyze the data and submit consolidated information to the National Pharmacovigilance Centre where a National Pharmacovigilance Advisory Committee evaluates the data and recommends appropriate regulatory interventions.
Finally, A Pharmacovigilant India!

The National Pharmacovigilance Center which was so far at the All India Institute of Medical Sciences is now based at CDSCO. The two Zonal Pharmacovigilance Centers are the major hospitals in New Delhi and Mumbai. All Regional Pharmacovigilance Centers participating in the project are medical college hospitals which have a dedicated area and infrastructure for the pharmacovigilance programme. Peripheral Centers participating in the programme are clinics, retail pharmacies or hospital pharmacies and their activities are coordinated by the Regional Pharmacovigilance Centers.

In order to overcome the deficiencies observed in the past pharmacovigilance initiatives, clear operational benchmarks and standard operating procedures have been agreed upon by all participating centers. A training programme has been organized for the participating centers where appropriate communication skills to elicit adverse drug reactions information, hands-down training on recording adverse drug reactions information and for collating and submitting the data has been imparted.

Keeping in view the large number of patients visiting Zonal, Regional and Peripheral centres, the following benchmarks have been established:

1. Each Peripheral Centre to record at least 30 suspected AEs each month (statistically speaking 30 AEs in about 1500 patients who visit each month would be quite feasible). Completed AE forms shall be forwarded to the concerned Regional Center at the end of each month.

2. Each Regional Centre to collate and scrutinize the data received from the corresponding 5 to 6 Peripheral Centres as well as the data generated at the Regional Center itself. Perform the causality analysis of all 120 to 150 forms received every month. The monthly report prepared in a specific form to be forwarded to Zonal Pharmacovigilance Centre every month.

3. Zonal Centres to collate the data (approx. 1000-1200 forms) received from corresponding Regional Centres. Shall verify / validate the causality analysis. Prepare a professional report for CDSCO in a specified format. Communicate data to WHO Uppsala Monitoring Center through the National Pharmacovigilance Centre.
<table>
<thead>
<tr>
<th>Responsibilities</th>
<th>Peripheral Centres</th>
<th>Regional Centres</th>
<th>Zonal Centres</th>
</tr>
</thead>
<tbody>
<tr>
<td>To collect ADE notifications</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>To receive blank ADE forms and acknowledge receipt</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>To fill or get filled the ADE forms [fill all mandatory data]</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>To forward duly-filled ADE forms to next higher level centre</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>To maintain a log of all ADE notification forms [blank or filled] received and forwarded</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>To identify, induce Peripheral / Regional Centres [with concurrence of CDSCO], provide them with general technical support, coordinate and monitor their functioning</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>To identify and delegate a pharmacologist for management of pharmacovigilance tasks</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>To identify and delegate a data manager for data management under NPPI</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>To carry out [or review] causality analysis of all ADEs or review such analysis by the Regional Centres</td>
<td>Optional</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>To forward all duly-filled ADE forms [those generated at the same centre and those received from immediate lower-level centre] as per pre-determined time line</td>
<td>*Weekly [Monday]</td>
<td>*Every 15 days [alternate Monday]</td>
<td>*Only archiving</td>
</tr>
<tr>
<td>To forward periodic report to next higher centre as per the MIS format [appendix I]</td>
<td>Every 15 days [1st &amp; 15th of every month]</td>
<td>Monthly [1st of every month]</td>
<td>Monthly [1st of every month]</td>
</tr>
<tr>
<td>To liaison with healthcare professionals in order to inculcate / foster the culture of ADE notification / reporting 1. Acknowledge the cooperation by the notifier 2. Share with notifier relevant feedback from higher centers</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>To organize and attend training programs/interactive meetings for all lower level centers</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

All participating professionals are highly buoyant about the success of the programme, particularly since the World Bank has provided US$ 100,000 for the project. UMC has committed unstinting technical support for the programme, which indeed has the potential to contribute large volumes of data to the UMC's database and enhance the global knowledge in the area of Pharmacovigilance.
PHARMACEUTICAL HEALTHCARE IN INDIAN SUB-CONTINENT

Population of India is approximately 103,00,00,000. The majority dwells in rural area and small towns where the people are hardly aware of organized Medicare. Both in rural and urban areas, several indigenous systems of medicine like Ayurved, Unani, Homeopathy and Siddha are operative and flourishing. In addition, Naturopathy, Yoga, Acupuncture/pressure are also practiced. Recently a new wave is setting in and gaining ground integrative treatment which is a fusion of many systems of medicine for optimal benefit to the patient at minimal/reasonable cost. Worldwide focus on herbal medicines has revamped the Ayurvedic system of medicine. However, Allopathy is practiced all over India in a large measure.

The public in general is not aware of health horizons. The pharmacist presents himself more as a trader than a competent professional. Possibly this image is due to lack of initiative shown by the regulatory system, educational institutions and the government.

Pharmaceutical service is a sub-system of healthcare, which the nation has built up and continuously maintains to combat (unnecessary) death, disease, disability, dissatisfaction and social disruption. It is a collection of curative, preventive, rehabilitative and promotive services. In addition, it is a social and economic endeavor encompassing activities by providers, consumers, financiers and Government within their respective value systems. The total quality should be the end point with focus on the patient (client satisfaction), professional quality (the pharmacist), system effectiveness (organization management), inter connections (Institution and environment) and a coherent unification of these parameters. The pre-requisites for achieving the objective are superior education and training, legal control, enforcement of highest ethical standards and a comprehensive approach by all concerned to improve pharmaceutical healthcare. A large section of the community visits the pharmacies/drug stores and the pharmacists for healthcare necessities, products and advice.

<table>
<thead>
<tr>
<th>Disease/health condition</th>
<th>DALYs lost (4 x 1000)</th>
<th>Share in the total burden of disease (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Communicable diseases, maternal and perinatal conditions</td>
<td>Tuberculosis</td>
<td>7.517</td>
</tr>
<tr>
<td></td>
<td>HIV/AIDS</td>
<td>5.821</td>
</tr>
<tr>
<td></td>
<td>Diarrhoeal diseases</td>
<td>22.025</td>
</tr>
<tr>
<td></td>
<td>Malnutrition and rickets</td>
<td>4.220</td>
</tr>
<tr>
<td></td>
<td>Lower respiratory infections</td>
<td>205</td>
</tr>
<tr>
<td></td>
<td>Diarrhoea</td>
<td>4.215</td>
</tr>
<tr>
<td></td>
<td>Maternal and perinatal conditions</td>
<td>31.207</td>
</tr>
<tr>
<td></td>
<td>Others</td>
<td>49.517</td>
</tr>
<tr>
<td>Non-communicable conditions</td>
<td>Cancer</td>
<td>8.992</td>
</tr>
<tr>
<td></td>
<td>Diabetes</td>
<td>1.986</td>
</tr>
<tr>
<td></td>
<td>Mental illness</td>
<td>22.944</td>
</tr>
<tr>
<td></td>
<td>Blindness</td>
<td>3.591</td>
</tr>
<tr>
<td></td>
<td>Cardiovascular diseases</td>
<td>26.932</td>
</tr>
<tr>
<td></td>
<td>COPD and asthma</td>
<td>4.551</td>
</tr>
<tr>
<td></td>
<td>Oral diseases</td>
<td>1.243</td>
</tr>
<tr>
<td></td>
<td>Others</td>
<td>19.821</td>
</tr>
<tr>
<td></td>
<td>Injuries</td>
<td>1.949</td>
</tr>
<tr>
<td></td>
<td>All listed conditions</td>
<td>205.624</td>
</tr>
<tr>
<td></td>
<td>Others</td>
<td>88.319</td>
</tr>
</tbody>
</table>

COPD: chronic obstructive pulmonary disease

Source: Peters et al 2001

THE PHARMACEUTICAL INDUSTRY

The Pharmaceutical Industry represents one of India's strengths. It has been growing annually at over 10% for the last decade and currently occupies the fourth position in the world in terms of volume. Exports and imports have grown from Rs. 2,179 crores to Rs. 6,475 crores and Rs. 1,527 crores to Rs. 3,370 crores respectively since 1994-95 (figures are upto 2000-2001).

THE PHARMACEUTICAL MARKET

The Indian Pharmaceutical market for prescription sales was around Rs. 19,000 crores in the year 2000. There are an estimated 9,000 large, medium and small manufactures in bulk drugs and drug formulations in the country. Besides, there are an estimated 3,900 loan licensees and 2,800 cosmetics manufacturers and more than 2,50,000 sales outlets. There are an estimated 65,000 brands and about three to four times that number, of formulations available in the Indian pharmaceutical market. There are, again, an estimated 12,900 selling companies, the bulk of whom depend upon the non-prescription drug market, that is, sales to institutions, and dispensing doctors and generic substitution.

PHARMACY IN INDIA
A Directory of organisations associated with pharmacy

Pharmacy Council of India (PCI)
Combined Council's Building,
Kotla Road, Awan-E-Ghalib Marg,
New Delhi 110 002
Tel : +91-11-2323 9184 / 1348
Fax : +91-11-2323 9184
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PHARMACY IN INDIA
Mission Statement

"The Indian Pharmaceutical Association (IPA) is the national professional body of pharmacists engaged in various facets of the profession of pharmacy. The IPA is committed to promote the highest professional and ethical standards of pharmacy, focus the image of pharmacists as competent healthcare professionals, sensitize the community, government and others on vital professional issues and support pharmaceutical education and sciences in all aspects".

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Mission and Vision 2020

PHARMA VISION 2020
Strategy for Pharmacy
Mission and Vision 2020

The Mission
To optimize health of all members of society through the promotion of safe, effective and rational medicine use, patient counselling and monitoring of disease management (through pharmaceutical care).

The mission is fundamental and is the reference point to promote the highest professional and ethical standards of pharmacy, focus the image of pharmacists as competent healthcare professionals, sensitize the community, government and others on vital professional issues and support pharmaceutical education and sciences in all aspects.

The Vision 2020
In the year 2020, pharmacists and pharmaceutical scientists working within various disciplines of pharmacy will be established and recognised as the medicines expert and an expert in health promotion and disease prevention.

- **The Pharmacists will interact with other professionals as the preferred source of information and advice on prescribing and medicine management of disease**
- **Pharmacists will develop their pharmaceutical expertise and facilities in order to deliver high-tech and individually-tailored medicines in the primary care setting**
- **Pharmacists will actively involve in the national health programmes, like, promotion of essential drugs, primary health care, HIV/AIDS, TB, Malaria, tobacco use or family planning**
- **Pharmacists will become knowledgeable to participate in medication management and outcome monitoring, including the ability to alter doses and change medicines within agreed therapeutic protocols**