



**Tamilnadu Pharmaceutical
Sciences Welfare Trust**

Pharma Web

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EDITORIAL

Dear Readers,

I wish you all a very Happy and prosperous New Year. Hope that the year 2013 will bring you all Health, Wealth & Happiness although. This is the second time I have got the opportunity to write the editorial in the absence of the editor Mr. R. Narayanaswamy.

The release of this 16th issue for the period October- December 2012 has been delayed by one month. The reason for this is that we hosted the 64th Indian Pharmaceutical Congress at Chennai from 7th to 9th Dec 2012. The Theme of the Congress was **“PHARMACY EDUCATION: INNOVATION, STRATAGIES AND GLOBALISATION”**. We are very happy to say that the congress was a grand success. The President for the Congress was Prof. Dr. K. Chinnaswamy who is our Philosopher and guide for the Pharmacy feternity.

The congress was attended by about 6000 people with a large representation from students. The congress was inaugurated by our Past President of India His Excellency Sri. A.P.J. Abdul Kalam. The Venue of the Congress was SRM University at Katangalathoor near Chennai. The facilities and the conduct of the Congress were excellent. There was an Exhibition of Pharmaceutical Machinery organized by FICCI and buyers Sellers meet by PHARMEXCIL. The three day meet ended with lots of Sweet memories to all the participants.

This issue contains the Highlights of the Congress. We have included the Inaugural Address of H.E. Sri. A.P.J. Abdul Kalam, and the Presidential address of Prof. Dr. Chinnaswamy along with the LOC Secretary's report. We have also included two of the presentations delivered during the Congress. One by Dr. B. Suresh, Vice Chancellor, J.S.S. University, Mysore & President Pharmacy Council of India on the theme “Pharmacy education: Innovation, Strategies & Globalisation - Present Status and Future Directions”. The second one by Dr. Appaji, Director General, PHARMEXCIL on the topic “Pharmaceutical Exports- Current Trends & Emerging Markets”. The other regular features like Notifications, Information, Events and News follows.

We request our readers to express their views and comments about the contents and usefulness of **Pharma Web**. Your Suggestions will help us to improve the Quality & Contents of our future issues.

With Best Regards'
Prafulla Chandra
(Associate Editor)

Address During the Inauguration of 64th Indian Pharmaceutical Congress

By

**His Excellency the former President of India Dr. A. P. J. Abdul Kalam
Chennai, Dec 6, 2012**

Paradigm shift in Pharma missions

Inventions and discoveries have emanated from creative minds that have been constantly working and imagining the outcome in the mind. With imagining and constant effort, all the forces of the universe work for that inspired mind, thereby leading to inventions and discoveries. The question is: are you willing to become a unique personality.

I am indeed delighted to participate in the inauguration of 64th Indian Pharmaceutical Congress here at Chennai. I am very happy that the Pharma institutions and Pharma industries have started providing quality drugs, and some industries have taken up the research of new drug discoveries. Of course, Pharma education definitely have to go through the lot of changes because Pharma vision 2020 requires the industry transforming into invention, development, production, and marketing of cost effective new drugs from molecule onwards. That means, Pharma education has to encompass advanced research on drug discovery and production in international standard. My greetings to organizers, doctors, Pharma industry leaders, pharmacists, Pharma students, and other members of Pharma community. I would like to share few thoughts on the topic "**Paradigm shift in Pharma missions**".

Pharmacy and healthcare delivery

Friends, in India, currently we have one million pharmacists and pharmaceutical scientists. Seventy-five per cent of this human resource is involved in distribution and retailing of drugs in community and hospital sectors. The balance 15-20% is deployed in manufacturing, quality, R&D, regulatory, and in academia. The remaining 5-10

percent go for higher studies or migrate. There are about 500 diploma and about an equal number of degree institutions in pharmacy with an annual intake of about 30,000 to 50,000. In addition, about 200 post-graduate degree specializations are available with an annual intake of about 12,000 students. It is projected that by 2020, the demand for pharmacists will be around 1.7 million in our country. I am very happy to know that 120 Post Graduate Pharma institutions has introduced Doctor of Pharmacy and clinical oriented. I am sure, these researchers will lead India to make number of new drugs from molecule. It is essential for Pharma industries and Pharma institutions to make academic institutions of repute as partner in drug development and clinic research.

While on the industrial pharmacy also in front, we seem to have done well, the pharmacy degree program is required to be realigned with the job requirements. Also, there is a need to restructure the diploma course which will provide the necessary skill and behaviour for discharging of professional obligations in community and hospital pharmacy. At the level of the primary health centers, where there is a shortage of medical and nursing professionals, pharmacists can play an important role in dispensing and counseling. In this context, pharmacists' valuable services can be relied upon for carrying out simple microbiological tests for malaria, TB, etc. He can also dispense medicines, monitor health status, take feedback from doctors, and counsel patients. On a long-term basis, the students who takes diploma course in pharmacy, should have an option to get upgraded to a degree program as pharmacists and get integrated at the community based health centers and primary health centers. At the post-graduate and doctoral level, the programs should be made more application oriented. We must

challenge traditional thinking in a world that is ever changing. In the context of changing perspectives, we have to develop a strategy to bring about continuous upgradation in pharmacy education to meet the changing needs of the profession.

Pharma Vision

Friends, the global production of pharmaceuticals, branded and generics put together is of the order more than of \$ 550 billion. The Indian pharma industry at present has a turnover of \$ 30 billion of generics and branded products. While evolving the Pharma Vision 2020, I would like to suggest that we should identify all such missions which will make India the leader in drug production. We should set a target of producing 20% of world generics production. India has got a core-competence of producing cost effective Pharma products. The Pharma community assembled here and the students studying in various disciplines must keep these targets in mind and contribute adequately for the realization of Indian Pharma Vision 2020.

Community Pharmacy

The first and foremost requirement is to enlighten the consumer about the role of pharmacists as an important member of the healthcare team. It is my strong belief that knowledge and expertise of a professional has to be enhanced so that he or she can contribute his/her best to the society. Pharmacists must be equipped with the state-of-the-art technical information so that he / she can advise patients and serve as an interface between the prescriber and consumer of medicines. Hospitals and doctors must ensure that pharmacist has patient specific information so that he/she can counsel the patients. This will infuse confidence in him. For example, for hypertension, diabetes, asthma, and/or hyper-cholesterolemia, intervention by specially trained pharmacists can provide patient education and monitor patient compliance. He should communicate regularly

with patients, physician for early intervention in drug related problems. The pharmacist can also be a valuable contributor to family planning, TB control, malaria education, HIV/AIDS information and prevention, vaccination, and anti-smoking campaigns. The pharmacist's intervention in such community medication management would substantially improve health care of citizens. These aspects must be included in the current and prospective training programs.

Hospitals and Clinical Pharmacy Practice

Hospitals can derive considerable benefits from a pharmacist if he or she is adequately trained in clinical pharmacy practices for providing cost effective treatment to patients. Such training will also help government hospitals to provide better healthcare delivery particularly in rural areas. Clinical pharmacists can also assist in setting-up of drug information centers. For adding value to healthcare delivery, multi-disciplinary approach involving medical, nursing, and pharmacy professional is desirable. Hence, the pharmacy course should provide knowledge to the students on information on the rationale for using a particular drug, chemical stability of dosage forms, proper storage, under- or over-use of medication, and adverse effects of drugs. This will enable the pharmacy graduates to provide the right type of counseling to the patients. The pharmacy curriculum may be suitably modified keeping these needs in mind.

Industrial Pharmacy

Pharmacists play a key role in the industry. To keep pace with the changes in the international scenario of customer needs, Pharma industrialists have to aggressively shift paradigms. We have to look beyond process development capabilities towards new drug research with adequate attention to quality, costs, and time dimensions. We need Intellectual Property Rights (IPRs) capabilities for drug discovery research, new drug delivery systems, state-of-the-art packaging systems,

automation, flexibility in manufacturing, and reliability of products. To minimize quality defects, we must change our mindsets for measurement from percentage to Six Sigma and improve process capabilities using statistical tools for consistent quality. The quality building process requires training people in advanced instrumentation techniques and information technology, exposing people to best practices, and impregnating them with a sense of security and team work. These characteristics must be the focus for training industrial pharmacists.

Recently I have come across a drug that will cure fast malaria called Synriam developed by Ranbaxy in collaboration with Department of Science and Technology. Ranbaxy has introduced Synriam in the Pharma market to the adult patients. Pharma industry would have studied about this new anti-malaria drug.

Now let me have a look at what an Open Source Software movement has brought a change in the research domain in India based on the new and innovative approach in soliciting the contribution from the young minds across the world.

Open Source Drug Discovery (OSDD)

The Open Source Drug Discovery (OSDD) programme is a CSIR led team India consortium with global partnerships, with a vision to provide affordable healthcare to the developing world.

Market forces discourage research-based pharmaceutical companies from developing drugs for infectious diseases like Tuberculosis (TB), Malaria, and Leishmaniasis (Kala Azar) that predominantly affect the developing world. Without a market attractive to global pharmaceutical industry, it would be naïve to expect drug discovery for infectious diseases (particularly in India) to become a lucrative standard business model. In the wake of the failure of market forces we need to explore new models of drug discovery. This is where OSDD offers a

promising new model.

OSDD has chosen TB as the first target disease. The current TB therapy was developed in the 1960s. The therapy is a combination of four drugs which has to be administered under observation of the physician for six to eight months. In India, an estimated 370,000 deaths due to TB occur each year. This amounts to over 1,000 deaths a day, or 2 TB deaths every 3 minutes. This disease which affects mostly our poor is a huge problem for the nation. OSDD aims to discover better and more effective drugs for TB by involving large number of researchers based on the open source philosophy that more eye balls make all bugs shallow.

The Open Source approach has been successfully adopted in software and collaborative approach is known in science. OSDD's effort to do discovery in the open with the aim of collaborate, share, discover makes it highly participative. It enables manifold expansion of resources for research.

Launched on 15 September 2008, OSDD has more than 4500 registered users from over 100 countries and more than 150 projects on TB drug discovery. A large part of the funding of OSDD comes from the commitment of the Government of India of Rs 46 crores for the 11th plan period. OSDD offers a model of open innovation in pharmaceutical research as it concurrently carries out research in many areas of drug discovery.

With many eminent scientists playing an active role, OSDD also has a large number of youngsters who want to do science and make a difference. From remote regions of the country they get connected through the website and network with peers to solve challenging problems in drug discovery.

One of the OSDD project which has made a big impact is the collaborative annotation of the bacteria causing TB, namely *Mycobacterium tuberculosis* (Mtb). The scientific purpose was to

improve the understanding of the biology of the organism to develop better tools to tackle the pathogen. It was done through a collaborative project involving about 800 researchers from India and abroad. They finished the task of re-annotation which involved reading of published literature from 1960 onwards and capturing the data in those papers. The task, which some experts estimated would take 300 man years was accomplished in four short months; amply demonstrating the power of collaborative research and what youth-power can do, given the right platform and guidance.

Enthused by this result OSDD is currently pursuing a collaborative Chem-informatics programme where about 400 researchers are participating.

All such top end research calls for a highly sophisticated collaborative platform. M/s Infosys has created a web 2.0 collaborative platform using open source tools in collaboration with OSDD for TB research. This was done pro bono by Infosys showing their commitment to support a scientific project seeking to develop drugs for the diseases that affect predominantly the poor.

OSDD provides an alternative way of looking at Intellectual Property as a tool of research. In the wake of failure of the patent driven model for drug discovery, OSDD treats its entire work as a collective property of the community while each contributor gets credit of the work done through a micro attribution system. The drugs that come out of OSDD are promised to be manufactured on a non exclusive basis, like a generic drug, removing the monopoly attached to drug production. This will ensure that the drugs are available and affordable in the developing world. OSDD has innovative ways of looking at patents as a concept. It is currently working on optimizing a patented molecule as a drug. OSDD plans to use this patent to ensure the drugs are affordable in the market by ensuring non exclusive licensing. This is an innovative way of using patents to the benefit of poor patients.

International Competitiveness

To be internationally competitive, we should incorporate courses in regulatory jurisprudence so that newer legislations, domestic as well as international, are understood and implemented with utmost care and speed. Our courses must include exposure to guidelines issued by International Conference on Harmonization (ICH), Good Manufacturing Practices (GMP), Good Laboratory Practices (GLP), Good Clinical Practices (GCP) and Generic Clearance Procedures for pharmaceutical products. Also, for submissions of technical dossiers for exports, we must familiarize students with regulatory specifications of international agencies and with our national book of standards for drugs, the Indian Pharmacopoeia, and other similar international compendia. As you may be aware, the Government has decided to share India's traditional knowledge in medicine with other countries in a digitally documented form, so that they can reject any patent application in their countries which use India's centuries old wisdom. This is an essential step for protecting our intellectual property rights.

Upgradation of the pharmacy education system

For enabling pharmacists in India to offer world class professional service, we must create continuing education as a pre-requisite for all pharmacists. The education system must train him or her to become lifelong learner. Pharmacy colleges can have a collaborative program with Pharma industries and hospitals for designing an appropriate continuing education course.

I understand that the Pharmacy Council of India has decided to make a degree in pharmacy as the minimum qualification for registration of pharmacists. Also, education-wise, we have three categories of pharmacists who are registered with the State Pharmacy Councils: those registered before the enforcement of the Pharmacy Act with only experience as the criteria for enrolment; those registered with 10+2 or intermediate plus one

diploma qualification; and, those registered with 10+2+2 diploma qualification. For all those who are currently practicing pharmacy, we must provide opportunities to upgrade their knowledge by carefully drafted condensed course of education and training. Every effort should be made to upgrade the existing persons to the level required for the degree program proposed by the World Health Organization (WHO) in their report entitled "The Role of Pharmacists in the Healthcare System".

Now, I would like to discuss about the need for inculcating entrepreneurship amongst pharma students.

Entrepreneurship

The aptitude for entrepreneurship should be cultivated right from the beginning and in the college environment. We must teach our students to take calculated risks for the sake of larger gain, but within the ethos of good business. They should also cultivate a disposition to do things right. This capacity will enable them to take up challenging tasks later and create small and medium pharma industries. The next important requirement of education system is the inculcation of moral leadership.

Moral leadership

Moral leadership involves two aspects. First, it requires the ability to have compelling and powerful dreams or vision of human betterment. Moral leadership requires a disposition to do the right thing and influence others also to do the right things. There is a perception that a large number of pharmaceutical products sold in India are counterfeit or of substandard quality. These drugs are generally made by unscrupulous elements and supplied surreptitiously to chemist shops through illegal channels. The pharmacy education has an important role to play in equipping the students with the knowledge and ability to detect the entry of unauthorized drugs into circulation. Also, every

effort should be made to check the manufacture, sale and distribution of spurious drugs. The Central and State governments have to ensure that the Drugs and Cosmetics Act is properly enforced to check this nefarious practice. Pharmacists must ensure that their sources of supply of drugs are reliable to check the menace of spurious drugs. The pharmaceutical curriculum must include subjects which will enable detection of spurious pharmaceutical products by all pharmacists.

Conclusion

Friends, in conclusion, for preparing future pharmacists with high values and ethical principles, we must build in our curriculum attributes enshrined in Good Education Practices such as care-giver, decision maker, communicator, leader, manager, life-long learner and teacher. As you are aware, profile of drugs are continuously varying in view of the characterization of the genes and the chromosomes. It is possible to design a genetic drug in future to suit a particular person with a particular disease. Pharma curriculum must include gene characterization and proteomics in the syllabus since it will be the future trend.

For preparing pharmacists towards drug discovery and development research, continuous evaluation and updation of educational programs is required with the introduction of molecular biology, biotechnology, nanotechnology, pharmacogenomics, pharmaco-vigilance, pharmaco-economics, pharmaco-epidemiology, and a host of tools like molecular modelling, combinatorial chemistry, high throughput screening, etc.

I congratulate all the member participants of 64th Indian Pharmaceutical Congress here at Chennai. My best wishes to the Pharma community in their mission of quality healthcare delivery to all the citizens of the country, particularly in the rural areas.

May God bless you.

Dear friends, now I would like to administer a five point oath for the Pharma students and Pharma professionals.

1. I realize Pharma is a noble profession.
2. I will always apply science and technology in pharmaceutical work.
3. I realize that pharmacy can provide cost effective pure drugs and medicines to the people.
4. While I am working in Pharmacy from design to formulation development, testing, quality control and marketing, I realize any flaw knowingly or unknowingly will result into a loss of human life. Hence, I consider every action of mine will be transparent and true.
5. I love my Pharmacy profession and I consider it as an honor to work as a Pharmacist. May God help me to serve the humanity.



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

Presidential Address Delivered by Dr. K. Chinnaswamy During the Inauguration of 64th IPC, Chennai

On 6th December 2012

Pharmacy Education: Innovation, Strategies and Globalization

It is my pleasure to extend a warm welcome to all the delegates attending the 64th Indian Pharmaceutical Congress (IPC), the historical event being organized here at the SRM University campus, Chennai. This three day event is organized this year by the Association of Pharmaceutical Teachers of India (APTI). The Indian Pharmaceutical Congress is an important event for the Pharmacy professionals and is quite often known as the spirit of the profession. Taking forward the Pharma Vision 2020, the theme for this year's Congress is **“Pharmacy Education: Innovation, Strategies and Globalization”**.

Pharmacy education in India has entered the second decade of the 21st century. Pharmacy education in the country continues to face a number of pressing issues that threatens its quality, at a time when globalization of pharmacy education and the Pharmacists work force is taking place. While the Pharmacists have unprecedented opportunities in the era of globalization and expanding roles and responsibilities, pharmacy education too needs to respond to these challenges from a global perspective with appropriate strategies in this environment. Innovation in curriculum, best practices in teaching and learning methodologies, sharing of educational and Pharmacy practice experiences from different parts of the country and globe if possible and quality assurance in pharmacy education could serve to overcome the challenges and enhance the quality of Pharmacy education and Pharmacist-provided patient care.

According to the Price Waterhouse Cooper's report Pharma: Vision 2020, the pharmaceutical market is anticipated to more than double to US\$1.3 trillion, with the E7 countries – Brazil, China, India, Indonesia, Mexico, Russia and Turkey -

accounting for around one fifth of global pharmaceutical sales. Further, incidence of chronic conditions in the developing world will increasingly resemble those of the developed world. The population is growing and aging; new areas of medical need are emerging; and the diseases from which people in developing countries suffer are increasingly like those that trouble people living in the developed world. These changes will generate huge opportunities for Pharma profession. The global population is projected to rise to 7.6 billion in 2020. It is also aging rapidly, by 2020, about 719.4 million people – 9.4% of the world's inhabitants – will be 65 or more, compared with 477.4 million (7.3%) two years ago. Older people typically consume more medicines than younger people; four in five of those aged over 75 take at least one prescription product, while 36% take four or more. So the grey factor will boost the need for medicines dramatically.

Clinical advances will reinforce this trend. The improvements of the past few decades have already converted some previously terminal illnesses into chronic conditions, thus increasing long-term demand for therapies to manage such diseases. The number of deaths from heart attacks has declined by over 50% in most industrialized countries since the 1960s, for example, while five year survival rates for US patients with cancer (expressed as an average for all sites) have risen from 53% in the mid-1980s to 66% today. The number of Indians with diabetes is projected to reach 73.5 million in 2025. The direct and indirect costs of treating such patients are currently about \$420 per person per year. If these costs remained the same as they are now, India's total bill for diabetes would be about \$30 billion by 2025. But as its economic wealth grows and standards of care

improve, treatment costs are likely to rise. The US spends an average \$10,844 per year on each patient with diabetes. If India's per capita expenditure rose to just one-tenth of this level, the total cost of treating all patients with diabetes would be \$79.7 billion by 2025. The value of prophylaxis in India alone would thus be substantial; preventing 10% of the population from developing diabetes would save nearly \$8 billion a year.

By 2020 the Pharma operates will be very different from that which prevails today. One of the recurring motifs in all the shifts is globalization – the globalization of the markets, as demand for medicine rises in the developing world; the globalization of R&D, as a growing share of R&D migrates to Asia; the globalization of the regulations governing the development of new medicines, as national and federal agencies collaborate; the globalization of information, as healthcare payers share data on the clinical and financial performance of medicines and last but not the least the globalization of Health work force as migration of health professionals will be inevitable to meet the increasing health care demands.

For the pharma sector to thrive in this new environment, it will have to make sweeping changes throughout the value chain. Pharma profession cannot do everything itself. It cannot train a new generation of research scientists unless there are scientists to train. We cannot expect charities and individual philanthropists to fund the research that is required to develop new therapies. Investing in R&D labs in universities, pharmacy colleges, specialist teachers and giving pharmacy education & academic research a more prominent place, restructuring of curriculum to meet the emerging needs, would encourage more students to pursue research at the university, thus creating a larger pool of researchers on whom the industry

could call.

The report also indicates that the current pharmaceutical industry business model is both economically unsustainable and operationally incapable of acting quickly enough to produce the types of innovative treatments demanded by global markets. In order to make the most of these future growth opportunities, the industry must fundamentally change the way it operates.

Some of the major changes the industry will have to undergo are:

- Health care will shift in focus from treatment to prevention
- Pharmaceutical companies will provide total health care packages.
- The current linear phase research & development process will give way to in-life testing and live licensing, in collaboration with regulators and health care providers
- The traditional blockbuster sales model will disappear.
- The supply chain function will become revenue generating as it becomes integral to the health care package and enables access to new channels.
- More sophisticated direct-to-consumer distribution channels will diminish the role of wholesalers.
- The need for clinically trained pharmacists to provide pharmaceutical care and personalized medicine.

By broadening our horizons and respecting Pharmacy education and practice worldwide and by fostering national and international collaborations, pharmacy educators can strive to produce the next generation pharmacist with global competencies and who can respond to local needs in providing pharmaceutical services and patient care.

Pharmacy Education:

Why is pharmacy education important?

“Inadequate human resources for health, including pharmacists and pharmacy technicians, threatens to undermine all efforts to strengthen health systems and improve healthcare”

Report of the 2006 UN Millennium project taskforce on HIV/AIDS, malaria, TB and access to essential medicines.

The term “pharmacy education” refers to the educational design and capacity to develop the workforce for a diversity of settings (e.g., community, hospital, industry, research and development, academia), across varying levels of service provision and competence (e.g., technical support staff, pharmacist practitioners, Pharmaceutical scientists, Pharmaceutical regulators, Academicians...), and the scope of education (e.g. undergraduate, post-graduate, doctoral and life-long learning).

Pharmacy workforce demands are incredibly diverse and complex, often varying widely within and between regions. Therefore, a “one size fits all” educational model or system is neither practical nor desirable. Need based education is a development strategy that calls for any given system to assess the needs of its community and then develop or adapt the supporting educational system, accordingly. The development of optimal educational systems should progress through a cycle that first seeks to assess and understand the needs. Upon determining the needs, the services required to meet those needs can be defined and the competencies of the workforce should be aligned to the delivery of these services. There is often a lack of consensus in assessing the needs of communities as each stakeholder engaged in the process has a different perspective. Therefore it is all the more important to have a clear, shared vision of how pharmaceutical services can meet the health-related needs of the country and to extend

this vision to all those involved in meeting these needs, from industry to hospital, from professionals to funders, from educators to politicians, and ultimately to patients and their caregivers. It also highlights the importance of adopting a vision and action plan for pharmacy profession that is grounded in a hierarchy of healthcare needs, progressing from local to regional, to national, and then international needs. Many countries are introducing, expanding, or undertaking major reform of pharmacy education. Such developments must, however, be accompanied by robust systems to assure the quality of educational structures, processes and outcomes.

Pharmacy Education – A Global Perspective:

The world of pharmacy and pharmacy education is small and so very interrelated. Issues that impact the academy in one region of the world resonate elsewhere to a significant degree as well. The need for timely dissemination of current issues in pharmacy education in a more global focus to meet extent needs worldwide to compare and contrast pharmacy education needs cannot be overemphasized here!

The World Health Report 2006 'Working together for health', estimates that 57 countries worldwide are experiencing a crisis in human resources for health, though the particular importance of an adequate pharmaceutical workforce is often

overlooked. The development, production, distribution and appropriate utilization of medicines, as well as the supportive functions of regulation, operational research, and training, all require the involvement of competent pharmaceutical professionals. The successful execution of these activities is essential for a strong health system. The dire shortage of pharmaceutical personnel, therefore, has deep implications for population health.

The first step in developing successful strategies, which aim to build the capacity of human resources in the pharmaceutical sector, is to engage in methodologically sound assessment upon which evidence-based policies can be built. For this a survey on human resources for the pharmaceutical sector is essential. The survey should collect responses from Ministries of Health, regulatory bodies, universities, manufacturers, and pharmaceutical personnel in selected facilities, on the following questions:

- How many workers currently provide pharmaceutical services in both the private and public sector?
- What is the distribution of pharmaceutical personnel in the country, both geographically and among sectors (public, private, teaching etc)?
- Do the work conditions differ between the public and private sectors?
- Does job satisfaction vary for pharmacists according to whether she/he works in the public or private sector?
- How many pharmacists have left the country in previous year or think of leaving the country?
- Is the curriculum current and relevant to meet the needs of the services being rendered by the Pharmacist?

After data collection and analysis, the report on the results, should be presented to all key stakeholders, governments, including ministries of health,

pharmacy council and academic institutions. After a broad-based consultation process on how to translate the findings into action, each sector should produce its own Strategic Framework for Human resources in the Pharmaceutical Sector.

Pharmacy Education – An Indian experience:

India's Pharma education has to address a series of challenges to elevate it to offer an international quality education by 2020. To confront these concerns and new challenges, there is an urgent need to reengineer the pharmacy education and scope of Pharmacist. There is need to develop a vision framework, competency guideline to come out with a quality assurance system and build academic and institution capacity.

India has experienced an expansion of its pharmacy educational centers but an uneven distribution has left poorer states with proportionally fewer colleges and the quality of the education is variable. As clinical services provided by pharmacists are fairly new to India, which has traditionally been industry-focused in its pharmacy degree programmes, there is also a shortage of clinical pharmacy trainers.

There have been several national and international initiatives in addressing quality issues in Pharmacy education in India. The Pharmacy council of India has proposed that by 2020 the National Quality Assurance Task Force will help overcome weaknesses in the education system and help produce appropriately-trained pharmacists with the competencies to not only meet the demands of our country, but also be part of a global competent healthcare workforce. Similarly the ACPE International Services Program (ISP) offers consultation, training and program certification to international stakeholders who seek guidance related to quality assurance and advancement of pharmacy education. The expertise, global

perspectives, staff resources, and formal processes within the ISP support international stakeholders to advance pharmacy education and quality is that the Universities, Colleges and Schools of Pharmacy should facilitate collaborative working relationships with other departments of the academic institution, as well as research, business, stakeholders, including students, wherever possible, in quality assurance and quality advancement strategies and activities. They should be able to foster and maintain an institutional culture of assessment and continuous quality improvement.

Pharmacy Education – Challenges

Globally, Pharmaceutical companies are not philanthropic ventures staffed by saints and, despite any noble intentions; they remain under pressure to satisfy the financial expectations of their shareholders. The pharmaceutical industry typically aims to attract the top pharmacy graduates and postgraduates from the best universities in the world. Moreover, an already-competitive market will become even more internecine, as two trends reshape the western world: the shrinking of the working-age population; and the decline in the number of students reading traditional science degrees or choosing a career in scientific research. As these trends take effect, Pharma will need to fish in fresh waters for the skills it requires. Hence some organizations are now looking to new markets. It is Asia – China, India and Singapore in particular – which has attracted the most interest so far. This is partly because English is widely spoken in India and Singapore, and also because standards of education in the region are generally high, as well as the fact that equivalent technologies and communication facilities exist there. Access to an educated workforce is one big advantage.

The Challenges that pharmacy education faces presently include:

1. Workforce shortages and education capacity more and more of the best talent believes in migrating to the developed countries for better job opportunities bringing about workforce imbalances. Migration is a symptom, NOT the cause – “International migration is neither the main cause nor would its reduction be the solution to the worldwide health human resources crisis.” (J Dumont, P Zurn, OECD. Immigrant health workers in OECD countries in the broader context of highly skilled migration 2007)
2. New sciences and technologies transforming the R & D process and products- Given the speed at which knowledge is growing, it is becoming more and more difficult for companies to stay at the forefront of learning and development and greater competition is accelerating the speed at which products are launched, therefore increasing the pressure on sales and marketing. This brings to the forefront the issue currency of the knowledge and training of the pharmacy workforce and the need for lifelong learning.
3. Consolidation of the pharmaceutical industry is reducing the overall headcount- Though this is a concern but new sciences and technologies are producing new “industries” which also require people with pharmacy qualifications. However, emerging sciences and technologies also need changing/updating the sort of skills that are needed.
4. Virtual working and shared talent- When physical presence is no longer the norm, with improvements in technology and the development of self-service solutions, shared service centers and outsourcing has

become the way in reducing cost! The profession will have to gear up to this newer concept and professionals working for multiple organizations working from home.

5. Training the trainers-

Unfortunately the Human resource in academic institutions today has a very poor understanding of the need of stakeholders and there is also reluctance in appreciating the need for currency in the need for knowledge. This needs to be addressed by the statutory bodies in emphasizing the need for continuous professional development.

6. Experiential training and innovation in teaching learning processes-

With the increase in the number of colleges there is a decreased emphasis on experiential training in industry or hospital sites. This brings about decreased appreciation of the challenges in the work environment resulting in not being able to meet the expectations of the industry. The need for innovation in teaching and learning processes is emphasized here.

7. Curriculum vs Need/Expectations-

There seems always an ever increasing gap between the expectations of the stakeholders in the profession vs the curriculum being taught to the students. This needs to be addressed by having stakeholders in curriculum planning and implementation.

8. Research in universities and Pharmacy colleges-

The emphasis on research at universities and pharmacy colleges is diminishing alarmingly. This is primarily due to increase in numbers of students enrolling for their postgraduate and doctoral programmes resulting in poor quality pursuit of research. There is an urgent need to infuse quality in the research programmes

failing which we may end up in creating workforce which is not industry ready.

9. Regulation of pharmacy education-

With multiple regulatory agencies and varying standards provided by different accrediting bodies the pharmacy education in our country is at crossroads. There can be no better time than the present to make a unified voice for the need of effective regulation of pharmacy education and a single regulatory mechanism.

10. Government funding for Pharma sector human resource development –

The government spending on the human resource spending in this essential sunrise sector is negligible when compared to other health science disciplines. There is a need for the government to invest in the human resource development through public private partnership model.

11. Leadership and advocacy-

The role of professional organizations and statutory bodies cannot be overemphasized here. The Pharmacy profession in general and pharmacy education in particular, should take upon themselves the aggressive role of leadership and advocacy at appropriate forums to infuse the much needed confidence among young professionals and aspirants who would like to take pharmacy as a career.

12. Recognition-

The social status awarded to a profession, results from the long-term psychological conditioning. Social respect of a profession usually goes up when it is in a position to directly interact with society. Pharmacists working in the industry interact with the society through a product designed or evaluated by him. Although an important constituent of the healthcare sector, unlike medicine, engineering and architecture, Pharmacy is yet to establish an identity in

India, as a profession. A measure of this prejudice is that Pharmaceutical Science is not included in the Indian Civil Services examination. It is in fact, a kind of discrimination towards this noble profession and subject by the Govt. of India.

Pharmacy Education – Innovations and strategies

Pharmacy Education – Innovations and strategies
The Pharmacy education needs to innovate and develop appropriate strategies to meet the above challenges. The four innovation pumps that can help take the profession to the next level are-

1. Science based innovation – Science play an unquestionable role in advancing knowledge. However although it can produce rapid progress in knowledge, its finding are often generalized and applied only slowly. There is a need to innovate in teaching the advances in pharmaceutical sciences in education through continuous updating and need based curriculum which can catalyze research leading to drug discovery and development.
2. Collaboration – among users and / or doers. New actors are being engaged in innovation processes, develop collaborative modes of knowledge generation, and this creates new opportunities. The Pharmacy profession has become increasingly possessive of its identity and has stopped to collaborate with other professions and within the profession with the various facets of profession.

There is a need to stimulate collaboration without sacrificing professional interests particularly with the other players in the health profession.

3. Modular structures – each with freedom to

innovate yet joined together in a whole innovative system. This devolved character of innovation in complex technological systems creates new needs for co-ordination and certification. Pharmacy education needs to shed its shackles of conventional training and teaching.

4. Information and communication technology (ICT) – harnessed effectively as an instrument of innovation, can be powerful trigger for transforming activities. ICT is yet to be fully exploited by the pharmacy education and profession. It is time that, the pharmacists of the country become a part of the information and communication technology revolution, lets they are left behind.

Vision 2020 for Pharmacy Education – Recommendations:

- Create opportunities and provide avenues for fostering the world's best human resources and develop individuals with the capacity to grasp the essence of issues, understand and appreciate others, and have the courage to take the lead as cultured professionals who are worthy of being 21st century global citizens.
- Enhance the abilities of Pharmacy education and research support staff by expanding the scope of their work and delegating greater responsibilities. Indicate the capabilities that pharmacy teachers and pharmaceutical scientist should possess, and present models for career development and skills improvement.
- Recognize individuals who have made a valuable contribution to the progress of the Pharmacy profession and education.
- Introduce and promote innovative learning and teaching practice supported and enabled by information and communication technology to enhance teaching and learning

approach. Create means for sharing innovative classroom/administrative strategies and techniques.

- Improve curriculum design, assessments, and/or administration system in universities and Pharmacy colleges to promote excellence in Pharmacy education and research.
- Continuing education and continuous professional development should become a part of lifelong learning process for all working professionals and teachers. Improve motivation and performance of the education community.
- Government to invest in Human Resource Development and Research Development of universities and pharmacy colleges for the further strengthening of Pharmacy Sector through public Private partnership model.
- Government to provide fellowships for meritorious student of undergraduate, postgraduate and doctoral levels for encouraging bright student particularly from rural areas to take Pharmacy as a career.
- Promote Industry Institute Interaction in a structured manner so as to provide experiential training to the students.
- Recognize Pharmacy profession and Pharmacists through the institution of National awards and celebration of National Pharmacists Day.
-

- Amend the various provisions of the National acts where entry to pharmacy profession in highly skilled areas is restricted only to the trained and qualified pharmacy professionals under the Pharmacy Act 1948.

I would like to conclude that this occasion cannot be more befitting as it was, His Excellency Dr APJ Abdul Kalam, as the then President of India in 2003 had inaugurated and presented to the nation, the Charter of Pharma vision 2020 eve of the Indian Pharmaceutical Congress at Chennai and exactly a decade later we are discussing the strategies for innovating pharmacy education to go global. I am sure the visionary address of Dr Kalam is going to inspire and ignite the minds of the Young Pharmacists for this country. The legacy of the Pharmacy profession is theirs now, our generation had nurtured it to the present and it is they who through the wings of fire and passion for the profession have to take Indian Pharmacy Education and profession to the Global platform as health care providers, Pharmaceutical scientists, Pharmacy educators, Pharmacy policy makers, Pharmacy regulators and above all as one of the most respected citizens of the society.

I thank the Association of Teachers of India for nominating me as the President of the 64th Indian Pharmaceutical Congress and wish the Congress all success.



64th Indian Pharmaceutical Congress – Chennai

LOC Secretary Mr. J. Jayaseelan's Report

The 64th Indian Pharmaceutical Congress was organized by Association of Pharmaceutical Teachers of India on 7th, 8th and 9th December, 2012 at SRM University, Chennai. The theme of the congress was **“Pharmacy Education: Innovation, Strategies and Globalization”**

The members of the core committee for the Congress were: President - Prof. K. Chinnaswamy, Chairman - Mr. S. V. Veerramani, Co Chairmen – Mr. G. Selvaraj, Dr. F. V. Manvi & Dr. P. G. Yeole, Vice Chairmen - Mr. R. Narayanaswamy, Dr. V. Ravichandiran, Mr. M. M. Yousuf & Mr. R. Sabapathy, Organizing Secretaries - Mr. J. Jayaseelan & Mr. B. G. Shivananda, Treasurers – Mr. Rajesh H. Bhandari & Mr. V. Madhavan and Joint Secretaries - Dr. Sirse Krantikumar, Mr. T. Sathish, Dr. R. Ilavarasan & Dr. Rajkumar Virbhadrappa Shete

The Chief Patrons of the Congress were Dr. T. R. Pachamuthu, Chancellor, SRM University, Mr. G. N. Singh, Drug Controller General of India and Dr. B. Suresh, President, Pharmacy Council of India.

A Press meet was conducted on 5th December, 2012 at Park Sheraton to brief about the Congress. The Press and media responded very well and have given very good coverage for the Congress. Around 6000 delegates participated in the congress.

A Pre-Conference workshop was held on 5th & 6th December 2012, which was inaugurated by Chief Guest Thiru. G. Selvaraj, Director of Drugs Control, Tamilnadu and Dr. G. Jagadeesh of US Food and Drug Administration, Maryland, USA. Thiru. S. V. Veerramani, Chairman, LOC gave the felicitations. The Presidential address was given by Prof. K. Chinnaswamy, President, 64th IPC. Pre-conference Workshop manual was released by Thiru. G. Selvaraj and first copy was received by

Thiru. M. M. Yousuf. The topic of the Preconference Workshop was **“The Critical Steps for Successful Research: The Research Proposal and Scientific Writing”**. The Workshop Convener was Dr. Mohammed Naseeruddin Inamdar of Al-Ameen College of Pharmacy, Bangalore.

On 6th December 2012 evening the Congress was inaugurated by our Chief Guest, His Excellency Dr. A. P. J. Abdul Kalam, Former President of India. Felicitations were done by Guest of Honour Dr. T. R. Pachamuthu, Chancellor, SRM University. Welcome address was given by Thiru. S. V. Veerramani. Thiru. A. Krishna Dev, IPCA Secretary read the Secretary's report.

Prof. K. Chinnaswamy, President for the Congress presented his Presidential Address. Vote of Thanks was given by Thiru. J. Jayaseelan, Organizing Secretary. Chief Guest His Excellency Dr. A. P. J. Abdul Kalam released the Souvenir. Various awards were presented on the occasion.

The Chief Guest in his address said that “Pharmacy is a very important component of the National Health System. He spoke about the production and supply of cost effective drugs. He also pointed out that out of every 3 tablets consumed in the world, 1 tablet is from India. He spoke about the **Open Source Drug Discovery** started by CSIR. The Inauguration was very well attended.

On 7th December 2012 in the morning, the inauguration of the Scientific Session was done by Chief Guest Dr. G. N. Singh, Drug Controller General of India. Guest of Honour was Thiru. Ravi Pachamuthu, Chairman, SRM University. Felicitations were done by Dr. B. Suresh, President, Pharmacy Council of India. Prof. K. Chinnaswamy, President IPCA, released the Scientific Abstracts.

Pharmaceutical EXPO 2012 was inaugurated by Thiru. Ravi Pachamuthu and inauguration of Pharmexcil Buyer Seller meet was done by Smt. Mridul Jain, Joint Secretary, Ministry of Commerce & Industry.

Out of 103 speakers 19 were from overseas and 84 from India. 19 Symposia, 3 Panel Discussions, 2 Student Forum, Student Quiz, IPA National Elocution Competition, Oral Presentation of selected papers and Women Pharmacists Forum were organized during the congress.

For poster presentation, 3581 papers were received, out of this 3286 have been selected for review. and 2694 papers were accepted.

President's Symposium Topics were Pharmacy Education: Present Status and Future Direction, Global Expectations and Pharma Industry – US and Indian Perspective

B. V. Patel Memorial Lecture Topic – Issues and Challenges with Indian Drug Regulatory System

M. L. Khorana Memorial Lecture Topic – Pharma Vision 2015 & Beyond

K. C. Chatterjee Memorial Lecture Topic- Leadership and Governance in Pharmacy Education

Symposia held during the Congress:

1. Indian Pharmaceutical Industry in Global Hub
2. Pharmaceutical Exports: Current Trends and Emerging Markets
3. Restructuring of UG and PG Pharmacy Education
4. Recent Advances in Cancer Research, Cell Targeting and Imaging
5. Pharmaceutical Regulations
6. Pharma Business - Opportunities and IPR
7. Pharmacopoeial Standards in Emerging Trends and Challenges
8. Nanopharmaceuticals and Novel Drug Delivery Systems: Present Status and Future

Prospects

9. Current Scenario of Indian Pharma Market
10. Challenges in Clinical Research
11. Pharmaceutical Manufacturing - Environmental Issues
12. Pharmaceutical Marketing: Present Scenario and Challenges Ahead
13. Accreditation and Quality Assurance in Pharmacy Education
14. Pharmaceutical Manufacturing in Herbal Drugs
15. Biosimilars
16. Current Trends and Future Prospects in Pharmacovigilance, Community and Hospital Pharmacy in India
17. Best Practices in Pharmacy Education

Cultural Programmes: On 7th & 8th December 2012 in the evening from 6.00pm Cultural program was organized in association with Madan Babu and Rack Academy. Seven college students participated and gave good performance.

Valedictory Function was presided over by Dr. B. Suresh, President, Pharmacy Council of India. President Prof. K. Chinnaswamy, Thiru. S. V. Veeramani, Co Chairmen, Vice Chairmen, Secretaries thanked the participants of the Congress. All the chief patrons, patrons, sponsors, volunteers, delegates, advisors, task committee members, core committee members all supportive staffs and others were thanked and honored by presenting mementoes.

Thanks giving and Felicitation function for the Sponsors and the supporters of 64th Indian Pharmaceutical Congress was held on 22th December 2012, 6.30 PM at Hotel GRT Grand.

I thank, President, Chairman, Co Chairmen, Vice Chairmen, Treasurer and other office bearers for their effective support to the success of 64th Indian Pharmaceutical Congress

ARTICLES

Pharmaceutical Exports – Current Trends and Emerging Markets

By

Dr. P.V. Appaji - Director General, Pharmexill

Lecture delivered at 64th IPC, Chennai on 7th December 2012

The Humble Beginning Of Indian Pharma Industry

- Indian Pharmaceutical Industry made a Humble beginning in 1901 with a capital of Rs. 700/- (Seven Hundred only) by Acharya P.C. Ray in Kolkata (Calcutta then).
- The second Organization to Join was Alembic Ltd in 1907.
- The first ever API company is Cipla (The Chemical Industrial & Pharmaceutical laboratories) started in 1935 By Mr. Khwaja Abdul Hameed.
- To-day Cipla produces the largest No of Anti Retroviral Drugs by way of actual doses. 40% of the HIV patients on ART therapy, world over are on Cipla's products.
- In 1990 's India attained positive trade balance in drugs, Pharmaceuticals & fine Chemicals and never looked back.

International Pharma Trade Scenario

- World's Pharma Market for 2011 - US\$956 bn.
- Growing at 5.1% YoY.
- Expected to reach US\$1,200 bn by 2016
- Generic Market in Yr 2011 is US\$242 bn
- Is expected to touch 432 bn US\$ by 2016
- Pharma Emerging markets expected to grow at 14- 17% till 2014
- EU, USA & Japan constitute 74.5% of world Pharma Market during 2011.
- Expected to constitute only 57% by 2015.
- Generics constituted 25% of total market during 2011.
- Expected to reach 35-38% by 2016
- India is among the Key players in Emerging Pharma Markets

(source: IMS)

Efforts to Enhance Exports

- Launched Brand India Campaign in CPhI Japan.
- Continued in CPhI Indonesia.
- Energised the campaign further with India Show at CPhI Worldwide ,Madrid.

India "The Pharmacy of the World"

The Indian Pharma Industry: The Flag Bearer

India's Exports of Pharmaceuticals during the last Five years(USD billion)

2007-08	2008-09	2009-10	2010-11	2011-12	CAGR%
7.6	8.8	8.95	10.7	13.2	16

India's share in World Generic Market is 3.3%, excluding India's domestic market

Over 55% exports of India are to highly regulated markets.

U.S.A the largest exports destination followed by UK

Largest exporter of formulations in terms of volume during 2010 with 14% market share

Source: UN COMTRADE

India's Exports of Drugs, pharmaceuticals & fine chemicals (figs. in US\$ Bn)

Year	Exports (US\$ Bn)
2007-08	7.6
2008-09	8.8
2009-10	8.95
2010-11	10.7
2011-12	13.2

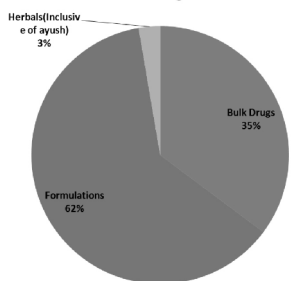
India's Pharmaceutical Contribution to Global HealthCare During 2011-12

Region	Contribution (%)
North America	27%
EU	20%
Africa	18%
Middle East	7%
Asia (Excluding Middle East)	4%
CIS	5%
LAC	6%
Oceania	2%

India's Pharmaceutical Contribution to Global HealthCare During 2011-12

Region	Values in USD million	% Contbn
North America	3509	27
EU	2576	19
Africa	2256	17
Middle East	919	7
Asean	857	6
LAC	830	6
CIS	693	5
Asia (Excluding Middle East)	564	4
South Asia	484	4
Oceania	223	2
Other European Countries	156	1
Other America	99	1
Others	44	0
World	13211	100

India's Pharmaceutical Contribution to Global HealthCare During 2011-12



India's Pharma Exports Region wise (USD mn)

Region	2009-10	2010-11	2011-12	Gr Fy12 %	% Contbn 2012
North America	2118	2644	3509	33	27.0
EU	1749	2005	2576	28	19.0
Africa	1406	1824	2256	24	17.0
Middle East	759	825	919	11	7.0
Asean	608	693	857	24	6.0
LAC	631	696	830	19	6.0
CIS	527	718	693	-3	5.0
Asia (Excluding Middle East)	423	460	564	23	4.0
South Asia	366	409	484	18	4.0
Oceania	129	156	223	43	2.0
Other European Countries	142	128	156	22	1.0
Other America	84	144	99	-31	1.0
Others	13	9	44	396	0.0
World	8955	10711	13211	23	100.0

Source: DGCIS

Top 10 Destinations of India's Pharma Exports During 2011-12 (USD mn)

Country	USD mn	CAGR% for last Syrs	YoY%	%contbn
USA	3255	23%	36	25
UK	491	15%	29	4
Germany	461	8%	33	3
Russia	410	7%	-2	3
South Africa	383	23%	19	3
Nigeria	310	17%	36	2
Brazil	278	10%	24	2
Canada	254	7%	34	2
Kenya	230	26%	24	2
Netherlands	230	17%	19	2
Total exports	13,221	16%	23	100

PRESENT SCENARIO OF GLOBAL PHARMACEUTICAL MARKET(USD BN)

Category	2011	CAGR 2007-11	% contbn in 2011
Global	956	6.1	
Developed	627	3.7	65%
USA	322	3.4	34
Japan	111	3.9	11.6
Germany	45	4.8	4.7
France	41.3	2.3	4.3
Italy	28.6	4.1	3
Spain	22.7	4.4	2.3
UK	21.5	3.9	2.25
Pharma Emerging	194	16.3	20
China	67	23.5	7.01
Brazil	30	15.6	3.14
Russia	16	15.7	1.67
India	14.3	15.4	1.50
Tier-3	67	11.2	7.01
Rest of World	135	6.8	15%

Source: IMS

Expected Scenario in 2016(Values in USD billion)

Category	Expected by 2016	Expect Cagr 2012-2016	Expcd Contbn
Global	1200	3-6%	
Developed	660-690	1-4%	55-57
USA	350-380	1-4%	30.4
Japan	105-135	1-4%	10.8
Germany	39-49	0 to-3%	3.9
France	31-42	-1 to -2	3.4
Italy	23-33	0 to-3%	2.6
Spain	13-23	-1	1.84
UK	18-28	0.30%	2.3
Pharma Emerging	345-375	12-15%	30
China	155-165	15-18%	13
Brazil	42-52	12-15%	4
Russia	23-33	10-13%	3
India	24-34	14-17%	3
Tier-3	90-100	7-10%	7
Rest of World	140-170	2-5%	13%

Source: IMS

India's exports of Formulations to Developed Countries(USD mn)

India's exports of Formulations (USD million)			
Country	2008-09	2009-10	2010-11
Formulations			
Canada	33.94	40.9	48.9
France	64.95	71.91	83.96
Germany	90.59	109.96	140.54
Italy	9.4	12.69	16.75
Japan	10.2	10.37	14.6
Korea Republic (South)	11.55	9.77	7.62
Spain	15.53	20.68	24.64
UK	192.17	269.28	276.37
USA	952	1243.83	1746
Grand Total	1380.33	1789.39	2359.38

Source: DGCIS

India's exports of formulations to Pharma emerging and rest of the world (Including Tier-2)(values in USD mn)

India's exports of Formulations (USD million)			
	2008-09	2009-10	2010-11
Country	Formulations	Formulations	Formulations
Brazil	144.54	79.06	87.66
China	12.54	14.03	8.59
Russia	321.25	258.52	402.52
Total of Three	478.33	351.61	498.77
Rest of the world	3249.34	3042	3624

Source: DGCIS



Observations:

Global generic spending is expected to increase from \$242Bn to \$400-430Bn by 2016, of which \$224-244Bn of the increase is from low-cost generics in pharmerging markets.

Patent expiries will reduce brand spending in developed markets by \$127Bn over the next five years offset by generic spending. Pharmerging countries, which account for nearly two-thirds of the world's population, will average \$91 in drug spend per capita in 2016 from the present USD 39

Increased generic spending in developed markets in the next five years will be driven by generic competition due to patent expiries, with some additional increases due to expanded generic use for off-patent molecules.

In pharmerging markets, generic and local companies will drive most of the increases in spending.

The largest segment of growth in the next five years will be pharmerging markets, driven by increased access through a variety of healthcare reforms and economic growth.



Source: IMS

Some salient features of Indian pharmaceutical Industry

- During the year 2010 as per UN Comtrade India ranks as largest exporter of formulations measured by Volumes.(14%)
- As on 31st March 2012, Thirty six percent of type-2 active DMF's (API's) filed with USFDA are from India.
- Indian companies hold 20% of USFDA Generic drug market authorizations(ANDAs) as on 31st March 2012.
- 26% of EDQM API authorizations are for Indian companies.
- As per Deutsche bank reports Cost of Pharmaceuticals production in India is only between 40 to 50% when compared to western countries.
- As on 31st march 2012 there are over 250 manufacturing sites approved by USFDA the highest number in a single country outside USA.
- The above facts amply demonstrate India's capabilities, chemistry skills & abilities to adhere to highest standards of manufacturing practices second to none in the most cost efficient manner.



Some salient features of Indian Pharmaceutical Industry

Autho rity	Name of Regulatory Agency	Nos.
USA	DMFs filed with U.S. FDA (companies)	225
	No: of Sites(Bulk drugs + Formulations) registered with US FDA (as on 31 Jan 2012)	513
	Total No Of DMF's (Type II Active) Filed from India (as on 31st March 2012)	2841
	ANDAs	2076
	Formulation companies with USFDA approvals.	29
EURO PE	Number of CEPs received (as of 30th March 2012)	851
	Number of companies with CEPs	131
	Number of Molecules for which CEPs have been filed with EDQM	317
	No of Sites approved by EDQM In India(As on 27th July 2012)	253
	UK MHRA (Medicines Healthcare Regulatory Agency), Market authorizations as March 2012	937
	Number of CEPs with Irish Medicines Board	300
	Number of companies registered in Irish Medicines Board	19
	number of Authorisations with Sweden MPA (Läkemedelsverket)	209
	Number of companies having MA's with Sweden MPA (Läkemedelsverket)	14
	DACA (Drug Administration and Control Authority), Ethiopia (companies)	50
Tanza nia	(TFDA) Tanzania Food and Drugs Authority(Market authorizations)	1379
India	WHO GMP Certified Plants (as per Drug Controller General of India)	1200(a pprox.)

Source: Regulatory Authority websites of respective countries, Pharmexcil Research



Pharmexcil Functions/ Incentives:

- Issue of RCMC
- Organizing Trade delegations/Buyer-Seller Meetings at abroad
- Organizing Reverse Buyer-Seller Meetings in India
- Assisting members to get their MDA/MAI claims refunded from Govt. of India
- Dissemination of trade enquiries received from abroad
- Issue of Certificate of Origin
- Organizing periodical Seminars/Interactive meetings on exports related issues
- Make suggestions to Govt. of India on policy issues relating to Pharma exports
- Make representations to Govt. of India and other agencies in India and abroad to get amicable solutions for the common problems of the industry.

Pharmacy Education: Innovation, Strategies and Globalisation

Present Status and Future Directions

By

Dr. B.Suresh,

Vice Chancellor, JSS University, Mysore and President Pharmacy Council of India, New Delhi
Chairman, Scientific Body, Indian Pharmacopeia

Lecture delivered at President's Symposium, 64th IPC, Chennai on 7th December 2012

Pharma Vision 2020



- In 2003, the Pharma Vision 2020 Charter was released by the then President of India, **Dr A P J Abdul Kalam**, at the 55th Indian Pharmaceutical Congress at Chennai.
- The Vision 2020 is focused on promoting the highest professional and ethical standards of pharmacy, focusing the image of pharmacists as competent healthcare professionals, sensitising the community, government and others on vital professional issues and supporting pharma education and sciences in all aspects.



Pharma Vision 2020



- Indian Pharmaceutical Association once again, with the support of the leaders of the pharmacy profession presented the road map to Pharma Vision 2020 at the 58th Indian Pharmaceutical Congress held in December 2006 at Mumbai.
- The themes of the subsequent Congresses in the country have been centred on Pharma Vision 2020.

Pharma Vision 2020 – Pharmacy education



- The World Health Organisation, in the report of its consultative group on "Preparing the Future Pharmacist" (Vancouver 1997) identified seven roles, (the "seven star pharmacist"), which should be considered essential, minimum common expectations of pharmacists by health care systems world-wide.
 - The identified roles and responsibilities were:-
Care giver Decision maker Communicator Leader
Manager Life-long learner Teacher
- "The pharmacy educators of our country shall imbibe these professional characteristics as required outcomes of basic education and training of pharmacists."**

Pharmacists!



- The pursuit of knowledge, calls on Pharmacists to access their collective intelligence, and 'hidden wealth', to create the futures they want rather than settling for the futures they get, or are thought to seek.



Present Status: Pharmacy colleges and student intake



Course	No. of Instt.	Intake / Annum
D.Pharm	u/s12 686 Conduct (40)	40898 (2270)
B.Pharm	u/s12 822 Conduct (204)	50613 (12100)
Pharm.D.	Conduct 109	3270
Pharm.D.(PB)	u/s12 19 Conduct (25)	190 (250)

Present Status: Pharmacy Faculty Work Force



Faculty Qualification	No.
B.Pharm	7,443
M.Pharm	15,498
Ph.D.	2,514
Others	219
Total	25,674

National Recognition

"The pharmacist, as I had mentioned earlier, is very closely aligned with the health sector. Pharmaceutical care entails the work of addressing a patient's medication related needs. The involvement of the pharmacist in India in this regard has been somewhat restricted, contrary to trends in developed countries. While seeking medical help, we think of a doctor or a nurse or a medical technician, but seldom does a pharmacist come to mind. This needs correction. The Pharmacy Council should work towards creating awareness about the very important role of a pharmacist in the well being and health of an individual."

HER EXCELLENCY THE PRESIDENT OF INDIA,
SHRIMATI PRATIBHA DEVISINGH PATIL



H'ble Minister for Health and family welfare
Sri Gulam Nabi azad

JSS
UNIVERSITY
MYSORE



National recognition

"As everyone else, I also recognise that the pharmacy profession serves the humanity when it is needed the most. Pharmacists are the most accessible health professionals who maintain the respect of their communities through provision of confidential and equitable service and care."

HE The President of India

JSS
UNIVERSITY
MYSORE



National recognition



"The pharmacist in the contemporary template is one who provides a vital connect between the health sciences and the pharmaceutical world. Their work in the medical field has become multifaceted, extending from the manufacturing of quality medicines, to the delivery of pharmaceutical care to patients. Hence, a pharmacist's work is linked with the pharmaceutical and the health sectors - both these in India are fast growing."

CO-PRODUCING KNOWLEDGE & SHARING WISDOM

JSS
UNIVERSITY
MYSORE



- Educational systems, and other institutions- designed for a by-gone Industrial age- have come to realize that they cannot unilaterally light that fire.
- Reshaping themselves into learning organizations, where conversations on how actionable change is brought about, that benefits the learner and teacher, customer and expert become ever more blurred.

'Education is not the filling of a bucket, but the lighting of a fire'
W.B. Yeats



Future Directions: Pharmacy education

JSS
UNIVERSITY
MYSORE



The pharmacy education needs restructuring and reimagining to meet the challenges that have arisen due to the unprecedented expansion in the number of institutions and intake to the pharmacy programmes through-

- Quality assurance of Pharmacy education
- Need assessment and manpower planning
- Quality in Academic Research
- Restructuring curriculum
- Address regulatory challenges
- Respond suitably to Globalization
- Job opportunities

Future Directions: Quality assurance of Pharmacy education

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MYSORE



The need for quality assurance of Pharmacy education cannot be overemphasized in the present educational scenario. This is envisaged through the following initiatives of the Pharmacy Council of India:

- Continuing pharmacy education
- Training the trainers
- Strengthening of Teaching learning processes
- Reengineering the pharmacy curriculum

Future directions: Restructuring Curriculum



- B.Pharm and M.Pharm qualified pharmacists predominantly seek job opportunities in the Pharmaceutical industry.
- The pharmacy curriculum has not kept pace with the advances in the pharmaceutical sciences and research with regard to currency and relevance.
- Need to assess the gaps and set right the mismatch through structured implementation across the country.



Future directions: Manpower survey and assessment



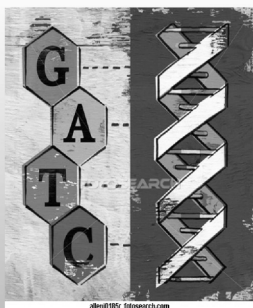
- 1 million pharmacists!
- Diploma, degree and Pharm.D qualified pharmacists.
- Competency, stakeholders expectations and job and professional satisfaction
- Services rendered, liabilities and risks and compensation
- Manpower needs by 2020 to meet national and global pharmacists workforce requirements.



Future Directions: Quality in Academic Research



- Student teacher ratio
- Relevance
- Currency
- Plagiarism
- Industry internship (or taken for a ride!???)
- Patents and publications



Future direction: Regulatory Challenges



- Multiple regulatory mechanism
- Assessment
- Ethical issues
- Responsible philanthropy and social responsibility
- Implementing states and universities
- Regulatory coordination from various pharmacy service providing agencies and governments.



Future directions : Globalisation



- Global competencies and qualifications
- Reverse migration from developing countries



Future Directions: Job opportunities



- Amendment of various pharmacy related acts restricting entry of Non Pharmacy qualified professionals in areas of pharmaceutical expertise
- Nurture pharmaceutical industry and research
- Promote professional pharmacy through entrepreneurship at community pharmacy levels
- Pharmacy practice in hospitals to be made mandatory at public and private levels.
- Promote pharmacy practice and pharmaceutical care in an aggressive manner.

NOTIFICATIONS

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health)

NOTIFICATION

New Delhi, the 5th October, 2012

G.S.R. 748(E). - The following draft rules further to amend the Drugs and Cosmetics Rules, 1945, which the Central Government proposes to make in exercise of the powers conferred by section 12 and section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), after consultation with the Drugs Technical Advisory Board, is hereby published for the information of all persons likely to be affected thereby, and the notice is hereby given that the said draft rules shall be taken into consideration on or after the expiry of a period of forty-five days from the date on which

the copies of the Gazette of India containing these draft rules are made available to the public;

Any objection or suggestion which may be received from any person with respect to the said draft rules within the period so specified shall be considered by the Central Government;

The objections or suggestion may be forwarded to the Secretary, Ministry of Health and Family Welfare, Government of India, Nirman Bhawan, New Delhi-110108.

DRAFT RULES

1. (1) These rules may be called the Drugs and Cosmetics (6th Amendment) Rules, 2012.
(2) They shall come into force after six months from the date of their final publication in the Official Gazette.
(3) Notwithstanding anything contained in the sub-rule (2), these rules shall not apply to the manufacturers, who are having licence for manufacture of drugs, for a period of one year from the date of such commencement.
2. In the Drugs and Cosmetics Rules, 1945,
 - (a) in rule 71, after sub-rule (7), the following sub-rule shall be inserted, namely:-

“(8) The applicant shall make application for grant of licence for a drug formulation containing single active ingredient in proper name only.”,
 - (b) in rule 71A, after sub-rule (3), and before the proviso, the following sub-rule shall be inserted, namely:-

“(4) The application for grant of licence for a drug formulation containing single active ingredient shall be made in proper name only.”,
 - (c) in rule 71B, after clause (iv), the following proviso, shall be inserted, namely:-

“Provided that the application for grant of a licence for a drug formulation containing single active ingredient shall be made in proper name only.”,

- (d) in rule 76, after sub-rule (8), the following sub-rule shall be inserted, namely:-

“(9) The applicant shall make application for grant of licence for a drug formulation containing single active ingredient in proper name only.”,

- (e) in rule 76A, the following proviso shall be inserted, namely:-number G.S.R.575(E), dated 17th July,2012.

“Provided that the application for grant of a licence for a drug formulation containing single active ingredient shall be made in proper name only.”

[F.No.X11014/5/2011-DFQC]

SUNDEEP KUMAR NAYAK, Jt. Secy.

Foot Note:- The principal rules were published in the Gazette of India vide notification No.F.28-10/45-H(1), dated 21st December, 1945 and last amended vide notification number G.S.R.575(E), dated 17th July,2012.

12st October, 2012

NOTICE

Ministry of Health and Family Welfare has issued directions under Section 33 (P) of Drugs & Cosmetics Act 1940 to Principal /Health Secretaries of all States / UTs for compliance of the concerned implementing authorities in respect of the following:

- 1.Grant/renewal of manufacturing licenses of drug formulations in proper /generic name only.(Annexure-A)**
- 2.Cancellation of licenses to manufacture drug formulations falling under purview of “New Drugs” including Fixed Dose Combinations (FDCs) as defined under Rule 122 (E) of Drugs & Cosmetics Rules, 1945.(Annexure-B)**

Drugs Controller General (India)

ANNEXURE-A

अति-तत्काल / स्पीड पोस्ट द्वारा
MOST IMMEDIATE / BY SPEED POST

सं.एक्स.11011/1/2011-डीएफक्यूसी/1✓

No.X.11011/1/2011-DFQC

भारत सरकार / Government of India

स्वास्थ्य व परिवार कल्याण मंत्रालय / Ministry of Health & Family Welfare

स्वास्थ्य व परिवार कल्याण विभाग / Department of Health & Family Welfare

..... !

निर्माण भवन, नई दिल्ली

Nirman Bhavan, New Delhi

दिनांक 1 अक्टूबर, 2012

dated the 1 October, 2012

To

Principal / Health Secretaries of
all States/Union Territories

Subject: Directions under section 33 (P) of Drugs and Cosmetics Act 1940 for grant / renewal of manufacturing licenses of drug formulations in proper/generic name only – reg.

Sir,

The Regulatory Control over the manufacture and sale of drugs is exercised by the State Licensing Authorities appointed by the State Governments under the provisions of the Drugs and Cosmetics Act, 1940. It has been observed that at the time of the grant of the license for manufacture of a drug formulation, the trade name as submitted by the manufacturer is also endorsed by the licensing authority alongwith proper name of the product thereby giving legitimacy to market the drug under the brand or the trade name. Under the provisions of the Drugs & Cosmetics Rules, 1945, applications in various forms for grant/ renewal of a license to manufacture for sale or distribution of various categories of drugs as well as various forms for grant / renewal of such licenses require the name of the drug to be specified. Such forms for application as well as grant / renewal of the licenses do not require mentioning of any Trade Name / Brand Name.

2. In view of the above, the grant of drugs manufacturing licenses under a trade or brand name is not in accordance to the spirit of the legislation. Therefore, manufacturing license for the drug formulation should be granted in proper / generic name only. In case of drug formulation containing multiple ingredients, the licence should be granted under the name of categories of product viz. "Multivitamin Tablets/Capsule/Syrup", "antioxidants, multivitamins & multi minerals tablets/ capsule/syrup' etc. However, the composition of such product shall mention the name of active ingredients as well as its strength. The

issue was also discussed in the Drugs Consultative Committee in the meeting held on 20th July, 2012.

3. In view of the above, in pursuance of the provisions contained in Section 33 (P) of the Drugs and Cosmetics Act, 1940, as amended from time to time, the Central Government hereby directs all States / Union Territory Governments to instruct their respective drug licensing authorities to grant / renew licenses to manufacture for sale or for distribution of drugs in proper / generic names only.

Yours faithfully

(संजय प्रसाद)

(Sanjay Prasad)

निदेशक / Director

टेलीफैक्स/Telefax: 23062352

Copy to: Drugs Controller General (India), FDA Bhavan, Kotla Road, New Delhi.

ANNEXURE-B

अति-तत्काल / स्पीड पोस्ट द्वारा

MOST IMMEDIATE / BY SPEED POST

सं.एक्स.11011/1/2011-डीएफक्यूसी/1

No.X.11011/1/2011-DFQC

भारत सरकार / Government of India

स्वास्थ्य व परिवार कल्याण मंत्रालय / Ministry of Health & Family Welfare

स्वास्थ्य व परिवार कल्याण विभाग / Department of Health & Family Welfare

निर्माण भवन, नई दिल्ली

Nirman Bhavan, New Delhi

दिनांक 1 अक्टूबर, 2012

dated the 1st October, 2012

To

Principal /Health Secretaries of
All States/ Union Territories

Subject: Direction under section 33(P) of Drugs and Cosmetic Act, 1940 of cancellation of licences to manufacture drug formulations falling under the purview of 'New Drugs' including Fixed Dose Combinations (FDCs) as defined under Rule 122 (E) of the Drugs and Cosmetics Rules, 1945 – regarding.

Sir,

The Regulatory control over the manufacture and sale of drugs is exercised by the State Licensing Authorities appointed by the State Governments under the provisions of the Drugs and

Cosmetics Act, 1940. Rule 122E of the Drugs and Cosmetics Rules, 1945 made thereunder provides the definition of the term 'New Drugs'. The drugs falling under this category require prior approval from the Licensing Authority defined under Rule 21(B) i.e. the Drugs Controller General (India) [DCG (I)] before the grant of a licence for manufacture by the State Licensing Authority. As per Rule 122E, new drug shall mean and include-

(a) A drug, as defined in the Act including bulk drug substance which has not been used in the country to any significant extent under the conditions prescribed, recommended or suggested in the labelling thereof and has not been recognized as effective and safe by the licensing authority mentioned under rule 21 for the proposed claims:

Provided that the limited use, if any, has been with the permission of the licensing authority.

(b) A drug already approved by the Licensing Authority mentioned in Rule 21 for certain claims, which is now proposed to be marketed with modified or new claims, namely, indications, dosage, dosage form (including sustained release dosage form) and route of administration.

(c) A fixed dose combination of two or more drugs, individually approved earlier for certain claims, which are now proposed to be combined for the first time in a fixed ratio, or if the ratio of ingredients in an already marketed combination is proposed to be changed, with certain claims, viz. indications, dosage, dosage form (including sustained release dosage form) and route of administration.

Explanation. - For the purpose of this rule-

(i) all vaccines and recombinant DNA (r-DNA) derived drugs shall be new drugs unless certified otherwise by the Licensing Authority under Rule 21;

(ii) a new drug shall continue to be considered as new drug for a period of four years from the date of its first approval or its inclusion in the Indian Pharmacopoeia, whichever is earlier.

2. Instances were brought to the notice of the Central Government from time to time that the licensing authorities of many States and Union Territories have been granting licenses for manufacture of new drugs including Fixed Dose Combinations (FDCs) falling in the category of new drug defined under Rule 122E of Drugs & Cosmetic Rules without the prior approval of the Licensing Authority defined under Rule 21 (b) in violation of the said provision of the Drugs and Cosmetics Rules. The Parliamentary Standing Committee on Health & Family Welfare has taken strong objection to this practice in its 59th Report on the Functioning of Central Drugs Standard Control Organisation (CDSCO). In the light of the observations made by the Parliamentary Standing Committee, the issue of cancellation of licences by the State Licensing Authorities for manufacture of drug formulations falling under purview of the new drugs especially in respect of Fixed Dose Combinations was accordingly discussed in the Drugs Consultative Committee in the meeting held on 20th July, 2012. It was reiterated in the meeting that such licence for new drugs for unapproved FDCs must not be granted by any State Licensing Authorities.

3. In view of above, in pursuance of the provisions contained in Section 33 (P) of the Drugs and Cosmetics Act, 1940, as amended from time to time, the Central Government hereby directs all States / Union Territory Governments to instruct their respective drug licensing authorities to abide by the provisions prescribed under the

Drugs and Cosmetics Rules for the grant of manufacturing licenses for the drugs falling under the definition of the term 'new drug' and not to grant licenses for manufacture for sale or for distribution or for export of such new drugs, except in accordance with the procedure laid down under the said rules i.e. without prior approval of the Drugs Controller General (India).

Yours faithfully

(संजय प्रसाद)

(Sanjay Prasad)

निदेशक / Director

टेलीफैक्स/Telefax: 23062352

Copy to: Drugs Controller General (India), FDA Bhavan, Kotla Road, New Delhi.

12th November, 2012

NOTICE

In continuation to the earlier direction issued by Ministry of Health and Family Welfare under Section 33 (P) of Drugs & Cosmetics Act 1940 to Principal /Health Secretaries of all States / UTs on 1.10.2012 for compliance in respect of Grant/renewal of manufacturing licenses of drug formulations in proper /generic name only, the Ministry has issued clarification on various points in connection with the implementation of statutory direction as per Annexure-I.

Drugs Controller General (India)

ANNEXURE-I

अति-तत्काल / स्पीड पोस्ट द्वारा
MOST IMMEDIATE / BY SPEED POST

सं.एक्स.11011/1/2011-डीएफक्यूसी

No.X.11011/1/2011-DFQC

भारत सरकार / Government of India

स्वास्थ्य व परिवार कल्याण मंत्रालय / Ministry of Health & Family Welfare

स्वास्थ्य व परिवार कल्याण विभाग / Department of Health & Family Welfare

निर्माण भवन, नई दिल्ली

Nirman Bhavan, New Delhi

दिनांक 9 नवम्बर, 2012

dated the 9th November, 2012

To

(i) Principal / Health Secretaries of
all States/Union Territories

(ii) Drugs Controllers of
all States / Union Territories

Subject: Directions under section 33 (P) of Drugs and Cosmetics Act 1940 for grant / renewal of manufacturing licenses of drug formulations in proper/generic name only – reg.

Sir,

I am directed to refer to this Ministry's letter of even number dated 1.10.2012 conveying the directions of the Central Government in pursuance of the provisions contained in Section 33 (P) of the Drugs and Cosmetics Act, 1940 for grant / renew licenses by the State / UT drug licensing authorities for manufacture for sale or for distribution of drugs in proper / generic names only and to say that clarifications have been sought on various points in connection with the implementation of this statutory direction. Accordingly, the following clarifications are provided by the Central Government:

(i) This direction has prospective effect only.

(ii) This direction has been issued under the Drugs & Cosmetics Act, 1940.

(iii) This direction is applicable only for the manufacturing license issued by the drug licensing authorities under the provisions of the Drugs & Cosmetics Act, 1940.

(iv) This direction does not apply to the various types of certificates, namely, COPP, GMP Certificate, Free Sale Certificate, etc required for the purpose of export of drugs, as these are not issued under the Drugs & Cosmetics Act, 1940. The exports have to comply with the regulatory requirements of the importing countries which require such certificates.

(v) This direction is not applicable to grant / renewal of license for import of drugs.

(vi) This direction is not applicable to grant / renewal of license for manufacture and import of medical devices.

(vii) This Direction is independent of the draft notification GSR 748(E) dated 5.10.2012 issued seeking comments of stakeholders on amending Drugs & Cosmetics Rules, 1945 allowing issuance of licenses of single ingredient drugs in generic / proper names only.

Yours faithfully


(तर्सेम चंद)

(Tarsem Chand)

निदेशक / Director

टेलीफैक्स/Telefax: 23062352

Copy to: Drugs Controller General (India), FDA Bhavan, Kotla Road, New Delhi for wide circulation.

13th December, 2012

DRUG ALERT

In order to regulate the import, manufacture, distribution and sale of drugs, medical devices and cosmetics in India, it has been decided that the CDSCO, is required to be informed about the quality defect in the medicinal products which require Recall or restriction on supply. Where a product is considered to be a risk to public health, the marketing authorization holder will withdraw the affected product from use and the CDSCO as well as concerned State Drug Regulatory authority are required to be informed about such products so that suitable 'DRUG ALERT' be issued for the information of the public.

Some of the States like Gujarat are already issuing alerts on drugs which are not of standard quality through SMS and other means in their States.

In order to ensure the safety of the patients from the drugs of doubtful quality, it is imperative that the drugs which are not of standard quality/spurious/adulterated/misbranded, as declared by the Drug Testing Laboratories of CDSCO, be put on website for immediate stoppage of such medicines from reaching to the patients.

The Drug Testing Laboratories under CDSCO are hereby directed to send the details of the drugs which have been found to be not of standard quality/spurious/adulterated/misbranded to the CDSCO HQ for uploading the information on the website of the CDSCO under column 'DRUG ALERT' on regular basis.


Drugs Controller General (India)

To

Dr. K. Bangarurajan, Dy. Drugs Controller to make a point that every first week of month, medicines which are found to be not of standard quality/spurious/adulterated/misbranded by the CDSCO Drug Testing Laboratories be put on the website under the column "DRUG ALERT"

Copy to:

1. Mr. A.K. Pradhan, Deputy Drugs Controller (India)
2. Dr. S.E. Reddy, Deputy Drugs Controller (India)

No.DCGI/MISC/572012
Directorate General of Health Services
Central Drugs Standard Control Organisation
FDA Bhawan, Kotla Road, New Delhi

29.11.2012

To

All State/UTs Drugs Controllers

Subject: Labelling of cautionary note under rule 97 of the Drugs and Cosmetics Rules, 1945 more conspicuously on the label of the drugs- regarding.

Sir,

Rule 97 of the Drugs and Cosmetics Rules, 1945 provides for printing of caution / warning in respect of drugs covered under Schedule H, Schedule G or substances coming under the purview of the Narcotic Drugs and Psychotropic Drugs Act, 1985 for the information of patients, doctors, pharmacists and others, so that there is no misuse of these drugs. It is however, observed that in many cases the caution does not appear in a conspicuous manner on the inner most label of these drugs and is overlooked by the consumers as well as other persons handling the drug. This leads to unethical use of these medicines by the patients because of difficulty in reading / noticing the cautionary note provided on the label.

You are therefore requested to kindly direct the manufacturers under your jurisdictions that while labeling medicines with cautionary warnings in compliance to the rule 97, should provide the caution / warning in a conspicuous manner to attract the attention. This would help in safeguarding and enhancing public health by assuring proper use of the medicines in accordance to the cautions printed on the label.


(Dr. G. N. Singh)
Drugs Controller General (India)

Copy to:-

1. All Zonal/Sub Zonal Offices of CDSCO
2. IDMA/OPPI/IPA for their information and compliance by their members.

File No.4-1/2012-DC (Misc.54)/Piog
Directorate of General of Health Services
Central Drugs Standard Control Organisation
FDA Bhawan, Kotla Road, New Delhi
(O/o DCG (I))

FDA Bhawan, Kotla Road
New Delhi-110002

Dated: 06 NOV 2012

To,
All State Drugs Controllers

Subject: Important safety label changes to cholesterol-lowering statin drugs-Regarding.

Sir,

The proposal of important safety changes to the labelling for some widely used cholesterol-lowering drugs known as statins was considered by New Drugs Advisory Committee in its meeting held on 21st April, 2012 at New Delhi.

The proposal was based on USFDA news release dated 28 Feb, 2012. These changes are made by USFDA to provide the public with more information for the safe and effective use of statins. The changes to the statin labels include the following:-

1. The drug labels have been revised to remove the need for routine periodic monitoring of Liver enzymes in patients taking statins. FDA now recommends that Liver enzyme tests should be performed before starting statin therapy, and as clinically indicated thereafter. FDA has concluded that serious liver injury with statins is rare and unpredictable in individual patients, and that routine periodic monitoring of liver enzymes does not appear to be effective in detecting or preventing this rare side effect. Patients should notify their health care professional immediately if they have the following symptoms of liver problems: unusual fatigue or weakness; loss of appetite; upper belly pain; dark-colored urine; yellowing of the skin or the whites of the eyes.
2. Certain cognitive (brain-related) effects have been reported with statins use. Statin labels will now include information about some patients experiencing memory loss and confusion. These reports generally have not been serious and the patients' symptoms were reversed by stopping the statin. However, patients should still alert their healthcare professional if these symptoms occur.
3. Increase in blood sugar levels (hyperglycemia) have been reported with statin use. The FDA is also aware of studies showing that patients being treated with statins may have a small increased risk of increased blood sugar levels and of being diagnosed with type 2 diabetes mellitus. The labels will now warn healthcare professionals and patients of this potential risk.
4. Health care professionals should take note of the new recommendations in the lovastatin label. Some medicines may interact with lovastatin, increasing the risk for muscle injury (myopathy/rhabdomyolysis). For example, certain medicines should never be taken (are contraindicated) with (lovastatin) including drugs used to treat HIV (protease inhibitors) and drugs used to treat certain bacterial and fungal infections.

The NDAC after deliberations agreed the line of action as taken by USFDA and in the light of decision taken by USFDA, India should also implement the safety changes as recommended for the statins.

It is therefore, requested that the State Licensing Authorities under your jurisdiction should be asked to request the manufactures marketing cholesterol-lowering statin drugs to implement the safety changes in the labellings.

Action taken in the matter may please be communicated to the undersigned.

Yours faithfully

(Dr. G. N. Singh)
Drugs Controller General (India)

Copy forwarded for information and necessary follow up to the Zonal/ Sub Zonal officers of CDSCO.

INFORMATION

M. Pharm Scholarship 2012-13 awarded by TNPSWT

Profile of 1st Rank Projects

PHARMACEUTICS

Name: Mr.K.Selvamani

Project Title: “Pulsincap Delivery System of Lovastatin– Derived from Marine source & Colesevelam for Hyper Cholesterolemia”

College : Periyar College of Pharmaceutical Sciences, Trichy

Guide's Name: Dr.K.ReetaVijaya Rani
M.Pharm.,Ph.D.,

PHARMACEUTICAL CHEMISTRY

Name: Mr. Gaurav

Project Title: Docking Studies, Synthesis of some novel Thiazine substituted 9- anilinoacridine derivatives and evaluation for their anticancer and antimicrobial activities.

College: JSS College of Pharmacy, Ooty

Guide's Name: Mr. R. Kalirajan., M. Pharm.,

PHARMACEUTICAL ANALYSIS

Name: Ms. Keerthy Atluri

Project Title: “Bioanalytical method development and validation for the simultaneous estimation of Moxifloxacin and Cefixime by RP-HPLC”

College: JSS College of Pharmacy, Ooty

Guide's Name: Mr.J.S.K.Nagarajan

PHARMACOLOGY

Name: Mr.M.Naveen Kumar

Project Title: Protective effect of 5-Amino salicylic acid (5-ASA) in cerebral ischemia induced neuronal damage: A mechanism based approach.

College: JSS College of Pharmacy, Ooty

Guide's Name: Mr. R. Vadivelan

PHARMACOGNOSY

Name: Ms.P.Karthika

Project Title: Formulation and evaluation of photoprotective potential of a herbal formulation.

College: Madras Medical College, Madras

Guide's Name: Dr. N. Jayshree

PHARMACY PRACTICE

Name: Ms. Lakshmi Devi Rakurthi

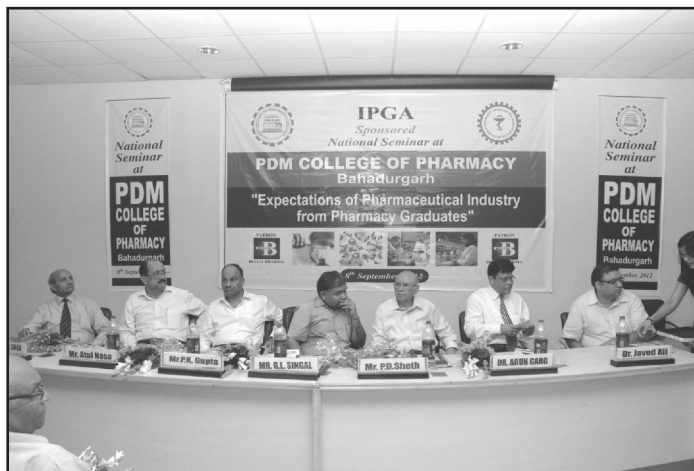
Project Title: A study on effect of patient counselling on medication adherence of oral chemotherapy in cancer patients.

College: Sri Ramachandra University, Chennai.

Guide's Name: Ms.S.Ramalakshmi, M.Pharm,

EVENTS

IPGA Sponsored National Seminar on, “Expectations of Pharmaceutical Industry from Pharmacy Graduates”, 8th September, 2012



An IPGA Sponsored National Seminar on “Expectations of Pharmaceutical Industry from Pharmacy Graduates” was organized by the Academic Division of IPGA at PDM College of Pharmacy, Bahadurgarh, Haryana on 08th September, 2012. About 350 delegates including teachers, students and research scholars from various Pharmacy colleges of the country participated in the national Seminar.

The programme commenced with Saraswati Vandana recited by students of PDM College of Pharmacy, Bahadurgarh which was followed by lightening of lamp by Mr. G. L. Singal, Drug Controller, Haryana (Chief Guest), Mr. P. K. Gupta, CMD, Belco Pharma, Mr. P. D. Seth - Vice President FIP (Key note speaker) and other dignitaries.

Dr. Arun Garg, Director, PDM College of Pharmacy & General Secretary IPGA welcomed all the dignitaries and the delegates and briefed them about the theme of the seminar. He pointed out the key areas where Pharma Industry can play

an important role in development of Pharmacy profession.

Dr. V. R. Singh, Director, PDMREA briefed about the PDM group of institutions, the facilities available to the students and the role of PDM educational society in the Pharmacy education.

Dr. Javed Ali informed that the seminar was planned with the intention to narrow down the gap between the Pharmacy graduates and the Pharma Industry.

Mr. Atul Kumar Nasa, during the inauguration addressed the gathering by a welcome note. He explained the background behind this seminar. He highlighted the role of IPGA in taking a proactive role in discharging the duties of a professional Association over the years.

Mr. G.L. Singal, Drug Controller, Haryana was the Chief Guest of the inaugural function. He congratulated the organizers for bringing together eminent speakers from pharmaceutical industry

and the Pharmacy graduates to a common platform. He shared his experience of the days when he worked in the Pharma industry and the expectations the industry had at that time. He also gave an overview of his present role in Pharma regulation in the state of Haryana. He emphasized the importance of quality education for the development of pharmacy profession. He appreciated the efforts of Indian Pharmacy Graduates' Association and PDM for conducting the seminar and announced support for training and placement of students in Pharma industries.

Mr. P. K. Gupta, CMD, Belco Pharma was the Guest of Honor. He briefed the gathering about the various statistical advancement of pharmaceutical Industry over the past 15 years. The desirable characteristics of Pharmacy graduates required for industry and the avenues present nowadays were also briefed by him. He assured Dr. Garg that he will discuss the issue of more proactive role by the industry towards the pharmacy institution and also about the placements of Pharma graduates in the Pharma industries. While casting his key note address Mr. P.D. Sheth, Vice President – FIP congratulated the organizers for choosing the most appropriate theme at the present time. He emphasized that the Pharma industry strategy is changing rapidly in tandem with global scenario. He enlightened the delegates that market access is the main driving function followed by marketing and medical affairs. He also threw light on the other function like R&D, sales and manufacturing.

He pointed out that for creation of opportunities collaborations between industry and teaching institutions is a highly workable model for skilled manpower.

The scientific abstract CD was also released during inauguration. The meritorious students of PDM College of Pharmacy, Bhadaurgarh, Haryana were also presented the merit awards and merit certificates. Vote of thanks for the inaugural

function was presented by Dr. Hema Chaudhary, Vice Principal, PDM college of Pharmacy, Haryana.

Dr. Bharti Khanna, Consultant - Regulatory Affairs enlightened audience about “Regulatory Competence In Product Development”. She discussed about relation between industry and academics and focused on “Quality By Design” (QbD) which is a systemic approach to development that begins with predefined objectives and emphasizes product and process understanding. She highlighted the impacts of QbD and included Critical Quality Attributes (CQA), Quality Target Product Profile, role of excipients, risk assessment and control strategy.

Dr. Sanjay Gupta, CMD – Catalyst Clinical Services, delivered talks on opportunities in clinical research organization related to the main theme of the seminar. He defined Clinical Trials as “an organized research conducted on human beings to investigate the safety and efficacy of the drugs” along with its phases and steps followed for a new drug development. He justified the significance of clinical trials taking different regulatory bodies into consideration like ICH, ICMR etc.

About 105 scientific Abstracts were received for poster presentation across the cross section of the country and out of these 83 of them were short listed by the scientific committee. It gave an excellent opportunity to the younger generation to use a professional platform for highlighting their scientific achievements and promoting the concept of knowledge dissemination and learning from each other.

The posters were judged by Prof. B. Srinivasan, Prof. UVS Sara, Mr. Vijay Bhalla, Prof. Satish Sharma, Dr. Javed Ali and Dr. Hema Chaudhary. The best poster in each division was awarded. The seminar ended with the National Anthem.

Periyar College of Pharmaceutical Sciences, Tiruchirappalli



Periyar College of Pharmaceutical Sciences, Trichy celebrated Graduation Day on 01.09.12 in their campus with Dr. A. Rajasekaran, M.S., M.Ch.,(Uro), F.R.C.S., (Edin), F.I.C.S., D.Sc., (Honoris Causa), Past President, National Board of Post Graduate Medical Examinations (DNB), New Delhi as Chief Guest who delivered the Graduation Day address. Dr. A. M. Ismail, Vice Principal,

welcomed the gathering. Dr. R. Senthamarai, Principal, presented institutional report. Dr. K. Veeramani, Founder Chairperson, presided over the function. More than 150 B. Pharm / M. Pharm students received their degree certificates in that function. Finally, Dr. S. Karpagam Kumara Sundari proposed vote of thanks.

K.K.College Of Pharmacy, Chennai



K. K. College of Pharmacy, Chennai organized a **“Inter Colligate Quiz Competition”** for Pharmacy students on 9th November 2012 to commemorate the 20th Anniversary celebrations. C. L. Baid Metha College team won the first Prize and K. K. College of Pharmacy team received the second prize.

As part of Celebrations the Department of Pharmaceutics released the first News letter **“NOVUS”**. **Prof. Dr. K. Chinnaswamy** released the News Letter and **Prof. K. R. Arumugam** received the first copy. The Chief Guest Prof. Dr. K. Chinnaswamy spoke about the scope of the Pharmacy for the budding Pharmacists. His

inspiring speech was well received by the students. **Prof. A. Meena**, Principal, K. K. College of Pharmacy presented the Annual Report of the College for the academic year 2011-12. **Prof. Dr. K. Senthilkumaran**, HOD, Department of Pharmaceutics welcomed the gathering and Prof. **Dr. V. Vaidyalingam**, Director, proposed the vote of thanks.

K. K. College of Pharmacy also organized a Guest Lecture on **“Role of Clinical Research in drug development”** on 3rd November 2012 by **DR. P. RAMKUMAR**, Research Scientist, Pharma Research, Orchid Health Care.

Faculty of Pharmacy, Sri Ramachandra University, Chennai



The Departments of Pharmacognosy & Pharmacology, Faculty of Pharmacy, Sri Ramachandra University conducted **“HERBOTECH 2012”**, a three days National conference on "Approaches of Nanotechnology in Herbal Drug Development" from 20th to 22nd November 2012, sponsored by Department of Science & Technology, New Delhi & Indian Council of Medical Research, New Delhi. The

Conference was inaugurated by Dr. Rita Banerjee, Scientist F, Science, Engineering & Research Council, Department of Science & Technology, New Delhi, and presided over by Dr. J.S. Sathya Narayana Murthy, Vice-Chancellor, Sri Ramachandra University, Chennai. Dr. D. Chamundeeswari, Principal, Faculty of Pharmacy, Sri Ramachandra University welcomed the gathering. Dr. S. P. Thyagarajan, Professor of

Eminence & Dean (Research), Sri Ramachandra University, delivered the theme address and Prof. K. V. Somasundaram, Dean of Faculties, Sri Ramachandra University, delivered the special address. Dr. C. Uma Maheswara Reddy, Professor & Head, Department of Pharmacology, Faculty of Pharmacy, proposed the vote of thanks. Dr. Rita Banerjee dedicated the Green House maintained by the Department of Pharmacognosy, Faculty of Pharmacy, Sri Ramachandra University that shelters 100 rare medicinal plants to Sri Ramachandra University. The scientific sessions comprised of lectures by eminent speakers from academia, industry and research. Poster and oral presentations, and technical sessions comprising of demonstration of sophisticated instruments at Faculty of Pharmacy and Central Research Facility, Sri Ramachandra University. The compact disc of the scientific abstracts was released by Dr. J. S. Sathya Narayana Murthy. 239 delegates from academic institutions, industries and research organizations of southern states of India participated. The prizes for the winners of the poster and oral presentations were distributed by Dr. Narashimham Jammi, Director, Jammi Pharmaceuticals, Chennai at the valedictory function held on 22nd November 2012.

The Alumni Association of Sri Ramachandra College of Pharmacy organized a program on

“Empowerment of Soft Skills” for the staff and students of Faculty of Pharmacy, SRU, on 1/9/2012, at Seminar Hall, II floor, Medical College Block, SRU. The speaker was Mr. S. Swaminathan, Director, Asktenali.com, Chennai. Dr. S. Umamaheswari, President, Alumni Association of Sri Ramachandra College of Pharmacy, welcomed the gathering. Dr. T. K. Parthasarathy, Pro-Chancellor, SRU, felicitated the guest speaker. Dr. K. V. Somasundaram, Dean of Faculties, SRU; Dr. A. Rekha, Associate Dean of Students, SRU; Dr. D. Chamundeeswari, Principal, Faculty of Pharmacy, and Dr. K. Chitra, Vice-Principal, Faculty of Pharmacy, addressed the gathering. Prof. S. Shanmuganathan, Member, Alumni Association of Sri Ramachandra College of Pharmacy, introduced the speaker and Prof. C. Uma Maheswara Reddy, Treasurer, Alumni Association of Sri Ramachandra College of Pharmacy, delivered the Vote of Thanks.

Faculty of Pharmacy and Department of Ophthalmology, SRU, organized a “Human Chain” in lieu of “Eye Donation Awareness Fortnight” from 9.00 to 10.30 AM, on 6/9/2012 in the Sri Ramachandra University Campus. Dr. K. V. Somasundaram, Dean of Faculties, SRU, inaugurated the program.



NEWS

Give details of Clinical Trial Deaths and Compensation: SC Petition Accuses MNCs of Using Indians as Guinea Pigs for Patented Drugs

The Supreme Court on Monday asked the Centre and the states to furnish details of clinical trial deaths, compensation paid to families of victims and the legal regime in force in the country to regulate such trials on humans.

This direction came from a bench of Justices R. M. Lodha and A. R. Dave after an Indore-based NGO 'Swasthya Adhikar Manch' alleged that foreign multi-national companies were using Indians as guinea pigs for clinical trial of their newly patented drugs.

The NGO quoted a parliamentary committee report which said 2,374 persons died during such trials between 2007 and June 2012 and that families of only 37 victims had been paid meager compensation in 2010-11.

Petitioner's counsel Sanjay Parikh said after the regulatory mechanism was relaxed through the 2005 amendment to the Drugs and Cosmetics Rules, 1945, there was a huge rush of foreign pharmaceutical companies to conduct clinical trials in India to exploit their patents and earn profits in shortest possible time.

The NGO said the foreign pharmaceutical companies holding patents of New Chemical Entities (NCEs) use developing countries as soft targets, given the low cost and absence of mechanism to fasten liability on them for mishaps, for finding out the efficacy and side-effects

through clinical trials.

Asking the Centre to compile data received from the states and submit it to the court within eight weeks, the bench of Justices Lodha and Dave said, "All these malpractices in clinical trials should be stopped forthwith... Why the Drugs Controller General of India (DCGI) should not take immediate steps to stop such malpractices in government and private hospitals."

Additional solicitor general Siddharth Luthra's assurance that a legal regime was in place to prohibit unethical clinical trials and regulate the valid trials did not address the court's concern over problem areas.

The bench said, "We are concerned about the lives of human beings who become subject to clinical trials unknowingly, helplessly due to the malpractices of doctors and drug manufacturers."

Luthra said there were independent investigators in ethics committee, which was mandated to monitor such trials. The petitioners doubted the investigators' autonomy. The bench said, "Problem is of non-implementation and non-performance of rules. System is in place but there is no adherence to it. If you had adhered to rules in letter and spirit, such litigation will not come to us."

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

New Drug Policy by Mid- November, Government Tells Supreme Court

People have to go hungry for paying the medicine bill, says Judge

The Union government on Thursday told the Supreme Court that it would put in place by mid-November a Drug Price Control Order (DPCO) after the Union Cabinet's approval.

Last week, the Bench asked the government to spell out a time frame within which a new policy would be put in place.

On Thursday, Additional Solicitor-General (ASG) Siddharth Luthra told a Bench of Justices G. S. Singhvi and S. J. Mukhopadhyaya that the policy required Cabinet approval, which would be done by month-end. "The Group of Ministers has taken a decision, but that decision is yet to be considered by the Cabinet. More time is required to allow the executive to take a decision. The process of legislative activity may not be curtailed by an interim mandamus," he said.

Not satisfied, the Bench asked him to give a definite time frame. Accordingly, the ASG sought instructions and came out with his reply in the afternoon. He said, "The Cabinet will finalise the drug policy by mid-November. The essential drugs list will be notified a week thereafter under the Drug Price Control Order to include 348 drugs. The existing essential drugs list has only 74 items." The government had finalised 348 drugs to be included in the DPCO schedule, but was yet to do so formally.

HAVE CONCERN FOR COMMON MAN

In the morning, Justice Singhvi conveyed the court's displeasure, saying: "Courts are extremely slow in interfering with policy. But for 17 years nothing happens, where people will go." He made it clear to the government that prices should not escalate further in the new policy. "Drugs prescribed by doctors, eminent and not so eminent, is going beyond the reach of the common man. People have to go hungry for paying the medicine bill. The government can have concern for drug manufacturers but it must have substantial concern for the common man," he said.

Justice Mukhopadhyaya told the ASG: "Drug prices have gone beyond the reach of the common man. Drug manufacturers have stopped manufacturing cheap drugs. Keep this in mind while framing the new policy."

The ASG said: "The new policy seeks to replace the earlier pricing formula with one in which prices would be decided on the basis of weighted average prices for all brands which have a market share of over 1 per cent."

The Bench, which is hearing a PIL filed by NGO All India Drug Action Network, posted the case to November 27.

Source: *The Hindu*, 12th October, 2012



Regulate Prices of Essential Drugs

The government has only itself to blame for the indictment it suffered at the hands of the Supreme Court. Its impatience over the government's failure to evolve a proper drug pricing policy was palpably evident when it gave the government four weeks' time to come up with a response. Drugs commonly used by poor people for a variety of ailments have gone out of their reach and the government cannot claim that it is not aware of this situation. A standing committee of Parliament had in 2005 and 2010 reported that the most commonly used drugs have become unaffordable to the poor.

Far from taking remedial action, the government has allowed the situation to deteriorate as can be inferred from the fact that the number of essential medicines under price control decreased from 347 to 76 over the last two decades. The reasons are not far to seek as it is a measure of the influence the drug industry wields on the government. Unlike in many countries where drugs are bought in bulk by the government and distributed through its agencies, in India, even most of those who depend

on government hospitals have to buy medicines from the open market. It is, therefore, no surprise that medicine cost accounts for 50 to 80 per cent of the cost of healthcare.

What's worse, the high cost of medicines is second only to dowry in causing rural indebtedness. There is considerable scope for reducing the prices of common drugs which, for instance, do not need any costly advertisement. Also, fancy packaging can be dispensed with to reduce the cost of manufacture. Some states have started forcing government doctors to prescribe only medicines by their generic names. The government medical system on which only a little over one per cent of the gross domestic product is at present spent needs to be strengthened so that the poor are not left to fend for themselves. The group of ministers finalising the national Pharma pricing policy should take into account all these issues.

Source: *Indian Express*, 13th September 2012

Dr. Reddy's acquires Dutch company

Drug major Dr. Reddy's Laboratories (DRL) on Monday announced its decision to buy Dutch drug firm OctoPlus for €27.4 million (Rs. 192 crore) as it looks to expand its Research and Development. The offer price is 30% higher than the market capitalisation of OctoPlus as on October 19, Dr. Reddy's said in a statement. OctoPlus is a service-based speciality pharmaceutical company that develops injectable dosages and provides various other clinical services.

“As we globalise our R&D efforts, we are looking forward to build a research base in Leiden (Netherlands),” said GV Prasad, Vice Chairman and Chief Executive Officer, DRL. “The

acquisition will help us ramp up our technology capabilities in drug delivery.”

DRL, which is keen to expand further into the fast-growing fee for service business, will retain OctoPlus as a standalone entity to develop specialty generics.

The transaction is expected to be completed by the end of the current fiscal year, said Prasad.

Following the news, the company's shares closed up 1% at Rs. 1,722 on the Bombay Stock

Source: *Hindustan Times*, 23rd October 2012

Sun Pharmaceuticals Under Scanner for 'Under- Reporting' **Israeli Drug Co Results**

A minority shareholder of Israeli drug maker Taro Pharma has alleged that the company's financial results have been under-reported by its Indian promoter, Sun Pharma. In a letter to the Special Committee Board of Directors of Taro, IsZo Capital said that Sun "might be under reporting Taro's third-quarter net sales data by artificially inflating reserves for product returns, charge-backs, rebates and other sales-related items". The allegation comes a day after Taro reported a 16% increase in quarterly net sales at \$161 million. Taro's shareholders are due to meet early next month to vote on the company's proposed merger with Sun Pharma.

"Taro's recently reported Q3 2012 numbers are inconsistent with the historic correlation between

IMS and Taro net sales data, substantiating market rumours that Taro is gaming its reserves for returned products and similar items to artificially deflate net sales data, conveniently, just a month prior to the December 6 special shareholder meeting to vote upon the proposed Sun merger," Brian Sheehy, managing partner at IsZo Capital, said in the letter.

Sun Pharma declined comment. IsZo said that based on data from IMS, Taro's net sales should have been \$176.4 million. It added that Taro's results were under-reported by about \$15.4 million in sales and a similar amount of EBITDA and profit.

Source: *Economic Times*, 8th November 2012

Pricing Policy to Cut Drug Rates by 10-15 %

After twists and turns over the years, the National Pharmaceutical Pricing Policy 2012, which caps the prices of essential drugs, has been finalized. Once implemented, it will result in the prices of medicines coming down by an average 10-15 %. It is expected to be notified over the next few days.

The policy caps prices of 652 commonly used popular medicines under 27 therapeutic areas such as anti-infectives (cetirizine), cardiac (aten),

gastro-intestinal medicines (acid), pain-killers (paracetamol) and anti-diabetic drugs (insulin).

Significantly, for the first time, imported drugs (for instance, insulin and crucial anti-cancer drugs) that are part of the essential drugs list are under its purview, with their prices getting capped.

Source: *Sunday Times*, 9th December 2012

Haryana DCA Starts online issuance of Sale, Mfg-licence to follow suit

Source: Chronicle Pharmabiz, 24th January 2013





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