

Annual Report of the Indian Pharmaceutical Association, Delhi Branch - 2007-08

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Activities of the State Branch

In keeping with the mission statement of the Indian Pharmaceutical Association, the Delhi branch of the Indian Pharmaceutical Association conducted a number of professional activities and awareness programmes in and around Delhi during the year.

The prominent activities carried out were:

I. Administrative Activities:

1. Executive Council meetings

Regular meetings of the executive council of the Delhi State branch were held during the year to chalk out plan, discuss and review various activities of the council. In addition, focused core group meetings were held in smaller groups to plan and execute the activities. In all, seven executive council and core group meeting were held during the year.

Representatives from the branch also regularly attended the Central Executive council meetings.

2. Annual General Body meeting:

The annual general body meeting of the branch was held on the 12th of Jan. 2008.

II. Professional Activities:

1. Interactive Session on Herbals:

IPA, Delhi branch, along with Indian Pharmacopoeia Commission (IPC) and Pharmexcil organized a one-day interactive session on "Putting Herbals Centre Stage-Pharmacopoeial Initiative" on 1st September 2007 at the Regent Room, Hotel The Connaught, New Delhi. The objective of the workshop was to create awareness about the utility of quality monographs for herbs, processed herbs and herbal products in the Indian Pharmacopoeia (IP) and to involve various stakeholders and prepare the list of herbs, processed herbs and extracts and finished products for which IP should introduce monographs for their quality. The response for this meet was overwhelming with more than 100 delegates representing cross section of different disciplines of pharmacy and allied professions attending the seminar. Delegates from not only Delhi and its surrounding areas but also far-off places like Bangalore attended the session.

The workshop began with the welcome address by Dr Praveen Khullar, president of IPA-Delhi branch. He said, "As the globalization is taking place world over, it is important that the generation of herbal products and natural medicines are taken care of because in the developed countries, it is documentation and quality norms,

which are essential. And it is to our own benefit that herbal medicines are standardized and there is sufficient documentary evidence to it."

Chief Guest, Dr M. Venkateswarlu, Drug Controller General of India (DCGI), while inaugurating the seminar said, "Certain critical herbal parameters are needed to be taken care of right from cultivation to the collection of plants from particular place or forest so that quality is built into our herbal preparations right from the initial stages." Further, he wanted experts to clarify when and at what doses can a herb be regarded as a dietary supplement and when can the same herb and at what doses be used as a medicine.

Dr G.N. Singh, Director-IPC Labs and Member Secretary-IPC gave a brief introduction of IPC and its activities. He said, "The main challenge currently confronting this newly formed commission is to update the IP and provide IP reference of standards." Giving highlights of the new IP, which will be released by December 2007, he said, "IP will have 52 monographs. Also, 30 monographs of anti-retroviral drugs (ARVs) will be included in the new IP, which will be the first time such drugs will be introduced in any pharmacopoeia world-over. The new IP will not only have a good appearance but also have a different presentation in terms of content, quality and acceptance."

A brief message of Dr Nitya Anand, Member-Governing body of IPC, was read on the occasion as he could not attend this important meet due to personal reasons. The message said, "We must devote our utmost attention to standardization of quality of the raw materials, i.e., botanicals and products made from them. This will result in their better acceptance, both nationally and internationally. No doubt, this is a daunting task, and here we are dealing with complex mixtures and products. But there has been a great scientific advancement in characterization of quality of plant cultivation and in the analytical techniques in recent years, which offers unprecedented opportunities to analyze and develop Pharmacopoeial standardization of botanical drugs."

Dr G.K. Raman, regional director of Pharmexcil-Delhi office, gave a brief presentation on 'Herbal/ayurvedic and value added products and the activities of Pharmexcil to promote them.' He said, "India is one of the major raw material-producing nations of South Asia and possesses about 8 per cent of the estimated bio-diversity of the world with approximately 8000 medicinal plant species from

flowering plants available in the world. Many species are being used in Traditional Systems of Medicine (TSM) such as Ayurveda (7000 species), Siddha (600 species), Unani (700 species), Homoeopathy (450 species) while Modern medicine has only 30 species. Thus, endowed with variety of species, we can provide a competitive edge to China & US." However, he cautioned, "Much of the scientific literature on TM provides inadequate evidence on safety and efficacy, with no control or comparison group. Thus, protection and preservation of TM knowledge is essential to ensure access to traditional forms of healthcare and respect for those who hold TM knowledge." Finally, he ended the lecture by outlining the stages involved in the manufacture of standardized herbal products and challenges ahead for safety, efficacy and quality of herbal medicines.

The inaugural session came to an end at this stage with vote of thanks proposed by Manish Narang, honorary secretary of IPA-Delhi branch.

After a brief tea break, technical sessions were held. The keynote address 'Standardized natural drugs: A quest for quality' was given by Dr Ashok D.B. Vaidya, Chairman-Pharmexcil Herbs Committee and Member USP-IPC Advisory Committee. He welcomed the initiative of the IP in making monographs for herbs in IP and cautioned that adequate care needs to be taken while doing so. He exhorted that safety and availability of the herbs should be reviewed and also herbals which are scientifically proven for their efficacy need to be considered for inclusion in IP.

Dr DB Anantha Narayana, Chairman of Crude Drug & Herbal Products Committee (CDHPC) of IPC & Head of Herbs Research, Hindustan Unilever Research Centre, Bangalore gave two simultaneous presentations on 'IP - Monograph development process for herbs & herbal products' and 'Standard operating procedures for preparing and issue of botanical reference substances and phytochemical reference substances by IP'. Dr Narayana laid a good foundation for the whole days' discussions and allayed many fears of the Ayurvedic community about IP's work. He explained the criteria for selection of candidate herbals for IP and emphasized the benefits of this initiative of IP both for domestic and export market. He urged the delegates present to contribute to this national effort by helping in Thin Layer Chromatography (TLC) profiles development, High Performance Liquid Chromatography (HPLC) method & profiles development, and as a participant in ring testing. He also clarified the strengths of the Indian scientists in Natural Product

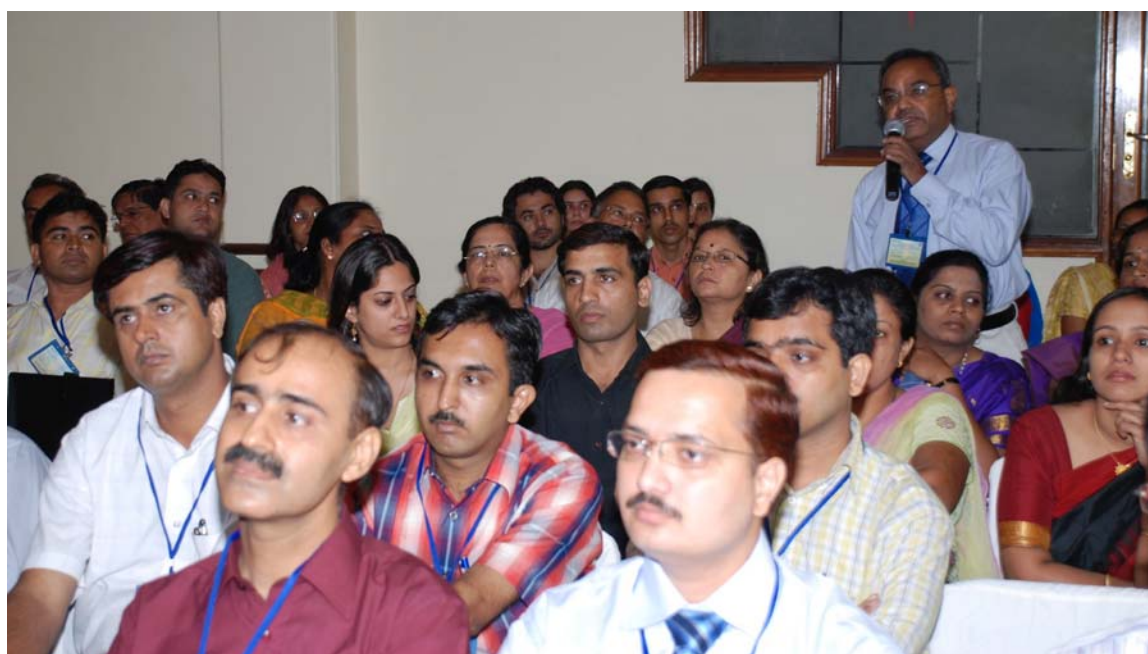
Chemistry, which is being strengthened again as most of the Indian Chemists had turned away from natural products and ventured into synthetic chemistry especially driven by the phenomenal growth of the Indian Pharma industry in active pharmaceutical ingredients. The next phase of growth, according to him, could be in naturals, if science & technology is adapted to this field, as there is resurgence into this field.

The post lunch session was presented by Dr C.K. Katiyar, Director-Herbal Drug Research, Ranbaxy Research Labs, Gurgaon who spoke on 'Identification of herbs for development of monographs in future editions of IP.' He gave a brief about plant selection criteria to be included in the future editions of IP and listed about 16 herbal monographs to be published in IP 2007. This was followed by a presentation by Dr Amit Agarwal, Director-R&D, Natural Remedies on 'Identification of extracts and processed herbs for monographs in future edition of IP.'

The next speaker, Dr George Patani, Director-Dr Patani Scientific and Research Foundation gave a presentation on 'Identification of finished herbal products for monographs in future editions of the IP.' He said that the combinations in herbal formulations, whether interaction of active constituents or with synthetic drugs should be based on safety data and scientific study based rationale. He also gave a brief overview of quality control of herbal formulations for tablets and liquid orals. The final speaker of the day was M.J. Saxena, MD of Dabur Ayurved Ltd., who gave a brief insight on quality monographs and their role in registration of herbal drug products abroad.

The workshop helped in identifying more than 50 herbs of Indian origin, extracts of many of these herbs, and several finished herbal products for which the IP may consider developing monographs in the coming editions. Finally, mementos were presented to all the speakers and chairpersons. The seminar ended with Dr DBA Narayana summarizing the entire proceedings of the seminar.





2. GMP and Regulatory Workshop:

IPA Delhi branch, along with co-sponsors Win Medicare Pvt. Ltd. and Jubilant Organosys Ltd., conducted a one-day workshop on GMP (Good Manufacturing Practices) and Regulatory on 28th October at India Habitat Centre, New Delhi. The objective of the workshop was to take a review of GMPs in the pharmaceutical industry. The workshop aimed to create awareness about the advantages of

following GMP & regulatory guidelines and the immense global opportunities unfolded before Indian Pharmaceutical industry thereof.

The president of IPA, Delhi branch, Dr. Praveen Khullar gave the introductory speech highlighting the aims and objectives of the workshop. Speaking on the global opportunity for the Indian Pharmaceutical industry, Dr Khullar said, Recent developments in the international pharmaceutical industry featuring global mergers & acquisitions, high investment activity, prohibitive R&D costs, changing regulatory environment, threat from generics, and compulsion for outsourcing, have proved to be a boon for Indian Pharmaceutical industry. With its pool of low cost and highly skilled pharmaceutical and medical professionals, manufacturing facilities of international standards, large number of manufacturing units & biotechnology companies, and progressive government policies, India is now looked upon as a reliable source across value chain. He further added, Indian industry has the capability to service the world markets by offering custom contract manufacturing for global supply of active pharmaceutical ingredients, quality generic products, process technologies and alternative systems of medicines (ayurvedic/herbal). With immense global opportunities and strengths to capitalize on them, the Indian Pharmaceutical Industry definitely has a bright future ahead.

Ms Bharti Khanna, Associate Director-Regulatory Affairs, Ranbaxy Research Labs, put forth her views on risk based approaches to GMPs. She said, Product, process, technology innovation and change management present challenges to the lifesciences industry. The ability to adapt and respond to rapidly changing technologies also is a significant risk area. Stringent rules contribute to this situation by inadvertently implementation of new technologies and fostering a change-averse environment. The rising number of recalls and associated quality problems has further compounded the problem and reached a record high with the regulatory agency. Thus, there was a need for empowerment & flexibility. To counter this challenge, European Union (EU) and Japan became involved at the International Conference on Harmonization (ICH)-GMP Workshop in July 2003 and agreed on a five-year vision to develop a harmonized pharmaceutical quality system applicable across the lifecycle of the product emphasizing an integrated approach to quality risk management and science. Consequently, ICH Expert Working Groups (EWG)

approved ICH Q8 (on pharmaceutical development), ICH Q9 (quality risk management) and ICH Q10 (quality systems) documents in 2005.

She further said that risk management as a discipline provides multiple benefits to create awareness, provide assurance, recognize risks at desired level and understand and influence the factors (hazards) which impact regulators and industry business. Ms Khanna concluded by suggesting that quality risk management (QRM) should be integrated during product life-cycle in which senior management should play a crucial role and stressed that even though the use of quality risk management is not mandatory, industry cannot gain from its benefits if it does not implement it. Finally, she summed up the proceeding by saying that integration of QRM into existing systems and regulatory processes will take time, trust and communication.

The informative interaction on QRM was followed by a short tea break after which Sharad Vedhera, Patent Attorney, Kan & Krishme, Delhi presented the current patent scenario in India. With a booming economy slated to be the fourth largest in the world after US, China and Japan, Indian pharmaceutical Industry is doing exceptionally well. Vedhera attributed the Indian success to the colossal number of PhDs awarded each year (numbering 4500), low R&D cost and skilled workforce. However, need of the hour is to provide adequate protection to the products developed by the R&D personnel, which can be only through patenting their products. In his lecture, Prafulla Nandi, Joint Director-Regulatory Affairs, Dabur Research Foundation elaborated the key differences in the registration requirements of US, EU and Canada. He said, In US, EU and Canada, agencies for imposing and implementation of regulations are USFDA, EMEA/MHRA and HPFB respectively. While the approval for setting up manufacturing unit in US comes by 18 months, in EU it only 12 months compared to 24 months in Canada. Its noteworthy to mention that the packaging material controls are strict in US requiring certification (for DMF, LOA, DSC/IR, MVTR data & Virgin grade/Toxicity data) but not so in case of EU and Canada where control is in case of only Virgin grade/Toxicity data.

He further added, GMP requirements in US are limited only to inspection by FDA under clause 21 CFR part 210 & 211. But GMP in case of MRA, batch release site,

distribution site and transportation study is required in Canada while in EU, batch release site and QP certification only is required under GMP guidelines. However, all the three key regions lay stress on stability as well as bio-equivalence requirements. The registration requirements may differ in the three regions in accordance with their respective government policies, at the end of the day servicing the market needs with good quality products is really what matters.

The speakers and delegates were invited for lunch after which Dr K.K. Chakraborti, Head-CQA, Jubilant Organosys Ltd., Noida spoke on *Essentials of Quality Assurance (QA) and Quality Management (QM) in Pharma Industry*. Defining pharmaceutical quality as a function of drug substances, excipients, packaging materials, manufacturing, distribution and storage, Dr Chakraborti said, GMP along with QA, Quality Control (QC) is an interrelated aspect of QM and it is the responsibility of the top management to see to it that QM is adhered to. He further added, Manufacturers must assume responsibility for the quality of their products to ensure that they are fit for their intended use, comply with the requirements of the marketing authorizations and do not place patients at risk due to inadequate safety, quality, or efficacy.

An overview of global pharma industry was highlighted by Neeraj Rajbanshi, Professor of Management, All India Management Association (AIMA). He said, Though the total number of blockbuster products continue to grow and is expected to reach 112 in 2007 up from 94 in 2005, market growth in the US is forecasted to decline slightly to 4-5% in 2007 compared to 6-7% in 2006. This is due to the fact that the US government is under pressure to control ever-rising healthcare expenditure and also is facing a negative impact due to loss of patents of key brands valued at \$10 billion next year. However, Japan! market is growing at 5-6% in 2007 compared to 1-2% in 2006. High ageing population, less severe competition and high entry barriers are some of the reasons for growth. Global demographics, economic changes, changing consumer demands and changing environment had a substantial effect on global pharma industry, both positive and negative He added, Factors like price control, new product pipelines, market diversification, investment in R&D, legal and regulatory issues, management quality and financial risks is playing a crucial role in shaping the present picture of the global pharma industry.

After a short tea break, Naresh Sharma presented his paper on stability studies. This is an important aspect of GMP & regulatory lacking which the pharmaceutical products quality will suffer to a considerable extent. Emphasizing right practice of stability testing, Naresh Sharma said, Stability testing is not done for creating data for regulators, but as an assurance to manufacturer itself on the quality of its products. It has to be done on all the products, irrespective of me-too brands in the market. Structured, systematic and documented stability testing based on right principles can save manufactures from lot of undue hassles that are faced when products are proved to be of inferior quality. Next Vikram Shukla, Head Quality, Dabur Pharma Ltd., spoke on recent trends in validation/qualification of area and equipment. He defined validation as documented act of proving in accordance with the principles of GMP that any procedure, process, equipment, material, activity or system actually leads to the expected results.

Considering the different aspects of manufacturing where validation compliances are not met with, and the fact that over the years the gap between documentation and practical aspects in validation has widened, Shukla stressed on incorporation and compliance of a master validation plan. This document should contain validation policy and approach; organizational structure of validation activities; summary of facilities, systems, equipment and processes to be validated; documentation format to be used for protocols and reports, planning and scheduling, change control, and references to existing documents. He further stated that qualification is a quality tool involving a planned risk assessment based activity. The activity consists of Design Qualification (DQ), Installation Qualification (IQ), Operational Qualification (OQ), Performance Qualification (PQ) and Retrospective Qualification (RQ). Though it is expensive and time consuming, manufacturers are required to assess which systems are critical and which are less critical as Qualification can be used to demonstrate that systems are under control. The session ended with a vote of thanks by the Joint Secretary, Mr. Naresh Sharma.

3. National Pharmacy Week Celebrations 2007:

As part of the National Pharmacy Week celebrations this year, the Delhi branch of the Indian Pharmaceutical Association organized a number of programmes in and

around Delhi from 18th to 25th Nov., 2007, in order to bring awareness amongst the professionals and public about the role of Pharmacists in health care.

The inaugural function for the National Pharmacy Week 2007 was organised at Maharaja Surajmal Institute of Pharmacy, Janakpuri, New Delhi. An awareness poster on the role of pharmacist on the right use of medicines and patient information leaflets on Tuberculosis were released on the occasion. The vice president of the Delhi branch of IPA informed that thousand of such posters were being distributed through the city to various hospital pharmacies, dispensaries and retail chemist shops for display and distribution to the public / patients. Also Banners displaying the message of the 46th national Pharmacy Week would appear at various places through the city.

“Know your Pharmacist: For right use of medicines”

“Davaiyon ka sahi upyog: jaaniye apne pharmacist ko!”

The inaugural function was attended by more than 200 delegates belonging to community pharmacists, trade associations, industry and a large number of students from pharmacy colleges.

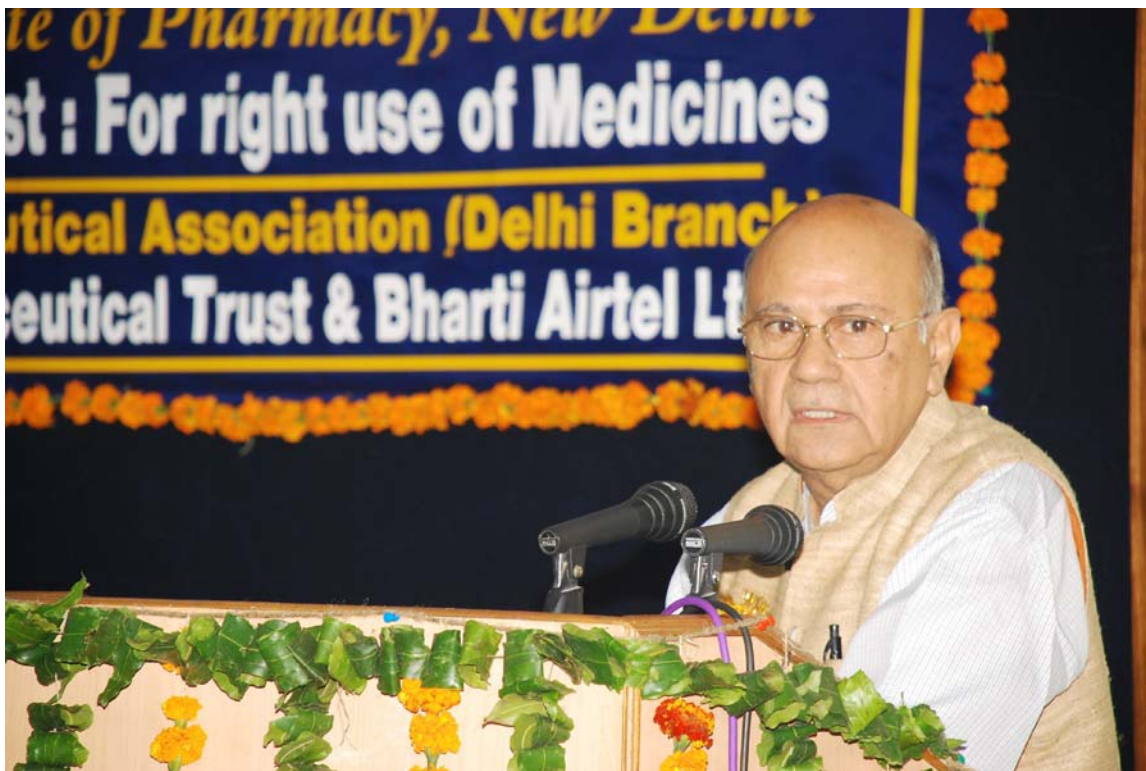
The function was inaugurated by lighting the lamp by the chief guest Mr. Prafull D. Sheth. Mr. Sanjay Talwar, Vice President IPA (Delhi Branch) delivered the Welcome Address. Mr. Prafull D. Sheth, Immediate past President, IPA and Professional Secretary, SEARPharm Forum, delivered the Key Note address on the theme ***“Know your Pharmacist: For right use of medicines”*** where he deliberated on the roles which the pharmacists should play in order to have their identity as an important member of the health care team.

Mr. S. L. Nasa, Registrar, Pharmacy Council of India and Executive Council member, IPA, Delhi branch spoke about the development of Hospital Pharmacy in India. In his address, he briefed the audience about the evolution of pharmacy profession in India starting from 1932 and also the initiatives taken by the Government for the development of hospital pharmacy in India.

Dr Sushma Drabu, Director, Maharaja Surajmal Institute of Pharmacy spoke about the role of pharmacist in the right use of medicines. She emphasized the importance of pharmacist in the rural area where the patients are illiterate.

Mr. Naresh Sharma, Joint Secretary, IPA, Delhi branch and Drug Inspector, CDCSO spoke about Career opportunities for Pharmacy Students in India and abroad. In his address, he briefed the students about the international scenario of various career opportunities in pharmacy profession.







As part of the public awareness program more than 3,000 Posters and 10,000 patient information leaflets on “Facts about TB and TB Medication” were printed and distributed through students of pharmacy colleges and chemist associations to various hospitals, nursing homes, pharmacies and retail chemist outlets to be displayed prominently throughout the week and for the year thereafter. Banners depicting the message of the National Pharmacy Week, 2007 – “Know your pharmacist – Role of pharmacist in health care” were displayed in full public view at over all major hospitals, pharmacies and pharmacy colleges in Delhi.

**ASK
your
PHARMACIST**



Your **Pharmacist** is the **Right Person** to guide you about:

- ✓ The **Right** way to take your **Medicines**
- ✓ The **Right** way to store your **Medicines**
- ✓ The **Right** way to use your **Medicines**
- ✓ The **Do's & Don'ts** of your **Medicines**
- ✓ The General **Guidelines** to a **Healthy Living**.

Ask your Medication Queries to your Pharmacist
Derive Maximal benefits from your medications

ENJOY GOOD HEALTH
 YOUR PHARMACIST – THE FRIENDLY PARTNER FOR YOUR GOOD HEALTH





Issued in public interest on the occasion of 46th National Pharmacy Week by :
Indian Pharmaceutical Association (Delhi Branch)
 Co-Sponsored by: **Delhi Pharmaceutical Trust & Bharti Airtel Limited**

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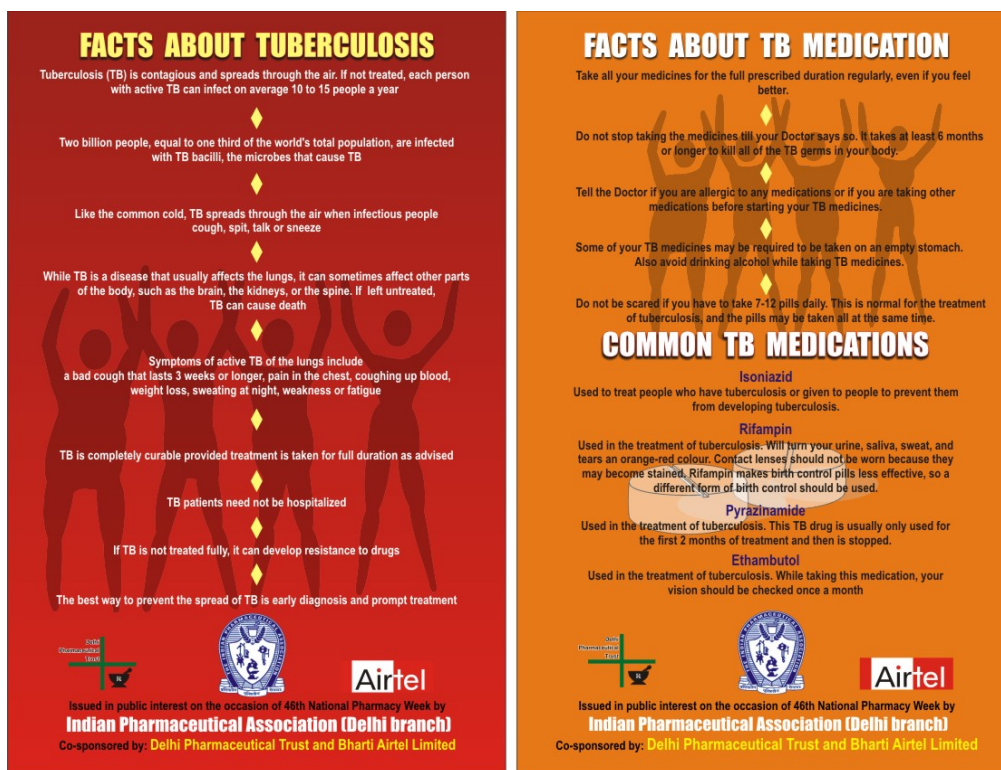
Indian Pharmaceutical Association (Delhi Branch)
Celebrates
47th NATIONAL PHARMACY WEEK
 28th to 25th Nov., 2007

Theme: Know your Pharmacist : For right use of medicines



Co-Sponsored by:
Delhi Pharmaceutical Trust & Bharti Airtel Limited





Career counselling sessions were organized in a number of pharmacy colleges and schools in Delhi where senior students were given a presentation on career in pharmacy and counselled on the various avenues available on taking Pharmacy as a Career.

Efforts were made before, during and after the events to ensure adequate media coverage of the events. All the activities organized during the week were covered by various Pharmacy and Non-pharmacy publications. Community pharmacists and students from various pharmacy colleges in and around Delhi were involved in a major way for making the events successful and to impart a sense of involvement and professionalism. Volunteers were given certificate of appreciation from the Delhi branch. A reinforced membership drive was also launched, coinciding with the NPW – 2007.

4. Pharma Rally 2007

A large Pharma Rally was successful organized on the 18th of Nov., 2007 to create public awareness about the role of Pharmacist as an important member of the Health care team. The Rally comprised of representatives from various facets of pharmacy profession like community pharmacy, hospital pharmacy, academia, regulatory along

with students from various pharmacy colleges in and around Delhi. The participants carried a number of Banners and Posters on the Role of Pharmacist and also enacted street plays at various busy intersections of the road. The rally was able to attract a lot of public attention and appreciation.



5. Scientific study on determination of real time stability of Drug products in selected chemist shops in Delhi

The final report of the scientific study for determining the effect of real time storage of selected drug products in chemist shops in Delhi was presented to Delhi Pharmaceutical Trust (DPT) on the 4th of Aug., 2007 by Dr. Rajesh Khanna and Mr. Manish Narang. The project had been started by the earlier council with sponsorship from DPT. The study scientifically captured the variations observed in the temperature and humidity levels in various retail chemist outlets in Delhi and helped in assessing whether the conditioning facility in retail outlets really has an impact on the stability of the pharmaceutical products stored therein. The professional and scientific manner in which the project was carried out and the manner in which the

results were compiled and interpreted was appreciated by DPT. Dr. DBA Narayana, the managing trustee of DPT proposed that the work should be presented during Indian Pharmaceutical Congress and should also be published in reputed journals.

6. Bridge Career Technical Seminar series

A series of Seminars on the Career Counseling and technical issues faced by the students of Pharmacy was started by the Delhi branch of the Indian Pharmaceutical Association. The first program in the series was held at Jamia Hamdard, New Delhi on the 20th of June, 2007 t Convention Centre, Jamia Hamdard, New Delhi and was very well received by the Student Community. BRIDGE is an attempt by IPA (Delhi Branch) to help Pharmacy students to face challenges of professional world.

In the inaugural seminar, Ms Vidhya Fernandes HR Manager-Abbott Vascular India made a presentation on “How to prepare a CV” & “Tips to prepare for an Interview” and Mr. Anil Suri, Marketing Manager-Abbott Vascular India Spoke to the students about “Expectations of a hiring manager”. The program was very well attended by large number pharmacy graduates from Hamdard University, DIP SAR, Surajmal college of Pharmacy and Rameesh college of Pharmacy (Greater NOIDA). Manish Narang, Hon Gen Secretary, and Dr. Farhan J. Ahmad, Executive member IPA (Delhi Branch) also shared their views on various issues related to career in pharmacy.



The second program in the series was conducted on 25th January 2008 at Seminar hall, Faculty of Pharmacy, Jamia Hamdard, New Delhi. Prof Mushir Ali, head, deptt of Pharmaceutics, Jamia Hamdard inaugurated the seminar by introducing the speakers to the audience.

In the first seminar, **Dr Manoj Kumar**, Associate Director, Dabur Research Foundation, made a presentation on “Analytical Method Development” . He spoke about basic analytical techniques, method development with respect to HPLC and ICH. student asked lot questions about method validation and impurity profiling. Second seminar was delivered by **Dr Rinku Kalra**, Group Leader, IPR Division, Ranbaxy Labs Ltd, on “When Intangible Matters”. She spoke about basics and importance of Intellectual property rights, how to write a patent and patent infringements. In the end Dr. Farhan J. Ahmad, Executive member IPA (Delhi Branch) thanked the speakers for sparing their valuable time sharing their knowledge & views with the students.





The programmes were a huge success and students had a lively interaction with various speakers during an informal gathering over tea. The students also came up with various suggestions for perpetuation of the series further which were keenly taken up by the IPA members.

7. Blood Donation Camp

A blood donation camp was organized at Jamia Hamdard on the 15th of March 2008 as part of the Rx2008 celebrations. A large number of students, faculty members, members from industry donated blood on the occasion.

8. Community Awareness Programs

Various skits and street plays were organized by students of pharmacy colleges in Delhi in order to increase general awareness on social issues like self-medication, dowry, etc.

9. Technical Presentations by Council members

A number of technical presentations on professional topics were delivered under the IPA banner by members of the executive council of IPA, Delhi branch.

Mr. Naresh Sharma, Joint Secretary, presented a talk on "Recent trends in Pharmacy and Technology Development" during "NATIONAL SEMINAR ON RECENT TRENDS IN R&D, QC & MARKETING (PHARMACEUTICAL & FINE CHEMICAL INDUSTRIES)" held at Jiwaji University, Gwalior. More than 300 participants from Industries, Alumni and Students of Jiwaji University attended the seminar. The deliberation from IPA was well appreciated by Dr. D.D. Agarwal, Director/Organizing Secretary and the participants were also sensitized about the various activities taken up in past few years by IPA.

10. Media coverage-through out the year

Efforts were made throughout the year to ensure that the various events organized by the branch were adequately covered by the media. Activities organized by the Delhi branch were covered by various Pharmacy and Non-pharmacy publications.