

AAiPS

Newsletter



AMERICAN ASSOCIATION
OF INDIAN PHARMACEUTICAL SCIENTISTS

P.O. Box 7244
Colonia, NJ 07067

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Editorial Committee: Krip Borah; Uday Doshi; Mike Yelvigi

Contributor: Anilkumar Gandhi

PRESIDENT'S MESSAGE

Dear Members,

Greetings and Best Wishes for Mothers day (May 13) and Fathers day (June 17). Hope you are enjoying the spring of 2012. The last few months have been very eventful. In keeping with our 2012-2013 goal to grow and increase diversity within AAiPS we have undertaken a few initiatives. Firstly, we have focused on increasing the number of student awards from 4 to 6 to give greater opportunities to the student community to get to the AAPS annual meeting and present their research work. Secondly we have extended the scope of the awards to include works in the area of clinical and regulatory affairs. Please read about the details in the newsletter and watch for announcements on our website.

On April 23, a few of the EC members had an opportunity to spend an evening with the students at Long Island University - College of pharmacy. This was organized by the LIU student chapter of AAiPS, read about it in the newsletter. It was a wonderful evening interacting with the students, engaging in discussions with the students on career choices and opportunities in the industry. I would like request our members to keep us informed of any internship opportunities you may have at you company. In turn we can forward this to the student members.

We had our first regional meeting of the year 2012 on March 15 at Akbar in New Jersey, the meeting was sponsored by Capsugel. Sri made a very interesting presentation on Probiotics for Gastrointestinal Health, read about this in the newsletter.

Finally I want to invite you all to attend our second regional meeting of 2012, coming up May 31 at the Morristown Hyatt, the event is sponsored by Cadmach and Shaffer Products, Inc. This promises to be an interesting meeting addressing some of the hot topics being debated in the industry today, the presentations will be on Quality systems and regulatory strategies as well as on recent news from the world of Intellectual property, and I am sure you will have several interesting questions for our speakers and some stimulating discussions during the Q&A.

The executive committee is looking for additional volunteers to help in several of AAiPS committees. I urge you to please come forward. Please feel free to contact me either by email at udaydoshi@aol.com with your suggestions and ideas.

Best wishes.

Uday Doshi

President

QUOTES

“The reasonable man adapts himself to the world; the unreasonable one persists in trying to adapt the world to himself. Therefore all progress depends on the unreasonable man.”- GB Shaw

“An important scientific innovation rarely makes its way by gradually winning over and converting its opponents. What does happen is that its opponents gradually die out, and that the growing generation is familiarised with the ideas from the beginning.” — Max Planck

AAIPS REGIONAL MEETING MAY 2012, NEW JERSEY

AAiPS is proud to acknowledge **Cadmach** and **Shaffer Products Inc**, as event sponsors

Thursday, May 31st

***Regulatory Compliance Management and Intellectual Property Challenges
in the Bio/Pharmaceutical Industry***

PLACE: Hyatt Morristown

3 Speedwell Ave

Morristown, NJ 07960 Tel: (973) 647-1234

Quality Systems & Strategic Regulatory Compliance Management

Satyam Upadrashta, PhD, RAC (US&EU), FAAPS
Senior Director of Global Regulatory Affairs - CMC
Millennium: The Takeda Oncology Company
Cambridge, MA

Methods to Adjust Drug Dosages Based on Blood Concentrations: Should such methods be patentable?

Srikumaran Melethil Ph.D., J.D. Counsel with the intellectual property and technology
Law firm of Fraser Clemens Martin & Miller, LLC,
Perrysburg, Ohio

AGENDA:

Social Hour: 5:30 pm

Seminar: 6:30 pm

Dinner: 7:45 pm

Register now at: <http://www.aaips.org/events.php>

Online Registration closes on Tuesday, May 29th (midnight)

Registration Date	Members	Non-Members	Students*
By May 29 (Tues)	\$ 45	\$ 55	\$ 20
Walk-ins (limited seating)	\$ 55	\$ 65	\$ 20

HIGHLIGHTS OF AAiPS REGIONAL MEETING APRIL 2012, NEW JERSEY

- *By Rashmi Thakur*

Our last AAiPS regional meeting was held on March 15th, at the Akbar restaurant, New Jersey. Considering the growing interest in the fast growing segment, our topic was Probiotics. The event started with Dr Uday Doshi welcoming the attendees. Dr Ramesh Raikar then introduced our speaker for the meeting, Mr. Srisailan Krishnamurthy from Allianz Biosciences. Mr Krishnamurthy led us through a highly informative session regarding probiotics. The market potential, the scientific justification and the current status of the market were all discussed at length. The different dosage forms, role of the intestinal microflora in influencing GI health, influence of probiotics on the microflora were presented in detail. Regulatory aspects and categorization of probiotics as medical food as well as the pros and cons of this categorization were highlighted. Stability and viability along with the wide range of indications were also discussed. It was an engaging talk which all members thoroughly enjoyed especially since the field is in a nascent stage and not too much information is available. Lastly Dr Rashmi Thakur gave the vote of thanks to the members, organizer, sponsors and speaker. Dr Mohan Kabadi presented Mr Krishnamurthy with a plaque of honor. We thank our sponsors Capsugel for their support in the event and look forward to more such interactive and useful sessions.



Dr Ramesh Raikar introducing Mr. Srisailan Krishnamurthy from Allianz Biosciences



Attendees at the March 2012 regional meeting in New Jersey at Akbar restaurant



Mr. Srisailan Krishnamurthy from Allianz Biosciences with Dr Mohan Kabadi

NEWS FROM STUDENT CHAPTER

On April 23rd 2012, Arnold & Marie Schwartz College of Pharmacy and Health Sciences hosted a joint reception with AAiPS student chapter and Long Island University. AAiPS committee members Uday Doshi, Rupa Doshi, Vijai Kumar, Mohan Kabadi and Hemanshu Shah were present to provide guidance to approximate 60 graduate students. Graduate students from M.S in industrial pharmacy/ cosmetic sciences and Ph.D. in pharmaceutics attended the session. Dean David Taft welcomed the AAiPS executive committee and showed his support for the student chapter and arranged for a warm reception at the end of the seminar. Rutesh Dave introduced the panel briefly and started the program. Each member gave a brief overview of their company and various key roles they play at the company.



AAiPS committee members from right: Dr Uday Doshi, Dr Rupa Doshi, Dr Vijai Kumar, Dr. Mohan Kabadi and Dr Hemanshu Shah

Graduate students were very excited to hear about the journey of the committee members and achievements along the way. It was an interactive session and students asked several questions ranging from current

trends in pharmaceutical industry to career development.



Students at LIU chapter meeting

Vijai Kumar also gave a very compelling presentation explaining "Pharmaceutical Development and Systems".



Students and EC members in interesting discussion

AAiPS president, Uday Doshi also gave a brief history of AAiPS and introduced the chapter to the students. Many students expressed desired to attend future meetings. Reflecting this sentiment, a decision was made to display future AAiPS meeting information on the bulletin board. We would like to thank AAiPS executive committee for taking valuable time out from their busy schedule to come and meet us. We would like to outreach to AAiPS for more future

students activities and guidance. We really appreciate your guidance and your entire amazing journey from students to scientific leaders.

Thanking you once again for all your help.

Sincerely,

Smruti Chaudhari, President

Dhaval Shah, Vice President

LIU student chapter

PHARMA NEWS FROM INDIA

-Anil Kumar Gandhi

India to examine drug approval procedures

India has set up a committee to examine the validity of scientific and statutory basis adopted for approval of new drugs without clinical trials. The government announced the decision to set up the committee after a report by the Parliamentary Standing Committee on glaring irregularities in the functioning of the Central Drugs Standard Control Organization (CDSCO). The committee will comprise renowned scientific figures. The committee has also been asked to outline appropriate measures to bring about systemic improvements in the processing and grant of statutory approvals and suggest steps to institutionalize improvements in other procedural aspects of functioning of the CDSCO. The Parliamentary standing committee report has also made recommendations and observations on various aspects such as organizational structure and strength of CDSCO, approval of new drugs, ban of drugs, approval of fixed dose combinations,

pharmacovigilance, spurious and sub-standard drugs.

India for pharma joint ventures with Russian companies

The Union Commerce, Industry and Textiles Minister, Mr Anand Sharma has proposed Joint Ventures (JV) between Indian and Russian pharmaceutical companies at the meeting of the Trade Ministers of India and Russia, in New Delhi. Russian side is to provide list of 500 drugs (mostly generic and strategic) of which 75% is imported by Russia and also information on volume of production is required in respect of certain number of strategically identified medicines. The issue found positive resonance in the Russian delegation. India hopes to tap huge Russian market and neighboring countries, like Belarus and Kazakhstan, where Russia has favourable terms of business. Russia, Belarus and Kazakhstan had recently formed a new customs union pact. If the proposal for JVs becomes a reality, Indian companies manufacturing these drugs in Russia will be able to access the markets in all these three countries, they said. Pharma sector accounts for the largest Indian export to Russia. Indian pharma companies export drugs worth \$ 600 million to Russia every year.

Piramal acquires Bayer R&D portfolio

India-based pharmaceutical company Piramal has agreed to acquire a research and development portfolio from Germany-based Bayer AG, including a potential treatment for Alzheimer's. As per the terms of the agreement, Piramal is set to acquire intellectual property, worldwide development, marketing and distribution of Bayer's possible Alzheimer's drug florbetaben, as well as other clinical and pre-

clinical assets of Bayer's molecular imaging business.

Florbetaben is currently in the final stages of clinical trials and works by detecting symptoms in patients who could be suffering from the disease, allowing earlier detection and specific treatment. During Phase III clinical trials, florbetaben was shown to reliably detect beta-amyloid plaque depositions on the brain, an indication of probable Alzheimer's disease, with accuracy. The drug could potentially enter a market that is estimated to be worth between \$1bn and \$5bn, but is expected to face stern competition from Alzheimer's imaging agents currently being developed by Pfizer, Eli Lilly and General Electric.

Piramal chairman Ajay Piramal confirmed that the deal was the second such purchase of late stage assets following the company's acquisition of BioSyntech assets in 2011. "We plan to build a promising portfolio in the pharma space, including our newly acquired Molecular Imaging assets, which will help us create a global branded pharma business," added Piramal.

Indian Pharma Industry's demand for balanced pricing policy

Indian Pharmaceutical Alliance (IPA) together with other stakeholders in a joint representation has demanded the Government to resolve the issue pertaining to the regulation of prices of 348 drugs along with other major issues. The industry has requested the Government to adopt an evidence based and balanced policy that can rationalize the effect on both sides. D G Shah, secretary general, IPA has said "When overall the pharma industry has shown a very strong growth, there have been strong indicators pointing to the decline in the growth in price controlled drugs over the decade. It is important to note that only 47 out of the 74 controlled drugs are currently

Indian Pharmaceutical Alliance produced in the country, whereas many companies have either limited or completely stopped producing 27 price controlled drugs as they did not give any margin to the company". There is also an observed demand for implementation of better regulatory infrastructure which needs to be both transparent and accountable in its functioning.

Patent office to undergo major technological up gradation under new Chief

Major technological up gradation is being planned in the patent office to enhance the quality of its services, according to the new controller general of patents who took charge last week in Mumbai. The patents office informed that the main aim behind initiating this drive is to upgrade the present system so as to bring in better quality while granting patents in the country. It is understood that the patent office has decided to develop a better information system in the office which is aimed at developing and improving the interface between the government and the stake holders which includes both the general public as well as the agents at large. They also are in process to set up information cells at the patent office with data base that is segregated sector wise for better and easy access to all patent information.

India welcomes investments from global companies in fast growing probiotics segment

With a view to support the booming probiotic industry in the country, the Centre has recently invited the world business community to come and do business in this potential area. Dr H G Koshia,

commissioner, Gujarat Food & Drugs Control Administration (FDCA), in his recent presentation delivered at the World Congress of Probiotics (WCP) 2012 in US, conveyed that the Indian government is open for investments opportunities in the probiotic segment from investors from across the world. Dr Koshia pointed out that today probiotic products are available in the country the way it is being claimed by the manufacturers. To support the growth of the probiotic products in the country the Government in its 2012-13 budget has slashed down the taxes on the probiotic food and drugs by 50 per cent, from 16 per cent to 8 per cent. At present, the Indian Council of Medical Research (ICMR) and the Food Safety and Standards Authority of India (FSSAI) are working together to bring out a draft guidelines for probiotic food. Whereas, most of the probiotic products that are available as drugs in the country currently falls under the category of patented and proprietary (P&P) medicines and requires to comply with standards as per Schedule V of the Drugs and Cosmetics Rules 1945.

APPLICATIONS

AAiPS Graduate Student Scholarship: Every year AAiPS recognizes graduate students who have made scholarly contribution in the field of Pharmaceutical Sciences and Technology. There is a selection committee, chaired by Dr. H. N. Bhargava. The committee seeks applications from deserving students from universities across the United States. Application process involves student's brief personal background and a summary of their research work. Till 2011, there were four awards and the awards were given primarily to students in Pharmaceutics and Pharmaceutical Technology. For year 2012, AAiPS has increased the number of awards

to six, and will seek applications from other branches of Pharmaceutical Sciences such as Clinical Pharmacy, Pharmacy Practice and Regulatory Sciences. Dr. Bhargava will be sending the announcement to various universities in June 2012. The award consists of a plaque recognizing the research work and a cheque for \$500 to each student. Anybody, interested, may contact Dr. Bhargava (hksv@aol.com) to submit the application or Dr. Vijay Naringrekar (vijay.naringrekar@gmail.com) to get further details about the award. The application deadline is July 31st, 2012. The selected candidates will be notified as soon as the review process is complete and the awards will be presented at AAiPS banquet during AAPS Annual meeting at Chicago.

JOB OPENINGS

If you are looking for a job or want to advertise a job, send the editor an email at thakurrashmi@gmail.com and we will post your requirements/credentials in the career section we intend to create on our website.

This forum is a great platform for informing every one of recent changes in your professional life. If you have moved to a new job or need to update contact information, email us and we will post it.

ADVERTISEMENT RATES

The rates of advertisement for the AAiPS newsletter are as follows:

One year (four issues): \$1000 full page, \$500 half a page, \$250 quarter page

One time (one issue): \$400 full page, \$200 half a page, \$100 quarter page.

Contact: Ramesh Raikar
rraikar5@yahoo.com

No advertisements under a quarter page

Opinions expressed in this newsletter belong solely to the authors, and do not represent the views of AAiPS or its members.

AAIPS Office Bearers for 2011-2012

President: Uday Doshi

Vice President: Ramesh Raikar

Secretary: Rashmi Pai-Thakur

Treasurer and advertising : Ramesh Raikar

Immediate past president: Mohan Kabadi

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Mukund (Mike) Yelvigi

Sponsorship Committee Chair: Barry Fox

Awards and Scholarship Committee Chair:

Vijay Naringrekar

Program Committee Chair: Rupa Doshi

Newsletter Editor: Rashmi Pai-Thakur

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