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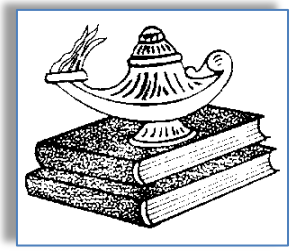
AAiPS

Newsletter



AMERICAN ASSOCIATION
OF INDIAN PHARMACEUTICAL SCIENTISTS
P.O. Box 7244
Colonia, NJ 07067

INSIDE THIS ISSUE

Newsletter Editor: *Mike Yelvigi*
Editorial Committee: *Krip Borah; Vijai Kumar, Sonia Raikar, Charchil Vejani, Uday Doshi*

PRESIDENT'S MESSAGE

Dear Members,

On behalf of AAiPS, I am thankful to all the EC committee members and others who put in their efforts to make our first regional meeting a success.

Dr. Sturgeon presented an excellent presentation and interacted with everyone present there. His knowledge, experience, presentation skills and future perspective on where the problems are occurring in pharma industry were very well acknowledged by audience present and I, on behalf of the EC committee thank him for taking the time off and sharing his thoughts and presenting at our first regional meeting.

We have started revamping our members database so our emails, announcements..etc. reach correct audience. I thank Sonia, Charchil and Bruhal to ensure that this happens quickly and systematically. If you have not updated your information and would like to do so, please email Sonia Talwar at Sonia.talwar@pharma.com or Charchil Vejani at vejanic@gmail.com

After the meetings we have received comments and suggestions to improve our regional meetings and work harder to get more sponsors to support our future meetings. These issues will be addressed in our upcoming EC meetings and I will keep you up-to-date on our activities and I look forward to meeting again in our upcoming meetings.

Sincerely,

Rutesh H. Dave

President

QUOTES

"TIME IS INFINITE MOVEMENT WITHOUT ONE MOMENT OF REST."

-Leo Tolstoy: War & Peace: Epilogue

"TIME IS THE IMAGE OF ETERNITY."

-Plato

"TIME IS SOUL OF THE WORLD"

-Pythagoras

OFFICE BEARERS FOR YEARS 2014-2016

We are pleased to announce the office bearers for 2014-2016 as follows. We have many committees, and if you are interested in serving in any committees, please contact us immediately.

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Kashiv Pharma
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Fellow, Long Island University
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Barry Fox

Program Committee Chair: TBA

Members at large:

Mike Yelvigi, Vijai Kumar

AAiPS P.O. Box 7244 Colonia, NJ. 07067

Or

Mike Yelvigi at
MYELVIGI@HOTMAIL.COM

Vijay Kumar at

Vijai25@gmail.com

HIGHLIGHTS OF AAiPS QUARTERLY MEETING , NEW JERSEY MARCH 13, 2014

Review by: Rina Chokshi-Program Chair

AAiPS hosted the first regional meeting of the year at Somerset, NJ on 24th April 2014. Dr. Roy Sturgeon was invited as a guest speaker, and he presented on the topic of "Quality Culture – by Design or Regulation?" Dr. Roy is the Senior Advisor, Outside Director to the Board of Lachman Consultants. He provides leadership and subject matter expertise for the assessment, analyses, planning, implementation and verification of projects from development to post-marketing surveillance. He presented appealing overview on growth of generic industry and associated challenges in respect to drug product quality standards. He also presented case studies based on various incidents of FDA consent decree and warning letters. The talk ended with remedial strategies and compliance enhancement programs initiated by pharmaceutical industry to standardize quality and regulatory requirements. This event was very well attended and well received. The educational evening, which started with a question of "What is Quality" ended with enhanced understanding and delicious dinner.

AAiPS Executive Committee Members with the Speakaer Dr Roy Sturgeon

Indian Pharma Sector News

Sun Pharma Indian Plant impacted by US FDA:

Source: FiercePharma March 13 2014

A Sun Pharma plant has joined the growing ranks of Indian operations banned by the FDA for manufacturing issues. Unlike Ranbaxy Laboratories and Wockhardt, two other Indian generics players that have recently felt the sting of import alerts, the Sun Pharma plant is not key to its financial success.

Sun did not say what issues have landed the plant in Karkhadi in Gujarat, India, in hot water with the regulator, but on Wednesday the facility was added to the FDA's import alert list. That means its products, made for human or veterinary use, are not to be allowed into the U.S.

A Sun Pharma spokeswoman told Reuters that the company was working on the issues raised by FDA inspectors. The plant--one of more than two dozen the generic drug maker has around the world--manufactures antibiotic cephalosporin. But she said it accounts for less than 1% of the company's sales, so the ban would not change its financial picture significantly.

That is not the same for Ranbaxy and Wockhardt, which have both seen the agency ban two of their FDA-approved plants each since May of last year. Wockhardt executives have said the ban of one of its key FDA-approved plants could cost it $100 million. Since then, the FDA has banned a second plant, and some European countries have blocked some of its products as well.

The regulatory picture is also dire for Ranbaxy. With an Indian production plant banned in September, and its main API facility added to the list in January, Ranbaxy has had its U.S. supply operations crippled. Its Toansa API plant supplies a majority of the ingredients for its U.S. approved drugs. It was also relying on its now-banned facility in Mohali to produce first-to-market generics for which Ranbaxy has been approved. Those include two blockbusters, Novartis' ($NVS) heart drug Diovan, which is already off patent, and Nexium, the stomach upset drug from AstraZeneca ($AZN). Ranbaxy now has only a plant in New Jersey which can still make drugs for the U.S. market. It is reportedly negotiating with outside suppliers for the APIs it needs for those two launches and may be seeking approval to make them in the New Jersey facility.

Ranbaxy's problems have been a boon to Novartis, which has had its finances buoyed by the unexpected windfall of Diovan profits since the drug went off patent in 2012. The same may come to pass for AstraZeneca, which will lose patent protection on blockbuster Nexium May 27. Reuters reported a forecast from a Barclays analyst this week that the U.K. company would enjoy a 10-cent boost to its 2014 earnings per share with each month of a generic delay.

The ban of the Sun facility comes only weeks after FDA Commissioner Margaret Hamburg returned from a trip to India where she discussed quality issues with government and industry officials. The country provides about 40% of the generic and over-the-counter drugs U.S. consumers take, and so the FDA has beefed up oversight there with an in-country inspection staff and more diligence. She noted during her trip that many of India's drug makers have modern facilities with top-notch operations, but she urged regulators there to step up their game to ensure that Indian companies were hitting international expectations.

Indian drug makers ponder opening plants in U.S., Europe

The publicity generated by quality problems uncovered by the FDA at some Indian generic med plants is making a growing number of U.S. doctors uneasy about their patients getting drugs that are manufactured there. While they really have no say over the source of the generic meds their patients get, the issue has at least a few Indian drug makers weighing the need to open plants in the U.S. or Europe to fight those perceptions.

According to Reuters, Jefferies India analyst Piyush Nahar said in a recent report that Indian drug makers told him that they have

boosted their investments in compliance. But some are also considering investing in U.S. or European facilities "to overcome challenges relating to both regulations and perceptions."

Among those with a perception that Indian drugs are inferior is Dr. Steven Nissen, head of cardiology at the Cleveland Clinic. "I'm just beginning to realize the gravity of the problem," he told Reuters. "It's terrible and it is starting to get a lot of traction among physicians."

Doctors can only prescribe branded or generic medications. Whether a patient gets a drug made by an Indian company whose operations the FDA has criticized or one made by someone else depends on what is on the pharmacy shelves.

The FDA recently added a Sun Pharmaceuticals plant to the list of facilities in India that have been banned. That list includes four plants operated by India's largest generics drug maker, Ranbaxy Laboratories, as well as two plants operated by Wockhardt. But the FDA has also taken actions against any number of U.S. facilities, as well as plants in Europe operated by the largest of big pharma companies. German drug maker Boehringer Ingelheim even shut down a sterile injectable drug plant in the U.S. last year after years of trying to fix problems pointed out by the FDA.
Some Indian industry officials see the dust-up as a conspiracy against Indian manufacturers. "We have heard doctors making generalized statements, without being specific on any product or company," D.G. Shah, secretary general of the Indian Pharmaceutical Alliance, told Reuters. "This is a deliberate and serious campaign to malign the Indian generic industry."

India's quality lapses sparking turmoil throughout the generic drug industry

India is a crucial player in the global drug supply chain. It produces 40% of the generics and over-the-counter drugs that U.S. consumers turn to, and the U.S. is the world's largest market. But there is a growing perception among doctors that Indian-made meds fall short on quality, leading some drug makers to cry conspiracy and others to wonder how best to respond.
Among those doctors whose perception about Indian-made drugs has changed is Dr. Steven Nissen, head of cardiology at the Cleveland Clinic. "I'm just beginning to realize the gravity of the problem," he told Reuters. "It's terrible and it is starting to get a lot of traction among physicians."

Doctors really have no control over whether their patients get a drug made in India or somewhere else. That depends on what is on the pharmacy shelves. And even then, many facilities in the U.S. and Europe have also been cited by the FDA for failures.
Some defenders see a conspiracy against Indian manufacturers. "We have heard doctors making generalized statements, without being specific on any product or company," D.G. Shah, secretary general of the Indian Pharmaceutical Alliance, told Reuters. "This is a deliberate and serious campaign to malign the Indian generic industry."

There has been an effort recently by a group of U.S. researchers and others, led by American Enterprise Institute drug authority Roger Bate, to convince lawmakers that Indian-made meds are something they should be concerned about. One of the doctors working on that effort is Dr. Harry Lever, a cardiologist at the Cleveland Clinic. "We are losing control over what people are swallowing," he told Reuters. He said he

often suggests that patients see if they can avoid buying generics made in India.

There has also been no lack of publicity about the failings at Indian drug plants. The issue received lots of press when FDA Commissioner Margaret Hamburg made a trip there to meet with Indian regulators and industry bigwigs. The FDA recently added a Sun Pharmaceuticals plant to the list of facilities in India that have been banned. That list includes four plants operated by India's largest generics drug maker, Ranbaxy Laboratories, as well as two plants operated by Wockhardt.

But the FDA has also taken actions against any number of U.S. facilities, as well as plants in Europe operated by the largest of big pharma companies. German drug maker Boehringer Ingelheim even shut down a sterile injectable drug plant in the U.S. last year after years of trying to fix problems pointed out by the FDA.

Some Indian drug makers are pondering how to respond. According to Reuters, Jefferies India analyst Piyush Nahar said in a recent report that Indian drug makers told him that they have boosted their investments in compliance. But some are also considering investing in U.S. or European facilities "to overcome challenges relating to both regulations and perceptions."

But some U.S. drug makers say there is spillover for the entire industry when questions of quality arise. Tony Mauro, the North American president of Mylan ($MYL), recently told Bloomberg: "The industry as a whole always suffers when there are challenges from a quality perspective because this whole industry's foundation is about sameness of the brand."

Indian regulator finds number of substandard drugs on the rise

With FDA bans of products from some of India's largest drug makers has come growing debate about the quality of drugs shipped to the U.S. A new report from the key drug regulator in India is likely to add to that discussion.

According to the Economic Times, sampling by the Drug Controller General of India (DCGI) since December 2012 found that about 2.3% of products tested failed to meet standards. Twenty-six of 1,123 samples failed to qualify, the report said. The sample was much smaller than the 24,000 drugs the regulator checked in 2009 amid reports of counterfeiting, but the percentage was much larger than the 0.046% it reported being substandard at that time.

Many of the products manufactured in India are not shipped to the U.S., and the FDA oversees the drug makers who do export to the U.S. But the publicity that has resulted from FDA actions against some Indian generic med plants has started to enter the public consciousness, and some doctors, in addition to lawmakers and regulators, have been expressing concern.
"I'm just beginning to realize the gravity of the problem," Dr. Steven Nissen, head of cardiology at the Cleveland Clinic, told Reuters this week. "It's terrible and it is starting to get a lot of traction among physicians."

A week ago, the FDA banned a Sun Pharmaceuticals plant in India from shipping to the U.S. That came after it banned a plant in January owned by India's largest generics drug maker, Ranbaxy Laboratories. And that action followed a ban of another Ranbaxy plant in September. The agency last year also banned two plants

owned by India's Wockhardt. Those actions drew a lot of attention during a trip to India in February by FDA Commissioner Margaret Hamburg.

Hamburg emphasized that most Indian drug makers shipping to the U.S. have high-quality operations, and some Indian industry officials think regulatory issues with Indian drug makers are being overblown. Still, worried about the potential fallout from the issues with their peers, some drug makers there are looking for ways to fight off the tide of bad publicity. According to Reuters, Jefferies India analyst Piyush Nahar said in a recent report that some are considering investing in U.S. or European facilities "to overcome challenges relating to both regulations and perceptions."

Ranbaxy shareholders to get 0.8 Sun Pharma share for each Ranbaxy share Laboratories Ltd. Sun Pharmaceutical gets FDA import ban on Gujarat plant Dr Reddy's Laboratories recalls 58,656 bottles of heartburn drug in US Ranbaxy Laboratories sold adulterated drugs in India? India's midcap pharma stocks surge on valuations Sun Pharmaceuticals Industries said it will buy generic drug maker Ranbaxy Laboratories Ltd, which has hit regulatory snags in its key US market over quality issues, in an all-share deal with total equity value of $3.2 billion.

Ranbaxy, India's No.1 drug maker by sales and 63.4 percent held by Daiichi Sankyo Co Ltd, is banned from exporting drug ingredients to the United States, while Sun Pharmaceutical's Karkhadi plant is also barred from shipping products by the US Food and Drug Administration.
Sun Pharmaceutical said Ranbaxy shareholders will get 0.8 Sun Pharma shares for each Ranbaxy share. It added that the merged company will become the world's fifth-largest specialty generics company and the largest drug firm in India.
Daiichi Sankyo said in a statement that it will hold about a 9 percent stake in Sun Pharmaceutical after the deal, which has been agreed to by the boards of both companies.

In a separate statement, Daiichi Sankyo said the US Attorney's Office in New Jersey had issued an administrative subpoena to Ranbaxy seeking information related to the company's Toansa plant in India. Ranbaxy is cooperating with the information request.
Shares in Daiichi Sankyo climbed as much as 4.1 percent to a 2-1/2 month high of 1,827 yen in early Monday trade, outpacing a 1.2 percent decline in the benchmark Nikkei.

Sun Pharma to buy Ranbaxy in all stock deal valued at USD3.2bn
(PTI) - Sun Pharmaceutical Industries will fully acquire troubled Ranbaxy Laboratories, in an all-stock transaction with a total equity value of USD 3.2 billion.

"Sun Pharmaceutical Industries Ltd and Ranbaxy Laboratories Ltd today announced that they have entered into definitive agreements pursuant to which Sun Pharma will acquire 100 per cent of Ranbaxy in an all-stock transaction," the two companies said in a statement.

Under these agreements, Ranbaxy shareholders will receive 0.8 share of Sun Pharma for each share of Ranbaxy. The transaction has a total equity value of approximately USD 3.2 billion.

"This exchange ratio represents an implied value of Rs 457 for each Ranbaxy share, a premium of 18 per cent to Ranbaxy's 30-day volume-weighted average share price and a premium of 24.3 per cent to Ranbaxy's 60-

day volume-weighted average share price, in each case, as of the close of business on April 4, 2014," it added.

The combination of Sun Pharma and Ranbaxy creates the fifth-largest specialty generics company in the world and the largest pharmaceutical company in India. The combined entity will have operations in 65 countries, 47 manufacturing facilities across 5 continents, and a significant platform of specialty and generic products marketed globally, including 629 ANDAs. On a pro forma basis, the combined entity's revenues are estimated at USD 4.2 billion with EBITDA of USD 1.2 billion for the twelve month period ended December 31, 2013.

The transaction value implies a revenue multiple of 2.2 based on 12 months ended December 31, 2013.

Commenting on the development, the Sun Pharma Managing Director said, "Ranbaxy has a significant presence in the Indian pharma market and in the US where it offers a broad portfolio of ANDAs and first-to-file opportunities. In high-growth emerging markets, it provides a strong platform which is highly complementary to Sun Pharma's strengths.

Ranbaxy Managing Director and Chief Executive Officer Arun Sahwney said the transaction brings significant value to all Ranbaxy shareholders.

"Sun Pharma has a proven track record of creating significant long-term shareholder value and successfully integrating acquisitions into its growing portfolio of assets.

We are confident that Sun Pharma is the ideal partner to help us realize our full potential and are excited to participate in future value creation opportunities," he added.

The proposed transaction has been unanimously approved by the Boards of Directors of Sun Pharma, Ranbaxy, and Ranbaxy's controlling shareholder, Daiichi Sankyo.

Ranbaxy's board and Sun Pharma's board have recommended approval of the transaction to their respective shareholders. The statement further said Ranbaxy has recently received a subpoena from the United States Attorney for the District of New Jersey requesting that Ranbaxy produce certain documents relating to issues previously raised by the FDA with respect to Ranbaxy's Toansa facility.
"In connection with the transaction, Daiichi Sankyo has agreed to indemnify Sun Pharma and Ranbaxy for, among other things, certain costs and expenses that may arise from the subpoena," it said.
Ranbaxy's all four plants have been banned by the USDFA for violations of manufacturing norms. In 2013, the company agreed to pay USD 500 million fine after pleading guilty to felony charges over manufacturing and distribution of adulterated drugs in the US.
In 2008, Japan's Daiichi Sankyo had acquired majority stake in Ranbaxy for Rs 22,000 crore.

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

AAiPS Research Awards: 2014

The American Association of Indian Pharmaceutical Scientists (AAiPS) is pleased to announce the availability of SIX awards for the graduate students in Pharmaceutical Sciences. Applicants in pharmaceutical sciences should submit their research findings. Applications for consideration to the regulatory and clinical science should be focused on the drug regulation and practice and science in the clinical setting respectively. FOUR awards will be given to the students of Indian heritage and TWO are open to all graduate students.

Criteria for submission:

Interested graduate students should submit a 350 words summary of their research findings. The format should include Title, Author/s, Affiliation, Purpose, Methods, Results and Conclusion. Title, author/s and affiliation would not be counted towards 350 words.

At the end of your abstract, please include contact details (primary author's name, email and phone followed by major advisor's name, email and phone)

All applicants must present their research findings at the 2014 Annual meeting of the American Association of Pharmaceutical Scientists (AAPS). Abstract should have been accepted by AAPS.

➢ Please include category on top of your abstract. You can apply to any one categories from the four listed below. See the format below for writing your abstract.

Section:

Title:
Authors name:
Affiliation:
Purpose:
Methods:
Results:
Conclusion:
Contact details:

Categories to submit abstracts:

1. Drug Delivery/Pharmaceutical Technologies: All topics related to formulation, physical pharmacy, biotechnology, drug discovery and manufacturing/manufacturing Science and Engineering

2. Analysis and Pharmaceutical Quality:
All topics related to Dissolution Technologies, In Vivo-In Vitro Relationships/Correlations, Method Development and Validation, Electrophoresis, High-throughput Analysis, Hyphenated Methods—Small Molecule (e.g., GC-MC, LC-MS, etc.), PK Samples, Theoretical and Statistical Aspects of Method Validation,

3. **Pharmacokinetics, Pharmacodynamics, and Drug Metabolism:**
All topics related to biopharmaceutics**,** bioavailability, First Pass Effects / Drug Absorption (Food Effects, Formulation Effects), Drug Interactions, PK and PK/PD Modeling, Tissue Distribution and Microdialysis, Toxicokinetics / Toxicology, Transporters.

4**. Regulatory Affairs:**
All topics related to regulatory affairs like cGMP, CMC, regulations/guidance, ICH guidelines, etc.

Please send your submissions by Friday, August, 29th 2014 to:

Hardeep S.Saluja Ph.D.; Chair
AAiPS Research Awards Committee,
Southwestern Oklahoma State University
College of Pharmacy,Weatherford, OK -73096
Email:hardeep.saluja@swosu.edu

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If you are looking for a job or want to advertise a job, send the editor an email at myelvigi@hotmail.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 EVERYONE 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.

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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
raikar5@yahoo.com
No advertisements under a quarter page

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AAiPS Regional Meeting: August 15th Friday, 6 PM

Theme: Meet and Greet event

At

Guru Palace Restaurant

2215 US Highway 1 South, North Brunswick, NJ 08902

Phone: (732)-398-9022

Social Networking meeting on Independence Day

This is first social networking event conducted by AAiPS where you will be able to enjoy networking with your peers and students. This also concludes with our independence day and we hope that you all will be able to join us with your family and friends.