CPhI
Feria de Madrid SPAIN
14 October 2015
Wednesday
SHOW DAILY
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The CPhI Pharma Awards' Top Choices

From among 16 finalists, six companies emerged as winners representing their respective industry categories. The awards celebrate innovation in a range of categories:

- Supply Chain Management—Trace Link
- Manufacturing Technology—Harro Hoefliger
- Packaging—Sulzer
- APIs and Excipients—OMYA International
- Partnering and Outsourcing—Centroflora
- Process and Formulation Development—Catalent
- Outstanding CEO—Vivek Sharma, Piramal

Full coverage, Thursday's CPhI Show Daily.

What's Inside

Tackling Issues Headon

Biosimilars, Trade Accord are Challenges Fueling Pharma's Future

An integrating pharma sector, biosimilars in advanced and emerging markets, and the recent trade accord affecting pharma companies operating in Pacific Rim nations were main issues at the media debate following the presentation of this year's CPhI 2015 Annual Industry Report on Tuesday.

"Generic manufacturers need innovators, and innovators need generic producers and governments need both," said Kate Kuhrt, senior director, Generics & Biotech, Thomson Reuters. "Without new drug launches by the innovator companies, there will be fewer generics brought to market.

"And right now, we are seeing more innovators becoming involved in the generics sector, while generic companies are themselves innovating by coming up with ways to cut costs and curb waste," she added.

More collaboration among pharma and others is needed to ensure the industry goes forward, the experts agreed.

"The government, academia, and the industry must cooperate to see that our universities produce the graduates so pharma can prosper," Kuhrt explained. "Human capital is what is going to guarantee that outcome."

Another major trend in the industry involves biologics and biosimilars with Ravindra Limaye, president of India's Biocon Limited, arguing for their importance to the industry.

Media debate panelists, left to right: Piramal's Vivek Sharma, Biocon's Ravindra Limaye, *Pharma Executive*'s William Looney, and Thomson Reuters's Kate Kuhrt

"Biologics have grown exponentially in recent years, but they are not becoming accessible due to the affordability gap despite breakthroughs in the business," he said. "However, it is proven that biosimilars, for example, can rapidly gain market share and improve access, and we are currently working on five to six biosimilars at various stages of development."

Limaye also noted that the regulatory structure was improving for biosimilars, as has acceptance in the medical community thanks to extensive clinical development programs which show that these drugs score highly in efficacy and patient safety.

"Another challenge is educating the physician community," he added.

Asked when Indian manufacturers will begin obtaining approval for biosimilars in advanced global markets, the Biocon exec stressed that his company was working with Mylan in developing biosimilars for the U.S., Europe and Japan.

"But it is important to understand that you need biosimilars in emerging markets to improve accessibility and we are launching or looking at launches in Latin America, the Middle East and Africa," he said.

Earlier this month, the U.S. and 11 other Pacific countries signed the Trans-Pacific Partnership (TTP) accord aimed at liberalizing the exchange of goods and services among the signatory nations, affecting around 40 percent of the world's economy.

Many industries cheered the news, but pharma execs, and more particularly, those on the biotech side, are less than ecstatic because the deal includes a clause on patent exclusivity for biologics with the countries compromising on the time period new biologics can be sold by one company.

It designates the length of time companies can have unique access to data it collects on treatments.

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Andreas Schütte
Member,
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FIVE MINUTES WITH

What are your major concerns within your market over the next two years?
Definitely quality. The US Food and Drug Administration (FDA) is setting the pace, Europe is following suit, and many other countries close behind. Zero-defect tolerance for pharmaceuticals is the right way to go. After all, we're talking about people's health. In the primary packaging and drug delivery device industry quality is a number one priority. Supplying high quality packaging and devices is essential to the pharmaceutical companies' success. I'm not just talking about meeting external requirements, like FDA requirements. I'm talking about a quality culture that is shared by the suppliers and their pharmaceutical customers.

Among the challenges facing the industry, which one do you think is the most pressing—and why?
New pharmaceutical drugs mean new requirements of packaging. Even glass, the traditional packaging material, doesn't tick all the boxes as a packaging for some of these new drugs. Innovative packaging solutions made of new materials—such as high-performance COP or tempered glass—should be considered as relevant options for some applications.

What innovation (not your own company's) do you believe has addressed a problem with an especially interesting and creative solution?
The word "innovation" brings to mind flashy inventions—such as smartphones, electric cars and delivery drones. In most cases, though, it is the many incremental improvements that make the real difference and benefit users and customers. I strongly believe that continuous improvement and the "smaller" innovations help people most and are most effective in the long-run. So instead of just looking at innovations that are associated with major changes like those in the IT sector and other industries, we should focus on continuous improvement. An innovation can also be a step up in quality, a new process or simply improved usability for customers. There are already a lot of innovations like that in the industry, but there can never be enough.

What should the common goals within the industry and/or marketplace be?
Quality and innovation should be high on the agenda, but not as an end in themselves. We have to make them really matter, i.e. they should deliver added value to the customer—which is the patient taking the drugs.

What is one relevant question (and your answer) that you believe no one is addressing adequately?
Drug usage and administration compliance is a very relevant and pressing issue that hardly anybody addresses successfully. These days, more and more people are self-medicating. At the same time, there are many things that can go wrong in self-medication. Thirty percent to 50 percent of all prescription drugs don't get taken at all, or they are taken at the wrong time or in the wrong dose. This leaves scope for the development of intelligent products, which is a big challenge for the primary packaging and drug delivery device industry.

Gerresheimer is a leading global partner to the pharma and healthcare industry providing solutions and products for primary packaging and drug delivery made of glass and plastics.

Pharma's Future *from page* **1**
the agreement, countries are able to choose between two exclusivity options—eight years of total exclusivity or five years of data exclusivity, plus three years of partial exclusivity.

U.S. negotiators at the trade talks argued for a 12-year exclusivity period for biologics that conforms with U.S. practice.

"While the U.S. Generic Pharmaceutical Association applauded the TTP deal as a positive step, the pharma industry in general was disappointed and the biotech sector was very disappointed," Kuhrt told the media debate. "Big and small pharma companies have to protect their innovations and their business."

#CPhIChat

Tweet Chat To Focus on Conversation Between Experts, Attendees

An industry-wide tweet chat today is broadcasting a conversation between the CPhI expert panelists and the attendees. Industry professionals and media are invited to participate in the #CPhIChat that will take place.

With the release of the annual report Tuesday, attendees will be able to analyze the contributions of the panelists and contribute to a live discussion displayed throughout the screens at the show. The aim is to facilitate shared knowledge building and stimulate conversations across the entire pharma supply chain on key industry issues.

For the second annual #CPhIChat, topics will focus on quality and continuous improvement, patent laws, and outsourcing growth.

CPhI encourages the entire industry to log into Twitter from 2 to 4 p.m. to join the debate by using the hashtags #CPhIChat and #CPhIWW. The debate will be streamed in real-time at the CPhI Conference, with a summary report released after the show.