



# Drug Information Bulletin

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## Editorial

A critical survey conducted in USA in 2013, revealed 70% of consumers said they wanting go to a pharmacist for health services if their insurance covered them. Twenty one percent out of these said they would still go to a pharmacist, despite having to pay \$75 out of pocket. These percentages suggest that patients would both trust and engage pharmacists for medial care. On a broader context this becomes important, particularly in rural areas where access to physicians is limited. A central point is that pharmacists can play a valuable role working with physicians and other providers to optimize medication therapy, deliver patient-centered care, and assist in managing acute and chronic conditions.

A crucial role a pharmacist can play is, he/she can have a huge influence in improving medication adherence. Medical care costs of people with chronic diseases account for more than 75% of the nation's \$2 trillion medical bill. Interestingly almost 50% of people prescribed medications for chronic diseases do not take their medications correctly. Compliance or adherence plays a great role in a patient's management of chronic conditions and providing a value to the cost of medications. This relationship actually costs the United States 300 billion annually in issues involving medication use. The data suggest that the pharmacist can play a critical role in adherence and a systematic review of the adherence literature found that five of six pharmacist-directed interventions in community pharmacies were effective in improving adherence by 7% to 27%.

Currently pharmacists can provide many services to their patients—from information to specific medicines. In fact, the pharmacy is often a first source of medical information for many, since the pharmacists are the first contact point of the patients and medications. Pharmacy services have evolved from strictly dispensing medications to offering services such as medication therapy management, medication education, improving medication adherence, administering immunizations, and promoting health care. In addition, pharmacists can now be found in specialty areas such as oncology, organ transplant and even psychiatry.

This development is gradually transmitting throughout the globe improving scope of pharmacists in health care system.

**Dr. Subhash C. Mandal**  
*Editor*

## **Ruling of London High Court pave the way to cheaper version of Herceptin**

Hospira has successfully overturned two patents on Roche's blockbuster breast cancer drug Herceptin in Britain, clearing the way for it to launch a cheaper copycat version in the country.

A ruling handed down by the High Court in London on Thursday determined that both the 115 and 455 patents on the drug, which relate to the drug's dosage and its composition, were invalid.

The basic underlying patent <[http://www.reuters.com/subjects/top-100-global-innovators?lc=int\\_mb\\_1001](http://www.reuters.com/subjects/top-100-global-innovators?lc=int_mb_1001)> held by Roche on its medicine was not challenged by Hospira. This patent expires on July 28 and Hospira told the court it wanted to sell its version of the product, known generically as trastuzumab, after that date.

Such a move would ramp up competition for a costly cancer treatment and could drive down prices. The potential to use copycat forms of biotech drugs like Herceptin is gaining increased attention from cost-conscious health authorities across Europe.

"We are very pleased with this decision, which helps pave the way for our trastuzumab product," U.S.-based Hospira said in a statement.

A spokeswoman for Roche said the Swiss drugmaker was analyzing the court ruling revoking its patents and considering its next steps.

Herceptin, an injectable antibody-based biotech drug, had worldwide sales of 6.08 billion Swiss francs (\$6.90 billion) last year, making it the company's third biggest-selling medicine after two other cancer drugs, MabThera and Avastin. British sales are a small proportion of that total.

Herceptin is designed to fight cancers that have too much of a protein called human epidermal growth factor receptor 2, or HER2, on the surface of their cells. That means it is only helpful for a minority of women with breast cancer but for this group it has proved to be an important treatment.

Hospira has pioneered the development of so-called biosimilar versions of biotech drugs. Unlike conventional chemical medicines, these biological drugs are complex to make and copies can only ever be similar to the original product rather than exact replicas.

Hospira recently launched the first antibody biosimilar in Europe, called Inflectra, which is a copy of Johnson & Johnson's and Merck & Co's Remicade drug for rheumatoid arthritis.

## **U.S. jury orders massive awards against Takeda and Eli Lilly**

A jury in Louisiana awarded \$6 billion in damages from Takeda Pharmaceutical, plus \$3 billion in punitive damages against Eli Lilly & Co., for claims that the companies hid cancer risks associated with the diabetes drug Actos. Takeda said it would challenge the finding through the appeal process. Another U.S. judge in May nullified a \$6.5 million award against Takeda, citing lack of evidence that the drug caused cancer.

## India's Sun Pharma plans gradual phase-out of Ranbaxy-branded drugs in US - sources

India's Sun Pharmaceutical Industries Ltd plans to begin phasing out sales of generic drugs branded as Ranbaxy Laboratories Ltd products in the United States, after completing a \$3.2 billion takeover of its loss-making rival by the year end, sources with direct knowledge of the matter said.

Ranbaxy drugs sold in the United States will be gradually rebranded as Sun Pharma treatments as part of a strategy to turn around the company being bought from Japan's Daiichi Sankyo Ltd . The brand is likely to continue to be present in other [markets](#), the sources said.

The sources declined to be named as they were not authorised to speak to the media on the subject.

Uday Baldota, Sun Pharma's senior vice president of [finance](#) and accounts, didn't comment directly when asked whether Sun Pharma will phase out Ranbaxy-branded products in the United States. "Overall Ranbaxy brand has a value," he said. "We will find ways of using it and preserving it."

The plan to phase out the brand from the United States will be part of a slew of changes at Ranbaxy, including an intense lobbying push with the U.S. Food and Drug Administration (FDA) to lift bans on imports from Ranbaxy's [India](#) plants over production quality concerns, the sources said.

Sun Pharma, which has been the subject of comparatively fewer regulatory actions in the past, on Monday agreed to buy Ranbaxy in an all-share deal, betting it can fix the factory quality glitches that plagued Daiichi Sankyo and got Ranbaxy's India-made drugs barred from the United States. India's market regulator is now taking a look at the deal, after shares in Ranbaxy surged before it was announced, a senior source at the regulator said on Wednesday.

Sun Pharma concedes the road to the recovery at Ranbaxy is set to be long and challenging. The all-share acquisition will create India's biggest and the world's fifth-biggest generic drugmaker with combined sales estimated at \$4.2 billion.

"(The Ranbaxy challenge) is quite big. In absolute size it is the largest challenge that we've had," Baldota said. "It will take time, it is not going to come easily, it will take a lot of effort, but hopefully we should be able to help them resolve the problem."

Some U.S. doctors are becoming concerned about the quality of generic drugs supplied by Indian manufacturers following a flurry of recalls and FDA import bans on companies such as Ranbaxy and Wockhardt Ltd.

The broader issue of the quality of drugmaking has become a major concern in the \$14 billion pharmaceutical sector in India, second only to Canada as a drug exporter to the U.S., where it supplies about 40 percent of generic and over-the-counter drugs.

In a statement issued to Reuters on Wednesday, the European Medicines Agency, the regional drug regulator, said an inspection of Ranbaxy's Dewas plant, one of the two plants from which the company voluntarily suspended shipments in February, was planned for June.

### IMPROVING OVERSIGHT

With an eye on competing with bigger global rivals such as [Teva Pharmaceutical Industries](#) Ltd and Sandoz, the generic division of [Novartis](#) AG, Sun Pharma has said making Ranbaxy's India plants FDA quality-compliant again is its top priority.

"There are definitely going to be challenges because Ranbaxy has gone through a lot of pain from the FDA side," said Mahesh Patil, a fund manager at Birla Sun Life Asset

Management. "The FDA issues and getting clearances will take its own time, but on the operational side, the integration I think they should be able to do in a year's time to a large extent."

Sun Pharma, the top Indian drugmaker by market value, could invite the FDA and regulators from other major [markets](#) to visit the four India factories of Ranbaxy after improving production processes at these sites as a "confidence-building measure", one of the sources said.

Getting the FDA bans lifted from the India plants of Ranbaxy would help Sun Pharma benefit from Ranbaxy's new product pipeline, including a generic version of AstraZeneca's big-selling heartburn drug Nexium, which had global sales last year of \$3.87 billion and U.S. sales of \$2.12 billion.

The changes to revive Ranbaxy, once the embodiment of the rapid growth in the Indian generic drugs industry, are also likely to include some management restructuring to boost oversight of plants in India, the sources said.

### Office bearers for the year 2014-2016 during charge hand over on 12.04.2014



**From L-R: Sitting:** Dr. Surendra P. Manek- Hon. Treasurer; Mr. Kaushik Desai-Hon. Gen. Secretary; Dr. Rao V. S. V. Vadlamudi – President; Mr. S.D. Joag – Secretary General  
**Standing:** Prof. T. V. Narayana – Chairman, Education Division & Vice President; Dr. Subhash C. Mandal-Chairman, Regulatory Affairs Division & Vice President; Mrs. Manjiri Gharat- Chairperson, Community Pharmacy Division & Vice President, Dr. Alka Mukne – Editor, Pharmatimes, Dr. Divakar Goli – Editor, IJPS

(Dr. S.B.Rijhwani- Chairman, Industrial Pharmacy Division & Vice President and Dr. Ramesh Adepu, Vice President, Hospital Pharmacy Division & Vice President-not in this Photograph)