Drug Information Bulletin

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7^{th} Year Inaugural Issue

Volume: 07 ***Number: 01*** ***14^{th} April 2013***

Content

Editorial:

On demand from the readers I am writing an editorial from this issue i.e. first issue of the 7^{th} year. It is a critical time in global pharmaceutical fraternity due to the recent verdict of the Supreme Court of India on patent issue of Gleevac. It appears to be a solace to the billions of poor people who are not in a position to afford the much needed medicines at the time of their need.
Though some people are expressing concern about the future of R & D investment in India, this verdict is most welcome to most of the quarters.
India's status as "Pharmacy of the world" is expected to be continued in the future.

Top Court in India rejects Novartis drug patent

India's Supreme Court rejected a Swiss drug maker's patent application for a major cancer drug Monday in a landmark ruling that allows cheap copies of important medicines to continue being distributed in much of the world.

The ruling allows Indian generic companies to continue making copycat versions of the Novartis drug Gleevec, which can have a miraculous effect on some forms of leukemia.

But the ruling's effect will be felt well beyond the limited number of patients in India who need Gleevec because it will help maintain India's role as the world's most important provider of cheap medicines, which is critical in the global fight against HIV/AIDS and other diseases.

Novartis had hoped that India's adoption under international pressure of a new patent law would lead the country to grant the company an exclusive license to produce Gleevec, which can cost up

$70,000 per year. Indian generic versions cost about $2,500 year.

But the court's ruling confirmed that India's criteria for the granting of such patents remain far higher than those in the United States, where patents are so easy to win that one was given in 1999 for a peanut butter-and-jelly sandwich. Which country's patent system does more to protect the sick and encourage invention has become an increasing source of international debate.

In recent decades, the United States has become increasingly insistent that countries wishing to do business there adopt far more stringent patent protection rules, with the result that poorer patients often lose access to cheap generic copies of medicines when their governments undertake trade agreements with the United States.

The ruling Monday is bound to be seen with some concern by the United States and the international pharmaceutical industry and may be yet another blow to India's standing among major multinational companies, many of whom view protection of their intellectual property as vital to their business interests.

For details:
http://www.nytimes.com/2013/04/02/business/global/top-court-in-india-rejects-novartis-drug-patent.html

India's vaccine regulator National Regulatory Authority of India meets WHO standards

The World Health Organization has cleared India's vaccine regulatory system for maintaining international standards, paving the way for easy export of vaccines produced in the country.

The National Regulatory Authority of India (NRA) and its affiliated institutions now meet WHO efficacy indicators for a functional vaccine regulatory system, after a WHO team of international experts from eight countries conducted its comprehensive review in December last.

India's Rs 19,000-crore vaccine industry accounts for exports worth 13 billion US dollars to 150 countries. India is a major vaccine producer that has 12 major vaccine manufacturing facilities.

In 2012, India had seven vaccine manufacturers producing 67 prequalified vaccines (dosage forms). Currently 16 vaccines are prequalified by WHO and exported through United Nations agencies. More than 70 per cent of all measles vaccines used globally are produced in India.

WHO assessment of a regulatory authority as functional means the country's vaccine production lines are efficacious and safe and can easily be trusted.

U.S. Consumers pay more for drugs

April 09--U.S. consumers and taxpayers usually pay more -- often much more -- than people in other developed nations for brand-name drugs, according to a series of papers published Monday in the journal Health Affairs.

Moreover, consumers here can't see through the fog of the pricing system to know how much their medicines should cost.

"On a personal level, U.S. citizens pay prices sometimes twice as high as most other countries for identical drugs," Gerard Anderson, director of the Center for Hospital Finance and Management at Johns Hopkins University and a coauthor of one of the studies, said.

"From a policy standpoint, we are supporting the drug companies' innovation for the rest of the world," Anderson said. A link to the Health Affairs paper he helped write is here.

Most other developed nations use various mechanisms to keep prices lower. Direct government payments to drugmakers are lower. Some compare the value of similar medicines and will not pay more than the average price for the group, not simply the price applied by the manufacturer. Some reduce the number of entities negotiating to lessen drug-company leverage.

In the United States, the biggest government medical insurance program, Medicare, has been restricted by law from imposing many such measures.

One paper, whose lead author, Joshua Cohen, is a researcher at Tufts University in Massachusetts, said that European evidence-based approaches appear to have led to reduced prices for those drugs deemed worthy of approval and reimbursement. Evidence-based approaches include patient outcomes and how well a medicine works, among other measures.

Drug companies have argued for years that richer nations should pay more than poorer nations for the same medicine, which might not be developed at all if higher prices are not paid by somebody.

"I don't have a problem charging Bulgaria less," Ken Frazier, chief executive officer of Merck & Co., said during the question-and-answer session after a speech at Princeton University on Thursday. "I have a problem when Germany wants to be charged what Bulgaria is charged."

Even if they generally follow U.S. government pricing practices, U.S. private insurers and the pharmacy benefit managers who run drug plans for employer-based health-care plans negotiate complicated deals with drug manufacturers on prices and do not reveal the numbers. The same insurance company might pass on different prices for the same drug to different clients, which results in a different out-of-pocket co-payment for two patients taking the same drug.

Within the U.S. pricing system, there are "average wholesale prices," "average sale prices," "federal supply schedule prices," and "Medicare Part D prices," along with rebates and discounts, one paper noted. But none is simple, clear and enforceable, perhaps even for the army of people employed in those public and private bureaucracies built around the U.S. system.

Prices are "confusing and camouflaged," said University of Michigan business

professor Erik Gordon, who follows the industry.

"True prices are nearly impossible to ascertain," he said. "Average wholesale prices are neither wholesale nor average. Rebates and discounts that are based on sales of single drugs and on sales of baskets of unrelated drugs make it impossible to calculate the actual price paid for a particular drug.

Quinidine unavailable in many countries

Reuters reports that, according to research published online in the Journal of the American College of Cardiology, the heart rhythm drug, quinidine, is unavailable in many countries.

Larry Husten writes in Forbes (4/9) that investigators "surveyed physicians around the world about the availability of quinidine in their country and received responses from 273 physicians in 131 countries." The researchers found that "in 76% of the countries quinidine was not available at all." Meanwhile, "in another 10% quinidine was available only through a regulatory process that can take several days to several months to obtain the" medication.

Heartwire reports, "In just 19 countries is quinidine freely available for prescription use." The investigators "note that one of the quinidine brands available in the US is made in India, yet it's not available to Indian physicians." Heartwire adds, "A lack of financial incentive, the result of low pricing and the low prevalence of clinical conditions for which the drug is approved, is just one possible reason for the current lack of availability, according to the researchers."

Govt. extends deadline for pharma barcodes

The government has extended the deadline for one more year to affix barcodes on primary level packaging by pharmaceutical companies till July 2014.

A barcode helps in tracking and tracing of origin of drugs, which in turn helps in minimising the chances of genuine drugs being considered spurious, sub-standard or counterfeit.

“Earlier the requirement of affixing barcodes on Primary Level packaging was to take effect from 01.07.2013. Now this date has been deferred to 01.07.2014,” Directorate General of Foreign Trade (DGFT) said in a public notice.

Primary level packaging is the first-level product packaging such as the bottle, can, jar, tube, that contains the item sold.

The government had asked pharmaceutical companies to build track and trace capability for their exported medicines using barcode technology at three levels of packaging primary, secondary and tertiary.

India exports over $ 10 billion worth of drugs annually.

The government wants to increase that figure manifold in the next few years. There is a big market for generics in the developed world.

Industry experts say the only way Indian pharma firms can tap the market is by ensuring quality, and barcoding will help ensure that.

Forthcoming Event