Drug Information Bulletin

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Content

Editorial

Recently Swiss Government and the pharmaceutical industry have agreed to a price control mechanism, which may reduce the price of huge number of medicines. Switzerland being a developed country is also concerned to reduce the price of medicines for the benefit of public health.
India has developed a mechanism since 1979, when the price of about 350 drugs was under price control and it has been reduced to 74 in 1995, which is continuing till the date. An alternative policy has been proposed recently, which is yet to be finalized, received mixed response from the stake holders.
A well thought price control mechanism is required to be in place to improve the access to Medicines.

Swiss drug prices to fall as govt/industry agree deal

The Swiss government and the pharmaceutical industry have agreed a deal under which the prices of around 2,500 medicines will fall on June 1, with estimates savings to patients of up to 720 million Swiss francs over the next three years.

June 1 will see the introduction, for the first time, of reference pricing for medicines in Switzerland. Recent surveys have shown that Swiss drug prices can be as much as 50% higher than in other countries in Europe, while for products still under patent protection, they are generally 12% more expensive than in six comparator countries.

Pharmaceutical manufacturers in the country have strongly opposed the introduction of reference pricing, with lawsuits. However, as part of the new deal, they have agreed to drop these legal actions, and any future price-related lawsuits, in return for government pledges to cut the approval times for new drugs to 60 days. According to industry

groups, approvals currently take an average of 200 days.

The agreement will run until the end of 2014, when it will be up for renegotiation, and approximately 800 drug products each year will have their prices adjusted based on the international referencing. In addition, a number of price reductions agreed by the cabinet in March 2012 and based on international comparisons, will now come into effect, under the agreement.

The industry had responded to the March 2012 price cut proposals with a legal challenge, claiming that the imposed prices did not reflect the drugs' therapeutic value.

Announcing the new agreement, Swiss interior minister Alain Berset said it was a "very good, balanced and mutually acceptable solution," while Walter Holzle, president of the association of pharmaceutical companies in Switzerland (Vips), was quoted in local reports as welcoming the government's pledge to significantly shorten the approval times for new drugs. “The agreement represents a major and important step towards implementation of needed reforms in the current price system," he said.

Another industry group, Interpharma, described the price cuts as a temporary concession which had to be agreed in order to reach the deal because they had already been factored in by insurers.

- A report recently released by Interpharma says that the pharmaceutical industry now contributes more than 30% of Switzerland's total exports, and that the sector is directly and indirectly responsible for added value of almost 30 billion Swiss francs, equal to a share of 5.7% of the nation's nominal Gross Domestic Product (GDP).

"Nominal added value has been increasingly burdened by growing price pressure and the development of exchange rates, so the very high growth rates of the past are no longer being equaled at present. Real growth, nevertheless, remains robust and high at over 4%," says the report, which was compiled for Interpharma by Polynomics and BAK Basel Economics.

And Vips reported recently that Switzerland's pharmaceutical market grew around 2% last year, reaching a value of 5.08 billion Swiss francs.

FDA OKs Sun Pharma for Generic Januvia, Glumetza

SUNPHARMA, BSE: 524715) announced that the US FDA has granted its subsidiary, two tentative approvals for its Abbreviated New Drug Applications (ANDA) for generic version of Januvia®, Sitagliptin Tablets and generic version of Glumetza®, Metformin HCl Extended-release tablets.

Sitagliptin tablets, 25 mg, 50 mg and 100 mg are therapeutic equivalents of Merck Sharp & Dohme Corporation’s Januvia® tablets. Sitagliptin tablets have annual sales of approximately USD2.7 billion in the US. Sitagliptin tablets are indicated as an adjunct to diet and exercise to improve glycemic control in adults with type-2 diabetes mellitus.

Metformin HCl Extended-release tablets, 500 mg and 1000 mg are therapeutic equivalents of Santarus Inc.’s Glumetza® tablets. Metformin HCl Extended-release tablets have annual sales of approximately USD140 million in the US. Metformin HCl Extended-release tablets are indicated as an adjunct to diet and exercise to improve glycemic control in adults with type-2 diabetes mellitus.

Januvia® is a registered trademark of Merck Sharp & Dohme Corporation. Glumetza® is a registered trademark of Santarus Inc.

Source: pharmalive.com

Recently launched website offers information about clinical trials worldwide

In a story profiling one cancer patient participating in a clinical trial, HealthDay reports on "a new Internet resource, MyClinicalTrialLocator.com," which "has just been launched to make it easier for people to find clinical trials that fit their needs." This "site offers information about clinical trials worldwide, provides a mapping function to pinpoint the location of a trial and will notify users when trials matching their needs become available." Additionally, "it...allows patients to email clinical trial researchers directly, and academic medical centers can update and correct information on the site in real time."

NIH grantees study H7N9 Flu Genetic Sequences

The novel H7N9 avian flu virus that, as of April 17, has infected 82 people and caused 17 deaths in China, has characteristics known to cause severe disease in mammals, including people, but it is too early to predict its pandemic potential, according to an analysis of the virus' genetic sequences by NIAID-funded researchers in the U.S. and Japan. The genetic sequences provided clues to the virus' origin and sensitivity to existing anti-flu drugs, and suggested it has mutated to more efficiently cause disease in mammals.

For more on the novel virus' origin, transmissibility, and possible treatments, see the NIAID press release at: http://www.niaid.nih.gov/news/newsreleases/2013/Pages/novelH7N9.aspx.

Progress in Antibiotic development alarmingly elusive

WASHINGTON, April 18, 2013 – Despite the desperate need for new antibiotics to combat increasingly deadly resistant bacteria, the U.S. Food and Drug Administration (FDA) has approved only one new systemic antibiotic since the Infectious Diseases Society of America (IDSA) launched its 10 x '20 Initiative in 2010 — and that drug was approved two and a half years ago.

In a new report, published online today in Clinical Infectious Diseases, IDSA identified only seven new drugs in development for the treatment of infections caused by multidrug-resistant gram-negative bacilli (GNB) bacteria. GNB, which include the "nightmare bacteria" to which the Centers for Disease Control and Prevention (CDC) alerted the public in its March 2013 Vital Signs report, represent the most pressing medical need. Importantly, there is no guarantee that any of the drugs currently in development to treat GNB will make it across the finish line to FDA approval and none of them will work against the most resistant bugs we're worried about today.

For details: http://www.pharmatimes.com/Article/13-04- 17/Swiss_drug_prices_to_fall _as_govt_industry_agree_deal.aspx

Team including Indian develops Tamiflu rival

An Indian researcher is part of a team led by a renowned Japanese scientist that has developed a new way of making the only known drug used for treating bird and swine flu. Presently, the drug oseltamivir, known by its brand name Tamiflu, is made solely by the Swiss pharma giant Roche through a costly and secretive process.

Kaliyamoorthy Alagiri, the son of a farmer in Nagapattinam district of Tamil Nadu, joined Masakatsu Shibasaki, a renowned organic chemist at the Institute of Microbial Chemistry, Tokyo, last year as a post-doctoral researcher.

The discovery of the new synthesis for tamiflu would shake up the pharma world and end the Roche patent monopoly. In 2009, Roche reportedly earned nearly $2 billion from tamiflu global sales as governments stockpiled the drug to fight swine flu. Roche is currently making tamiflu by two methods. One involves extraction from the fragrant spice star anise, grown primarily in China and the other is biofermentation.

Professor Shibasaki's team used an easily available natural substance called glutamic acid as the starting point and synthesized the flu-drug.

"Our process involves simple synthetic methods with inexpensive chemicals and minimum number of cost- and time-consuming chromatographic purification," Shibasaki explained to this reporter.

The real question now is whether the process discovered by Shibasaki and his colleagues can be upscaled and commercialized. Alagiri is confident that it can be.

"There is high possibility for industrial scale production of tamiflu using our latest protocol starting from L-glutamic acid. We are now collaborating with a pharmaceutical company," Alagiri told this reporter from his village Karuvazhakkarai where he has come to spend a few days with his parents.

Alagiri elected to join the Shibasaki Lab because of the fame of the Japanese master. Professor Shibasaki has authored over 500 papers and several books and he is one of the leading chemists in the world, Alagiri said.

"Working in Prof. Shibasaki's lab is a great learning experience. He gives full freedom and encourages his students to give their inputs towards research," he said.

On his part, Professor Shibasaki is quietly appreciative of Alagiri. "Alagiri was one of the top candidates and I offered him a postdoctoral position supported by my research grant," he said.

There have been many attempts to synthesise tamiflu earlier including one by E.J.Corey, the Nobel winning Harvard chemist, and one by Shibasaki himself. Although laboratory level success has been achieved, up-scaling to production levels has been difficult.

The recent outbreak of a new H7N9 bird flu virus in China has again revived interest in drugs to deal with these mutating viruses.

USP unveils new logo and tag-line evoking its global health mission

In a strategic move marking the two centuries of dedication to science, standards and health, the US Pharmacopeial Convention (USP) recently unveiled a new logo and tag line that conveys the organisation's key role in helping to maintain quality of medicines and foods around the world.

USP's new look is a visual expression of the principles embodied in the organisation's strategic plan, which articulates a truly global vision supported by organisational initiatives and beliefs. Remaining committed to strengthening and expanding its core compendial mission, USP will also continue building allied compendial programmes and exploring emerging health needs.

The new logo and the strategic plan both grow out of USP's fundamental strengths that is based on global expertise and trusted standards that improve health.