OPPI

Daily News Monitor

December 25-28, 2015

1. India adds more cancer, HIV/AIDS drugs to essential medicines list – Reuters

India has revised its list of essential medicines to add drugs for diseases ranging from cancer and HIV/AIDS to hepatitis C, in a move aimed at making them more affordable.

The update to the National List of Essential Medicines (NLEM) is just the third since it was compiled in 1996.

It increased the list to 376 medicines from 348 and includes drugs ranging from analgesics and antivirals to contraceptives, cardiovascular and anti-tuberculosis drugs.

Reuters reported in April that more HIV/AIDS and tuberculosis medicines were likely to be added to list, which is posted on the Central Drug Standard Control Organisation's website.

The revision comes after months of deliberations by a committee of experts formed by the central government last May. Views of the pharmaceutical industry and NGOs were also considered, the CDSCO said.

In initial thoughts, industry executives said they were yet to study the list's impact.

"We will be seeking clarification and a better understanding of its implications," said Ranjana Smetacek, director general of the Organisation of Pharmaceutical Producers of India (OPPI) which represents large foreign drugmakers.

The Indian Pharmaceuticals Alliance, which represents large local drugmakers, did not respond to requests for immediate comment.

Also appeared in Times of India, Economic Times, Hindustan Times, Mint, Mumbai Mirror, Huffington Post

2. M&As peak in pharma industry – The Hindu

Facing an increasingly watchful eye of the health regulator in the U.S., Indian pharmaceutical firms are gearing up to tap new markets in 2016 as they look to consolidate their positions after a spate of mergers and acquisitions consummated this year.

Globally, it remained a year marked with record mergers led by the 160-billion-dollar deal between Viagra-maker, Pfizer Inc and Botox manufacturer, Allergan.

These deals came at a time when the domestic pharma firms continued to remain under intense regulatory spotlight, specially of the U.S. Food and Drug Authority (FDA) while they stared at yet another challenge domestically over possibility of prices of more drugs coming under government control.

Also appeared in Business Standard

3. Why India must beware the side-effects of Pacific Treaty – Hindu Business Line

The scope of the recently concluded Trans-Pacific Partnership Agreement (TPPA) goes well beyond conventional trade concerns. It includes extensive obligations on intellectual property (IP) exceeding the minimum standards of the World Trade Organisation (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

Viewed against the backdrop of India's disappointment at certain outcomes of the WTO talks in Nairobi — countries like India will need to examine TPPA implications especially on non-violation complaints. Particularly as developed countries like the US can take developing countries like India to the WTO dispute settlement body for using TRIPS flexibilities contained in Section 3 (d) of Indian Patent Act. A number of flexibilities are not part of the TPPA.

Patent linkages are the other concern for developing countries like India as this could extend the period of additional monopoly in other markets that do not have a formal system, similar to the Orange Book in the US (that binds the drug regulator to approve a generic product within the stipulated time frame), thus delaying the introduction of generics.

The list of concerns does not end there. There is, for instance, the restriction on the government's ability to utilise a compulsory licence as a means to negotiate price with the patent holder as was done by Brazil for antiretroviral medicines; and allowing private rights-holders to review and arbitrate the meaning of the WTO TRIPS Agreement.

4. POEM: Draft rules spark off double taxation fears – Business Standard

The proposed guidelines to determine the 'Place of Effective Management (POEM)' for multinational companies (MNCs) have met with some criticism.

The phrase refers to the location determined as to where key decisions of the company are made, needed by tax authorities where a company is incorporated in another country. The concept was introduced in India in this year's Union Budget proposals, as a means to check tax avoidance. Feedback on the proposals have been invited for another 10 days.

Multinationals with significant operations in India in terms of revenue, employees and assets will also be considered residents in India if the majority of board meetings are here.

5. Centre Mulls Dilution of Drug Testing Norms – New Indian Express

The government is planning to dilute norms for drug testing and regulation, a move that is likely to benefit pharmaceutical companies, despite a hue and cry over unethical practices followed during clinical trials. "In the last three years, drug testing and registration has suffered due to strict norms," Soumya Swaminathan, secretary, Department of Health Research, told Express.

Government data shows that more than 2,600 patients participating in clinical trials in India died between 2005 and 2012, and nearly 12,000 suffered serious adverse effects. Of these, 80 deaths and more than 500 adverse effects were attributed to trials.

Swaminathan, who is also Director-General of the Indian Council for Medical Research (ICMR), said strict norms being followed for clinical trials during drug testing was resulting in less research in medicine, and no new drugs were being registered.

6. India, China in focus: US lawmakers write to GAO over fake drug concern – Indian Express

Raising concern over the "still inadequate oversight with regard to foreign drug plants", lawmakers in the US have written to the Government Accountability Office (GAO) to assess the US Food and Drug Administration's (FDA) activities and accomplishments in the areas of foreign drug inspections in wake of counterfeiting and sub-standard manufacturing in India and China.

The letter comes amid India's largest drug maker Sun Pharma receiving a warning letter from the US FDA for its manufacturing facility based in Halol, Gujarat. This is amongst the largest site for Sun Pharma from where multiple formulations are sent to the US. The FDA has notified over 20 issues of violations of standard manufacturing norms. It is expected to mount pressure on India's pharma

industry, already under fire due to alleged lack of good manufacturing practices brought to fore by several FDA inspections in the recent past.

7. Unresolved trade pact: India to meet EU in Jan – Indian Express

Months after it called off talks between chief negotiators of the two sides on free trade agreement (FTA) to protest against the ban on sale of around 700 pharma products of a domestic company, India will meet officials from the European Union (EU) later next month to "take stock of the negotiations" on the long-pending FTA. The meeting on the proposed Broad-based Investment and Trade Agreement (BITA), which was earlier scheduled for August 28, will now be held on January 17-18, a senior official said adding that the issue of ban is yet to be resolved.

8. Abbott unit's divisional patent application for drug rejected in India –Financial Express

The country's patent office has rejected a divisional patent application by AbbVie Biotechnology Ltd, the biopharmaceutical arm of US-based Abbott Laboratories, for multiple-variable dose regimen for a tumor necrosis factor alpha (TNFa) drug, treating disorders including Crohn's and Psoriasis diseases. According to documents filed with the Delhi patent office, the claimed invention is related to Adalimumab, a medication marketed under the Humira brand.

Opposing the application, the Indian Pharmaceutical Alliance (IPA), which represents research-based national pharmaceutical companies, had filed a pre-grant opposition against the application.

While AbbVie argued for the patent initially, the company later informed the patent office that it lost interest in the application and would not pursue it further.

9. Experts to discuss nitty-gritty of personalised health care – The Hindu

Over three days from Tuesday, medical luminaries from across the country will discuss ways to take personalised health care and optimised drug therapy deeper mainstream at a conference hosted at Jipmer.

The three-day "National Conference on Clinical Research and Personalised Therapy" is said to be the first national conference on the subject in India.

The theme of the conference is "Clinical trials in the genomic era."

The meet is being held against the backdrop of optimal drug therapeutics for several diseases including hypertension, cancer, psychiatric illnesses and diabetes mellitus remaining an unrealised goal.