OPPI

Daily News Monitor

July 21, 2016

1. **Indian firms get approval for generics of AstraZeneca's Crestor** – Mint

   Indian drugmakers won U.S. approval to sell generic versions of the cholesterol pill Crestor, gaining permission to sell cheaper copies of an AstraZeneca Plc best-selling pill that brings in $7 million in U.S. sales every day.

   India's Aurobindo Pharma Ltd., Glenmark Pharmaceuticals Ltd. and Sun Pharmaceutical Industries Ltd. received approval from the U.S. Food and Drug Administration to sell the generics, according to stock exchange statements from the companies on Wednesday.

   Drug-makers in race to make smart inhalers

2. **Impact of Brexit on India to be minimal: Nirmala Sitharaman** – The Financial Express

   India is well prepared to deal with the situation considering its sound macro-economic fundamentals, comfortable external position, commitment to fiscal discipline and declining inflation, added Sitharaman.

   "The need for India to rework the proposed FTA with the EU (minus UK) and the timing of such recalibration are dependent on the terms and conditions of UK's withdrawal arrangement from the EU," Sitharaman said in a written reply to the Rajya Sabha.

3. **Stents set to come under price control, government brings it under NLEM** – The Hindu Business Line

   Stents look set to come under price control following a Union Health Ministry notification to include it in the National List of Essential Medicines (2015).

   While the move brings some cheer topatients, an uneasy calm prevails over sections of the medical device industry, following the Ministry's communication late on Tuesday. The

government has accepted the recommendations of the sub-committee looking into issues involving stents, the Health Ministry said.

4. **Drug-makers in race to make smart inhalers** – The Hindu Business Line
   Makers of inhalers to treat asthma and chronic lung disease are racing to develop a new generation of smart devices with sensors to monitor if patients are using their puffers properly. Linked wirelessly to the cloud, the gadgets are part of a medical "Internet of Things" that promises improved adherence, or correct use of the medication, and better health outcomes. They may also hold the key to company profits in an era of increasingly tough competition.

   Drugmakers believe giving patients and doctors the ability to check inhaler use in this way could be a big help in proving the value of their medicines to governments and insurers, though they need to tread carefully on data privacy.

5. **Karnataka to get its own policy on palliative care in two weeks** – The Times of India
   While the nation debates the right to passive euthanasia, Karnataka is all set to get its first palliative care policy in about two weeks. The policy will ensure terminally ill patients in the state mandatorily get all-round care. Teams of dedicated doctors and volunteers will ensure such patients have access to complete care -- physical, psychological, social and spiritual -- in the last days of their lives.

   Karnataka will be the third state in the country, after Maharashtra and Kerala, to get a palliative care policy of its own. Experts say this is a better alternative to euthanasia, whether passive or active.

6. **Aurobindo Pharma gets final USFDA nod for rosuvastatin calcium tabs** – dna
   Aurobindo Pharma has received final approval from the US health regulator USFDA for rosuvastatin calcium tablets, used in lowering cholesterol.
   "The company has received final approval by the US Food and Drug Administration (US FDA) for Rosuvastatin Calcium tablets," Aurobindo Pharma said in a BSE filing. It further said: "Aurobindo was one of the first ANDA applicants to submit a substantially complete ANDA with a paragraph IV certification, therefore, Aurobindo is eligible for 180 days of generic drug shared exclusivity. The product is launched in the US market."

7. **Risky Medicine: Why FDI in India's Generic Drugs Industry Could be a Bad Idea** – The Wire
   India needs a domestic pharmaceutical industry that is unfettered by foreign dominion and control, particularly by a rapacious multinational industry that so consistently prioritises supra profits for its executives.

   FDI in the pharmaceutical sector has been promoted on a series of false promises of increased biomedical and pharmaceutical research and development, including on so-called neglected and tropical diseases that disproportionately affect India and other low and middle-income countries. Investments in new plants were also deemed to facilitate transfer and adoption of new technologies within India, increasingly its specialised capacity to manufacture medicines cost effectively and in turn to spur further incremental innovations and technical prowess. Contrary to these projections, recent studies find almost no new R&D investments and further find very little evidence of any meaningful technology transfer.

8. **Sanofi-Synthelabo India launches 2 diabetes drugs** – ET Healthworld.com
   Drug firm Sanofi-Synthelabo India has expanded Sanofi's diabetes portfolio in the country with launch of two drugs - Lyxumia and Zemiglo - for lowering blood sugar levels. While Lyxumia is a once daily, non-insulin injectable drug, Zemiglo is a once daily, oral tablet, Sanofi-Synthelabo (India) Pvt Ltd said in a statement.

Commenting on the development, Sanofi India Pharmaceutical Operations Country Head & General Manager N Rajaram said: "The launch of two additions to Sanofi India portfolio - Lyxumia and Zemiglo, is our step forward in developing new solutions for people with type 2 diabetes."

9. **Act For Medical Devices** – Pharmabiz.com
   The Union ministry of health announced last week that a Medical Device Act would be tabled in the winter session of the Parliament. The announcement came from minister of health while taking part in a consultation convened by the Prime Minister's Office for promoting Make in India initiative in the medical devices sector. The announcement is a long awaited one for this critical sector as it remained outside effective regulatory control of the government for several years. In fact, the Department of Pharmaceuticals had come out with a draft National Medical Device Policy in 2015 to give a proper direction to the growth of this sector in the country. The main objective of the policy is to set up National Medical Device Authority, an autonomous body for regulating the manufacture and sales of these products in the country.

10. **FDA minister advises Maha FDA to be considerate while issuing closure notices to blood banks** – Pharmabiz.com
    Maharashtra Food and Drug Administration Minister Girish Bapat has suggested the Maharashtra Food and Drug Administration (FDA) to be considerate while issuing closure notices after inspecting the city blood bank premises keeping in view of the difficulties faced by civic-run hospitals in maintaining adequate blood bank staff for its effective functioning.

    The state FDA has, however, maintained that suspension orders on the blood banks detected for non-compliance is applicable after granting appeal period of 3 months which is sufficient amount of time to rectify the problem to avert suspensions of licenses in the worst-case scenario.

    This comes close on the heels of the state FDA recent crackdown on 4 civic-run hospitals recently for failing to appoint blood transfusion officers (BTOs) in violation of Drugs and Cosmetics Act, 1940. BTOs are responsible for supervising as well as looking into aspects involving transfusion reaction, grouping and cross matching of blood.

11. **Medtronic receives US FDA approval for two-level Prestige LP Cervical Disc to treat cervical disc disease** – Pharmabiz.com
    Medtronic plc announced the US Food and Drug Administration's (FDA) approval of the Prestige LP Cervical Disc for the treatment of cervical disc disease causing nerve or spinal cord compression at two adjacent levels between the C3-C7 segments of the neck. The Prestige LP Disc is designed to allow motion in the neck at the operated levels, unlike a fusion surgery that does not preserve motion.

    The Prestige LP Disc is Medtronic's third clinically-proven artificial cervical disc and its first to be determined safe and effective for both one- and two-level procedures. Additionally, it is the first artificial disc on the US market to be proven statistically superior in overall success for both one- and two-level procedures.

12. **EMA committee classifies Advaxis' Lm immunotherapy candidate, AXAL as advanced-therapy medicinal product** – Pharmabiz.com
    Advaxis, Inc., a clinical stage biotechnology company developing cancer immunotherapies, announced that its lead Lm immunotherapy candidate, axalimogene filolisbac (AXAL), has been classified as an advanced-therapy medicinal product (ATMP) for the treatment of cervical cancer by the European Medicines Agency's Committee for Advanced Therapies (CAT).

    "Classification of AXAL as an ATMP is reflective of a groundbreaking new opportunity for the treatment of HPV-associated cancers," said Robert Ashworth, PhD, vice president, regulatory

affairs. “Building upon the approach endorsed at Advaxis’ meetings with National Competent Authorities earlier this year, it allows us to take advantage of a specific EU regulatory framework, akin to fast-track in the United States, designed to facilitate the review, approval, and access of AXAL in the EU market.” In the next phase of this regulatory process, CAT assessment of currently available quality and non-clinical data may help resolve some issues prior to the submission of a marketing-authorization application (MAA).

13. **India is the worst place for retirement; worst in healthcare system too** – Zee News
    The Natixis Global Asset Management's fourth annual Global Retirement Index (GRI) released on Tuesday has ranked India last (43) out of 43 countries.

    Norway is the best country for retirement followed by Switzerland and Iceland. New Zealand, Sweden, Australia, Germany, Netherlands, Austria and Canada completed the top 10. The list was cut down to 43 countries as against 150 in the previous years. Of the 43 countries, 34 were from the IMF's advanced economies, five from OECD and four from BRICS.