OPPI

Daily News Monitor

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1. **PM likely to chair meeting on FDI roadmap on Tuesday - The Economic Times**
   The Prime Minister's Office has convened a meeting on June 21 to deliberate upon a roadmap for further easing FDI norms to attract more foreign investment. "Prime Minister Narendra Modi is likely to chair the meeting in which officials from ministries, including Commerce and Industry, Finance and Home Affairs, would participate," sources said.

2. **Government set to release revised biosimilar guidelines in July 2016 – The Economic Times**
   The government is set to release the much awaited revised guidelines for the approval of biosimilar drugs in the first week of July, a move that would bring clarity to the launch of such drugs in the country. Biosimilar drugs are copies of complex products based on living cells. The country's biosimilar guidelines were first unveiled in 2012. "These revised guidelines (on similar biologics 2016), expected in the first week of July, will not deviate much from the draft released earlier in March," a senior health ministry official who did not wish to be identified told ET. The guidelines also specify the conditions that biosimilar makers need to meet to exempt themselves from certain clinical trials, the official said. The proposed changes in the draft guidelines, which could more than halve the approval time for biosimilars here, had earlier met with concerns from multinational pharmaceutical companies. The Organisation of Pharmaceutical Producers of India (OPPI), a lobby group of MNC drug companies, had then suggested that the draft diluted requirements in the 2012 guidelines which could compromise patient safety.

3. **Health Ministry's own survey projects bleak picture – The Economic Times**
   A landmark survey released by the Ministry of Health and Family Welfare presents a somewhat bleak picture of India's health. The survey, a quick but robust snap shot of India's health, was revealed as part of the National Family Health Survey-4 (NFHS-4), presents data for 13 states and 2 union territories. Data for rest of the country is expected to be released later in the year. In its report the health ministry asserts that "fewer children are dying in infancy and early childhood" yet some startling results emerge when the data is carefully teased out.

4. **Cipla in pact with Russian firm for HIV, Hepatitis C drugs – The Economic Times**
   Drug major Cipla has inked a pact with Russia's National Immunobiological Company to collaborate on HIV and Hepatitis C drugs, entailing an investment of 2.8 billion roubles (around Rs 289 crore). The companies have inked a Memorandum of Understanding on innovative antiviral medical products for HIV and Hepatitis C treatment and on technology transfer and active pharmaceutical ingredients (API) manufacturing, Cipla Ltd said in a statement.

5. **IIPA seeks level playing field for e-pharmacy space – The Economic Times**
   The Indian Internet Pharmacy Association (IIPA) has urged the government to ensure an end to the "local level harassment" being faced by new entrepreneurs in the e-pharmacy space. "The IIPA is demanding a level field for all players in the e-pharmacy space, without favour or bias. "We seek clarity on guidelines to enable legitimate players to develop their business in this space and bring in the much needed innovation and technology driven transparency in this sector, leveraging best practices from across the world," IIPA President Prashant Tandon told PTI here. Indian Pharmacovigilance Day 2016 to be observed in Mumbai on July 29

6. **13-yr-old bill being redrafted to cover emerging health sectors – ETHealthWorld.com**
   The existing act is very old and the amendment bill is now pending for over 13 years. Meanwhile, there have been many changes in the market. New products and segments have also been introduced. In a move to strengthen drug regulation in the country, the health ministry has scrapped the Drugs and Cosmetics (Amendment) Bill, and is instead drafting a new law to cover various new therapeutic areas and emerging segments such as stem cells, nutraceuticals, online sale of medicines and medical devices. "The idea to revisit the law completely and introduce provisions which can address and take care of such changes as well as is forward looking in nature," the official said. The proposed act will also include stricter penalties and punishments for those violating the law or selling substandard medicines

7. **Gujarat trying to woo pharma firms: Nitin Patel – Business Standard**
   With tax holiday offered to pharma companies in Himachal Pradesh drawing to an end, the Gujarat government is trying to attract pharma companies to the state, a state minister said today.

   "In Baddi (Himachal Pradesh), most probably in 2016, the tax holiday for pharmaceutical industries will end. Our effort will be to attract the pharmaceutical companies to Gujarat," Health Minister Nitin Patel said after the inauguration of the new office of the Food And Drugs Administration here. A special cell had been set up for this in the Chief Minister Anandiben Patel's office, he said.

8. **Patent office caps fast-track requests – The Hindu**
   The government, which opened a 'tatkal' window to expedite examination of patent applications in the backdrop of 2.37 lakh pending patent applications, has now set a limit on applications that it will consider under the fast-track clearance mechanism. In a notice on June 14, the Controller General of Patents, Designs and Trade Marks said in terms of the provisions relating to expedited examination of applications, the number of requests for expedited examination to be received by the Patent Office on or before December 31, 2016 has been limited to 1,000 requests. The notice did not specify any reasons for imposing the cap on the number of applications. The 'tatkal' window was opened after the amendments to the patent rules came into effect from May 16.

9. **Punjab govt launches fund for treatment of Hepatitis C – Deccan Herald**
   Punjab Chief Minister Parkash Singh Badal has launched a special fund called 'Mukh Mantri Punjab Hepatitis C Relief Fund' to provide free treatment for patients affected by Hepatitis C. With this initiative, Punjab has become the first state in the country to provide free treatment to confirmed cases of Hepatitis C, a spokesperson claimed. Punjab government has created a special fund with an initial contribution of Rs 20 crore called the 'Mukh Mantri Punjab Hepatitis C Relief Fund' for this purpose.

10. **'Guided chemotherapy missiles' will only target cancer cells – The Times of India**
    A team of researchers has used an engineered protein to direct chemotherapy drugs to tumours, in the hope of creating "guided missiles" targeting only cancer cells. The work by Jennifer Cochran, associate professor of bioengineering at Stanford University in northern California, builds on the antibody approach to deliver a drug directly to tumours, bypassing healthy cells and overcoming some of the uglier aspects of chemotherapy, Xinhua news agency reported. In cancer chemotherapy, the drugs do often kill cancer cells but also damage other quickly dividing cells in the body, causing side effects ranging from cosmetic, like hair loss, to disabling; and the ugly occurs when the drug dose needed to kill a tumour is more than what a person's body can handle.

11. **New med for drug resistant TB introduced – The New Indian Express**
    The Kerala State government began using a new drug for this from Saturday, administering it to two selected patients at the Government Hospital for Thoracic Medicine, Tambaram. This drug, which is on the World Health Organisation's list of essential medicines, is the first new tuberculosis drug to be approved by the USFDA in over four decades, the patients for which are chosen only after careful screening. "The drug will be a boon for multi-drug resistant tuberculosis (MDR-TB) patients. The effectiveness of the drug has been proven during the clinical trials in other countries," Health Minister Dr C Vijaya Baskar, a doctor himself, told Express. The treatment using Bedaquiline, the new drug, was launched a week before its scheduled launch in the State.

12. **Shops selling drugs at old MRP under scanner in Kerala – Deccan Chronicle**
    A fortnight after the Central Government reduced the prices of 25 essential drugs, the state government has decided to carry out state wide inspections to ensure people get these drugs at the revised rates. The decision comes in the wake of allegations that most medical shops across the state are continuing to sell these drugs at old Maximum Retail Price (MRP). The reduced price difference ranges from Rs 2 to Rs 500 for medicines including those for treating cancer, infections including cold and allergy, epilepsy, gastrointestinal disorders, tumours, fungal infections and immunosuppressants. Health Minister K K Shailaja has directed the drugs control department to conduct inspections. Since the new stocks of medicines with revised rates are expected to arrive only after a fortnight, the officials are wary of medical shop owners concealing their old stocks thus creating an artificial shortage.

13. **DTAB diktat on generic medicine pours cold water on PM scheme – The New Indian Express**
    The Union Health Ministry's highest decision-making body on technical matters, the Drugs Technical Advisory Board, has forbidden retail chemists and pharmacists from selling 'cheaper drugs with same ingredients'.

    The Board headed by the Director General of Health Services Jagdish Prasad in a recent meeting decided that chemists should adhere strictly to the doctor's prescription. The Board noted that selling a cheaper drug with the same ingredients could be ineffective and even harmful to patients. Retail chemist stores are not empowered to sell a matching drug of a branded medicine prescribed by the doctor.

14. **Pharma companies need to ride the digital wave – Deccan Herald**
    With the doctor-to-patient ratio of 1:1,700 in India, it is extremely important to digitise the pharmaceutical sector to maintain the quality of service provided. It is leading to a paradigm shift in the relationship within the nexus of stakeholders, including doctors, pharma reps and

patients. Digital fever has not even spared the health care professionals (HCPs), with over 64% of the doctors having smartphones and them spending more than eight hours a week over internet, accessing information about new medical approaches, providing their availability details, real-time updates with the patients about their appointments, patient history or face-to-face therapy sessions, among others.

15. **The Bugs Just Got Bugsier – Outlook**
Authored by Priyadarshini Sen, the piece highlights how the overuse of antibiotics. The steady rise in use of antibiotics is not itself the problem. However, studies of prescription and sale patterns point to their use in inappropriate ways. And, of course, it's common knowledge that, short of psychotropic drugs, anything can be bought from most medical stores. Patients' habits, too, play a role: instead of completing a course of antibiotics, most people stop once the symptoms begin to wane and remnant bacteria develop resistance. According to a 2011 report of the Indian Journal of Medicine, drugs are being prescribed in incorrect doses, for incorrect duration and in wrong frequency of intake. Some prescriptions are redundant, some have the potential to interact adversely with other drugs.

16. **Centre to notify revised Sch M III for medical devices by June end – Pharmabiz.com**
Following strong representation from the medical devices industry, the Centre has agreed to align Schedule MIII with IS/ISO 13485 by delinking it from Schedule M for Pharma. The revised Schedule MIII will be notified by end of this month and is expected to attract huge investments into R&D which will enable India to emerge as a world class-manufacturing hub for medical devices. Delinking Schedule M III from pharmaceutical sector, has been a long standing demand of medical device industry. They have been steadfastly pushing for changes in drug rules covering regulatory quality management framework and infrastructure requirements on the lines of the BIS and international ISO 13485 standard for regulatory purposes. Drugs & Cosmetics Act, 1940, currently governs the Indian medical device sector, which has very different R&D, technologies, investment, production and taxation requirements from that of pharma sector. This, the industry pointed out had a detrimental impact on medical device sector making India import dependent, leading to unfavourable business environment especially for the domestic manufacturers.

17. **Karnataka govt set to introduce a expired drug disposal policy, draft getting ready – Pharmabiz.com**
Karnataka government is expected to complete a draft of the new drug disposal policy by next month. The policy will put in place a set of procedures for the disposal of date expired and not-of-standard quality drugs in the state. The move is the wake of accumulation of stocks of date expired drugs in the warehouses of the state health department. Last month the Karnataka State Pollution Control Board (KSPCB) and the Karnataka drugs control department identified Satva Health Solutions to initiate a pilot project for finding innovative methods of management of discarded medicines. All efforts to dispose of expired drugs valued over Rs.10 crore stored in warehouses of the health department will be made within the next six months, said Karnataka minister for health and family welfare U T Khadar. He said that the policy will be finalised by next month and expired drugs stored from the past 14 years in warehouses will be disposed. "With the introduction of the new policy, we can dispose of drugs every year and 0.5 per cent drug destruction cess will be collected from public to meet the expenditure," said the Karnataka health minister Khader.

18. **Indian Pharmacovigilance Day 2016 to be observed in Mumbai on July 29 – Pharmabiz.com**
India is emerging as a target destination for procuring support services required for the global pharmaceutical industry, especially in pharmacovigilance. Several steps have been taken by the Indian regulatory authorities recently to strengthen the pharmacovigilance such as XML-E2B format reporting of ICSRs to the Pharmacovigilance Programme of India (PvPI). The gazette notification of March 8 this year legally mandates pharmacovigilance for all pharmaceutical companies, says Dr. Vijay Venkatraman, managing director of Oviya MedSafe, a global pharmacovigilance consulting and drug safety services organisation in Coimbatore in Tamil Nadu.

19. **Medical device sector to have separate rulebook under D&C Act – Pharmabiz.com**
    In a major victory to the industry, the government has conceded three major recommendations of the medical device sector. After a long wait the government has finally agreed to set up a separate regulatory framework and law for the medical devices industry. In fact keeping in the interest of the stakeholders, the CDSCO has also conceded to have a separate rulebook for medical devices for import, manufacture, clinical investigation and sale under the Drugs and Cosmetics Act until its regulatory framework is in place. This move comes as huge relief for the stakeholders as a separate rule-book will enable prompt and timely redressal of the manufacturers issues. While bringing in more confidence and clarity to its members on different regulatory aspects. Once medical devices bill comes into place these rules will be added to it subsequently.