OPPI

Daily News Monitor

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1. **OPPI releases 'Healthcare in India: New Milestones New Frontiers' with McKinsey and Co as knowledge partner – Pharmabiz.com**
   'Healthcare in India: New Milestones New Frontiers', a publication which highlights some existing and future challenges for policy makers and other stakeholders in healthcare sector, was released by Organisation of Pharmaceutical Producers of India (OPPI) with McKinsey and Company as Knowledge Partner recently. The publication also draws attention to crucial aspects of the industry and identifies some new priorities bringing forth five revolutionary themes like using digital data and analytics, leveraging multi-stakeholder partnerships, upgrading capabilities and raising the bar of 'quality of care' among others.

   It was released by Telengana Minister for IT, Industries and Urban Development Kalvakuntla Taraka Rama Rao (KTR), renewing OPPI's commitment to make a difference and strive for a better tomorrow - of ushering in a "Healthy India and an Innovative India".

2. **DIPP working on aligning sectoral regulations with FDI policy – The Economic Times**
   The government is working to remove all anomalies which are restricting foreign direct investment (FDI) into the country, a top official today said. Secretary in the Department of Industrial Policy and Promotion (DIPP) Ramesh Abhishek said that there are certain "sectoral regulations which are not in conformity" with the FDI policy. "So, we are working on that," he said here at FICCI function. He also said that the department is working with ministries of health and pharmaceuticals on amending the Drugs and Cosmetics Act, 1940.

   Speaking at the event, Health Secretary C K Mishra said that the "roadmap is ready" for the amendment in the Drugs and Cosmetics Act.

3. **'Government needs to support pharma sector' – The Hindu**
   The pharmaceutical sector, both domestic and export, has been growing at an exponential rate of 10 to 12 per cent per annum in the last few years. The current domestic market is $15 billion and the export is $17 billion, and in total it grosses up to $32 billion. The projected market is 60 billion by 2020. Against this background, the support from the government is not encouraging, according to chairman of Indian Pharmaceutical Congress Association and national president of Indian Drug Manufacturer's Association S.V. Veerramani. He was here in Visakhapatnam as part of the ongoing three-day 68th Indian Pharmaceutical Congress and during an exclusive chat with The Hindu on Sunday, he spoke about the future of the pharmaceutical sector.

4. **Wake-up call on superbugs – The Hindu**
   Before the discovery of antimicrobials, infections with serious disease-causing organisms were often a death sentence. Occasionally, people recovered if their natural immunity was good, but the rest either ended up dead or with severe disability. The earliest antimicrobials were made of heavy metals such as gold or antimony compounds, which also had a lot of side effects. However, they were found to be effective against infections such as syphilis and leishmaniasis. The first antibiotic was penicillin, discovered by Alexander Fleming. Fleming presciently warned that indiscriminate use of penicillin could one day lead to its loss of effect. Today, we have reached a situation where less than 50 per cent of some groups of bacteria are resistant to almost all the antibiotics we have.

5. **Top pharma firms hike complex drug R&D spend to Rs 8,500 crore in 2015-16, eye buyouts – The Economic Times**
   Leading Indian drug makers have sharply increased their R&D budgets over the past five years, as they stare at tempered growth in the US from the launch of plain generics. The R&D spending of the top seven Indian drug makers rose to around Rs 8,500 crore in the last fiscal year from Rs 2,700 crore in fiscal 2011, according to one estimate. Experts predict the launch pipelines for generic players in the US will be impacted as drugs coming off patent may see a fall in the 2017-2020 period. Amid gloomy outlooks of weakening growth in the large markets of the US and Europe and competition-induced price erosion, Indian companies are focusing on the development of complex drugs to offset the impact.

   Industry experts and analysts opine that the US market is set to see limited major first to file launches in the near term. Companies that file first to sell copies of drugs that come off patent get exclusivity to sell those for the initial months in the US, giving them pricing power and better returns.

6. **Indian pharma industry set for a leap: PDA – The Hindu Business Line**
   The Indian pharma industry is set for a great leap forward in the coming years and therefore all the stakeholders should brace up for the development, according to Sanjit Singh Lamba, the Managing Director of Eisai pharma India Private Limited and the president of the Indian chapter of Parenteral Drug Association (PDA). He said here on Sunday at the valedictory session of the Indian Pharmaceutical Congress that the industry was growing at 15.92 per cent per annum in the country and the size would grow to $ 55 billion by 2020, making India the sixth largest market globally.

7. **2,500 papers to be presented at 3-day 68th Indian Pharmaceutical Congress – The New Indian Express**
   The three-day 68th Indian Pharmaceutical Congress (IPC) began at Andhra University on Friday where thousands of delegates gave an overview of the past editions of the Indian Pharmaceutical Congress.
   During the inaugural, the members of Indian Pharmaceutical Congress Association (IPCA) presented

the global pharmaceutical market scenario and scientific programmes of the 68th IPC. A Ramakrishna, convener, Scientific Service Committee of the IPCA, said, “The programme will have medical technology and devices, sustaining quality and regulatory compliance, research and novel development, best pharmacy practices, pharmexcil and AIDCOC symposium, women symposium and student session.”

8. **BRICS roots for affordable medicines – The Hindu**
   Union Health Minister J.P. Nadda has pressed for public health targets to be placed above trade deals. “Trade regimes are important, but must be seen as being subservient to the shared international public health goals,” he said at the two-day meeting of the Health Ministers of Brazil, Russia, India, China and South Africa (BRICS), which concluded here on Friday. Referring to the World Health Organisation’s recent decision to drop the term “counterfeit” and use “falsified” instead to describe medicines of inferior quality, Mr. Nadda said he was “happy” that the WHO member-states arrived at a consensus on doing so as the word “counterfeit” usually referred to intellectual property rights violations.

9. **Rajasthan healthcare needs treatment: Jan Swasthya Abhiyan – The Times of India**
   More than 300 people gathered at Shaheed Smarak in the state capital to discuss the problems faced in accessing quality healthcare in Rajasthan. The meeting was held under the aegis of Jan Swasthya Abhiyan Rajasthan, a state wide network of organizations working on health rights. Less than 2% of the state's GDP is allocated to healthcare services - this is grossly inadequate, public health specialists said, even as over 30 case studies of people deprived of timely medical health were presented at the gathering on Wednesday. Some people complained of being denied timely treatment as they had not taken the Bhamashah health insurance card to the hospital at the time of treatment; at Sawai Madhopur district hospital, an eye ward was inaugurated in 2002 but no surgeries have occurred there in all these years. Rajasthan, with a population of about seven crore, has seen rising expenses on healthcare burden of poor families. The state has been increasingly outsourcing healthcare services to private hospitals.

10. **Norms eased for makers of biologic products – The Economic Times**
    India’s drug regulator has eased licencing norms for vaccine and recombinant-DNA manufacturers in a move expected to promote research and development of new drugs in the country. The Central Drugs Standard Control Organisation (CDSCO) has done away with the need for joint inspections to issue licences to allow such companies to make biologic products for testing and analysis purposes. The regulator has also clarified that these biologics can also be exported only for the purpose of examination, test or analysis and not for commercial purposes in a circular dated December 13. According to CDSCO’s latest decision, State Licencing Authorities will issue ‘Form 29’ licences to vaccine and r-DNA makers within three working days of them submitting their application. The joint inspection of these applicants will now be carried out using a risk-based approach only after the licence is issued.

11. **Price fixing lawsuit slapped against Aurobindo Pharma, Mylan Pharmaceuticals, others in US – The Financial Express**
    A lawsuit has been filed by 20 state attorneys in the US, accusing six pharmaceutical firms from America, India and Australia for alleged conspiracy to raise the price of the antibiotic doxycycline and diabetes drug glyburide. The generic drug makers include Heritage Pharmaceuticals Inc, Aurobindo Pharma USA, Citron Pharma, Mayne Pharma (USA), Mylan Pharmaceuticals and Teva Pharmaceuticals USA. Shares of Aurobindo Pharma fell by nearly 4% to R691 on BSE following the report. The lawsuit alleged that these companies entered into illegal conspiracies in order to unreasonably restrain trade, artificially inflate and manipulate prices and reduce competition in the US for two drugs: doxycycline hyclate delayed release, an antibiotic, and glyburide, an oral diabetes

medication. The lawsuit was filed under seal in the US District Court for the District of Connecticut, George Jepsen, Connecticut Attorney General, said in a written release. Incidentally, Sun Pharmaceutical Industries and Dr Reddy's Laboratories recently disclosed having received subpoenas under a US Department of Justice investigation into drug price rises by generic drugmakers.

12. **Alembic receives USFDA approval for Itraconazole capsules – Business Standard**
    Alembic Pharmaceuticals Ltd on Friday announced that the company has received approval from US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) for Itraconazole capsules. "We have received approval from USFDA for our ANDA for Itraconnazole capsules 100 mg. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Sporanox capsules 100 mg of Janssen Pharmaceuticals Inc," a company statement said here. Itraconazole capsules are indicated for the treatment of blastomycosis, histoplasmosis and aspergillosis in immunocompromised and non-immunocompromised patients and onychomycosis in non-immunocompromised patients.

13. **DCGI gives approvals for license renewal of blood banks following state FDA inspections – Pharmabiz.com**
    In a major boost to blood banks in Maharashtra, the state Food and Drug Administration (FDA) has received approvals from the Drug Controller General of India (DCGI) for renewal of licenses of civic run blood banks at Bhagwati Hospital, Borivali, KEM Hospital, Parel and Rajawadi Hospital, Ghatkopar. Renewals for civic run blood banks LTMG Hospital, Sion and Bhabha Hospital, Bandra are also currently in the process of being approved.

    As per the Drugs and Cosmetics Rules, 1945, blood bank licenses are valid for five years. Central licensing approving authority of Central Drugs Standard Control Organisation (CDSCO) renews licences after the state Food and Drug Administration (FDA) satisfies and recommends the same for renewal. Inspection reports were sent recently to the DCGI office for approval after Maharashtra FDA inspections. This comes close on the heels of Maharashtra FDA directive to 306 blood banks in the state to submit applications of renewal of licenses by December 31, 2016.

14. **NPPA asks cos to submit info on production & supply of sch drugs to ensure availability of essential drugs – Pharmabiz.com**
    The National Pharmaceutical Pricing Authority (NPPA) has asked the pharmaceutical manufacturers to submit information regarding production and supply of scheduled medicines under 28 and 29 of Drug Price Control Order (DPCO), 2013 to ensure the availability of essential drugs in the country. The NPPA's action in this regard comes following reports that there are severe shortages of some essential drugs in the country as the manufacturers have drastically reduced production of these medicines due to profitability and other reasons.

15. **PvPI recommends CDSCO to initiate action against 24 drugs for showing ADRs – Pharmabiz.com**
    The Indian Pharmacopoeia Commission (IPC), which is the National Coordination Centre for the Pharmacovigilance Programme of India (PvPI), has recommended to the Central Drugs Standard Control Organisation (CDSCO) for regulatory actions against 24 drugs which have been found to show adverse drug reactions (ADRs).

    According to sources, the India specific drug safety signals, drug alerts and others have been identified from the reported ADRs by the Signal Review Panel (SRP) of the PvPI and has recommended to the CDSCO for the appropriate regulatory actions against the list of 24 suspected drugs.