

Daily News Monitor

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1. India risks missing boat as biosimilars shake up drug industry – Reuters India India, which has dominated the generic drugs industry for decades, is falling behind in the race to make copies of complex biotech drugs, which are expected to generate tens of billions of dollars in sales in the coming years.

While Indian firms have launched a few such products on the domestic market, where regulatory barriers are relatively low, they are being overtaken by European, American and South Korean firms in the race to supply lucrative Western markets. Just three Indian groups -Biocon Ltd (BION.NS), Reddy's Laboratories Ltd (REDY.NS) and Intas Pharamceuticals Ltd - are working with partners on socalled biosimilars aimed at the United States and Europe.

Rs 1,800-cr plan for tightening drug regulations in the works
 Times of India

In a bid to upgrade the country's drug regulatory processes, the health ministry has worked out a Rs 1,800-crore package for a sweeping revamp of the central as well as state drug regulatory agencies.

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- 2. Rs 1,800-cr plan for tightening drug regulations in the works Times of India
- India battles big pharma over cough syrup abuse, reducing supplies - Economic Times
- 4. Ease of doing business: Government likely to remove sectoral conditions like minimum capitalisation Economic Times
- 5. <u>Lupin, Boehringer To Co-market Diabetes Drug</u> <u>Linagliptin In India – Business World</u>
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- 7. Pharma companies take the lead as cross-border M&As rise Mint
- "Make in INDIA" Brings IP Regime Change –
 Newswire
- 9. <u>Japan's drug regulator PMDA set to open office in</u>
 <u>India Economic Times</u>
- 10. <u>Private players in e-pharmacy space form</u> association Economic Times
- US seeks more investments from India Inc Times of India
- 12. Frost & Sullivan hosts 7th Annual India Healthcare
 Excellence Awards 2015 in Mumbai Pharmabiz

According to an official source, the proposal focuses on four main areas: strengthening the inspection apparatus - both at the central and state levels, bolstering manpower at the Central Drugs Standard Control Organisation, ramping up national laboratories across the country and creating a strong database of products, clinical trials etc.

3. <u>India battles big pharma over cough syrup abuse, reducing supplies</u> - Economic Times Indian regulators are privately pressuring major drug firms to better police how they sell popular codeine-based cough syrups to tackle smuggling and addiction, a move that is reducing supplies of a medicine doctors say is an effective treatment.

India's Cipla stopped making the product last year owing to regulatory demands, and U.S.-based Abbott Laboratories and Pfizer have had to reduce batch sizes by up to half, cutting how much medicine their factories can produce.

4. <u>Ease of doing business: Government likely to remove sectoral conditions like minimum capitalisation</u> – Economic Times

India is expected to remove sectoral conditions such as minimum capitalisation, shareholding restrictions and non-compete clauses for foreign investors to create a level playing field with domestic companies as part of the next phase of a proposed ambitious clean-up of FDI policy.

Foreign investors will be subject only to those norms imposed by sector regulators or departments, ensuring parity with domestic investors. Sectors that would benefit the most from this clean-up are nonbanking finance, venture capital, construction, pharmaceutical and retail. The attempt would be to remove most conditions tied to foreign direct investment, retaining only those that have strategic or national security considerations.

5. <u>Lupin, Boehringer To Co-market Diabetes Drug Linagliptin In India</u> – Business World Local drug maker Lupin Ltd and German drug multinational Boehringer Ingelheim on Wednesday (14 October) signed a strategic alliance for co-marketing the latter's new diabetes management drug linagliptin in India. With this alliance, Lupin will market and sell this Boerhinger drug formulation under a separate brand name Ondero. Boehringer, which has a strong presence in this anti-diabetes therapy segment in the domestic market, will continue to sell its linagliptin under the brand names Trajenta. Both the companies will also co-market the

6. <u>Drug stores shut as eight lakh chemists go on strike in protest against e-pharmacies</u> – Daily

Thousands of pharmacies across the country remained closed on Wednesday following a nationwide strike called by the All India Organisation of Chemists & Druggists (AIOCD).

brand extension Ondero Met and TrajentaDuo (a combination of linagliptin and metformin) in

The industrial action was called to oppose the central government's move towards regularising the sale of medicines through the internet or e-pharmacies. About eight lakh members involved in the distribution of medicines across the country are protesting against the online sale of drugs.

7. Pharma companies take the lead as cross-border M&As rise – Mint

India, using their existing field forces dedicated to diabetes portfolio.

Cross-border merger and acquisition (M&A) deals rose 10% in terms of deal value in the July-September quarter this year compared with the same period last year, said law firm Baker and McKenzie's quarterly cross-border M&A Index launched on Wednesday. The 1,230 deals in the quarter were worth \$375 billion.

India ranks among the top 10 acquirers in the US market for 2015, with 16 transactions valued at \$1.7 billion. The majority of those deals are in the life science sector, with six transactions totalling \$1.5 billion, as Indian companies seek to increase their scale in the US generic drugs market, said Baker and McKenzie, a Chicago-based firm.

8. "Make in INDIA" Brings IP Regime Change – Newswire

"Make in India" is the major national program organized by the Indian Government to transform India into a global manufacturing hub. This campaign encourages International Investors to setup their manufacturing plant in various cities in the country. The domestic manufacturing industries are encouraged to enhance their R & D team to support innovation. Innovation of any kind leads to Intellectual Property Rights involvement.

Einfolge anticipated the change and took a step to understand the global market's need and requirement.

9. Japan's drug regulator PMDA set to open office in India – Economic Times

Japan's drug regulator, the Pharmaceuticals and Medical Devices Agency (PMDA), is set to open an India office soon, amid concerns over an aging population and burgeoning healthcare costs in a country dominated by branded drugs.

The move is expected to help Indian generic drug manufacturers, which have been seeking to increase their presence in Japan either through exports or by forging joint ventures with partners in that country. Japan's market, the second-largest in the world after the US, is worth \$110 billion.

10. Private players in e-pharmacy space form association – Economic Times

Amid a nationwide strike of chemists today against "illegal" online sale of medicines, private players in the e-pharmacy space have come together to form an association.

"The Indian Internet Pharmacy Association (IIPA) officially formed with the mission to promote and protect the public health by ensuring that its members operate in accordance with the existing Drugs & Cosmetics Rules... of Information Technology Act, 2008, and Pharmacy Practice Regulations, 2015," IIPA said in a statement.

11. US seeks more investments from India Inc - Times of India

The United States wants more investments from India as the two nations have set a target of increasing bilateral trade to USD 500 billion in the next few years from the present USD 100 billion, a top official has said.

"We see lot of potential in bilateral trade and investment between India and the United States. We have set a USD 500 billion bilateral trade target from the present USD 100 billion," United States consul general in Mumbai, Tom Vajda said at the 'SelectUSA' roadshow here today. "We want more Indian companies to come and invest in helping grow the US economy," Vajda said.

12. Frost & Sullivan hosts 7th Annual India Healthcare Excellence Awards 2015 in Mumbai – Pharmabiz

Frost & Sullivan hosted the seventh edition of its India Healthcare Excellence Awards recently in Mumbai to recognize companies and individuals for their contribution to the country's healthcare industry. Awarded for their growth strategies, due diligence in development and innovation, showcasing best practices adoption and host of other critical factors, the 25 award recipients at the 7th Annual Healthcare Excellence Awards represented the best-in-class of the healthcare business.

The awards were presented across four major award categories; Pharmaceuticals And Biotechnology, Healthcare Delivery Services, Medical Technologies, And Research-Based Awards. The awards jury comprising eminent industry experts, key opinion leaders, and visionary innovators, rated nominees across eight to 10 parameters, backed by the research data from Frost & Sullivan. Besides these categories, there were two special awards conferred by Frost & Sullivan to exemplary individuals who have contributed significantly to the healthcare industry for its advancement and furtherance.