

1. [Inviting Higher Risks By Challenging FDA](#) –

Business World

Are Indian drug exporters gearing up for challenging the US Food and Drug Administration on its “wrong doings”? If the industry sources are to be believed—yes, a massive campaign is afoot in the local pharmaceuticals industry against the big regulator, which has tightened its scrutiny on the manufacturing standards compliance level of Indian export units of late. The top drug makers in the country (most of them are already under the US regulatory scan) are joining hands to agitate against a series of ‘flaws’ that they have found in the action procedures initiated by the FDA in the recent period.

The industry captains

allege that the FDA does not follow systems while conducting audits and follow-up actions and it doesn’t respond on time to company replies.

2. [50% margin cap on chemists' profit?](#) – Times of India

In a move that could significantly bring down prices of medicines, the government is planning to cap the margin of chemists and wholesalers at 50%, sources said.

The department of pharmaceuticals is working on a proposal to cap trade margin of pharmaceutical products that are priced above a certain level. The department has worked out three different slabs for ceilings based on the MRP of the product. For products priced at Rs 2 per unit, the chemist margin may be capped at 50%. There may be two more slabs of 45% and 35%, an official said.

3. [Dashing innovators' hopes](#) – Deccan Herald

Govt needs to shed its current intransigence. It should stop viewing patent laws from a prism that ‘only MNCs benefit from these. These MNCs spend billions of dollars on research and development to discover and develop new medicines and crop protection products and have a fundamental interest in the protection of IPRs. They had flagged Section 3[d] of Patent

1. [Inviting Higher Risks By Challenging FDA](#) – Business World

2. [50% margin cap on chemists' profit?](#) – Times of India

3. [Dashing innovators' hopes](#) – Deccan Herald

4. [‘Make in India’ initiative partners with BioAsia 2016](#) – Express Pharma

5. [Challenges galore on funding, patent and IPR fronts](#) – Hindu Business Line

6. [Two Indian states halt sales of Roche's Avastin drug](#) – Reuters

7. [Patent Office refuses divisional patent for GSK Biologicals' vaccine](#) – Business Standard

8. [MSF asks India to resist EU pressure to include harmful provisions on IP in EU-India FTA](#) – Pharmabiz

9. [Focus medical research on Indian issues: Nadda](#) – Press Trust of India

10. [Implementation of POEM rules may hit investments](#) – Financial Express

11. [Union govt's 'Start-up India' campaign enthuses biotech and pharma sectors](#) - Pharmabiz

[Amendment] Act 2005 and provision relating to grant of compulsory licenses as major concerns.

4. [‘Make in India’ initiative partners with BioAsia 2016](#) – Express Pharma
BioAsia announced that the Make in India initiative by the Government of India has partnered with the 13th edition of BioAsia to be held in Hyderabad from 8th to 10th February 2016. The partnership will make BioAsia the only BioPharma event to associate with this ambitious initiative of the Government of India. ‘Make in India’ partnership will also enhance the level of the impact of the deliberations at the event, given that the relevant policy makers will be attendance at the event, to interact and engage with the industry and academic stakeholder.

5. [Challenges galore on funding, patent and IPR fronts](#) – Hindu Business Line
First generation entrepreneurs across the country are applauding the government’s efforts to recognise their business ventures under the banner of Start-Up India, but for most challenges of funding, patents and creation of intellectual property remain.

“The Prime Minister seated with entrepreneurs on a national platform is a very positive signalling,” said Abhishek Sinha, Co-Founder and CEO, Eko India Financial Services, who was also a panellist in one of the session. However, small problems such as bank funding in the lack of any collateral turn out to be big roadblocks for many entrepreneurs.

“Banks are careful while giving out loans. When we started out, we had to depend on loans and credit cards. Even today the story is same,” he told BusinessLine.

6. [Two Indian states halt sales of Roche's Avastin drug](#) – Reuters
Two Indian states have put sales of Swiss drugmaker Roche's blockbuster drug Avastin on hold, officials said on Tuesday, after it hampered the vision of 15 patients who used it for a condition it is not officially meant to treat.

Avastin is a cancer drug but is often used by doctors to treat vision loss even though it has not been approved by the U.S. Food and Drug Administration for that purpose. Studies have shown that eye injections of Avastin curb vision loss.

Roche's India unit said the company does not promote the use of Avastin for treatments for which it is not approved, but has initiated an internal investigation.

7. [Patent Office refuses divisional patent for GSK Biologicals' vaccine](#) – Business Standard
The Patent Office has rejected a divisional application of GlaxoSmithKline (GSK) Biologicals, filed seeking patent for vaccines against cancer, for various reasons including lack of inventive step. The parent application, filed at the Kolkata office of Patent authority in May 2007, was withdrawn by the company earlier.

The company filed the divisional patent application titled ‘Vaccines’ on May 2007 claiming priority to an international application and UK patent application. The first examination report was issued on February, 2010. The application was divided out of the patent allocation, which was directed to an immunogenic composition, method of treatment using the same, use of the composition and a method of manufacturing the composition.

8. [MSF asks India to resist EU pressure to include harmful provisions on IP in EU-India FTA](#) – Pharmabiz
Even as the senior officials from the European Commission (EC) and India are expected to meet soon in Brussels to hold talks on resuming negotiations on the proposed EU-India free trade agreement (FTA), the international medical humanitarian organisation Médecins Sans Frontières (MSF) has warned that India must resist European Union (EU) pressure to include harmful provisions on intellectual property that could restrict access to medicines for people in developing countries.

“As the Indian government considers resuming trade negotiations with the EU, we urge both sides to think about the lives that hang in the balance if access to affordable generic medicines is shut down or blocked due to IP enforcement measures,” said Leena Menghaney, Head – India, MSF’s Access Campaign. “Millions of people around the world depend on affordable medicines made in India to stay alive, and they can’t afford to have cumbersome trade rules stand in the way of the treatment they need.”

9. [Focus medical research on Indian issues: Nadda](#) – Press Trust of India

Union Health Minister J P Nadda today asked Indian Council of Medical Research (ICMR) to do focus-based research on issues being faced by Indian community and incorporate traditional knowledge in biomedical research.

"We have got many things to address but we should focus on few pressing issues which the Indian community is facing and start in a holistic manner to find answer to them. Let us list 10 most pressing health issues and undertake research in these areas to find local solutions," Nadda said at ICMR's award presentation ceremony.

He said an integrated approach needs to be applied in biomedical research and traditional medicines should also be involved.

10. [Implementation of POEM rules may hit investments](#) – Financial Express

The implementation of place of effective management (POEM) rules in the current scenario in India could not only hurt the nation’s outbound investments, but also discourage overseas multinational companies from setting up their regional hubs here, feel industry watchers.

The draft guidelines for implementing POEM, which was released on December 23 and aimed at bringing clarity on residency status of firms for the purpose of taxation, need to offer more clarity, they say. The companies would also require six to nine months to make back-end changes to implement the new norms, they feel.

11. [Union govt's 'Start-up India' campaign enthuses biotech and pharma sectors](#) - Pharmabiz

The Union government's efforts to boost the start-up eco-system with its 'Start-up India' campaign has made the pharma and biotechnology sectors more confident to steer innovation backed by technology and intellectual property. Companies view the Insolvency and Bankruptcy Bill allowing start-ups to exit faster, within 90 days, without the fear of failure as the pick of the bunch among the slew of announcements.

The 19-point action plan under the Start-up India campaign provides not just tax waivers but encourages public private partnership model for 35 new incubators, 31 innovation centres at national institutes and 7 research parks, and 5 new bio-clusters. These along with tax waiver for three years, no inspection for 3 years of start-up businesses, 80 per cent rebate in patient costs, introduction of self-certification and a mega fund of Rs.2,500 crore and alter to Rs.10,000 crore are seen to accelerate the growth of entrepreneurs.