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1. US pharma sector demands keeping India in patent violator list – Business Standard

America's pharma sector has asked US Trade Representative (USTR) to continue to keep India on its priority watch list (PWL) which includes countries that are alleged violators of US patent laws, claiming that the environment on the ground remains "challenging" in India. Among the key issues of concern for the US pharma sector in India are unpredictable IP environment, high tariffs and taxes on medicines, regulatory data protection failure, discriminatory and non-transparent market access policies and unpredictable environment for clinical research. Pharmaceutical Research and Manufacturers of America (PhRMA) in a submission requested US Trade Representative (USTR) to continue to keep India on the Priority Watch List in the 2017 Special 301 Report.

"Further, we urge USTR to provide an opportunity for a meaningful assessment of India's IP regime through an Out-of-Cycle Review, so that the US government can evaluate progress on these important issues and dedicate the required bilateral attention necessary to translate India's commitments into substantive and real policy change that addresses the IP and market access barriers confronted by US businesses in India," PhRMA said in the Indian section of its submission.

Also reported by –

- US pharma sector demands keeping India in patent violator list – Mint
- US pharma sector demands keeping India in patent violator list – India Today
- US pharma sector demands keeping India in patent violator list – The Economic Times

2. Authentication Forum To Address Counterfeiting Concerns In India – Business World

In a strong move against counterfeiting and enabling the "Make-Sure-India" movement in the country, Authentication Solutions Providers Association (ASPA) and Messe Frankfurt India (MFI) on Wednesday (08 February) launched India's first authentication conference cum exhibition – The Authentication Forum 2017.

Top notch people from the industry and stakeholders including Arvind Gupta, National President (Convener) – IT Cell, Bhartiya Janta Party (BJP), Anil Rajput, Senior Chair – Federation of Indian Chambers of Commerce & Industry – Committee Against Smuggling and Counterfeiting Activities Destroying the Economy (FICCI CASCADE) & Vice President - Corporate Affairs, ITC, Rama Shankar

Pandey, Co-Chairman, Consumer Affairs & Anti – Counterfeit Committee, Automotive Component Manufacturers' Association of India (ACMA) & Managing Director, Hella India, Vivek Padgaonkar, Director – Project & Policy, Organization of Pharmaceutical Producers of India (OPPI) and Pradeep Shroff, Noted Anti-Counterfeiting Expert, Author, Former President, ASPA & Former Managing Director – PRS Permacel aimed at mitigating counterfeiting concerns.

3. **Coronary stents' price fixation: Public health groups call it a 'bold step' – The Times of India**
Public health groups welcomed the National Pharmaceutical Pricing Authority (NPPA) fixing the ceiling prices for coronary stents which they expected would not only make angioplasty with stents more affordable, but would also put an end to the corrupt practices associated with the marketing of stents. The price of drug eluting stents (DES) which were being sold for anything between Rs 24,000 to Rs 1.5 lakh has been capped at Rs. 29,600 and that for bare metal stents (BMS) at Rs 7,260. The groups noted that the order was an important first step in checking the corrupt practices of the unethical triad of industry, doctors and hospitals that had become commonplace across the health sector. "After months of consultations, we welcome the strong and determined action of the government, particularly in the face of a concerted campaign by industry and profit-oriented hospitals to prevent any form of effective price control," said Malini Aisola of the All India Drug Action Network. Describing the price fixation as a "bold step" by the government, the Swadeshi Jagran Manch's statement said that bringing the price down to less than one third of the current price would bring great relief to patients. "The ceiling prices on BMS and DES also brings a level playing field for Indian stent manufactures to compete with foreign manufactures," added SJM which had recently written to the minister for chemicals and fertilisers urging him to fix "an affordable price" for stents. It warned that the benefit of price reduction should not be curtailed through increasing charges of angioplasty procedures or unwanted insertion of stents.

4. **Why 2017 is a landmark year for the medical device industry in India – The Financial Express**
After an uphill battle for recognition, India's medical device sector was greeted by a landmark announcement in the Union Budget 2017. In his budget speech, India's Finance Minister Arun Jaitley declared that the government would formulate new norms, 'harmonized with international rules', for the medical devices sector. This would attract more foreign investment and reduce prices of medical devices, the minister stated. Barely a day after the budget announcement, the Ministry of Health and Family Welfare released a media statement that it had notified the Medical Device Rules 2017 on Jan 31, which would be enforceable from January 2018. Often quoted as the 'pharmacy of the world', India has struggled with an ambiguous and archaic regulatory framework for the medical devices sector. Medical devices, 75% of which are imported, are currently treated as drugs under the Drugs and Cosmetics Act. Without legislative backing, the regulator – Central Drug Standard Control Organization – was helpless to curb both the flood of substandard imports as well as the production of poor quality medical devices in the country.

5. **Some hosps slash stent price, others face patient ire on bills – The Times of India**
Within hours of the Centre capping prices of coronary stents, a few private hospitals slashed the cost of their packages by 12-15%. Most hospitals assured benefits of the price regulation will be passed on to consumers, but activists fear rates of components other than implants may see a spurt to make up for the lost profits. The Kokilaben Ambani Hospital in Andheri and Lilavati in Bandra said the price change would reflect immediately. "The cost of our single stent angioplasty has dropped by Rs 30,000-35,000 effective immediately. The cost of multiple stents too will be reworked accordingly," said the Andheri hospital's executive director Dr Ram Narain. Corporate hospitals such as Fortis chose not to comment. The National Pharmaceutical Pricing Authority (NPPA) on Monday fixed the ceiling price of stents. The billing departments of hospitals went into a tizzy on Tuesday as patients wanted to be charged accordingly. A Vile Parle hospital said it had to put a case on hold as the patient refused to pay more than Rs 30,000 even though he was explained about the additional taxes.

6. **Cancer drugs cheaper, but where? – Deccan Chronicle**
   The cost of cancer drugs like trastuzumab and temozolomide, used to treat breast and brain cancer, was slashed by 54 per cent by the National Pharmaceutical Pricing Authority, but this is not reflected in the market as they are only sold at hospital pharmacies. The new treatment of immunotherapy or biological therapy which have shown good results is proving to be very expensive and are not available in the open market. A senior pharmacist on condition of anonymity said, "The hospitals have a monopoly and insist that all the medicines have to be bought from their pharmacy. Patients do not have a chance to compare the cost of the medicines in the market outside."

7. **Vasant Narasimhan: Can I do trials without trial sites? – The Hindu**
   Global Head of Drug Development at Novartis Dr. Vasant Narasimhan is all for the pharma industry embracing tools of modern technology. Predictive learning analytics and digital technologies in clinical trials can help improve process efficiency, cut costs and gain time. He also sees a greater role for the company's development centre in Hyderabad. The insight we had is other industries, whether aerospace, oil and gas, other industrial sectors and consumer packaged goods, started investing in technology in their operations to become much more efficient. The pharmaceutical industry did not do that at the same time. We lagged the rest. But if you now look at how sure predictive learning analytics, digital technologies are, there is an opportunity to put that to make [clinical] trials much more efficient. We would like to lead in it and be more advanced.

8. **Indian & MNC pharma cos scout for qualified pharmacy graduates & post graduates to work in regulatory depts. – Pharmabiz.com**
   Regulatory departments of domestic and multinational companies in the country along with and drug control departments and start-up enterprises are scouting for qualified pharmacy graduates and post graduates, said Dr. Shenaz Khaleeli, founder and technical director, PharmaLeaf India. The key reason, according to Dr. Khaleeli, is that regulatory affairs has evolved in India. "The country is looking to build its efficiency in this space. Regulatory operations require expertise across products, therapeutic areas and global markets. Therefore pharmacy graduates and post graduates can consider this field as a promising career growth path", she added. Speaking at the pre-conference inauguration of the three-day Alfacon 2017 organised by the Al-Ameen College of Pharmacy in Bengaluru which is being held from February 9-11, Dr. Khaleeli, said "Drug life cycle management, R&D commercialisation , post approval compliance require regulatory services. There is a need for dedicated and qualified pharmacy workforce."