

1. [India's central drug regulator earns highest rating in WHO assessment](#) – **The Times of India**

The Central drug regulator has earned the highest rating during a latest assessment by the World Health Organisation. A WHO-led team of international experts evaluated systems and procedures at different drug regulatory offices around the country as well as at laboratories and gave ratings based on the assessment. India has scored in four out of five parameters, the highest possible score, according to officials. "This is indeed a great achievement and we would like to congratulate the Ministry of Health & Family Welfare and its affiliated institutions: Central Drugs Standards Control Organization (CDSCO); Central Drugs Laboratory, Kasauli; Pharmacovigilance Programme and Immunization Division, and other relevant institutions engaged in the regulation, control and testing of vaccines," said Dr Alireza Khadem, WHO Team Leader for the National Regulatory Authority Re-benchmarking. The assessment was made by a team of international regulators including representatives from the US and Germany. The comprehensive review was conducted from 13-17 February 2017.

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2. [Government invokes emergency power to prevent stent shortage](#) – **The Times of India**

Moving to ensure there is no shortage of stents due to price control, the government has invoked an emergency provision making it mandatory for manufacturers to maintain production and supply of coronary stents at previous levels for at least six months. Stent makers and importers have also been directed to submit a weekly report on stents production and distribution to the National Pharmaceutical Pricing Authority (NPPA), which regulates prices of drugs and medical devices. Following reports of artificial shortage of stents after it imposed price caps, the NPPA had written to department of pharmaceuticals asking it to invoke the provisions. "After due deliberations on the current situation and alternatives available with the government to resume normal supply of the coronary stents, it has been decided to invoke the powers of Section 3 (i) of DPCO, 2013," DoP said in a letter to stent makers. NPPA maintained, "Withdrawal of any brand having got a license earlier without NOC (No objection Certificate) from NPPA shall be dealt firmly". The regulator also tweeted that it is probing alleged violation at three hospitals.

3. [Supply all stent brands, government tells companies](#) – **The Economic Times**

The government has ordered cardiac stent makers and importers to continue supply of all brands of the device they were marketing in India before the country's drug pricing regulator slashed their prices by over 75% last week. The move, a response to reported shortages of some stent brands at hospitals, is expected to ensure uninterrupted supply of a variety of high quality stents to patients. A

cardiac stent is a wire mesh tube used to unclog blockages in the arteries carrying blood to the heart and prevent heart attacks. The National Pharmaceutical Pricing Authority (NPPA), India's drug pricing watchdog, has capped the prices of drug eluting and bioresorbable vascular stents at Rs 29,600 and bare metal stents at Rs 7,260. After including VAT, these stents are expected to cost Rs 31,080 and Rs 7,623, respectively. The chemicals and fertilizers ministry's Department of Pharmaceuticals (DoP) on Tuesday wrote to all stent manufacturers and importers directing them to maintain supply of their coronary stents, an official aware of the developments told ET. DoP has invoked powers under the Drugs (Prices Control) Order, 2013, to mandate companies to continue sale of their stent brands, the official added.

4. ['Not shy of bringing other devices under price control': NPPA](#) – The Indian Express

The National Pharmaceutical Pricing Authority (NPPA) has clearly stated that if it finds 'similar exploitative system' of pricing like what was observed in the stent trade channel, it will not 'shy away' from bringing those devices under price control using special powers, which have been provided under section 19 of Drug (Prices Control) Order, 2013, or DPCO, 2013. Meanwhile, invoking special powers under section 3(1) of DPCO, 2013, the Department of Pharmaceuticals (DoP) on Tuesday asked the stent manufacturing companies to submit a weekly report on stents, which have been produced and distributed till date, and maintain their current supply in the market. The NPPA works under the DoP. "They will also submit a weekly production plan for the next week to NPPA and Drug Controller General of India (DCGI)," said the DOP on Tuesday. Section 3(1) of the DPCO, 2013 states that Centre can "direct formulators to sell the formulations to institutions, hospitals or any agency" with a view to achieve adequate availability "in case of emergency or in circumstances of urgency". Centre has invoked these powers as it has been receiving reports regarding shortage of stents in hospitals and market.

5. [Arrival of foreign tourists on medical visa witnessing phenomenal growth](#) – Business Standard

India is emerging as a hotspot for medical tourism with arrival of foreign tourists on medical visa showing a phenomenal growth in the last two years. The year 2015 witnessed the growth of 140 percent of foreign tourist's arrival on medical visa from 2013, where more than 50,000 people visited India on medical visa, according to a study - titled 'Medical value travel (MVT)' - jointly undertaken by Assocham and research firm Indian Institute of Tourism and Travel Management (IITTM). This number rose to approximately 134,000 in 2015. In fact, the number of foreign tourist's arrival on a medical attendant visa also doubled from 2013 to 2015, increasing from 42,000 odd in 2013 to more than 99,000 in 2015. The study revealed that in the first 6 months of 2016 alone, close to a lakh foreign tourists have arrived on a medical visa making it a very lucrative market. As per the report, Indian health care is expected to rise at a rate of CAGR of 29 percent during 2015-20 to \$ 280 billion with rising income, greater health awareness, increased precedence of lifestyle diseases and improved access to insurance.

6. [FIPB clears 15 FDI proposals worth Rs12,000 crore, defers 6](#) – Mint

Inter-ministerial body, foreign investment promotion board (FIPB) on Tuesday approved 15 investment proposals, including that of Apollo Hospitals, Hindustan Aeronautics Ltd, Dr. Reddy's Laboratories and Vodafone, envisaging foreign investment of Rs12,200 crore. "15 out of 24 FDI proposals were approved while three were rejected," people familiar with the matter said. The FIPB, headed by economic affairs secretary Shaktikanta Das, deferred 6 proposals, including that of Gland Pharma with the proposed FDI inflow of Rs8,800 crore. These proposals were deferred for further consultation and want of more information, sources added. Among the proposals approved, Twinstar Technologies will alone bring foreign capital of about Rs9,000 crore into the country.

7. [Healthcare, patient groups oppose hep-C drug patents](#) – ETHealthworld.com

Healthcare aid and patient groups have come together in patent courts to fight against "abusive strategies" of Big Pharma to ensure access to affordable treatment in hepatitis C. The Initiative for Medicines, Access & Knowledge (I-MAK) - together with the Delhi Network of Positive People

(DNP+) and international medical humanitarian organisation Medecins Sans Frontieres (MSF) - on Tuesday filed two patent challenges on daclatasvir, one on velpatasvir and a further challenge on sofosbuvir. The patent challenges could remove barriers to production and distribution of affordable generic versions of direct-acting antiviral (DAA) medicines, including Gilead's sofosbuvir and velpatasvir, and Bristol-Myers Squibb's daclatasvir. Sofosbuvir (brand name Sovaldi) is Gilead's blockbuster drug for hepatitis C, also embroiled in another patent challenge. The Indian Patent Office granted a patent on the drug last year, with the decision challenged by patient groups. In the present challenge, the two cases oppose crystalline forms of sofosbuvir and daclatasvir and should be rejected for not being in compliance with Indian law, a statement from MSF said. Indian law recognises that crystalline forms of known medicines are not inventions and should not be awarded patents. This was confirmed by Supreme Court on April 1, 2013, which refused a patent on Novartis cancer drug Gleevec by holding that a crystalline form of a known pharmaceutically active compound cannot be regarded as involving an inventive step.

8. [US Chamber ranks India at bottom in its IP report, Indian Pharmaceutical Alliance terms it flawed assumption – Pharmabiz.com](#)

Expressing concern over US Chamber of Commerce's Global Intellectual Property Report ranking India at bottom level due to balanced IP system, Indian Pharmaceutical Alliance said that the report proceeded on the flawed assumption. India has made effective policies for promotion and enforcement of IP rights which are compliant with TRIPS where the country is a signatory. The International IP Index of Global Intellectual Property Centre (GIPC), an organisation under the US Chamber of Commerce, has ranked India 43 in the list of 45 countries followed only by Pakistan and Venezuela. The highest ranked country is the US followed by UK, Germany and Japan. According to the report, National Intellectual Property Rights Policy failed to resolve fundamental weaknesses in India's IP framework. The country has lengthy pre-grant opposition proceedings and has limited participation in international IP treaties. Its patentability requirements fall outside international standards and has earlier used compulsory licensing for commercial and non emergency situations, it said. GIPC's International IP Index urges maximal patent regimes for all countries and asserts that increasing patent monopolies would drive greater innovation.