

1. [Roche's reputation at stake if Avastin biosimilar approved without trial: Kapil Sibal](#) – Economic Times

The Delhi High Court on May 20 asked Swiss biotechnology giant Roche to prove how it would be impacted if the government granted approvals for a biosimilar or copy of its blockbuster biotech drug bevacizumab. Justice Valmiki Mehta, who was hearing the case, asked Roche's counsel to explain its personal interest in the current approval process for Hetero Drug's bevacizumab. "In a suit of this nature, you must have a personal or private interest," he told Roche's counsel. The court will continue to hear the case on May 24. "(Roche's) goodwill is associated with (bevacizumab) all over the world," said Roche's counsel, Kapil Sibal. "Such misrepresentation is likely to deceive patients and doctors. If something goes wrong tomorrow (with Hetero's drug in the market), (Roche's) reputation is at stake," he argued.

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2. [The big picture missing in healthcare](#) – Mint

Large-scale vaccinations govt's biggest success but low allocations have dealt a blow to healthcare targets. The biggest achievement of the two-year-old National Democratic Alliance government in the health sector is the large-scale vaccination of children in a phased manner. But when it comes to financing healthcare, the government has been unable to depart from the idea of low financing that started towards the end of the previous United Progressive Alliance government's second term. There have been many much-needed initiatives despite the fund crunch. In the latest budget, the finance minister announced dialysis facilities to be made available at all district hospitals. He also announced the opening of 3,000 Jan Aushadhi stores to give inexpensive generic medicines to all. But health experts rue that what India is lacking is a clear direction in which all efforts regarding health should move.

3. [Two years of NDA: Reforms, transparency aid ease of doing business](#) – Mint

Speedy approvals and new tax regime are among the National Democratic Alliance government's business-friendly changes. Based on reforms undertaken in the first year of the National Democratic Alliance (NDA) government, India's ease of doing business rank went up by four notches to 130 in the 2016 ranking. The department of industrial policy and promotion (DIPP) also involved state governments and ranked states on the basis of 98 parameters last year, in which Gujarat topped the list. Most of the reforms undertaken by the central government in the last two years include easier company registration, simpler export-import rules and electronic approvals through. It has also taken a number of steps to revamp the tax

administration and make the tax regime more friendly and transparent. It sought to streamline the tax administration and reduce disputes by minimizing the interface between the tax department and the taxpayer. But at the same time, the government has initiated steps to check tax evasion, including enacting stringent provisions to curb black money and negotiating tax treaties to check tax avoidance and evasion by companies.

4. [Tanoubi Ngangom: Navigating the IPR maze](#) – Business Standard

The Indian Patent Office's decision to grant the patent for Gilead's Hepatitis C treatment drug, Sovaldi, has attracted much criticism. This change of heart - given the rejection of the same patent application in January last year - reflects a broader trend toward a more stringent Intellectual Property Right (IPR) regime. Rather than fight an obviously losing battle for patent rejections, a more constructive strategy would be to explore access expansion mechanisms that do not necessarily impinge on IPR. When India joined the World Trade Organization in 1995, the country had to reverse its anti-TRIPS position and bring medicines under the patent domain. Despite the re-structuring, the Indian patent system has continued to support its indigenous generic manufacturing industry through certain provisions. The strict anti-evergreening helped deter successive patents on minor enhancements of existing drugs. Issues of access were also prioritised through the extensive range of compulsory licensing conditions. For India - one of the world's largest generic drug suppliers - this is another such juncture where the practical approach would be to seek creative solutions to retain its pro-public health stance in spite of ceding to the mounting external pressure. Geographical restrictions imposed by licensors can hinder access for a large portion of low-income patients. Gilead's licensing agreement for Sovaldi excludes sale to 50 middle-income countries, which are home to about 49 million people living with the Hepatitis C Virus (HCV). If the objective of the VLs is to ensure access to affordable drugs for the poorest patients, Gilead Sciences must dilute these restrictions. The broader issue here is not to lay blame on one specific stakeholder or another - it is to identify new channels of improving access that take into account the changing political landscape. Because the VL approach provides a way around the traditional 'access' versus 'protection' impasse, it emerges as a prime candidate for future access expansion. However, this will increasingly hinge upon the manner in which these licenses are rolled out. While not as captivating as a patent tug-of-war, scrutinising this process would undoubtedly be a more productive effort.

5. [Tighten clinical trial norms for patient's safety, say Doctors](#) – Times of India

Doctors and investigators expressed concerns involved in medical research. They expressed ambiguity in the interpretation of guidelines relating to 'vulnerable' subjects and 'new drugs' while conducting research studies. The term vulnerable (with context to subjects) is not very clear and may include practically all patients from whom informed consent needs to be taken for conducting research studies to test safety and efficacy of drugs before these are approved for general public use, Dr Siddharth Laskar of Tata Memorial Hospital said. The definition of new drug also needs to be clarified. Rules regarding informed consent and compensation need to be followed so that the rights of patients are protected. Clinical trials' guidelines as part of the Drugs and Cosmetic Rules have been revised in 2015 with regard to compensation in an adverse event, and informed consent of subjects. But there is still room for clarity, industry experts say. India accounts for 20% of the world's disease burden and 16% of the world's population, but less than 1.4% of global clinical trials are done here.

6. [People want modern medicine, not miracle cures](#) – Hindustan Times

Sanchita Sharma in her editorial highlights the gaps in current healthcare services. She talks about the lack of clinically-tested alternative therapies by AYUSH on their claims to treat ailments. Making claims that are yet not scientifically proven may make the sick and ailing junk their prescription medication and head for the cowsheds in search of cure. Later she gives an indication of the gap between doctors, nurses and paramedics to treat 1.2 billion population in India. India has close to 960,000 doctors, 790,000 auxiliary nurse midwives, 1,800,000 nurses and midwives, and 160,000 dentists registered across the country. With people are living

longer, the other challenge is to ensure people lead healthier lives. The top five causes of disability in India are anaemia, low back pain, major depressive disorder, lung disease and migraine, all of which can easily be prevented and managed if clinical care is available. The way forward is to consolidate existing initiatives to make delivery efficient and work accountable. Overlapping policies and programmes – nutrition and sanitation, to name two -- run by different ministries such as health and family welfare, women and child development, water supply and sanitation, rural development, urban development, among others, need to be integrated to improve quality and reach. Expanding health expenditure support, providing free medicines and diagnostics, promoting inexpensive generics, and strengthening primary health by engaging both public- and private-sector providers to deliver services paid for by universal health insurance will help make healthcare more inclusive.

7. [Standing up to patent bullying](#) – The Hindu

Low-cost, quality and generic medicines will play a critical role, if governments are to realise the sustainable development goal (SDG) of universal access to health care. India is at the centre of the world's generic drug production as it is one of the few countries with the technical capacity to produce raw materials, also known as active pharmaceutical ingredients. When generic substitutes are not available in India —due to patent monopoly — they lead to high drug prices as only the proprietary companies can manufacture them. The Ministry of Commerce must be cautious of Free Trade Agreements being negotiated with the European Union as well as the Regional Comprehensive Economic Partnership that further strengthen or extend intellectual property (IP) monopolies. These will subsequently delay generic competition and the associated drop in prices, which will have a negative impact upon access to affordable medicines from domestic producers. India must reject IP laws which the U.S. is trying to force on us. These have led to an unprecedented health crisis in the U.S. itself, with spiralling prices of medicines. The issue of affordable health care has dominated the primaries in the ongoing American presidential elections. This failed model, which has allowed companies to profit from misery and rejected even in its own country, is not worthy of our consideration.

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8. [Drugged to hilt](#) – Financial Express

Rising antimicrobial resistance will kill nearly 10 million annually by 2050 if nothing is done to check it. A UK government-commissioned review of antimicrobial resistance (AMR)—antibiotics resistance is a part of this larger spectrum of drug resistance—has warned that it could kill as many as 10 million per year by 2050. Today, it kills over 700,000 a year globally. AMR has grown so rapidly over the last decade that the WHO had termed it a threat to global public health. Overuse of antibiotics/antimicrobials, coupled with improper calibration of dosage and duration of drug administration, has led to previously curable diseases like TB becoming nearly impossible to cure as the pathogen mutates to beat the drug and leads to emergence of superbugs such as methicillin-resistant Staphylococcus aureus (MRSA). The cost of all action to control AMR will amount to roughly \$40 billion over the next 10 years whereas the cost of rising AMR in 2050 could be well over \$100 trillion, warns the UK study.

9. [Delhi HC seeks Centre, Novartis response on Troikaa Pharma petition for ban on painkiller](#) – Financial Express

The Delhi High Court on Friday sought response from the Centre, Novartis India and others on a petition by Gujarat-based Troikaa Pharmaceuticals Ltd asking the Drug Controller General of India (DCGI) to stop sales and cancel licence of popular painkiller injection Diclofenac over safety concerns. The Indian pharma company further alleged that Novartis itself does not use Transcutol in injection marketed by it elsewhere in the world and appears to have selected only India to introduce an unsafe drug. Justice Manmohan issued notice to the ministries of health and family welfare and chemicals and fertilisers, Drugs Controller General, Drugs Controlling and

Licensing Authority, Novartis India, Themis Medicare and others. The matter will be further heard on May 26.

10. [Court Asks Pfizer to Withdraw Drug 6 Months before expiry](#) – NDTV

The Delhi High Court has asked pharmaceuticals major Pfizer Ltd to withdraw stocks of its already imported drug Medrol, used to treat a wide range of inflammatory, allergic and immune disorders, six months before the expiry period of 60 months prescribed under the rules. Justice Rajiv Sahai Endlaw issued the direction to bind Pfizer to its statement before the court that it will withdraw stocks of the drug six months before date of expiry. "This court by interim order in this petition having restrained DCGI (Drugs Controller General of India) from consequential action pursuant to impugned notice-cum-order of September 15, 2015 against the petitioner (Pfizer), it is deemed appropriate to bind the petitioner to its statement, of withdrawing the drugs from the market six months prior to their expiry..." the court said. According to Pfizer, it had shown data indicating that Medrol was stable for 62 months, but this was not considered by the authority. The pharma major had also said Medrol was a fast moving medicine and therefore, the possibility of it being in the market close to its expiry date is inequitable, but this too was rejected by DCGI.

11. [IDMA urges DGFT to give full authority to Pharmexcil for scrutinizing exemption application on barcoding](#) – Pharmabiz.com

The Indian Drug Manufacturers' Association (IDMA) has urged the Director General of Foreign Trade (DGFT) to give complete authority to the Pharmaceutical Export Promotion Council of India (Pharmexcil) for granting exemption to the exporters in the implementation of barcoding, without seeking prior approval of the government as this would only delay the export consignments. Recently, the association has submitted a representation to Anup Wadhawan, DGFT, department of commerce, ministry of commerce and industry in response to government's notification authorising Pharmexcil as the nodal agency for processing applications of pharma exporters for exemptions from government's barcoding provisions. The association is of the view that the Pharmexcil is experienced in issuing RCMC judiciously and has been providing excellent support to exporters in their export activities, tracking regulatory requirements of all countries etc for over the past decade.