



**News summaries: February 14, 2014**

FDA / Drug Regulatory / DCGI / Pharma Policy/ Pharma Industry

**Publication: MINT**

**Edition: National**

**Date: February 14, 2014**

**Headline: [Indian clot-buster drug enters phase-2](#)**

**Synopsis:** Clot-specific Streptokinase (CSSK), a drug that breaks down blood clots, developed by an arm of the Council for Scientific and Industrial Research (CSIR), has been cleared by the office of the Drug Controller General of India (DCGI) for phase two human clinical trials. The CSSK is the first so-called biotherapeutic drug developed in India— meaning it entailed the use of antibodies, proteins and enzymes, unlike conventional chemical drugs. If and when the drug reaches the market, it could offer an affordable alternative to expensive thrombolytic drugs used to treat patients of myocardial infarction or heart attacks, and other severe heart conditions like deep vein thrombosis.

Work on the drug began seven years ago under a partnership between the CSIR's Institute of Microbial Technology (IMTECH), Chandigarh, and Nostrum Pharmaceuticals LLC of the US.

**Publication: Business Standard**

**Edition: Online**

**Date: February 14, 2014**

**Journalist: Shishir Asthana**

**Headline: [Time to call the US bluff on pharmaceuticals](#)**

**Synopsis:** Margaret Hamburg, Commissioner of the US Food and Drug Administration (US FDA) is in India to ensure that products shipped to the US from India meet their requirement of safety and quality. The visit is a welcome move, especially after a series of penalties and bans have been imposed on Indian pharmaceutical companies who were exporting to the US. In all the cases, evidence has been given that companies had not followed ethical manufacturing practices. There is nothing wrong in banning them and, in fact, that is what Indian drug enforcement authorities should be doing. If something is not good for human consumption in the US, it certainly is not good in India. Rather than following stricter manufacturing policies and monitoring them through surprise checks, it is surprising that the Indian government has asked US FDA to announce its arrival to manufacturing companies, thus giving drug makers time to get their act right.

**Publication: DNA**

**Edition: Mumbai**

**Date: February 14, 2014**

**Headline: [US FDA steps can help Indian pharma firms](#)**

**Synopsis:** After a series of penalties and bans imposed on Indian pharmaceutical companies, Margaret Hamburg, commissioner of the US Food and Drug Administration (US FDA) visited India to ensure the quality of products that enter her country. Indian companies have been pulled up by US FDA authorities for not following their laid down norms. Indian companies, however, say that their point of view is never heard and that rules of the games are changed abruptly without intimation. As a result of these bans and penalties, various US organisations have started raising quality issues on Indian products.

**Publication: The Times of India**

**Edition: Chennai**

**Date: February 14, 2014**

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**Headline: Generic Drugs to make healthcare cheaper (no link)**

**Synopsis:** Along the lines of a similar scheme in Rajasthan, the government plans to open 100 Amma pharmacies across the state to sell generic drugs at a discount. The scheme, announced by finance minister O Paneerselvam on Thursday, is expected to have twin benefits for patients as doctors at least those in the government sector will be forced to prescribe generic drugs. Earlier they used to prescribe brands they favoured. The scheme is expected to be a solution to the corruption and overpricing in the medical sector. The allocation for health has gone up from 4,395 crore in 2010-11 to above 7,000 crore this year. The Tamil Nadu Medical Services Corporation will be in charge of procuring drugs on wholesale and distributing it to the low-cost pharmacies. Allotting 20 crore for the scheme, Paneerselvam said there were already 210 state co-operative medical stores and the Amma pharmacies would be part of the public distribution scheme.

**Publication: The Indian Express**

**Edition: National**

**Date: February 14, 2014**

**Headline: [India Inc to defend domestic trade policy at USITC hearing](#)**

**Synopsis:** Industry body Confederation of Indian Industry (CII) is set to depose before the US International Trade Commission (USITC) on Friday to defend India's policies, which are facing criticism from American industry lobbies. The USITC, which began hearing on the impact of India's trade policies on the US industries and jobs, has already heard American lobby groups including the country's chambers of commerce, and Alliance for Fair Trade on Wednesday. Depositing before the commission, US India Business Council (USIBC) president Ron Somers has cautioned the US to avoid unnecessary steps that would threaten the US-India relationship, while former Nasscom chairman Jerry Rao has said US President Barack Obama should care about creating jobs in both Bangalore and Buffalo and not only the latter. While the FAA has downgraded the Indian aviation sector, citing a lack of safety oversight, the USFDA has taken a series of actions against Indian pharmaceutical firms including banning Ranbaxy's fourth plant from selling drugs to the US market. USTR meanwhile has dragged India to the WTO over its local content requirement condition for its National Solar Mission programme.

#### Drug Pricing/Clinical Trials/Intellectual Property/Patents

**Publication: Hindustan Times**

**Edition: National**

**Date: February 14, 2014**

**Journalist: Yashwant Raj**

**Headline: [Medicines for all: Woman threatens anti-India drug cabal in America](#)**

**Synopsis:** Nina Mahmud can't bear to watch her husband grieve as his father battles liver cancer. His last bottle of Nexavar, the only thing keeping him alive, runs out on Saturday. But there was hope: Mahmud could tell her story at US International Trade Commission's hearing into India's patent regime, which began on Wednesday.

Nexavar, which was compulsorily licensed by India in 2013 to the collective indignation of its maker and other multinationals, was the same drug that doctors said could save her father-in-law. The drug is at the core of the US case against India that the commission is investigating at the urging of Congress - that India's disregard for IPR harms US businesses.

**Publication: The Hindu Business Line**

**Edition: Chennai, Hyderabad**

**Date: February 14, 2014**

**Headline: [‘Scotland offers Indian pharma cos many advantages for clinical trials’](#)**

**Synopsis:** Scotland is offering a slew of facilities for Indian pharma and biotech companies to conduct clinical trials, according to Roma Bussi, Country Director – India, Scottish Development International (SDI). Scotland was an ideal location for conducting clinical trials in view of the simple regulatory procedures, eco-system and expertise, she told newsmen here today. She is in the city along with a business delegation from Scotland to take part in the BioAsia 2014 scheduled for next week. “Though the cost of clinical trials per patient is higher in Scotland when compared to India, the advantages include regulatory clearance within 90 days, among others,” she said.

#### Union health secretary Keshav Desiraju

**Publication: The Indian Express**

**Edition: National**

**Date: February 14, 2014**

**Headline: [Transfer of Health Secy kicks off row](#)**

**Synopsis:** The transfer of Union Health Secretary Keshav Desiraju barely 11 months after his appointment has evoked protests from groups working on public health. “The Centre must explain why this top bureaucrat has so unceremoniously been transferred,” Dr Vikram Patel, member of Mental Health Policy Group, Ministry of Health and Family Welfare said on Thursday. Desiraju, a 1978 batch IAS officer has been shifted to consumer affairs. Dr Amit Sengupta, of Jan Swasthya Abhiyan, a coalition of 20 networks and over 1,000 organisations working on public health said the transfer was “unjust and uncalled for”.

Also appeared in:

Business Standard - [Health Secy Transfer Controversy](#)

The Telegraph - [Activists question secretary’s transfer](#)

The Times of India – Health secy a victim of Cong courtier culture?

Millennium Post - Honesty is the worst policy, evidently

#### General Industry/ Diseases

**Publication: Mint**

**Edition: National**

**Date: February 14, 2014**

**Journalist: C.H. Unnikrishnan**

**Headline: Sun Pharma raises revenue forecast, Q3 profit jumps 74%**

**Synopsis:** Sun Pharmaceutical Industries Ltd sharply raised its revenue forecast for this financial year ending March, after posting a 74% jump in net profit for the December quarter on strong overseas sales. The country’s most valued drug maker said it now expects consolidated revenue growth in fiscal 2014 at 29%, up from its earlier 25% forecast.

“The revised guidance takes into account the performance achieved in the first nine months and the higher base of the December quarter in fiscal 2013 on consolidation of acquisitions as well the risks associated with increase in competition for some products,” the company said in a statement on Thursday. Sun Pharma’s profit improved to Rs.1,531 crore in the December quarter from Rs.881 crore in the same period a year ago.

Also appeared in:

Business Standard: [Sun Pharma beats the Street again](#)

**Publication: Financial Chronicle**

**Edition: National**

**Date: February 14, 2014**

**Headline:** [Aurobindo's US unit hopes for 50 approvals in 2 years](#)

**Synopsis:** Auromedics, the US subsidiary of Aurobindo pharma which markets generic injectables, expects 6 to 8 drug approvals this year, followed by around 50 in a span of next two years. Three years from now the total could be around 70 products. This subsidiary has increased its sequential sales over the past eight quarters and generated over \$10 million of quarterly revenues, for the first time in the third quarter this fiscal, said N Govindarajan, managing director of Aurobindo Pharma. The subsidiary expects a run rate of \$5 million per month over the next fiscal.

**Publication:** The Times of India

**Edition:** National

**Date:** February 14, 2014

**Headline:** [Delhi doctors call off strike after assurance from health minister Ghulam Nabi Azad](#)

**Synopsis:** Striking senior resident doctors and medical students of top Delhi hospitals, including AIIMS, called off their agitation on Thursday after Union health minister Ghulam Nabi Azad made it clear that there is no proposal to extend the duration MBBS Course. To the relief of the students, the minister also said rural posting will not be mandatory for those appearing in PG examination for the year 2015-16. An official press statement issued by the health ministry stated, "Health minister, Ghulam Nabi Azad, met with the representatives of agitating medical students here today." "He listened to all their concerns patiently and allayed their fears regarding Medical Council of India (MCI) Notification in respect of one year mandatory rural posting of PHC after completion of MBBS, before they seek admission to PG Course. The Minister has directed concerned officials of the Ministry to keep the Notification in abeyance."

Also Appeared in

The Hindu: [Azad rules out extension of MBBS course](#)

Outlook: [Azad Says No Extension of MBBS Course, Docs' Strike Ends](#)

**Publication:** Deccan Herald

**Edition:** National

**Date:** February 14, 2014

**Headline:** [Doctors' strike hits OPDs](#)

**Synopsis:** Protest called off after govt assurance on MBBS course. Senior resident doctors and medical students of AIIMS and several other Delhi hospitals went on a strike on Thursday demanding revision of the proposed MBBS course structure. OPD and ward services were badly affected due to the protest. The doctors called off the protest after Union Minister Ghulam Nabi Azad asked the officers concerned to keep the notification in abeyance. A letter to this effect has been issued to the Medical Council of India.

**Publication:** Deccan Herald

**Edition:** National

**Date:** February 14, 2014

**Headline:** [Has treatment of breast cancer taken a wrong route?](#)

**Synopsis:** 'Mammography screening might work if you don't have any awareness of the disease'. One of the largest and most meticulous studies of mammography ever done, involving 90,000 women and lasting a quarter-century, has added powerful new doubts about the value of the screening test for women of any age. It found that the death rates from breast cancer and from all causes were the same in women who got mammograms and those who did not. And the screening had harms: One in five

cancers found with mammography and treated was not a threat to the woman's health and did not need treatment such as chemotherapy, surgery or radiation.

**Publication:** Deccan Herald  
**Edition:** National  
**Date:** February 14, 2014  
**Headline:** [Sickness strikes](#)

**Synopsis:** I was recently assailed by an illness so virulent that I doubted I would survive it. Every joint in my body was racked with pain and I was reduced to virtual immobility. Rising each day was a challenge and, once I had dragged myself to a chair, I chose to stay there. Getting to my feet entailed such enormous effort that I assiduously avoided the exertion. In short, I was only comfortable if I lay in bed, as motionless as a mummy. By this time any self-respecting Bangalorean would have guessed my problem. Indeed, well-wishers were quick to diagnose it. My heart sank to my swollen ankles! While 'chikungunya' had an impressive ring to it.

**Publication:** The Pioneer  
**Edition:** New Delhi  
**Date:** February 14, 2014  
**Headline:** [Docs strike against longer duration MBBS course](#)

**Synopsis:** Expressing solidarity with the medical students protesting against the proposed MBBS structure extending the duration of the course, senior resident doctors and medical students of top hospitals in Delhi, including AIIMS, RML and Safdarjung Hospital, went on strike leading to closure of their Out Patient Departments (OPDs). The hospitals, which are expected to keep their OPDs shut with only emergency services available, include several Delhi Government hospitals besides the Central Government-run facilities. Doctors from All India Institute of Medical Sciences (AIIMS), Ram Manohar Lohia Hospital, Safdarjung Hospital, Guru Teg Bahadur Hospital, Lady Hardinge Medical College and Deen Dayal Upadhyay have joined the MBBS students and are expected to go on an indefinite strike if their demand to review the "prolonged" course structure of MBBS was not met. This step by doctors is likely to cause distress for the patients.

**Publication:** The Asian Age  
**Edition:** National  
**Date:** February 14, 2014  
**Headline:** [India develops clot-buster drug](#)

**Synopsis:** A novel clot buster developed by the Council of Scientific and Industrial Research and the Institute of Microbial Technology (CSIR-IMTECH) has been cleared for Phase 2 human clinical trials. The drug, titled Clot Specific Streptokinase (CSSK), a novel patented thrombolytic therapeutic protein drug, is the first innovative compound developed by an Indian institute. The drug will be administered to patients suffering heart attacks and reduces the side-effects associated with clot buster bleeding. The Phase 1 clinical trials saw a single bolus drug being administered to healthy human volunteers who tolerated it without any side-effects. Clot buster therapies with streptokinase often cause increased internal bleeding but this has not been the case with CSSK.

**Publication:** The Asian Age  
**Edition:** National  
**Date:** February 14, 2014  
**Headline:** [Firms' medical claims set to be put to test](#)

**Synopsis:** Tall claims made by companies regarding their new medical technologies and health interventions will have to undergo a final test before they are put up for public use. The Department of Health Research, under the ministry of health, has proposed to set up a medical

technology assessment board (MTAB) for evaluation of the appropriateness and cost-effectiveness of medical technologies before a product is introduced into the public health care system of India. Dr V.M. Katoch, director-general, Indian Council of Medical Research (ICMR), has written to the principal secretaries of all states inviting them to identify 10 top health problems of the widest national importance so that technologies, drugs, diagnostics, devices, health interventions that are critical relating to them are focused on priority. An advertisement inviting all other stakeholders, like health managers in government systems, doctors, public health professionals and voluntary agencies, will soon be put up too.