

1. SC notice to Centre on plea on anti-diarrhea vaccine - PTI

New Delhi, Jul 5: The Supreme Court today sought responses from the Centre and the Christian Medical College at Vellore on a PIL seeking complete centre-wise results of the clinical trial of anti-diarrhoea vaccine 'Rotavac'. Rotavirus vaccine, 'Rotavac', claims that it protects children from viruses, which are the leading cause of severe diarrhoea among them. Besides the medical college, a bench of Justices Madan B Lokur and R K Agrawal also issued notices to Ministry of Health and Family Welfare, Department of Bio-Technology (DBT) of Ministry of Science and Technology on the plea filed by S Srinivasan, Managing Trustee of 'LOCOST' (Low Cost Standard Therapeutics), based in Vadodara, Gujarat. The plea has sought direction to the Centre and others to make public the "segregated data" on the results of

third phase of clinical trial of 'Rotavac' involving 6799 infants. The trials were conducted at three centres in Delhi, Pune and Vellore to gauge safety and efficacy of the vaccine, the plea claimed. The plea filed through advocates Prashant Bhushan and Neha Rathi said the segregated data was crucial to know if the vaccine is safe in all areas or if some groups are more "susceptible to adverse effects of the vaccine". The plea stated that the data should have been examined by National Technical Advisory Group on Immunization (NTAGI) in "public interest but such is the secrecy surrounding it, it has not been provided even to this apex body". "Issue an appropriate direction to respondents (Centre and others) to provide the petitioner the complete segregated results (centre-wise data) of the clinical trial of 'Rotavac' vaccine conducted in all three centres, including the number of 'intussusceptions' in the two-year trial period at each centre. "Direct respondents to place before NTAGI the complete segregated results of the clinical trial of 'Rotavac' vaccine for examination and scrutiny," the plea said. It also sought a direction for framing of guidelines regarding publication of complete and segregated research results in clinical trials on humans, in accordance with WHO statement of April 2015 on the issue. The plea urged the apex court to set aside the Delhi High Court's October 2015 order dismissing a plea to restrain the Centre from conducting any further clinical trials of rotavirus vaccine in India. The high court order had come on a plea filed by Dr Jacob Puliyeel, a member of NTAGI, seeking to restrain the government from moving on to phase IV trials in which over one lakh children would be administered the vaccine. Puliyeel in his plea had also sought directions to provide complete data of the multi-centre clinical trials of the vaccine. The high court, however, had said that NTAGI, which is the highest technical advisory body in the country on immunisation, on being satisfied about its efficacy and safety, recommended introduction of the vaccine in question for National Immunisation Programme. Meanwhile, Srinivasan, the petitioner before the apex court, submitted that not providing the complete

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results of the clinical trials involving human beings was in violation of ethics of medical research and global norms governing such trials. On March 26, Ministry of Health officially launched rotavirus vaccine to combat deaths in infants caused due to diarrhea. Before the launch of the vaccine, a clinical trial (phase III) was conducted between 2011 and 2013 at Delhi, Pune and Vellore to gauge the efficacy and safety of the vaccine. Under this clinical trial, 6799 infants were administered the said vaccine to ensure its safety in terms of the number of intussusceptions in the two year trial period. Intussusceptions are intestinal obstructions that may need an urgent surgery to prevent death among infants and is diagnosed by ultrasound examination, the plea said.

2. [Abbott wins U.S. approval for stent that absorbs into body](#) – Reuters

U.S. health regulators said on Tuesday they approved a stent by Abbott Laboratories that is the first designed to be absorbed into the bloodstream after it is implanted. The stent, called Absorb, is made of a plastic similar to dissolving sutures and offers patients an alternative to metal stents currently used to prop open arteries cleared of blockages. Unlike traditional stents that remain in place after implantation, Absorb is designed to disappear fully within three years of the procedure.

3. [Expensive Hepatitis C drug pushes people to make their own medicines](#) – Economic Times

An expensive drug in many parts of the world, the pill is turning out to be a study on how hapless patients are pushed to desperation. While those in affluent countries like the US are shunning a tag of \$84,000 for the full course of treatment and arriving in droves to cheaper destinations, some of those in low and middle income nations are finding unique routes, often dangerous, to beat the disease. A highly organised and popular website that is enabling Hepatitis C patients in the West to purchase cheaper versions of Sofosbuvir, or Sovaldi a wonder drug, saving millions of patients from the debilitating liver disease.

4. [Full list: PM Modi's new-look cabinet](#) – Economic Times

PM Modi today inducted 19 new ministers in his Cabinet and carried out a reshuffle of the portfolios of his ministers. Here's the complete list of the new Council of Ministers.

5. [GSK rolls out code for ethical marketing](#) – EHealthworld.com

Faced with charges of unethical marketing practices which have long tarnished its image and reputation, the pharmaceutical industry is trying to clean up its act. In one of the first such attempts, GlaxoSmithKline has rolled out a new healthcare marketing code covering doctors and its field staff, Annaswamy Vaidheesh, vice-president, South Asia & managing director of GSK Pharmaceuticals India. Under the policy, the company has withdrawn target-linked incentives for its 3,000-strong sales force, and stopped direct payments to doctors for speaking engagements, he said, adding the company has also put in place an "aggressive growth model to get back being one of the fastest growing MNCs in India by 2020".

6. [SC issues notice on plea seeking centre – wise data on clinical trials of Rotavac](#) – Mint

There is a need for disclosure of the segregated data to ascertain if a certain section of the population is more susceptible to adverse effects of the clinical trial of Rotavac, says the petition. The Supreme Court on Tuesday issued notice to the Centre, Department of Biotechnology (DBT) and Christian Medical College, Vellore on a plea seeking disclosure of complete centre-wise data on the clinical trials of anti-diarrhoea vaccine, Rotavac. A public interest litigation brought by S. Srinivasan, a healthcare expert and member of the All India Drug Action Network (AIDAN), highlights the importance of disclosing complete segregated results (centre-wise) of the clinical trial conducted in all three centres, namely Delhi, Pune and Vellore.

7. [458 new patent examiners added to reduce application pendency](#) – Business Standard

The Commerce and Industry Ministry has added 458 new patent examiners with an aim to reduce pendency of applications and enhance administration. In March, the Commerce and Industry Ministry has said that as many as 2.37 lakh patent applications are pending with the government, mainly due to shortage of manpower. "458 new patent examiners added to

existing strength of 130; would reduce pendency and enhance administration," the Department of Industrial Policy and Promotion said.

8. [India keeps lead over China in pharma exports](#) – The Hindu

India's pharmaceutical exports have maintained their lead over China's in 2015, according to a commerce ministry statement. While India's pharma exports grew year-on-year by 7.55 per cent to \$12.54 billion in 2015 from \$11.66 billion in the year-earlier period, China recorded only a 5.3 per cent growth in the same period to \$6.94 billion from \$6.59 billion. India overtook China in important markets such as the U.S., EU and Africa, according to the ministry. India's pharmaceutical exports to the U.S. rose from \$3.84 billion in 2014 to \$4.74 billion (23.4 per cent growth) in 2015 as against China's marginal rise from \$1.16 billion to \$1.34 billion (15 per cent growth) in the same period.

9. [Kerala yet to tap Centre's SIPP scheme for free IPR protection for start-ups](#) – Times of India

Start-ups in India can protect their innovations free of cost under the Union government Start-up India scheme for Facilitating Start-ups Intellectual Property (SIPP). Even as the Centre has set July 10 as the last date for facilitators including state governments and agencies to apply for the Scheme, Kerala is yet to tap the potential opportunity. As many as 215 facilitators for trademarks and 277 facilitators for patents and designs from different parts of the country have already applied to the Union government responding to the notification issued by the Controller General of Patents, Design and Trademark (CGPDTM), yet not a single facilitator from Kerala has applied so far.