News Updates: November 13, 2013

Clinical Research / Trials

Publication: The Financial Express *(Reproduced from PTI)*
Edition: National
Date: November 13, 2013
Headline: SC issues notice to Centre, NGO on clinical trials

Synopsis: The Supreme Court on Monday issued notice to PATH, an international NGO working in the health sector, on a PIL alleging that it indulged in unethical conduct of clinical trials in collaboration with ICMR in 2009-10 in Andhra Pradesh and Gujarat. A bench of Chief Justice P Sathasivam and justice Ranjan Gogoi also sought response from the Centre and state governments on the petition filed by an NGO Sama which works in the field on feminist activism and health. The bench tagged the case with other petitions on clinical trials being heard by a different bench. The petitioner alleged that there were serious failures on the part of PATH (Program for Appropriate Technology in Health (PATH)) and Indian Council of Medical Research (ICMR) in complying with legal and ethical requirements to obtain written 'informed' consent and it caused serious adverse events.

Publication: Deccan Chronicle
Edition: National
Date: November 13, 2013
Headline: The umbilical cord advantage

Synopsis: Stem cell banking is advocated as a revolutionary technology to preserve your child's stem cells for future use by extracting them from the umbilical cord blood, i.e., the blood remaining in the umbilical cord after the baby is born. Around 1,500 clinical trials are happening around the world and billions of dollars are being invested for this research. All this is because scientists have recognised the capacity of the stem cells to repair, rejuvenate and heal the body organs because of their virgin nature and nonexposure to external environments maintaining their potency to differentiate into various organs, says Dr Salahudeen, Vice President of Life Cell, India's largest accredited Stem Cell Banking company based in Thrissur.

Publication: Pharmabiz
Edition: Online
Date: November 13, 2013
Headline: Health ministry to ban all hazardous and doubtful therapeutic efficacy drugs in market

Synopsis: The Union health ministry will soon ban all the hazardous and irrational drugs in the pharmaceutical market in the country. In this connection, the ministry will soon constitute a 'special expert committee' which will review all drug formulations in the market and identify drugs which are potentially hazardous and/or of doubtful therapeutic efficacy. Based on the final report of the committee, the ministry will weed out hazardous and irrational drugs from the pharmaceutical market in the country. According to senior officials in the ministry, a mechanism would be put in place to remove these drugs from the market by the CDSCO at the earliest. The decision to constitute a 'special expert committee' to review all drug formulations in the market was taken at a meeting held by the ministry recently. The meeting was convened to discuss and examine the report of the Prof Ranjit Roy Chaudhury expert committee, which had submitted its report to the government recently, recommending sweeping changes in approval of new drugs, clinical trials and banning of drugs in the country.

Publication: Pharmabiz
Edition: Online
Date: November 13, 2013
Headline: Suven's net profit surges seven-fold to Rs. 45-cr in Q2

Synopsis: Riding on higher sales from its contract research and manufacturing services (CRAMS) business, the Hyderabad-based biopharmaceutical company Suven Life Sciences Ltd has reported a seven-fold increase in its net profit in the second quarter ended September 30, 2013. Suven's new chemical entity for dementia, SUVN-502, entered phase Ib clinical trial in the US. The company has been trying to find a partner who will further develop the molecule. Suven has spent 9.8 per cent of its revenue on research and development during the half-year ended September 2013. It had 607 product patents for 18 inventions and 35 process patents.

Publication: Pharmabiz
Edition: Online
Date: November 13, 2013
Headline: Indian analytical instruments industry poised to grow at 10% with new technology advancements: Expert

Synopsis: The Indian analytical instruments market, currently around US$ 1 billion market with 95 per cent imports accounting for advanced technology products, is poised to grow at 10 per cent per annum considering the potential Indian market holds in the coming years, said K V Venugopalan, president, Indian Analytical Instruments Association (IAIA). Speaking on the sidelines of Analytica Anacon India - the 7th international trade fair for lab technology, analysis, biotechnology and diagnostics-- Venugopalan said, fueled by demand drivers like the pharma industry, contract research, clinical research, manufacturing and government labs, analytical instruments segment bears a lot of relevance and importance because the Indian healthcare system is laboratory dependent and relies on accurate diagnosis.

Drug Pricing

Publication: BusinessWorld
Edition: National
Date: November 13, 2013
Headline: A Panacea For All Ills

Synopsis: In India, Sanofi and Ayyangar have concentrated on creating new assets in the past few years and completed three acquisitions to expand business. Sanofi's biggest breakthrough — the acquisition of vaccine major Shantha Biotechnics in 2009 — was for around Rs 3,800 crore. "We have invested over $300 million in Shantha after the acquisition and it is going to be a key vaccine production unit for global markets," Christopher A. Viehbacher, CEO of Sanofi Group, told BW | Businessworld in a recent interaction. Ayyangar says the biggest challenge was coming up with a strategy to tackle the fact that 30 per cent of the company's portfolio fell under price controls and had several ageing brands.

Publication: Pharmabiz
Edition: Online
Date: November 13, 2013
Headline: Six months of new DPCO

Synopsis: The implementation of the new DPCO, 2013 commenced six months ago with National Pharmaceutical Pricing Authority notifying new prices of formulations of 348 drugs under price control. But its enforcement has been faulty from the very beginning and now it is in a mess. First of all, the manufacturers were given just 45 days time to withdraw old stocks of drugs and implement the new rates. Any sane bureaucrat should understand that it is just impossible to call back old stocks from 7 lakh retail chemists and reprint the new prices in a country as vast as India with its pathetic infrastructure. The issue

was repeatedly represented by the industry and trade soon after the order was issued but the officials refused to make any changes to the order. The patient community was the victims of this unreasonable stand of the bureaucrats as the chemists were unable to get fresh stocks of several essential drugs with new prices from the manufacturers on time.

Publication: MoneyLife
Edition: Online
Date: November 13, 2013
Headline: Medicine prices: Encouraging profiteering from essential drugs

Synopsis: According to the new drug pricing policy, the ceiling price of essential medicines is fixed, based on the simple average of the prices of all brands of that drug that have a market Medicine prices: Encouraging profiteering from essential drugs – Part1share of at least 1%. The national list of essential medicines lists 348 bulk drugs, which are sold as 650 formulations. The good news is that for two-third essential medicines, there can be average price reduction of 22% (even though some reports claim reduction by 30%-40%). The bad news is that there are far too many loopholes to really see reduction in your chemist bill. Market-based pricing (MBP) actually sets the ceiling price higher than even the market leader in the remaining one-third of essential medicines.

Publication: Morung Express
Edition: Online
Date: November 13, 2013
Headline: Hepatitis C: A public health threat

Synopsis: The prevalence rate of Hepatitis C among people who inject drugs in Nagaland is 20.8 percent, as documented by the Indian Council of Medical Research (ICMR), through the Integrated Bio-Behavioral Assessment study. “If this situation is not addressed now, there will be a huge burden on healthcare in the years to come,” stated Abou Mere, Convenor of NepCoN during the culmination programme of the Hepatitis C signature campaign at DUDA Guest House, Kohima on November 12. The event was conducted by the Kohima Users Network (KUN) along with HepCoN. Mere informed that government employees can claim reimbursement for the treatment of Hepatitis C; however, people without government employment continue to die because they cannot afford or access the medicines. He appreciated the initiative of Naga Hospital Authority Kohima in collaboration with Merck to provide free diagnostics and preferential pricing for the treatment of the infection. Yet, even the so called preferential pricing is out of question for many Nagas, especially from marginalized community like people living with HIV or people who use drugs.

FDI

Publication: The Financial Express
Edition: National
Date: November 13, 2013
Headline: Should FDI in brownfield pharma be curbed?

Synopsis: The Planning Commission has opposed a proposal by the Department Of Industrial Policy & Promotion (DIPP) to limit foreign direct investment (FDI) in companies making critical drugs to 49% for brownfield investment and 100% for greenfield investments, saying that it will reverse the general direction in which the overall FDI policy should move. Currently, 100% FDI is allowed after securing the Foreign Investment Promotion Board (FIPB) approval. A brownfield investment involves acquiring existing plants and facilities and a greenfield investment is when an MNC establishes its own production by setting up its plant. Some of the myths/arguments put forth for restricting FDI investments in the pharmaceutical sector are mainly on emotional grounds and are not rational or logical.

Publication: BusinessWorld

Edition: National
Date: November 13, 2013
Headline: Small Sector Key To Growth

Synopsis: The FDI policy for retail has already provided the required safeguard for the MSME sector in the form of mandatory 30 per cent sourcing of (local) goods by multi-brand retailers. The MSME ministry is already in the process of aiding capacity-building so that they (MSMEs) are able to meet this requirement. This includes quality management standards and quality technology tools, Credit-Linked Capital Subsidy Scheme, Design Clinic Scheme for design expertise, marketing support/assistance (such as barcodes), and a national campaign for investment in intellectual property rights. In such a situation, I don't see any reason for MSMEs to have fears as long as they are quality-conscious and cost-competitive. Products like auto components, biotech products, coir products, drugs and pharmaceuticals, manufactured by MSMEs can excel in the global market.

FDA

Publication: Business Standard
Edition: National
Date: November 13, 2013
Headline: Eliminating microbial contamination with eco-friendly clean-in-place systems

Synopsis: Process industries like pharmaceutical, chemical, agrochemical, etc have technically intense applications. Processing is done for the active ingredient, which is the primary ingredient for that specific pharmaceutical, or chemical. This active ingredient is a biologically active substance, hence a natural medium for unwanted growth and/or contamination through micro-organisms. For pharmaceutical industry, the guidelines for active pharmaceutical ingredients (APIs) are stringently defined for manufacturing capsules, tablets or bulk drugs. Integrated centralised CIP modules have been increasingly welcome by the pharma, chemical, nutraceutical and probiotics processing industries. The economics of the cleaning process in conjunction with plant sanitation and strict hygienic requirement cannot be neglected any more. Food and drug safety standards like FDA, HACCP and ISO demand effective CIP procedures, to eliminate microbial contamination.

Publication: The Hindu
Edition: National
Date: November 13, 2013
Headline: Ranbaxy 'recognises and regrets' past flaws

Synopsis: India-based drug manufacturer Ranbaxy has responded to whistleblower comments aired on U.S. television news channels, and said that the issues raised regarding substandard drug manufacturing processes and fraudulent data in reports given to the U.S. Food and Drug Administration were "historical in nature'', and there have been "no incidents of any patients… adversely harmed. A week ago CBS news aired a series of reports regarding Ranbaxy, including comments by whistleblower and former Ranbaxy director Dinesh Thakur and former Ranbaxy advisor Kathy Spreen. Although Ranbaxy pled guilty to seven felony charges brought by the U.S. Department of Justice in May, and despite its manufacturing plants in Paonta Sahib and Dewas being subject to import restrictions or alerts, even as late as September yet another Ranbaxy facility, in Mohali, was found by the FDA to have made drugs with human hair or rubber particles in tablets and subjected to a similar import alert.

Publication: Daily News and Analysis
Edition: National
Date: November 13, 2013
Headline: Chemists stir, FDA fails to keep 30% shops open

Synopsis: Nearly 6,500 chemists in Mumbai had threatened to go on strike, and many of them ended up remaining closed. The strike was in retaliation to the consistent crackdown initiated by the state-run Food and Drug Administration (FDA) officials. Over 30 drug inspectors were employed by the FDA to pursue chemists to keep shops open. FDA claimed that on Monday, nearly 30 per cent of shops were forced to open up.

Publication: Mumbai Mirror
Edition: National
Date: November 13, 2013
Headline: FDA orders recall of tuberculosis drug with wrong dosage

Synopsis: The FDA has now directed its inspectors to suspend the sale of '4D' belonging to batch no. DD 4670 and '4D Plus' belonging to batch no DF 7161 from retail stores across the state. The drug administrator is now in the process of alerting its counter-parts across six states where Sandoz markets '4D' and '4D Plus'. FDA officials on Tuesday raided Sandoz's warehouse in Bhiwandi, but found no stock of '4D' and '4D Plus'. A team of inspectors also visited the Cumballa Hill Hospital pharmacy, where they found some '4D Plus' strips with wrong dosage.

Drug Regulatory

Publication: The Times of India
Edition: National
Date: November 13, 2013
Headline: Drug Controller General of India turns down Puducherry drug firm's application

Synopsis: Puducherry-based drugmaker GuruFcure has come under the Drug Controller General of India's scanner for allegedly submitting fabricated data while seeking approval for manufacturing seven fixed dose combination drugs. The investigative team concluded that all the data submitted (by the contract manufacturer in case of the seven combination drugs) is fabricated and not authentic, the central drug regulator told the drugmaker while rejecting its application last week in a letter, which was reviewed by ET. GuruFcure did not respond to ET's email query. As per the company's website, its clients include leading pharma companies such as Abbott, Alkem, Glenmark, Wockhardt, Unichem and Intas Pharma, among others. The contract manufacturer, which started operations in 2007, calls itself "one of the leading pharmaceutical formulation manufacturers in India.

Publication: Pharmabiz
Edition: Online
Date: November 13, 2013
Headline: Manufacturers of FDCs for veterinary use not required to file safety data: DCGI

Synopsis: The authorities have clarified that fixed dose combinations (FDCs) for veterinary use are exempted from the purview of the controversial order by the Drugs Controller General of India (DCGI) to prove safety and efficacy within a stipulated time-frame. The clarification comes in the wake of representations made by the manufacturers of FDCs for veterinary use, following the DCGI order in January this year which asked the manufacturers of FDCs, approved without prior permission of the DCGI, to prove safety and efficacy before September 30.

Innovation in India

Publication: Business Standard
Edition: National
Date: November 13, 2013
Headline: John Chambers: Smart cities, sustainable cities

Synopsis: Cisco's CEO says India's urban planners urgently need to think innovatively to prepare for the unprecedented migration from villages that is expected over the next decade**.** In a fast-urbanising world, India is setting the pace. Over the next ten years, more than one hundred million Indians will move from villages to cities, seeking schools for their children, health care for their families, and jobs for themselves. With more than 833 million people still living in the country's 640,000 villages, this unprecedented exodus will only accelerate. Without radical innovation, expansion on such scale will place an unsustainable strain on the environment.