Daily News Monitor

27 to 29 June 2015

IPR & Innovation

'Emerging markets critical for pharma sector growth', The Hindu Business Line **(27 June 2015)**

Emerging markets are critical for the sustained growth of pharma industries, as they are likely to account for 30 per cent of the global pharmaceutical spend by the end of next year, according to a new report. The report, 'Emerging Market and Sustainable Growth Report 2015', on the Indian pharmaceutical sector, revealed that innovation and technology will be important differentiators as pharma organisations try to drive growth in developing countries. The emerging markets cover nations in Africa, the Middle East, South-East Asia, Brazil, Russia, India and China.

Biosimilars is the new focus of Gujarat pharma companies, Business Standard **(28 June 2015)**

At a time when the biosimilars market in India is expected to clock a 30 per cent growth rate between 2014 to 2018, pharma companies in Gujarat are increasingly focusing on this segment, eyeing the regulated markets in the long run. Biosimilars are biological products that are similar or highly similar to the originator products and have similar level of efficacy and safety. As the efficacy of the biosimilar or biologics is established against chemical drugs, the demand is set to rise. Moreover, patent expiries in regulated markets is expected around 2017, when a lot of opportunities would open up. For the time being, the companies are targeting the emerging markets," Mumbai-based analyst said.

Access to Healthcare

Health ministry plans major thrust to improve health indicators in northeast states, The Times of India **(27 June 2015)**

Concerned over poor health facilities, delayed implementation of various schemes and under-utilization of funds by north-eastern states, the health ministry has drawn up a master plan to improve health indicators in the eastern-most states. The plan aims to focus on four main areas - creation of infrastructure, deployment of more health workers, streamlining the procurement and supply chain, and improving health indicators such as maternal mortality rate (MMR) and infant mortality rate (IMR).

Similar reports have appeared in:

Asian Age

Business Standard **(28 June 2015)**

Mass medicine scheme needs a booster dose, Business Standard **(28 June 2015)**

Launched in 2008, the Jan Aushadhi Scheme was initiated by the United Progressive Alliance (UPA) government during its first term. The aim was to achieve three objectives: make generic medicines available in the market; encourage doctors in government hospitals to prescribe generic medicines; and lastly, reduce out-of-pocket expenses for patients. These were to be stores where patients could walk in and buy generic drugs that the government would sell at the lowest possible price. But, the programme flopped with only a few stores seeing the light of day. Against the target of 626 stores - one in each district - by the end of the 11th Plan period in 2012, the government had managed to open only 157 stores by 2013. Most of these stores too became non-functional as they became non-profitable. Even now, only 99 out of the 176 stores are functional.

Ethics & Compliance

IMA endorsement slammed, The Hindu **(28 June 2015)**

"Why are you demeaning us?" is the question doctors across the country are asking the Indian Medical Association (IMA), which currently has under its belt endorsements for a water purifier, soap and toothpaste. While the Medical Council of India has excused itself from taking action stating "lack of

jurisdiction", whistleblower Kerala-based physician K.V. Babu has written to the Advertising Standards Council of India (ASCI) complaining against endorsements by the IMA. The rule book, according to Dr. Babu, states that soliciting of patients directly or indirectly by a physician, a group of physicians or institutions or organisations is unethical.

Medical & Regulatory

Pharma Price Data Bank launched in Bengaluru, The Times of India **(27 June 2015)**

The Union minister of chemicals and fertilizers Ananth Kumar launched Pharma Price Data Bank in Bengaluru on Friday. It is an integrated Pharmaceutical Database Management System, managed and operated by National Pharmaceutical Pricing Authority (NPPA). Speaking at the release ceremony, the Minister said that this is the first data bank of Pharma industry that will help the manufacturers, regulator as well as the common masses. He said that now Manufacturers can fill their mandatory forms online, the Government and NPPA can have comprehensive data, and consumers can benefit by having full information about the medicines.

Similar reports have appeared in:

Pharmabiz.com

Express Pharma

Govt plans to set up Rs 500 crore VC fund for pharma industry, The Economic Times **(29 June 2015)**

The government plans to set up Rs 500 crore venture capital fund to boost domestic pharma industry and provide cheaper loans to entities looking to establish or upgrade manufacturing facilities. The government is working on various proposals, including single window clearance for drug approvals, to rejuvenate the local pharma sector and make medicines more affordable. The steps were suggested by a task force formed by the Department of Pharmaceuticals (DoP) in a report submitted to Chemicals and Fertilisers Minister Ananth Kumar.

Similar reports have appeared in:

Business Standard

Deccan Chronicle

Quality check: Pharmaceuticals regulator set for revamp, Hindustan Times **(29 June 2015)**

India's drug regulator Central Drug Standard Control Organisation (CDSCO) is all set to be revamped into a world-class body. With the rise in import alerts from the US Food and Drug Administration (USFDA), the government has geared up to increase the efficiency and quality of the pharma sector. CDSCO regulates quality standards of drugs and is also responsible for the approval of new drugs. The ministry has floated the draft Cabinet note with an aim to upgrade the body at par with the world's best health regulator, US Food and Drug Administration (US FDA).

Deadline to buy medicines proposed, Deccan Chronicle **(29 June 2015)**

The Drugs Controller of India has proposed a 48-hour deadline for consumers to use medical prescriptions to purchase medicines. Pharmacists have complained that people return with the same prescriptions time and again, and they have to give the medicines if they have to retain their customer base. The reuse of prescriptions amounts to misuse as it encourages the abuse of antibiotics, psychotic and anti-inflammatory medicines, which the drugs controller wants to prevent.

Indian Pharma's Struggle to Tighten Standards Paves Way for M&A Deals, The New Indian Express **(29 June 2015)**

India's smaller generic drugmakers, struggling to cope with a bruised reputation and tougher regulation in the United States, are under pressure to consider branching out to new, less-profitable markets or sell out to larger rivals. Two years after its most high-profile regulatory setback to date in the United States - Ranbaxy's $500 million U.S. fine for drug safety violations - India's $15 billion a year generic drug industry is still rebuilding its image in its biggest market. Many of its top firms are facing sanctions at some of their factories, as the U.S. Food and Drug Administration (FDA) tightens checks and its approvals process.

Task force recommends strengthening of CDSCO and to create a regulatory cell in NIPERs & other institutes, Pharmabiz.com **(29 June 2015)**

The task force on 'Enabling the private sector to lead the growth of pharmaceutical sector in the country', constituted by the Department of Pharmaceuticals (DoP) in November last year, has recommended to the government to create a regulatory cell in NIPERs and other institutes to support the Indian pharma sector understand the global regulatory landscape. The regulatory cells in NIPERs will play a key role across the functionalities of process support, capacity building and infrastructure support. These cells should have working relationships with other regulatory institutes like Centre for Innovation in Regulatory Sciences UK, DIA (USA), Centre for Regulatory Excellence at the Duke- NUS Graduate Medical School (Singapore), etc, the task force in its recommendation said.

Other News on Pharma

Consultants on foreign agency payroll at odds with national health policy, The Times of India **(27 June 2015)**

The health ministry's practice of engaging hundreds of consultants paid by foreign aid agencies is totally at odds with the government's own draft National Health Policy which talks about the conflict of interest in such an arrangement. An RTI filed by a student researcher, Krishna Teja, has revealed that there are 363 consultants working with the health ministry, a large number of them being paid by external aid agencies such as United States Agency for International Development (USAID), Department for International Development (DFID) of the UK and United Nations Population Fund (UNFPA) who hire consultants and pay them through agencies such as Deloitte, a US based financial company, IPE Global which describes itself as a development consultancy or SPC Management, a consulting company.

Gujarat pharma companies focus on OTC herbal products, The Times of India **(27 June 2015)**

Leading drug makers from the state are turning to plant extracts. Gujarat based companies, primarily engaged into manufacturing of drugs, are now focusing on over-the-counter (OTC) herbal products. "The market for herbal products is growing and companies will have to fight for their market share but most of these products are still under OTC. A lot of effort will be needed by companies to reach to the level of bringing them under prescription. With the rise in lifestyle diseases, consumers are looking at natural solutions," said Sarabjit Kour Nangra, a Mumbaibased analyst.

Heart of the matter: unblocking the stent superhighway, The Hindu Business Line **(27 June 2015)**

On any given day, at least 50 per cent of patients who have been advised stents to remove heart blockages do not require it, says heart surgeon Ramakanta Panda, head of the Asian Heart Institute. “Though stents play a critical role in the lives of those with heart blockages, it is grossly over used in the country,” he says, indicating the reason for mistrust among patients when it comes to stents. In fact, a recent study by interventional cardiologists in the country also revealed interesting data on stents usage, triggering an intense debate on stents, pricing, its use and abuse.

IPSF World Congress makes maiden entry into India, to be held in Hyderabad from July 30 to August 9, Pharmabiz.com **(27 June 2015)**

The International Pharmaceutical Students’ Federation (IPSF) - World Congress will be organized by the Indian Pharmaceutical Association – Students’ Forum (IPA-SF) for the first time in India from July 30 to August 9, 2015, at Marriot Hotel and Convention Centre, Hyderabad. The event represents a confluence of pharmacy students from all over the world. It is a platform to connect and integrate the diversity in the world of pharmacy and create an opportunity for generation of new ideas, blend of cultures and exchange of knowledge. Nearly 500 students and leaders from about 83 countries will be participating in the Congress.

Pharma expo on July 3, 4, The Hindu **(28 June 2015)**

Indian Drug Manufacturers Association organises ‘Pharmac South 2015,’ an international exhibition for showcasing the innovative pharmaceutical products, on July 3 and 4 at Chennai Trade Centre, Nandambakkam. Around 2,500 people from across south India are expected to participate in the expo. Dr. V.K. Subburaj, Secretary of Pharmaceutical Department of India, will inaugurate the exhibition. J. Radhakrishnan, IAS, will be releasing the directory of the 90 stalls put up at the exhibition.

Panel submits recommendation on aligning GMP requirements for medical devices in lines with ISO standards, Pharmabiz.com **(29 June 2015)**

In a strategic move that would give a huge thrust to the medical device sector, the DTAB sub-committee that was set up by the Centre to deliberate over the possibilities of formulating and aligning the good manufacturing practice (GMP) guidelines for the sector with the globally accepted ISO standards, recently submitted its detailed report to the CDSCO. It is understood that experts from the government and the industry had been brainstorming over working towards balancing and aligning the GMPs for medical devices and in vitro diagnostics with the ISO 13485 quality management system standard, which is focused on quality system requirements.