News Updates: January 31, 2014

Drug regulation/R&D

Publication: The Economic Times
Edition: National
Date: January 31, 2014
Headline: Regulate domestic pharma to be truly world class

Synopsis: Regulation of pharmaceutical production in India seems to be stuck in the pre-reform days of autarky, bereft of ambition and oblivious of the global opportunities the sector holds out for India. The drug controller general of India has reportedly admitted that if we followed US standards, we would need to shut down most domestic pharma facilities. It betrays a defeatist mindset and worse. Instead, we surely need world-class quality control in domestic pharma to realise our potential to be the pharmacy of the world. True, the Indian pharma industry does already supply generics to over 200 nations and territories. But the potential upside is simply huge if we follow the highest global standards. The size of the US generics drug market alone is $80 billion, and fast growing. Also, when it comes to advanced manufacturing capability, pharma is the lone sector where we have something of a toehold.

Publication: Pharmabiz
Edition: Online
Date: January 31, 2014
Headline: Three MNC R&D centres shut down in Karnataka and shifted to their global headquarters

Synopsis: Three R&D centres of multinational companies have been shut down in Karnataka and have been shifted to their global headquarters, thanks largely to the global slowdown, slashing budgets for research and disappearance of blockbuster drugs. The centre are Accelrys, a subsidiary of Pharmacopeia Inc., Actavis and UK's AstraZeneca Avishkar research and development unit.While pharma experts view such moves as a serious blow to the Indian research acumen, others opined that partnerships with small research outfits for multinational companies (MNCs) is the future strategy.

Publication: The Indian Express
Edition: Online
Date: January 31, 2014
Opinion Article – Anil Sasi
Headline: Now, Indian firms face global watchdogs

Synopsis: The flip side of globalization, as many Indian companies and even sectoral regulators would testify, is the increased levels of scrutiny by foreign regulators, especially US watchdogs.

Clinical Trials

Publication: The Times of India
Edition: Online
Date: January 31, 2014
Headline: Video-recording of consent for clinical trials driving away subjects, SC told

Synopsis: The new draft protocol for clinical trials of drugs, on the lines suggested by the Supreme Court, is making it difficult for global drug manufacturers to find subjects for testing new chemical compositions. The protocol has made it mandatory for companies intending to conduct human trials of drugs to video-record the

free consent of patients to be part of the trial. It also mandates them to inform patients about the possible adverse health effects of the drug, which is under clinical trial.

General Industry News

Publication: Business Standard
Edition: Online
Date: January 31, 2014
Opinion Article-Bhupesh Bhandari
Headline: Ranbaxy, then and now

Synopsis: Yet another factory of Ranbaxy, this time in Toansa (Punjab), has been banned from selling in the United States. Once again the company faces charges of unclean manufacturing practices. The company's reputation has taken such a beating in the last few months that any attempt at image management will be an uphill task. That's perhaps why the company has become some sort of recluse - its silence is understandable. I don't envy the Ranbaxy spokesperson his job.

Publication: The Economic Times
Edition: National
Date: January 31, 2014
Headline: How lifesciences startups are turning futuristic ideas into successful business ventures

Synopsis: Sea6 Energy, the Bangalore based startup which has struck a partnership with global industrial enzyme maker Novozymes to create new products to enhance the process of converting seaweed into ethanol. In addition, Sea6 has also developed technology to generate natural gas from the same process. Today, with three patent applications filed and nearly Rs 6.5 crore in angel funding, the startup is well on its way to finding commercial applications. Sea6 is one of several startups that are taking on higher risks in an attempt to turn their 'blue sky research' into businesses, marking a shift in India's life sciences sector. A decade ago, life sciences companies were mainly focused on services like contract manufacturing or development of generic drugs, where the business model consisted of supplying scientists who would work for a specific period on a specific problem.

Publication: The Economic Times
Edition: National
Date: January 31, 2014
Headline: Ranbaxy suspects staff behind Toansa plant woes

Synopsis: Ranbaxy Laboratories, the troubled drugmaker, has hinted at the possibility of sabotage by disgruntled employees at its manufacturing facility in Toansa, Punjab, which was blacklisted by the US drug regulator early this month. According to two persons who have been briefed by Ranbaxy executives, preliminary findings of the company's internal investigations indicate that some of the manufacturing violations at the Toansa plant detected by US Food and Drug Administration (FDA) could be the handiwork of a few disgruntled employees.

Publication: Business Standard
Edition: Online
Date: January 30, 2014
Headline: Time for Ranbaxy management to raise the threshold for healthcare

Synopsis: It's like hearing a song in a loop. The same questions come up on data integrity, the Ranbaxy management vows to fix the problem, Indian regulators promise to investigate transgressions, etc. Last May, when Ranbaxy agreed to pay $500 million to settle criminal and fraud charges against it in the US, the hope was that the ghost of the drug-maker's Paonta Sahib and Dewas plants were finally put to rest. But that was not to be, as cGMP or current Good Manufacturing Practices, violations were reported at Ranbaxy's Mohali plant and more recently at the Toansa facility (both in Punjab). And the import ban on products into the US from these plants followed. Industry representatives explain the fine print, that the US regulator slams its brakes on companies even if there is a slip-up in documentation or the manufacturing process.

Publication: DNA
Edition: Online
Date: January 31, 2014
Headline: Now, Apps that help you cut your medical bills; Healthkart Plus, My Dawai and Get Med suggest cheaper generic alternatives

Synopsis: Android phone applications such as Healthkart Plus, My Dawai and Get Med are some of the many popular and useful Apps tech savvy patients are now turning to. Doctors say at times certain B Complex and multivitamins, painkillers, anti-allergic and antibiotic drugs are up to 10 times costlier depending on the manufacturing pharmaceutical company. The margin of pricing between two or more multinational pharma company brands is extremely steep.

Publication: Hindustan Times (Page 16, Mumbai Edition)
Edition: Online
Date: January 31, 2014
Headline: Indian drug regulator likely to fast-track scrutiny of Ranbaxy

Synopsis: India's pharmaceutical industry regulator is expected to fast-track the testing of drug samples from Ranbaxy Laboratories, which is embroiled in a controversy in the US over the safety of its manufacturing facilities.

Publication: The Economic Times
Edition: National
Date: January 30, 2014
Headline: KKR-Gland Pharma deal gets Competition Commission nod

Synopsis: Global private equity player KKR's proposed deal, including stake purchase, with domestic drug maker Gland Pharma has received green signal from the Competition Commission. KKR, in November last year, had announced it would acquire minority stake for $200 million in Gland Pharma.