News Updates: January 17, 2014

FDA / Drug Regulatory / DCGI / Pharma Policy

Publication: The Economic Times
Edition: National
Date: January 17, 2013
Journalist: Soma Das
Headline: Regulator mulls changes in labelling norms for drugs

Synopsis: India's drug regulator is considering changes in the norms for labelling medicine packs after some state drug controllers raised concerns that consumers may be getting misled by the way marketing companies are displaying their names on packs. Officials at the Drug Controller General of India (DCGI) said the changes in the norms will ensure that consumers do not mistake the marketing firm to be the manufacturer of the drug. State drug regulators had recently raised concerns on the varied formats of labelling on drug packs. At a recent meeting of the drug consultative committee, the drug regulator of Andhra Pradesh said it has come across several instances where large pharma companies, which are only marketing products manufactured by smaller and lesser known firms, print their own names in bold fonts, giving the impression that the drugs have been manufactured by them.

Publication: Business Standard
Edition: National
Date: January 17, 2013
Headline: Bhupesh Bhandari: The half-baked pill

Synopsis: It is becoming clearer with each passing day that the decisions of the Aam Aadmi Party, or AAP, government in Delhi are not well thought through. Lost somewhere in the din over power tariffs, water entitlement, plebiscite in Kashmir, interface with the judiciary and foreign investment in retail was an order given by Delhi's health minister, Satyendra Jain (an architect by training and a former employee of the Central Public Works Department, he is also responsible for industries and gurudwaras), last week that doctors in government-run hospitals can only write generic medicine in their prescriptions, not brands. The idea is to bring down the cost of medication. Some AAP sympathisers would say this will also help break the unholy nexus that exists between drug makers and doctors. It is an open secret that drug companies shower numerous inducements on doctors so that they prescribe their medicines. These "gifts" can range from stationery to overseas junkets to even picking up the bill for children's weddings. The higher the doctor in the pecking order, the bigger the gift. This frequently results in over-prescription and, at times, under-medication.

Publication: The Financial Express
Edition: National
Date: January 17, 2013
Journalist: Jayati Ghose
Headline: High BP pill brings revenue-sharing anxiety for Ranbaxy

Synopsis: Ranbaxy Laboratories may have to share 30% of the revenues from sale of the generic version of Novartis' blockbuster anti-hypertensive 'Diovan' with the multinational firm it has tied up with for the raw material used to make the drug. Revenue opportunities from other big first-to-files in the US, including anti-viral Valcyte and antacid Nexium, could also be affected if Ranbaxy's Toansa plant comes under import alert from the US Food and Drug Administration (USFDA), said analysts. Such a situation would force Ranbaxy to seek partnerships with foreign players to procure raw material or active pharmaceutical ingredients (APIs), which, at present, are supplied from Toansa. Analysts said the total estimated revenue from the launch of Diovan, Nexium and Valcute is around $800 million for the six-month exclusivity period. Earlier, Ranbaxy had tied up with an MNC firm to source API for Lipitor. The company had to share 45% of its profits from the sale of the generic version of Pfizer's blockbuster Lipitor with

its API partner. Last week, the FDA rapped Ranbaxy for not maintaining its Toansa plant in line with the required manufacturing standards.

Publication: The Financial Express
Edition: National
Date: January 17, 2013
Headline: FDA concerns a worry, neutral rating on on Ranbaxy shares: HSBC

Synopsis: Recent report indicated that Ranbaxy Laboratories Ltd may have inked a deal with an MNC for API (bulk ingredient) for generic Diovan in the US. Diovan is a first-to-file opportunity for Ranbaxy in the US; however, it has seen delays due to FDA inspection concerns at the company's facilities. A recent inspection at an API facility at Toansa for Diovan produced several Form 483-related observations (deviations from cGMP), which we believe explains why Ranbaxy might look for a partner to commercialise this long-awaited opportunity. While it is possible that the FDA may approve a partnership for Ranbaxy to source API (given it was a similar case in the approval of gLipitor), this would trim the potential opportunity as the company would have to share part of its profits with the partner.

Publication: Business Standard
Edition: Online
Date: January 17, 2013
Journalist: Rakesh Rao
Headline: Indian bulk drug industry: Maintain quality conscience to face competition

Synopsis: In last few months, there have been many news pertaining to regulatory issues with respect to some of the leading Indian-based pharmaceutical companies. US FDA and UK's MHRA have issued many warnings to manufacturing facilities in India. While causes of these quality issues are being looked into, some experts point fingers at raw materials being used to produce drug formulations. It is a well-known fact that Indian companies import intermediates required for making active pharmaceutical ingredients (APIs) from China to become cost-competitive. To control the menace of low-quality imports, it was reported that the Indian drug regulator may conduct routine inspections at Chinese manufacturing facilities, which supply APIs to Indian pharma companies. But the question is will this move curb imports? "It definitely will impact the supply. Our Government must have a dialogue with their Chinese counterparts to streamline their regulatory procedures. There have also been instances in the past of our DCG(I) having to ban imports of raw materials from some Chinese companies for supplying products without having the mandatory drug manufacturing standards," said Daara B Patel, Secretary-General, Indian Drug Manufacturers' Association.

Publication: The Pioneer
Edition: New Delhi
Journalist: Archana Jyoti
Date: January 17, 2014
Headline: Oxytocin sale to be restricted soon

Synopsis: The sale of Oxytocin drug will be restricted soon to curb its rampant misuse by dairy owners who inject it into cows and buffaloes to get them produce more milk. The Drugs Technical Advisory Board (DTAB), under the Union Health Ministry, in its latest meeting has recommended a series of steps including streamlining the sale of the drug's active ingredient to licenced manufacturers, ensuring the sale on prescriptions, besides making sure distribution takes place only through veterinary hospitals and increased surveillance and raids on "clandestine manufacturers." The move follows concern over the frequent abuse of the drug, as was pointed out recently by MP Maneka Gandhi who in a letter to the Health Ministry said that the drug has harmful effects on the health of cows and as well as the consumers.

Publication: Pharmabiz
Edition: Online

Date: January 17, 2014
Headline: Blue Star Infotech sees SMAC trends to transform pharma sector in 2014

Synopsis: Blue Star Infotech has noted that there would be a considerable increase in the adoption of SMAC (social, mobility, analytics and cloud) technologies in 2014 in the pharma industry. The key reason is that these technologies are compliant with the FDA regulations and can identify patterns in patient behaviour, and is therefore seen as an important tool for drug development. The pharmaceutical industry has shown a gradual uptake in taking up enterprise technology in 2013, when it had taken incremental steps to implement SMAC. It is predicted that this trend of investment in SMAC will be accelerated in 2014, and in turn, would pave the way for innovative solutions towards patient-centric and customized healthcare delivery, Susmita Nandi, practice manager- BI & Analytics, Blue Star Infotech told Pharmabiz.

Drug Pricing

Publication: Pharmabiz
Edition: Online
Date: January 17, 2014
Headline: NPPA asks manufacturers to suo-moto pay dues on drugs sold at higher prices still after 15 days of price revision

Synopsis: The National Pharmaceutical Pricing Authority (NPPA) has asked the drug manufacturers to suo-moto work out the overcharged amount by themselves in respect of drugs sold without implementing the new price revision and deposit the money with the government along with interest. The NPPA, through letters sent to all the leading industry bodies, made this direction following the Supreme Court dismissal of the petitions filed by some manufacturers regarding the provisions of the DPCO to implement the price revision within 15 days from the date of notification. “As part of self-regulatory exercise, you are requested to advise your member units to suo-moto work out the overcharged amount by themselves in respect of quantities manufactured before issue of the price notification order but sod to the consumer/public at higher price without implementing the new revised price even after expiry of the 15 days as specified in paragraph 14(1) of DPCO, 1995 duly certified by chartered /cost accountant and deposit the same with the government along interest at the rate of 15 per cent per annum due thereon,” said a notice by the NPPA.

General Industry

Publication: The Indian Express (The Economist)
Edition: New Delhi
Date: January 17, 2014
Headline: Not-so-bitter pill *(published online on Jan 11, 2014)*

Synopsis: FACED with death, most people will do almost anything to stay alive. That is why many millions around the world either stick needles in themselves at frequent intervals to inject a hormone called insulin, or wear a device called an insulin pump that does the same thing automatically through a catheter that penetrates their skin. A body’s failure to make insulin, which regulates how cells burn glucose, their primary fuel, causes the symptoms doctors call type-1 diabetes. Until the discovery of insulin, in the 1920s, this form of diabetes was a death sentence. In principle, it might be possible for diabetics to take their insulin by mouth, as the hormone can be absorbed into the body through the walls of the small intestine. Unfortunately, insulin molecules cannot survive the acidity of the stomach, an organ they need to traverse to arrive in the intestine. But, as he describes in a paper in Biomacromolecules, Sanyog Jain of the National Institute of Pharmaceutical Education and Research, in Ajitgarh, India, thinks he has found a way around the problem—or, rather, through it.

Publication: The Times of India
Edition: Online
Date: January 17, 2014
Headline: 'New law to regulate clinics should focus on rights of patients'

Synopsis: As a 19-member high-powered committee drafts the clinical establishment law for the state before the

forthcoming budget session, citizen groups have demanded that it should be focused on patients instead of on doctors. "The Maharashtra act should have a charter of patients' rights that should be prominently displayed in each clinical establishment as a condition for registration," a Jan Arogya Abhiyan (JAA) press release said on Thursday. The Centre had drafted the Clinical Establishments Act in 2010, which was passed in some union territories. As health is a state subject, the state government appointed a committee under the chairmanship of Maharashtra Medical Council chief Dr Kishor Taori to address issues peculiar to the state. The Indian Medical Association had raised several objections (see box) to specifications for clinics, prompting the state government to set up the Taori committee.

Publication: The Hindu
Edition: National *(Op-Ed)*
Date: January 17, 2014
Headline: Keep an eye on gene therapy

Synopsis: Two men with progressive blindness have partially regained their vision after taking part in the first clinical trial of a certain gene therapy. The men were among six patients to have experimental treatment for a rare, inherited, disorder called choroideremia, which steadily destroys eyesight and leaves people blind in middle age. After therapy to correct a faulty gene, the men could read two to four more lines on an optician's sight chart, a dramatic improvement that has held since the doctors treated them. Writing in The Lancet, doctors maintain that further trials are as effective, the team could apply for approval for the therapy in the next five years. Some other forms of blindness could be treated in a similar way.

Publication: The Tribune
Edition: National
Date: January 17, 2014
Headline: Polio becomes history

Synopsis: FINALLY, there is something to bring cheer to the UPA government. India has declared itself to be polio free for the third consecutive year. WHO (World Health Organisation) is expected to formally certify India's polio-free status the next month. The unthinkable has been made possible by a strong political will, a seamless partnership of the Ministry of Health, WHO and UNICEF, and other private organisations like the Rotary Club and the Bill & Melinda Gates Foundation. Above all, it was the tireless hard work of millions of front-line workers - vaccinators, social mobilisers and community and health workers who carried out the operation of oral vaccination against polio type 1 and 3 on a scale that is almost unmanageable for the diversity of population involved. The achievement is no less than a miracle.

Publication: Daily News & Analysis
Edition: Bangalore
Date: January 17, 2014
Headline: 'City patients not tackling silent killer well' (Link not available)

Synopsis: According to a new survey, more than 15% of diabetic patients in Bangalore do not adhere to proper insulin treatment practices. The survey says 20% patients
do not know about right injection techniques. As insulin treatment is vital for blood glucose control, inappropriate injection skills compromise the dosage accuracy and its efficacy. Moreover, it may also lead to pain with bleeding and a risk of contamination, stated Dr C Munichoodappa. head, department of diabetology. Bangalore Hospital.

Publication: Pharmabiz
Edition: Online
Date: January 17, 2014
Headline: PHO opposes state govt's decision to allow homoeopathy doctors to practice allopathy

Synopsis: The Mumbai-based People Health Organisation (PHO), a medico social organisation dedicated towards

prevention and control of HIV/AIDS, has also joined the chorus against the Maharashtra government's recent decision to allow homoeopathy doctors to practice allopathy after one year’s bridge course in pharmacology. The Indian Medical Association (IMA), the parent body of allopathy practitioners, the Maharashtra Medical Council (MMC) and Maharashtra Association of Resident Doctors (MARD) are already up in arms against the Maharashtra government's decision on the plea that it will have an adverse impact on patient safety.