News Updates: January 10, 2014

OPPI

Publication: Pharmabiz
Edition: Online
Date: January 10, 2014
Headline: BDCDA seeks CCI intervention against unfair trade practices of KCDA & pharma cos

Report: The Bangalore District Chemists & Druggists Association (BDCDA) has approached the Competition Commission of India bringing to its notice the Restrictive Trade Practices & Anti Competitive Conduct indulged in by the Karnataka Chemists and Druggists Association (KCDA). According to BDCDA, KCDA is demanding No Objection Certificate (NOC) for supply of drugs to wholesalers. The move by KCDA is also a violation of the Para 28 of the Drugs Price Control Order (DPCO) 2013. The BDCDA comes under the umbrella of the KCDA.

In addition, the manufacturing and marketing companies which are the members of Indian Drug Manufacturers Association (IDMA), Organisation of Pharmaceutical Producers of India (OPPI) and Indian Pharmaceutical Association (IPA) also have to obtain NOC from KCDA. The companies have been asked to enter into an agreement with stockists to supply medicines which violates the norms of the wholesaler licences under the Drugs & Cosmetics Act & Rules granted by the state drugs control department.

The Para 28 of DPCO 2013 clearly states that no manufacturer or distributor should withhold from sale or refuse to sell customers any drug without good and sufficient reasons. In a letter to Justice (Retd) SN Dhingra, member, Competition Commission of India, via reference number BDCDA/1743/13 dated January 4, 2014, it stated that KCDA is indulging in practice of Restrictive Trade Practices & Anti Competitive Conducts, which are not followed by our members. In this regard it resisted the decisions of KCDA, V Hari Krishnan, president, BDCDA told Pharmabiz.

The letter to the Competition Commission of India has also highlighted that KCDA is an ordinary member of All India Organization of Chemists & Druggists (AIOCD).

BDCDA has a total membership of 3017 representatives from pharmacy trade who ensure easy accessibility to medicines for customers round-the-clock. Hence the Competition Commission of India should look into the issue and ensure exemption of NOC which is demanded by KCDA and members of OPPI, IDMA and IPA, said Krishnan.

Further BDCDA has requested Justice Dhingra to issue necessary circulars to the manufacturing and marketing companies coming under the banner of IDMA, OPPI & IPA. Besides it has also sought for clarification from CP Singh, chairman, NPPA, Dr GN Singh, DCGI & Raghurama Bhandary, Karnataka Drugs Controller on whether a NOC is required from KCDA. It has also sought instruction on whether it should enter into an agreement with the pharma companies for the supply of drugs, he said.

Publication: Pharmabiz
Edition: Online
Date: January 10, 2014
Headline: Safety of PET bottles: A point of view

Report: Apropos to the edit dated 2nd January 2014, entitled 'Safety of PET Bottles' published in Pharmabiz. At the outset, I wish to inform that the undersigned has been associated with PET Industry in particular and plastics in general for last 2 decades both as a professional and entrepreneur. It is highly regrettable that the aforesaid edit seems to convey that the Union Health Ministry has taken a decision to ban PET and plastic bottles for pharma packing.

We wish to state that this message is totally wrong. The article tends to hit at the multibillion plastic and pharma industry of India and millions employed. It is true that DTAB has suggested a phase out of plastic and PET bottles

but no order has been issued by the Ministry. Regrettably, the advice has been given despite accepting that there is no evidence to confirm accusations of Him Jagriti against plastic and PET bottles.

It would be in order to add that leading industry associations - IDMA, OPPI, PCMA, FOPE, ICPE, APM-Haridwar have expressed their strong reservation to the DTAB advise and have represented to DTAB and the Ministry against the same.

Polyethylene terephthalate (PET) is a food grade thermoplastic resin and is widely used globally in packing of water, liquor, medicines, food items and carbonated soft drinks. Over 20 mn tonnes of PET is used for packaging globally and the use is growing @ 10 % p.a. PET is approved by US FDA, BIS, US Pharmacopoeia, Indian Pharmacopoeia, EU and others. Stability tests to establish suitably of PET for packing food Items have been conducted by govt recognised labs, and pharma companies conduct its own test for each formulation with PET packaging.

There has been much reporting in media wrt phthalates in PET. The term 'phthalates' refers to the diesters of 1, 2-benzenedicarboxylic acid, better known as phthalic acid. It is important to appreciate the difference between PET and phthalates. Both are chemically dissimilar. Phthalates or phthalate esters, are esters of phthalic acid and are mainly used as plasticizers (substances added to plastics to increase their flexibility, transparency, durability, and longevity). They are used primarily to soften polyvinyl chloride (PVC).

It seems that industry experts and media are assuming that Polyethylene Terephthalate and Phthalates are same. Regrettably, it is like comparing apples to oranges.

Endocrine disruptors - United States Environment Protection Agency is running an Endocrine Disruptors Screening and Testing Programme for a universe of 10,000 chemicals. These chemicals are shortlisted from 85,000 chemicals sold commercially. Polyethylene terephthalate does not appear in this list and therefore clearly it is not endocrine disruptor. However, glass does appear in this list of 10,000 chemicals as potential endocrine disruptor.

Migration/leaching - Heavy metal migration studies have been conducted by Industrial Toxicology Research Centre, Lucknow for several PET bottle customers for evaluation of packaging of ethyl alcohol. The comparisons of PET bottles are done with glass bottles. The migration in glass as well as PET is comparable and is much below the permissible limits.

International Life Science Institute in its report mentions substances which readily migrate are of low molecular weight and volatile. PET has high molecular weight and hence low migration propensity.

We wish to add that already 5 PILs against use of PET bottles in various states have been rejected by High Court in the year 2013. In addition the Supreme Court has not even admitted a PIL seeking ban on PET bottles, says Sarabjit Singh from Polyuno Ventures India, Janakpuri, New Delhi.

Patents / Intellectual Property Rights / Compulsory Drug Licensing

Publication: Financial Chronicle
Edition: New Delhi
Journalist: Trushna Udgirkar
Date: January 10, 2014
Headline: Suven Life secures three product patents

Synopsis: Suven Life Sciences has fetched three product patents, one each from Australia, Sri Lanka and South Korea for their New Chemical Entities (NCEs) meant for the treatment of disorders associated with Neurodegenerative diseases. These patents are valid until 2029. The company said that the granted claims of the patents include the class of selective 5-HT compounds discovered by Suven. These are being developed as therapeutic agents and could be useful in the treatment of cognitive impairment associated with neurodegenerative disorders like Alzheimer's disease, attention deficient hyperactivity disorder (ADHD), Huntington's disease, Parkinson and Schizophrenia.

Clinical Trials

Publication: The Hindu
Edition: Bangalore

Date: January 10, 2014
Headline: 'Rules governing clinical research are stifling'

Synopsis: Expert says trials have almost come to a halt. The rules governing clinical research in India are not entirely thought out and it is important for the Ministry of Health to re-look at the notified revised regulations, consult people both in India and abroad with knowledge and experience in ethics as well as the science of clinical trials, averred Prem Pais, professor of Medicine and Head Division of Clinical Research and Training, St. John's Research Institute. Speaking to reporters on Thursday, he said that it was most important that the rights of clinical trial participants were protected while the greater good of people was not harmed by killing off clinical trials. He said that the new regulations have some problematic clauses, as a result of which trials have almost come to a halt. Scientific agencies, such as the National Institute of Health of the U.S., have also stopped trials in India while a large number of multinational pharmaceutical companies have excluded India from their list of participating sites.

Publication: Reuters
Edition: Online
Date: January 10, 2014
Headline: Swiss biotech firm starts new Alzheimer vaccine trial

Synopsis: AC Immune, a privately held biotech company based in Switzerland, has launched the world's first trial of a vaccine against a protein believed to cause Alzheimer's after securing funding from private investors. Its ACI-35 vaccine aims to stimulate the immune system to produce antibodies which target the tau protein that forms twisted fibers and tangles inside the brain. Many scientists believe tau is an important cause of Alzheimer's, alongside another protein known as amyloid, that has been the main focus of drug development efforts so far. Although there is still no treatment that can effectively modify the disease or slow its progression, a number of big pharma companies - including Roche, Eli Lilly, Merck & Co and Johnson & Johnson - are pursuing a variety of approaches to get to the root cause.

FDA / Drug Regulatory / DCGI / Pharma Policy

Publication: The Hindu Business Line
Edition: National
Date: January 10, 2014
Headline: Zydus gets US FDA nod for two drugs (Online Headline: Zydus gets US FDA nod for Sirolimus tablets, Duloxetine capsules)

Synopsis: Zydus Cadila on Thursday said it has received the final approval from the USFDA to market Sirolimus tablets (0.5 mg) with 180-days of marketing exclusivity. As per IMS data in 2013, the sales of Sirolimus 0.5 mg was estimated at $11.7 million and the total market for Sirolimus was approximately $203.8 million, the Ahmedabad-based company said in a statement here. The Group also received approval for Duloxetine delayed release capsules in strengths of 20, 30 and 60 mg. The sale for Duloxetine was estimated at $5.5 billion in 2013.

Publication: Business Standard
Edition: New Delhi
Date: January 10, 2014
Headline: Indian pharma's challenges

Synopsis: A shift to research and higher quality is overdue. India's pharmaceutical industry, one of the country's most globally competitive, faces a challenging 2014. The most important challenge comes from regulators in developed markets, which have imposed strictures on several leading Indian exporters like Ranbaxy, Wockhardt and Strides for failing to comply with good manufacturing practices. Unfortunately, the word is being spread around that Indian exporters, who are growing in strength, are being unfairly targeted. This is a negative approach and can be counterproductive. G V Prasad, chairman of Dr Reddy's Laboratories, has said that the share of Indian pharmaceutical companies that have been warned by the United States Food and Drug Administration - from which many regulators across the world take their cues - is not all that high.

Publication: The Hindu Business Line
Edition: National
Journalist: Deepa Nair
Date: January 10, 2014
Headline: General insurance companies pitch for healthcare regulator

Synopsis: The General Insurance Council, representing the interests of 25 non-life insurance companies, has strongly pitched for a regulator to oversee the healthcare industry and prescribe norms for standardisation and inspection of services across hospitals. The Council wants a healthcare regulator as sub-standard healthcare services to the patients in hospitals cannot be left unregulated or unchecked. The Council made these submissions in response to a public interest litigation filed by activist Gaurang Damani in the Bombay High Court seeking declaration of pre-package rates for various ailments in the policy document by non-life insurance companies.

Publication: Pharmabiz
Edition: Online
Journalist: Joseph Alexander
Date: January 10, 2014
Headline: Dept AIDS Control to take up matter of blood bank licensing with DCGI

Synopsis: With the target of setting up 39 district-level blood banks (DLBB) during the third phase of the National AIDS Control Programme during the 11th Plan period still not fulfilled, the Department of AIDS Control will take up the matter of licencing issue with the Drug Controller General of India (DCGI). As per the latest updates, 28 DLBBs become operational by the end of the March last year. For early functioning of the remaining 11 DLBB spread in different states, communications have been sent to State Health Secretaries to remove the bottlenecks in setting up of these blood banks immediately. Communication has also been sent to the CDSCO to expedite the issuance of pending licenses, sources said. “The matter is being perused with the states. The matter of issuance of license to these DLBB will be taken up with the DCG(I) after the infrastructure facilities are made available by the State Government on priority basis,” sources added.

Publication: The Economic Times
Edition: Mumbai, Bangalore
Journalist: Divya Rajagopal
Date: January 10, 2014
Headline: Workhardt gets Dr. Reddy’s Whiz to help it through regulatory maze *(link not available)*

Scan:

Wockhardt Gets Dr Reddy's Whiz to Help it Through Regulatory Maze

DIVYA RAJAGOPAL
MUMBAI

Mumbai-based Wockhardt in an attempt to put its house in order with regards to quality issues has hired Zoher Sihorwala to lead its regulatory and compliance division, according to a close company official of Wockhardt. Sihorwala comes from Dr Reddy's where he held the position of Vice President, Global Regulatory Affairs for the past five years. Sihorwala takes charge of Wockhardt at a time when the company is battling huge reputation crises due to its poor regulatory record with the US and UK drug regulatory authorities.

Sihorwala has a tough job ahead of him since he would be responsible for clearing the regulatory issues of the company. An old hand in the industry, he has spent 20 years in the pharma business, primarily handling regulatory affairs. Sihorwala who holds a Masters of Pharmacy in Medicinal and Pharmaceutical Chemistry from the Jamia Hamdard University started his career as a junior assistant with Nicholas Piramal (now Piramal healthcare) in 1993 and then went on to work with companies like Glenmark, Cadila healthcare and Ranbaxy.

He was one of the key members of the Dr Reddy's team that successfully resolved the company's warning letter for its Mexico facility. Dr Reddy's managed to resolve the issue with the US Food and Drug Administration within a year. It is this experience that Wockhardt is banking on as the company has to pull all stops to resume its US sales.

Trouble for Wockhardt began last year as the US Food and Drug administration last year banned two large manufacturing facilities of Wockhardt at Aurangabad for violation of good manufacturing norms and practices. The ban, which halted the US exports for Wockhardt, has cost the company $500 million worth of sales.

Publication: The Asian Age
Edition: National
Journalist: Teena Thacker
Date: January 10, 2014
Headline: FDA approves tablets for obese diabetics *(link not available)*

Scan

FDA approves tablets for obese diabetics

TEENA THACKER
NEW DELHI, JAN. 9

Obese diabetics will soon have a better option to reduce their weight and blood sugar levels, with US. Food and Drug Administration (FDA) approving Farxiga (dapaglifozin) tablets to improve glycemic control, along with diet and exercise, in adults with type 2 diabetes.

Farxiga, a sodium-glucose co-transporter 2 (SGLT2) inhibitor that blocks the reabsorption of glucose by the kidney, increases glucose excretion, and lowers blood glucose levels. The drug's safety and effectiveness were evaluated in 16 clinical trials involving more than 9,400 patients with type 2 diabetes.

The trials showed improvement in HbA1c (haemoglogin A1c or glycosylated haemoglobin), a measure of blood sugar control. The drug is expected to hit the stores soon in India — one of the countries with the highest disease burden and which has over 650 brands of anti-diabetic drugs already available.

● The trials showed improvement in HbA1c (haemoglogin A1c or glycosylated haemoglobin), a measure of blood sugar control

"This class of drugs which inhibit enzyme SGLT 2 in kidneys could be useful addition to treatment of diabetes, especially in obese people, as it causes weight loss," said Anoop Misra, chairman, Fortis-C-DOC Centre of Excellence for Diabetes, Metabolic Diseases and Endocrinology.

The new drug, according to doctors, will be another option to injectable Byetta, introduced in 2008, and other oral weight-reducing diabetes drugs.

Farxiga has been studied as a stand-alone therapy and in combination with other type 2 diabetes therapies including metformin, pioglitazone, glimepiride, sitagliptin, and insulin.

Dr Misra said that the drug is an improvement over the other anti-diabetes drugs used to reduce weight and can delay insulin.

"While there is hardly any drug that can replace insulin. This drug can help delay it or avoid it in some cases," added Dr Misra.According to the US/FDA, Farxiga should not be used to treat people with type 1 diabetes; those who have increased ketones in their blood or urine (diabetic ketoacidosis); or those with moderate or severe renal impairment, end stage renal disease, or patients on dialysis.

Publication: The Economic Times
Edition: Online *(Reproduced from Reuters)*
Date: January 10, 2014
Headline: **Novartis in talks with Merck to exchange business units**

Synopsis: Novartis AG is in talks with Merck & Co Inc to exchange its animal-health and human vaccines businesses for the drugmaker's over-the-counter health-products unit, Bloomberg reported, quoting people familiar with the matter. The two drugmakers may each trade about $5 billion in assets as part of the trade, the report said. The Swiss drugmaker was ready to sell its animal health subsidiary and opened its books to Bayer and other rivals for the business that could change hands for more than 3 billion euros ($4.1 billion), sources familiar with the matter had told Reuters last month.

(also appeared in The Financial Express and Financial Chronicle)

Publication: Mint
Edition: New Delhi
Journalist: C.H. Unnikrishnan
Date: January 10, 2014
Headline: **Ranbaxy to sell Epirus arthritis biosimilar in India, emerging markets**

Synopsis: Epirus will develop and supply product, and Ranbaxy, will market it in India and other emerging markets. India's largest drugmaker by sales, Ranbaxy Laboratories Ltd, said on Thursday it had signed a licensing agreement to sell drug researcher Epirus Switzerland GmbH's copy of arthritis and rheumatic disorder drug infliximab in India and other emerging markets. Epirus' version, BOW015, is a biosimilar of the original biotechnology drug developed by US-based Janssen Biotech Inc. and sold under the brand name Remicade in global markets.

Also appeared in
Business Standard: **Ranbaxy inks licensing pact with Epirus Switzerland**

Publication: Mint
Edition: Mumbai
Journalist: Malvika Joshi
Date: January 10, 2014
Headline: **The next Infosys | Creating long-term value—Sun Pharmaceutical**

Synopsis: Sun Pharmaceutical Industries Ltd isn't a new kid on the block. The company was founded in 1983 with a manufacturing plant in the small Gujarat port town of Vapi, a product line consisting of five therapies to treat psychiatric ailments and a marketing team consisting all of two people. It's only 30 years on that the firm is hitting its stride, having become one of the world's most profitable generic drug makers—net profit for fiscal 2013 stood at Rs.516.55 crore—and India's biggest pharma company by market value. At Rs.1,21,811 crore, as of 6 December, Sun Pharma's market value is about three times that of Dr. Reddy's Laboratories Ltd, the next most valuable Indian drug maker. With $12.6 billion of personal wealth, founder and managing director Dilip Shanghvi, 58, is ranked the fifth richest person in India and 89th in the world as of 6 December, according to the Bloomberg Billionaires Index.

Also Appeared in **Hindustan Times: Sun Pharma director buys stake in Ranbaxy** *(no link available)*

Publication: The Times of India
Edition: New Delhi
Journalist: Rema Nagarajan
Date: January 10, 2014
Headline: **Order on doctors's right to be a whistleblower awaits MCI nod**

Synopsis: The Medical Council of India's (MCs) ethics committee, in its meeting in June 2013, upheld a doctor's right to be a whistleblower against members of his own profession and professional associations. However, with the

minutes of the committee's meeting not being ratified more than six months later, this significant decision is yet to come into force. The MCI's response to repeated RTI applications regarding the decisions taken in the June 28-29 ethics committee meeting has been, "the matter is under consideration".

Publication: The Times of India
Edition: National
Date: January 10, 2014
Headline: **US good competitor to India in corruption, Stiglitz says**

Synopsis: Interview with Nobel laureate and economist Joseph Stiglitz where he mentioned that the US is a good competitor to India in corruption. The US drug industry succeeded in getting a provision incorporated wherein the government cannot bargain with the industry on drug prices. That added $500 billion in costs to the government's healthcare expenditure. Such provisions happen because of campaign contributions that are a form of corruption. We tend to focus on public sector corruption, but there is corruption in the private sector.

Publication: The Times of India
Edition: New Delhi
Date: January 10, 2014
Headline: Docs told to give generic drugs *(No link availaible)*

Synopsis: All doctors working in Govt hospitals in the capital have been directed by the Delhi Govt to prescribe generic drugs and salt names and not brands. The order has been issued by SCL das, the principal secretary of the health department. Delhi's health secretary noted that this practice of was in contravention to existing policy. A common complaint from patients was that the doctors prescribed the expensive brands of medicines when cheaper, generic options that are equally effective were available.

Publication: Business Standard
Edition: New Delhi
Journalist: Sheetal Agarwal
Date: January 10, 2014
Headline: **IT, pharma rally expected to continue**

Synopsis: Notwithstanding a strong run by the S&P BSE Information Technology (up 60 per cent) and S&P BSE Healthcare (up 22 per cent) indices in 2013, most brokerages are still positive on these two sectors in 2014. While the Street view on consumer sectors remains weak, given peak valuations and slowing volumes, they remain optimistic about these two defensive sectors, on a favorable demand scenario in domestic and export markets, along with the likelihood of a weaker rupee.

Publication: Mint
Edition: New Delhi
Journalist: C.H. Unnikrishnan
Date: January 10, 2014
Headline: **Dec quarter earnings may mark turnaround for pharma industry**

Synopsis: Analysts expect the Rs.1.5 trillion industry to report a profit growth of 15%, on an average, for the December quarter. After plodding through nine difficult months that were marked by pricing uncertainty, a trade boycott and increased input costs, India's drugs and pharmaceuticals industry may have turned the corner in the final quarter of last year. Analysts expect the Rs.1.5 trillion industry to report a profit growth of 15%, on an average, for the December quarter.

Publication: The Hindu Business Line
Edition: Online
Date: January 10, 2014

Headline: Japan probes Novartis over drug advertising

Synopsis: Japan's Health Ministry on Thursday filed a criminal complaint with prosecutors against Novartis Pharma KK over alleged exaggerated advertising for a popular blood pressure drug. The local arm of the Swiss pharmaceutical giant Novartis AG apologized on its website "for causing trouble and concern" over the advertising. The company said it "took the situation extremely seriously and will continue to cooperate fully with authorities." Novartis in Tokyo used clinical studies of the drug, Diovan, by two Japanese universities that contained false data. The ministry said it suspects Novartis continued to use ads citing the studies even after they became aware that clinical data in them had been manipulated.

Publication: The Telegraph
Edition: New Delhi
Journalist: G.S. Mudur
Date: January 10, 2014
Headline: D therapy answer to diabetes risk

Synopsis: Doctors in Calcutta have suggested that vitamin D therapy can reduce the risk of onset of diabetes among people who are already susceptible to developing the disease in the first such study in India. The doctors at the Institute of Postgraduate Medical Education and Research (IPGMER) and SSKM Hospital have shown that vitamin D can delay diabetes in sections of patients who have impaired glucose tolerance. Endocrinologists have described the study's findings as significant because vitamin D deficiency and impaired glucose tolerance — a precursor to diabetes in which the body cannot efficiently mop up blood sugar despite normal insulin levels — are believed to be widely prevalent across India. The findings are published this week in the international journal Diabetes Research and Clinical Practice.

Publication: The Financial Express
Edition: New Delhi
Date: January 10, 2014
Headline: Teva picks Vigodman as CEO amid rejig efforts *(Link not available)*

Scan:

Teva picks Vigodman as CEO amid rejig efforts

Teva Pharmaceutical Industries chose board member Erez Vigodman to run the world's biggest generic drug maker, seeking to revive earnings growth and the stock after the previous CEO left in a dispute with the board. Vigodman, 54, will become president and CEO on February 11, the company said. He replaces Jeremy Levin, who left in October amid differences over how to overhaul Teva as patents expire on its top-selling product, the Copaxone multiple sclerosis drug.

Innovation

Publication: Deccan Herald
Edition: New Delhi
Date: January 10, 2014
Headline: Diagnostic network to detect fungal infections on anvil

Synopsis: As life-threatening fungal infections often go undiagnosed despite affecting lakhs of Indians, public health researchers plan to set up a nationwide network of 1,000 laboratories to pick undetected cases, besides creating a

database on the disease burden to fight the silent health threat. Fungal infection kills 150 people every hour worldwide and is a major public health threat in India. But the government does not have any data on the disease burden though these infections are common here because of conducive climate and sub-optimal hospital care. A study conducted by health researchers at Post Graduate Institute of Medical Education and Research in 27 intensive care units in large hospitals shows 10 out of every 1,000 ICU patients develop fungal infections with 50 per cent mortality, said Arunaloke Chakrabarti, professor and head of the department of medical microbiology at PGI.