

News Updates: January 18-20, 2014

## FDA / Drug Regulatory / DCGI / Pharma Policy

**Publication: The Asian Age** 

Edition: National
Date: January 20, 2014
Journalist: Olga Tellis

Headline: India's Drug Security at Risk (No link available, scan attached)

**Synopsis:** With the government ruling out any restrictions on FDI in pharma, India is on the threshold of going back to the 1970s when pharma MNCs dominated the pharma market. The Indian pharmaceutical companies have over the years been low hanging fruits for the multinational pharma companies that not only had free access to the third largest market in the world, but are the world's leading generics drug supplier. Indian companies have heralded a revolution in generics. The giant MNCs that currently have over 28.46 per cent of the India market have taken over some of the biggest names like Piramal Healthcare, Ranbaxy, Santha Biotech etc., and have strategic alliances with most of the big Indian firms for supply of branded generic formulations for their export markets in developing countries. India is on the threshold of going back to the 1970s when multinational pharma companies dominated the pharma market.

**Publication: The Times of India** 

**Edition: Bhopal** 

**Date: January 20, 2014** 

**Headline:** Labs to test free drugs random samples in process

Synopsis: Distribution of free medicines worth crores in government hospitals will now come for additional screening. Health department is in the process of appointing accredited drug testing laboratories to carry out random samples of the drugs. Currently, the government relies on certification assurance provided by the drug suppliers and state Food and Drugs Administration (FDA) for quality assurance. The later can only manage about 1,000 samples per year. Department of Public Health and Family Welfare additional director procurement Dr BS Ohri said six National Accreditation Board for Testing and Calibration Laboratories (NABL) have been roped in for the process. The department is only procuring from manufacturers who are World Health Organisation (WHO) 'good manufacturing practice' (GMP)-certified. Health officials privately admit a trust deficit in quality assurance of drugs supplied through government set-up needs to be overcome.

**Publication: The Times of India** 

Edition: New Delhi Date: January 20, 2014

**Headline: No haste in health reforms** (no online link available)

**Synopsis:** The Delhi Govt will not take any hasty decisions in health reforms and will study all subsidy models for implementation to make treatment affordable for the poor, health minister Satyendra Jain. Cost of medical treatment today has increased so much that poor people are not able to afford it, he said.

**Publication: Business Standard** 

Edition: National
Date: January 20, 2014
Journalist: Sushmi Dey

Headline: Drug regulator lets pharma firms fix own penalty

Synopsis: Pharmaceutical companies could enjoy a leeway while pricing their products, with the drug regulator facing a resource crunch in its attempt to prevent the industry from selling over-priced medicines in the retail market. Even as the Supreme Court had recently dismissed the industry's plea against prices fixed by the regulator and its timely implementation, the National Pharmaceutical Pricing Authority (NPPA) has asked companies to pay the overcharged dues with 15 per cent interest. It means, the companies have been left to calculate their own penalty. Top drug makers such as GlaxoSmithKline Pharma, Sun Pharma, Cipla and Alembic had approached various courts, including the Supreme Court last year, immediately after the price regulator started fixing prices of essential medicines according to the new price regime in May. These companies argued it was not feasible to replace or re-label older stocks with revised lower drug prices under the new pricing policy within the stipulated 45-day period.

**Publication: The Times of India** 

**Edition: National** 

Journalist: Rupali Mukherjee Date: January 18, 2014

Headline: <u>Unbranded generics way to cheaper cure</u>

**Synopsis:** States like Rajasthan and Tamil Nadu have adopted a model where they sell unbranded versions of generic medicines, eliminating marketing and distribution costs and bringing down prices by at least 30%. This could emerge as a possible mechanism for lowering prices of essential medicines and increasing their affordability across the country. The move will not only benefit patients, but companies stand to gain with expansion of the market. Certain companies charge margins as high as 300-400% on their brands, making them completely out of reach for millions in the country. The report also mentions about the new pharma policy that was implemented last year that brings down prices of essential medicines to a small extent but covers only 30% of the overall market, leaving out many exorbitantly priced brands.

## **Clinical Trials**

Publication: The Pioneer Edition: National Date: January 20, 2014

**Headline:** DCGI mandates recording in clinical trial approvals

**Synopsis:** Under constant attack from the Supreme Court for lax clinical trial norms, the Drug Controller General of India (DCGI) has finally issued draft guidelines on the audio-visual recording of informed consent process in the clinical trials to make the system more transparent. As per guidelines, before seeking an individual's consent to participate in clinical trial, the investigator must provide the individual with the all the information in a simple language to be recorded through audio-visual means. According to an official from the DCGI, the guidelines aim to make the clinical trial process more friendly to the volunteers participating in the clinical trials.

## **FDI/Pharma Industry**

**Publication: The Hindu Business Line** 

Edition: National (Opinion)
Journalist: Pradeep S. Mehta
Date: January 18, 2014

**Headline:** Don't carry on, doctor!

Synopsis: The article talks about the need to break the nexus between the pharma industry and doctors. Britain's largest pharmaceutical company, GSK, has just said it will stop offering allurements to doctors to promote their drugs. It will also stop linking the bonuses of sales staff to the number of drugs they sell. This is a much appreciated initiative from a leading player in an industry that has for long been accused of unethical sales and marketing practices by governments and regulators. In a survey carried out by CUTS International in 1995, over 2,000 prescriptions were collected by consumer groups of West Bengal, Rajasthan, Gujarat, Maharashtra, Tamil Nadu and Andhra Pradesh. The survey revealed that there was a gross tendency to prescribe useless medicines, like tonics, restoratives, vitalisers and vitamin formulations. Sixty per cent of the prescriptions were considered to be irrational in various ways. There is no direct regulation of the pharmaceutical companies which offer bribes to healthcare providers. Last year, the Department of Pharmaceuticals introduced a code for pharmaceutical marketing practices, but it is voluntary in nature. Self-regulatory measures are crucial for an industry battling scandals over its sales marketing practices.

**Publication: The Financial Express** 

Edition: National Date: January 20, 2014

Headline: Indian drug firms fare better than MNCs in '13

**Synopsis:** Domestic pharmaceutical companies including Cipla, Lupin, Glenmark and others grew 11.4% during calendar 2013, significantly outperforming their multinational counterparts, according to an industry report. Overall, MNC drug makers including Pfizer, GlaxoSmithKline, Abbott, Fresenius Kabi and others grew by only 6.5% during the year. Pfizer's cough syrup Corex, however, continued to be the top-selling brand last year, followed by Phensedyl cough syrup made by Piramal Healthcare and GSK's antibiotic Augmentin. Anti-diabetics and dermatologicals were the fastest-growing therapies in 2013, with anti-infectives lagging way behind. During calendar 2013, the pharmaceutical market was reported at R78,644 crore, up 9.9% over the same period a year earlier, according to a report from IMS Health. Essential medicines, which constitute 17% of the pharma market, showed a decline of 1.1% over the previous year due to implementation of a new price control order. The rest of the market grew at a healthy rate of 12.4%.

**Publication: The Financial Express** 

Edition: National Date: January 19, 2014

Headline: Aurobindo to buy Actavis' ops in 7 European nations

**Synopsis:** Aurobindo Pharma on Saturday said it will buy generic drug operations in seven western European companies from Dublin-based Actavis Plc for about 30 million euros, or Rs 249.81 crore as per the current exchange rate. The Hyderabad-based company will buy personnel, commercial infrastructure, products, marketing authorisations and dossier licence rights related to Actavis' operations in France, Italy, Spain, Portugal, Germany, Netherlands and Belgium. The deal will add about 1,200 finished products and an extra pipeline of over 200 products to Aurobindo's portfolio. Aurobindo said the acquired businesses are currently loss-making; however, it plans to return them to profitability. It estimated the net sales for the acquired businesses would be around 320 million euros in 2013 with a growth rate of over 10% year-on-year.

**Publication: The Times of India** 

Edition: National Date: January 20, 2014 Journalist: Rema Nagarajan

Headline: After smallpox, now Guinea worm disease to be eradicated

**Synopsis:** There were just 148 people worldwide in 2013 with the highly debilitating Guinea worm disease going by provisional estimates. This is a historic low, which holds out the promise that this could be the first disease to be eradicated after small pox. This was announced by the Carter Center established by former US president Jimmy Carter. The centre has been leading a campaign to eradicate this disease since 1986 when there were an estimated 3.5 million cases of this disease spread across 21 countries in Asia and Africa. The number of cases had been reduced by 99.9% to just 542 cases in four endemic countries by 2012. By 2013 end, it fell by a further 73% to just 148. The vast majority of cases, about 113 cases, are in South Sudan, the newly formed country torn by civil strife. 14 cases were reported from Chad, 11 from Mali and seven from Ethiopia. India was certified a Guinea worm disease free country in February 2000 by the World Health Organisation. The population across 7 states, an estimated five million people, mostly poor, illiterate and living in remote communities, were believed to be at risk from the disease. In the 1980s, over 40,000 cases of the disease were reported.

**Publication: The Times of India** 

Edition: National Date: January 19, 2014

Journalist: Padmaparna Ghosh Headline: Why Indians die

Synopsis: Death data — especially cause of death — is crucial for determining how the country spends its health budget because a death foretold is a life saved. Jha's Million Death Study (MDS), which dovetailed into the Census of India's Sample Registration System (SRS) set up to provide demographic data, has emphasized the failure of our civil death registration system, dating back to 1886, to capture deaths. Started in 2001 and aiming to cover a million 'verbal autopsies' MDS has thrown up big surprises, overturned various estimates of deaths and exposed new causes. The MDS has helped India reexamine cause of death. For instance, data from the last decade has shown that. Malaria deaths were 13 times higher than the number reported by WHO. HIV/AIDS deaths were lower than official estimates Suicides and snakebites were taking more young lives than estimated from crime or hospital records. The epidemiologist, demographer and public health researcher all agree that while sample surveys like MDS, which are expert led, are important, a civil registration system needs to be the basic source of data.

**Publication: Hindustan Times** 

**Edition: National** 

Journalist: Rhythma Kaul Date: January 20, 2014

Headline: New risks threaten young hearts (link taken from Silobreaker)

**Synopsis:** With men aged just 25 years dying of heart attacks caused by Coronary Artery Disease (CAD), health experts are making trying to identify risk factors among young people. New Delhi's Sir Ganga Ram Hospital (SGRH), for one, has identified two new biomarkers — serum Cystatin C and small dense LDL (form of "bad" cholesterol) — in the blood that help in the early diagnosis of CAD in Indians below 45 years. Biomarker, short for biological marker, is a molecule found in blood, other body fluids, or tissues that is a sign of a condition or disease. "Coronary Artery Disease in younger people is very diffused and aggressive, which makes it difficult to treat. In

medical terms, it is called premature CAD and the earlier it occurs, the severe is the form," said Dr Anjali Manocha, senior consultant, department of biochemistry, SGRH, who is also one of the authors of an Indian Council of Medical Research (ICMR)-funded study done in 2011-2013 and accepted for publication in Molecular and Cellular Biochemistry, an International Journal for Chemical Biology in Health and Disease.

**Publication: Business Standard** 

Edition: National Date: January 19, 2014

Headline: World's 1st biosimilar drug for breast cancer

**Synopsis:** Bangalore-based bio-pharmaceutical company Biocon on Saturday launched the world's first biosimilar (developed in an organism) Trastuzumab injection for the treatment of breast cancer here. This is the first drug developed by Biocon in partnership with US-based generic drug maker Mylan. The new drug, CANMAb, will be used to treat HER2-positive advanced breast cancer. Kiran Mazumdar-Shaw, chairperson and managing director, Biocon, said the company would also launch the injection in other emerging markets. The CANMab injection will compete with Roche's Herceptin. Herceptin's global sales were \$6.4 billion in 2012 and Indian \$21 million. The drug has been jointly developed out of five molecules with Mylan, since a partnership was signed in 2009. Mylan will also launch CANMab under a different brand in India.

**Publication: Business Standard** 

Edition: National Date: January 19, 2014 Journalist: Rajat Ghai

**Headline:** A virus conquered

**Synopsis:** This past week, India marked three years since its last reported polio case. As the country gets ready to be declared 'polio-free', the author looks back at a well-deserved victory. January 13, was a milestone in the medical history of India. It marked three years since the last polio case was detected in the country - that of Rukhshar Khatoon of West Bengal. The pride over this achievement will likely be doubled in the last week of March, when representatives of the South-East Asia Regional Certification Commission for Polio Eradication meet in Delhi. If the commission is convinced that there is no wild polio virus in the region and the surveillance quality is good enough to pick up any, it will certify the region as 'polio-free'. For a country whose public health system is persistently beset by problems, this development is nothing short of extra-ordinary.

**Publication: Business Standard** 

Edition: Online (Reproduced from IANS)

Date: January 20, 2014

Headline: No hasty decision on health reforms: Delhi minister

**Synopsis:** The Delhi government will not take any hasty decision in health reforms in the city and will study all subsidy models for implementation to make treatment affordable for the poor, Health Minister Satyendra Jain said Sunday. Cost of medical treatment today has increased so much that poor people are not able to afford it, he said. "Cost of treatment today is very high and it has become immensely difficult for the common man to afford it. So we have to think about ways and means to make it affordable," Jain said on the occasion of 108th birth anniversary of Dharma Vira, the first chairperson of the Sir Ganga Ram Hospital Trust. "Our agenda is to improve health care facilities in government hospitals. I have visited 21 hospitals till now and one of the areas of our immediate focus will be the cleanliness of hospitals," he said.

Publication: Deccan Herald Edition: National ( Oped) Date: January 19, 2014

Journalist: Meenakshi Gautham & Manish Pant

Headline: Health needs more care

**Synopsis**: By proposing a staggering, never-before increase of 10,000 medical seats in existing government medical colleges in five years, the Union Cabinet has made an important statement: that it is serious about health and recognises the need for swift and extraordinary strategies to improve the state of health services and human resources in India. Media reports say that this increase will improve the doctor: population ratio from 1:2000 to 1:1000, address the country's increasing burden of disease, and bring doctors to rural areas. Yes it can, but only if the government is also willing to address the numerous hidden challenges rather than follow the same old 'business as usual' paradigm in medical education. This increase needs to be understood in the context of ground realities that would impact the effective utilisation of this additional human resource.

**Publication: Deccan Herald** 

Edition: National Date: January 19, 2014

Headline: 'How many doctors it takes to fix India's healthcare glitches?

**Synopsis**: The 2006 WHO World Report, which focussed on the state of the health workforce, noted that to achieve the standard 80 per cent healthcare coverage, a country must have no less than 2.5 health workers for every 1,000 people. India currently has about 0.57 physicians and 0.6 nurses for every 1,000 persons. This constitutes a critical shortage of human resources for health, and is significantly below the WHO standard. India's mandate for Universal Health depends, to a great extent, on adequate and effective Human Resources for Health (HRH) providing care at primary, secondary and tertiary levels in both the public and private sectors.

Publication: The Hindu
Edition: New Delhi (Editorial)
Date: January 20, 2014
Journalist: K. VijayRaghavan

Headline: Genes and environment in brain development

**Synopsis:** The overlap between the behaviors of 'genes' and the 'environment' challenge the age-old debate of the apparent dichotomy between 'nature' and 'nurture'. The age distribution of India's population shows a young country, our so-called 'demographic-dividend'. Yet, poor maternal and foetal nutrition, poor sanitation, open defecation, infections and diseases — such as diabetes in mothers — severely affect the development of India's children.

**Publication: The Hindu Business Line** 

**Edition: National** 

Journalist: P.T. Jyothi Datta Date: January 18, 2014

Headline: WHO public-health programme gasping for want of donors

**Synopsis:** According to a group of former WHO directors and academics, an international public-health programme (Prequalification Programme) run by the World Health Organisation is at risk, as it is dependent on

just two international organisations for funding. Every year, billions of US dollars' worth of medicines is purchased by or through international procurement agencies and non-governmental organisations such as Unicef, Unitaid, The Global Fund, Médecins Sans Frontières and governments, for use in developing countries. The WHO PQP helps ensure that these medicines meet acceptable standards of quality, safety and efficacy. India-based generic companies, including Cipla and Ranbaxy have featured on WHO's pre-qualified list that gives countries a ready-reckoner of companies from whom they can source quality, generic drugs.

Publication: The Hindu Edition: National (Editorial) Date: January 18, 2014 Headline: Scoring over polio

**Synopsis:** India has remained free of polio, and analysis of sewage samples have not turned up any signs of the virus lurking silently in the environment. Once final tests confirm that the wild virus has not been seen here for the last three years, the World Health Organisation's 11-nation South-East Asia Region (of which India is a part) can be formally certified as polio-free. This region will then join the three that already enjoy this status: the Americas, Western Pacific and Europe. For India, this is an enormous public health achievement. Although no child in India has been paralyzed by wild polio viruses over the last three years, several have been affected during the period when live but weakened strains of the virus used in the oral polio vaccine turned virulent again. Such vaccine-derived viruses can also spread like wild ones and be just as dangerous. In order to safely withdraw oral vaccines, all countries that rely on them have been asked to introduce at least one dose of an injectable polio vaccine based on killed viruses into their routine childhood immunisation.

Publication: The Hindu Edition: National Date: January 18, 2014

**Headline: Organs transplant Act notified** 

**Synopsis:** The government has notified the Transplantation of Human Organs (Amendment) Act, 2011 that allows swapping of organs and widens the donor pool by including grandparents and grandchildren in the list. Rules of the amended law are yet to be notified, without which the Act cannot be implemented. The Act, which has come into effect in Goa, Himachal Pradesh, West Bengal, Delhi and all Union Territories from January 10, also provides for the establishment of a National Human Organs and Tissues Removal and Storage Network, and development and maintenance of a national registry of recipients of organ transplants. It also prescribes stringent punishments for commercial dealing in human organs and contravention of any provisions of the law.

**Publication: The Financial Express** 

**Edition: New Delhi** 

Journalist: Sudhir Chowdhary Date: January 20, 2014

Headline: Home healthcare is complex to execute

**Synopsis:** Ganesh Krishnan is a serial entrepreneur with four successful green field ventures and exits. Most recently, he founded and led TutorVista which was acquired by US and UK listed education leader Pearson for \$213 million in January 2011. He is a strategic investor and promoter of India-based consumer internet and ecommerce companies bluestone.com (online jewellery), Bigbasket.com (e-grocery), MustseeIndia.com (travel packages and content), bookadda.com (academic focused online books) and delyver.com (hyper local delivery).

On his new venture, he tells Sudhir Chowdhary that home healthcare is relatively a new concept in India, but with a lot of market potential. An innovative startup from Bangalore, Portea Medical, uses the latest technology and tools to accurately monitor vital parameters such as ECG, BP, and temperature and oxygen saturation, in the comfort of a patient's home. Interview Excerpts.

**Publication: The New Indian Express** 

**Edition: Online** 

Date: January 20, 2014

Headline: 83.56 percent Kids Administered Polio Drops in BBMP Limits

**Synopsis:** The first phase of the National Pulse Polio Campaign kicked off in the State on Sunday. Even with the World Health Organisation (WHO) declaring India a polio-free country and there being no cases of polio reported in Karnataka since 2004, authorities are doing their best to keep children in the State safe from the ailment. On Sunday, the first day of the campaign, over 83.56 per cent of children below the age of five were immunised in BBMP limits. While the aim was to reach and immunise 6,50,592 children in the area, the officials administered vaccination to 5,43,673 children. There were 2,094 polio booths with 8,376 volunteers. Over the next two days, the volunteers will go door-to-door administering the vaccine to make sure not a single child is left out.

**Publication: The New Indian Express** 

**Edition: Online** 

**Date: January 20, 2014** 

Headline: WHO Likely to Declare India Polio-free by End of March

**Synopsis:** With no case of polio detected in the country in the last three years, the World Health Organisation is going to declare India free from polio in February or March this year, minister for health and family welfare Kondru Murali Mohan has said. The minister, after administering polio drops to children aged below 5 years at UPHC at Chintalbasti here on Sunday, said that every parent should take care of his or her children and immunise them with two drops of polio vaccine. As many as 6,56 lakh children aged below five years, including the newborn, were administered oral polio vaccine (OPV) during the Pulse Polio Immunisation (PPI) programme held in the city on Sunday.

**Publication: Bangalore Mirror** 

Edition: Bangalore
Date: January 19, 2014
Journalist: Niranjan Kaggere

Headline: Karnataka task force gears up to nix traces of wild poliovirus

**Synopsis:** With only a few months remaining for the <u>World Health Organisation (WHO)</u> to certify India as poliofree, the Karnataka government has woken up to a new threat in the form of wild poliovirus. A task force headed by the additional chief secretary, with bureaucrats and health officials as members, is now entrusted with the responsibility to identify diagnostic centres and medical laboratories across the state on a war footing, where traces of wild poliovirus are still believed to exist. The Regional Certification Commission of WHO is expected to certify the entire South-East Asia region, including India, as polio-free in March 2014, once the final clearance of December and January laboratory samples are done. This has now put the state government on high alert mode.

**Publication: Mail Today** (Reproduced by PTI)

**Edition: New Delhi** 

Date: January 20, 2014

Page No.: 22

**Headline:** Ranbaxy & Daiichi face legal tangle

**Synopsis:** Court issues summons to top officials of two firms on criminal complaint. A COURT in Hyderabad has issued summons to top officials of Japanese multinational company Daiichi Sankyo and Indian pharma major Ranbaxy on a criminal complaint filed by a cofounder of Zenotech Laboratories, now a Ranbaxy entity. Jairam Chigurupati had approached the court alleging that senior officials and directors of Daiichi and share registrars—Karvy and ICICI Securities— acted with mala fide intention and transferred his sensitive confidential information and documents to Ranbaxy with the intent to defeat his participation in the open offer announced by Daiichi.

Publication: NDTV Edition: Online

Date: January 19, 2014

Headline: WHO to soon issue polio-free certificate to India: minister

**Synopsis:** The World Health Organisation will soon certify India as a polio-free country, Punjab Health and Family Welfare minister Surjeet Kumar Jayani said today. India no longer figures in the list of active polio virus transmission country, he said inaugurating a state-level Pulse Polio vaccination drive in Fazilka. "The WHO will soon issue polio-free country certificate to India," Jayani said. No case of polio has been reported in Punjab since 2010, he said. In view of polio cases in Pakistan, transit teams have been set up at Wagah-Attari border to ensure vaccination of children crossing the border, the minister said. Over 15,000 booths have been set up across Punjab for vaccination of 37.69 lakh children in the age group of 0-5 years during the current polio vaccination drive, he said.

## Innovation/Affordability

**Publication: The Hindu (Metroplus)** 

**Edition: New Delhi** 

Journalist: Karthik Subramanian

**Date: January 18, 2014** 

**Headline: Your health in your hands** 

**Synopsis:** The article talks about the gadgets that made a buzz at CES 2014 at Las Vegas: a smart sock that monitors every step and provides feedback to an App on your smartphone; a toothbrush that sends feedback on how well a person brushes teeth; an earphone that monitors heart rate as a person jog around a park or walk on the treadmill; and there's even a smart collar for dogs that gives feedback that the vet will find useful. The big technology companies have been targeting preventive healthcare in a focused manner for more than a decade now.

Publication: Mint Edition: New Delhi

Journalist: Deepti Bhaskaran
Date: January 20, 2014

Headline: The best insurance for your health

**Synopsis:** Health insurance is becoming the most sought after product due to rising medical costs. Buying health insurance is like walking a tight rope between price and benefits. You may feel lost given the number of products and features. To help you choose the right insurance plan, we bring to you Mint Mediclaim Ratings developed by

SecureNow Insurance Broker Pvt. Ltd. These ratings measure basic health insurance or indemnity policies on the basis of some crucial parameters.

**Publication: The Hindu Business Line** 

Edition: National (Opinion)
Author: P.M.Murali

Date: January 18, 2014

**Headline:** Inject investment into biotech

**Synopsis:** Despite this optimistic scenario for the healthcare and biotech sectors, there is a danger of the potential coming unstuck if we fail to bolster it with some critical investments. India is already the preferred destination for MNCs seeking to outsource much of their research and manufacturing activities. The development of world class research facilities and the presence of well-trained research talent will make it more attractive in this respect. Along with the right tax incentives and policies, these positive trends will cement India's status as a biotech hub. Investment in other key sub-sectors of the biotech industry namely, bioinformatics, agri-biotech and industrial biotech is also essential at this juncture of India's development.

**Publication: Financial Chronicle** 

**Edition: New Delhi** (Reproduced from PTI)

Date: January 20, 2014

Headline: PERDA proposes 25% withdrawal for NPS subscribers after 10 years (No online link available)

**Synopsis:** Pension regulator PERDA has proposed allowing subscribers of national pension system (NPS) to withdraw up to 25% of accumulated funds for meeting medical treatment expenses, higher education of children, marriage of daughters and house purchase.