OPPI

Daily News Monitor

May 7-9, 2016

1. **Parliamentary panel for penalizing those putting out misleading advertisements** – Economic Times

   A Parliamentary panel has recommended a ban on showing "misleading" advertisements on television about traditional medicines providing relief in serious ailments and suggested penalizing the offenders by amending the relevant law. The Act controls advertisements of drugs in India. It prohibits advertisements of drugs and remedies that claim to have magical properties. The Indian Medical Association (IMA) had recently issued a circular to all its 2.5 lakh members warning them not to advertise "no cure, no payment" or "guaranteed cure" claims stating both violated Medical Council of India (MCI) Code of Ethics Regulations as well as Drugs and Magic Remedies Act. "The committee recommends that the Ministry should vigorously pursue the matter of amending the said Act and Rules there under.

2. **Govt eases tax regime on royalty income of inventors** – Mint

   The 'patent box' regime seeks to tax royalty income of firms from commercialized patents at a lower rate of 10%, rather than the prevailing tax rate of 30%. To encourage more research and development activity in India, the government has made the tax regime for royalty income of inventors more liberal. As per the changes made in the patent tax regime, the government has now allowed for deduction of expenditure from income before the calculation of tax. However, if the assessee exercises this option, he will have to stay in this regime for five years. If he decides to opt out before the completion of five years due to lower profits or losses, he will not be entitled to access the concessional tax scheme for five succeeding years. Also, the government has made under reporting of income a wilful default liable for prosecution.

3. **Impacted by expansion of NLEM** – Business Standard
   Terming the expansion of National List of Essential Medicines (NLEM) 'a dampener', drug firm Pfizer said the government's move has impacted it as some of its big products coming under the revised list. The company also termed the recent move by the government to ban around 344 fixed drug combinations (FDCs) as challenging. The NLEM list impacts company's 11-12 products including major drugs like Zosyn or Claribid. Pfizer said the company also faced problems due to the government banning about 350 formulations overnight. "Yes, we are disturbed by the sudden turn of events, but we do believe the current system does recognise factual situations and therefore we are presenting our case to the court, the best of what we can," said Pfizer Ltd Managing Director S Sridhar.

4. **Indo-Japan collaboration in the field of Science & Technology** – Business Standard
   India and Japan have immense potential to further strengthen their collaboration in Science & Technology. There are several joint projects which are already in progress and more are in the planning process. The Union Minister for Science & Technology and Earth Sciences Dr. Harsh Vardhan held a meeting with the Japanese Minister for Education, Culture, Sports, Science & Technology (MEXT) Mr. Hirodie Hase in New Delhi.

5. **T N Ninan: The urge to control** – Business Standard
   T N Ninan, columnist in Business Standard focuses on the price control agenda set by government. While referring to various industries on the impact of price control in their respective areas, Ninan also refers to the steps taken by government on drug price control in the pharma sector. In 2014, the new government forced the drug price authority to roll back a decision to impose controls on the prices of a range of non-essential drugs. In the case of pharmaceuticals, those in the industry argue that irrational price controls have led to the shutting down of production in India, its place in the market taken by imports from China.

6. **China regulator to launch probe into foreign, local drug firms** – Business Standard
   China is pursuing an ambitious programme of healthcare reforms to improve the public health system and to reduce its reliance on generic and more innovative drugs from overseas. China's price regulator plans to launch a "large-scale and systematic" anti-trust investigation soon into foreign and local drug firms, state newspaper China Daily said, citing a source close to the regulator. The planned probe comes after China's state planning agency, recently summoned US pharmaceutical firm Pfizer, as well as a number of distribution companies and medical device manufacturers, to collect data and information, the newspaper said on Saturday. It said that the National Development and Reform Commission (NDRC), which wants to improve order in the drug market, is collecting evidence to see whether these companies may have violated competition regulations, though there was no proof so far that any currently do.

7. **Injecting innovation into Indian Pharma** – The Hindu Business Line
   Tie-ups with MNCs will help the industry scale up from merely replicating drugs to developing new ones. The Government is due to announce a major reform of intellectual property laws, which it sees as crucial for developing modern, high tech industries. Meanwhile, the Make in India campaign and the last Budget created a number of tax incentives and R&D initiatives aimed at increasing private and public sector research investment. If the pharmaceutical sector is to help propel India towards the next stage of economic development, it needs to be generating much more value, and that means creating medicines instead of just manufacturing copies of what's invented elsewhere. There is no reason why India cannot grow its own innovative bio-pharmaceutical sector. It has a well-developed scientific base, with a large number of highly skilled researchers and scientists. India is one of the six most bio-diverse countries, and its 7,517-km coastline has a wealth of marine organisms that could provide fertile territory for drug research. India spends just 1 per cent of its GDP on R&D, with up to 80 per cent of that money coming from the Government. By contrast, about 75 per cent of research funds in wealthy countries come from the private sector. On an average, Indians spend around $160 on healthcare (annualised, per-capita figure), of which only 25 per cent is contributed by the Government — a figure lower than many Sub-Saharan African countries. One way to accelerate the transformation of Indian pharma manufacturers into R&D companies

is for them to enter into international alliances with multinational companies. Such cross-border alliances import skills, finance and knowledge which are not always locally available, giving Indian companies a shortcut to upgrading their ability to conduct R&D.

8. **Funds to promote pharma sector** – The Hindu Business Line
   The government is taking a number of initiatives to help pharma firms upgrade technology and promote drug discovery and innovation in the country, Parliament was informed on Friday.
   The Department of Pharmaceuticals is formulating a Pharmaceutical Technology Upgradation Assistance Scheme to support the pharma industry (medium enterprises only) "to upgrade their regulatory technology compliance from Schedule M of the Dugs and Cosmetics Act, 1940 to WHO-GMP norms by facilitating low interest loans", Minister of Chemicals and Fertilisers Ananth Kumar said in a reply to the Rajya Sabha.

9. **Parenteral drug units face shortage of skilled workers** – Hindu Business Line
   Parenteral drug units in the country are facing shortage of skilled workforce, which is the greatest handicap faced by the segment of the pharma industry, and the issue should be addressed in earnest, according to Sanjith Singh Lamba, president of the India chapter of the Parenteral Drug Association, a US-based organisation. "A few major parenteral drug manufacturers such as Hospira and Dr Reddy's Labs have set up units in Visakhapatnam district. But there is vast scope for more units here, especially with the second pharma city coming up near Nakkapalli in the district," he said. The Indian chapter of PDA was formed three years ago.

10. **US on its own TRIP** - Hindu Business Line
    It has been 27 years since the USTR office launched its Special 301 report to rate other countries on their IPR regime. Although India overhauled its IPR legislation completely in 2005 and moved over to the products patent regime to honour commitments under the TRIPS agreement, its status in the Special 301 report remained the same. This year, too, India was placed in the 'priority watch' list of countries that, according to the US, need to tighten their IP laws. The US' problem with India's IPR regime has nothing to do with adherence to WTO norms. The powerful US pharmaceutical lobby has a problem with Indian pharma producers, who have managed to serve the poor not just in India but across the world. Cheap generic medicines (copied versions of drugs whose patents have expired) manufactured in India have been making medical care affordable for millions in Africa and Latin America, not to mention the US itself. With patented medicines worth several billion dollars going off-patent in the current decade, pharmaceutical giants, many US-based, are trying to evergreen their patents through cosmetic changes, and applying for fresh patents. But they have been largely unsuccessful in India. A special provision in the Indian Patents Act, Section 3 (d), allows the Indian Patents Controller to deny patents on items that are not significantly different from their older versions. Through its Special 301 report, the US is trying to push India to drop Section 3 (d). It also does not want compulsory licences to be issued for manufacture of copies of patented drugs to address situations of national emergency, as permitted by the TRIPS agreement. With the multilateral trade laws on its side and the interest of millions of poor, India should either ignore or laugh off the USTR's efforts.

11. **2,776 centres to vaccinate children, pregnant women** – Times of India
    As many as 2,776 centres in rural and urban areas in the district have been set up for the second round of the third phase of Mission Indradhanush which began on Saturday. Based on prioritization, India has been categorized in high, medium and low focus districts. It covers all children less than two years, who are either not vaccinated or are partially vaccinated against seven vaccine preventable diseases (diphtheria, whooping cough, tetanus, polio, tuberculosis, measles and hepatitis B) by 2020. Pregnant women are also vaccinated. In the first round of third phase of the mission, over 2,500 children and over 5,000 pregnant women were vaccinated at 2,673 centres in the district.

12. **New guidelines will boost cancer trails, say doctors** – Hindustan Times
    Government's latest notification on clinical trials will make the research on this rather inexpensive form of cancer treatment easier. Experts said according to the new notifications by

the ministry of health and family welfare, researchers will now not be required to take prior permission from the Drug Controller General of India (DCGI) as long as the research is approved by the ethics committee and is not intended for marketing the drug. “The new notification by the government on clinical trials will streamline the process of initiating research across the country, including Metronomics,” said Dr Shripad Banavali, professor and head, department of medical and paediatric oncology.

13. **Ranbaxy-Daiichi Singh brothers case brings to fore issue of drug quality in India** – Financial Express
    Data integrity violations are a serious concern given they are seen as evidence of poorly managed production processes and, ultimately, of poor drug quality and safety. These violations thus often lead to delayed clearances and imposition of import alerts against suspect drugs/manufacturers. Quality control issues are far more endemic in domestic drug market, as Ranbaxy whistleblower Dinesh Thakur points out with his painstaking research on the quality check ecosystem in the country. While there is no system for a nationwide recall of a substandard drug—by the time a drug is tested for quality and found to be substandard, it would have already been sold to thousands—there is also a regulatory gap in the fact that states alone can revoke or suspend production licences of manufacturers in their jurisdiction.

14. **Combination of insulin, diabetes pill can cut mortality risk** – Indian Express
    Increased dosage of insulin has been previously known to raise the risk of cancer, heart attacks and mortality. Insulin when taken in conjunction with metformin — a cheap and common drug that helps control blood sugar levels — has the potential to reduce mortality risk and heart attacks in people with Type 2 diabetes, a new study has found. Increased dosage of insulin has been previously known to raise the risk of cancer, heart attacks and mortality. But the findings have shown that metformin can attenuate the risks associated with insulin. According to researchers, there was no difference in the risk of cancer between people treated with insulin as a single therapy or in combination with metformin.

15. **Chipped treatment** – Indian Express
    The technology allows more precise and reliable clinical trials using cultured human organs. At present almost all drug-testing relies on animal tests and clinical trials. While animal testing comes with the obvious negative of how animals could respond very differently from humans to a particular drug, clinical trials are dogged by questions of ethics and costs. The technology that the University of Michigan researchers are working on, called organ-on-a-chip, uses a cultured sample of kidney cells between the top and bottom parts of a microfluidic device to almost accurately simulate human physiological environment, mirroring the biological, mechanical and biochemical properties of the organ in a human body. The study has found that the antibiotic gentamicin is more harmful to the kidneys when delivered as a continuous infusion than as one large dose.

16. **Discussion on standard patents not needed as part of IP policy: Industry** – Financial Express
    Standard Essential Patents are basic technologies that are crucial in building a product or service. With the government inviting views on new intellectual property rights through a discussion paper, industry veterans have urged the officials to keep the issue of standard essential patents out of the purview of the current consultation, since it is already covered under the Patents Act, and the patent owners and licensing companies should negotiate between them. “Adoption of any other type of SEP policy which could result in dilution of IPR value disproportionately and lead to serious jeopardy of R&D investment in India even by interested and supportive local OEMs, should be discouraged and disallowed.”

17. **CDSCO, Pharmexcil to meet PDMA, Japan to strengthen pharma trade between India & Japan** – Pharmabiz.com
    To strengthen the pharma trade between India and Japan, Central Drugs Standard Control Organisation (CDSCO) has organised a meeting with Pharmaceuticals and Medical Devices Agency (PMDA), Japan, supported by Pharmaceuticals Export Promotion Council (Pharmexcil) and other pharma associations to discuss on investment promotion, issues related to import

and export in both the countries and to exchange regulatory information. The meeting will be held on May 18-19, 2016 at CDSCO head quarter, Delhi. It is a part of the Memorandum of Understanding (MoU) signed between CDSCO and PDMA, Japan on December 11, 2015 with the objective to strengthen the relation between India and Japan with regards to medical products in line with international responsibilities. The MoU also focused on understanding the laws and regulation related to the medical product in both the countries.

18. **US FDA issues draft rules on Comparability Protocols for Human Drugs & Biologics, seeks response before July** – Pharmabiz.com
    US FDA has issued a draft guidance on Comparability Protocols for Human Drugs and Biologics: Chemistry, Manufacturing, and Controls Information. The regulatory authority expects the industry to comment and revert with the same before July 1, 2016. This guidance provides recommendations to holders of applications for human drugs and biologics on implementing a chemistry, manufacturing, and controls (CMC) post approval change through the use of a comparability protocol (CP). It replaces the draft guidance that published in February 2003, titled Comparability Protocols: Chemistry, Manufacturing, and Controls Information. According to Prema Desai, pharma consultant, the guidance is applicable to Human Drugs and Biologics for implementing a CMC post approval change through the use of a CP.