OPPI

Daily News Monitor

December 31, 2016 – January 2, 2017

1. **Medical device companies may get code respite for 6 months – The Times of India**

The Department of Pharmaceuticals (DoP), which is drafting a separate marketing code for medical device manufacturers, might give the companies six months for voluntary implementation of the code before making it statutory. Medical device manufacturers were already a part of the uniform code of pharmaceutical marketing practices (UCPMP) announced on January 1, 2015, which was to be made statutory after six months but the voluntary code has been extended indefinitely.

Following the implementation of the UCPMP, on March 9, 2015, the DoP issued a clarification that it "was also applicable to the medical devices industry".

Following this, the Association of Indian Medical Device Industry (AIMED) wrote to the DoP saying it was willing to follow the code devices. But in 2016, DoP engaged the National Health Systems Resource Centre (NHSRC), the Union health ministry's technical support institution, to draw up a code suitable for India. The first meeting to discuss the 'uniform code for medical device marketing practices' was held by the DoP with the industry on August 24, 2016, followed by another on November 5.

2. **2016: A busy year for health ministry – The Economic Times**

The health ministry dedicated a fixed day every month for free antenatal care, launched a new drug to combat multi-drug resistant tuberculosis, and deployed apps for blood banking, tobacco control, and dengue prevention among its initiatives during 2016. The year also saw conduct of a single and uniform entrance examination for admissions to virtually all government and private medical colleges, after the Supreme Court in April directed that NEET (Under Graduate) will come into effect immediately. The ministry also launched for the first time a rotavirus vaccine to reduce childhood diarrhoea, extended Japanese encephalitis immunisation to adults in high-burden districts of Assam, Uttar Pradesh, and West Bengal, and pledged a nationwide dialysis programme for patients with kidney failure. It released Rs 445 crore to 17 states to support the establishment of new medical colleges linked to district hospitals and released Rs 110 crore to upgrade 22 government medical colleges in eight states.

3. **IMA to launch awareness campaigns on vector-borne diseases – Business Standard**

The Indian Medical Association (IMA) will launch two campaigns under which all households will be visited to raise awareness on how to control vector- borne diseases like dengue, malaria and chikungunya. "Community participation is a must for vector control. No house should be left unattended. The IMA campaign against mosquito breeding, especially Aedes, will be called 'Dengwar'," said K K Aggarwal, the newly appointed President of IMA. The campaigns will termed 'Aapke ghar me machhar to nahi' and 'Katwaiga to nahi'. Aggarwal said a large number of diseases can be controlled by teaching and practising hygiene. The campign will comprise personal, food, water, sleep, hand, sexual, pet, kitchen, cough, respiratory, and mobile hygiene and its slogan will be 'Kahin mein gandagi to nahi fela raha'.

4. **Health Ministry dragged to court over curbs on TB drugs – The Economic Times**

Kaushal Kumar Tripathi, a government employee from Gaya in Bihar has been making the rounds of New Delhi's Lal Ram Swarup TB (LRS) hospital to get hold of the new tuberculosis (TB) drugs which is his last hope of saving his 18-year-old daughter suffering from Extensively Drug Resistant (XDR) TB. The drugs — Bedaquiline by US drugmaker J&J and Delamanid by Japanese drugmaker Otsuka Pharma — are the only treatment option for patients like Tripathi's daughter. However, it is not available in private markets and it is only through a donation programme that both companies have agreed to supply these drugs to Indian patients. According to the Condition Access programme signed with J&J, the health ministry will procure 600 doses of Bedaquiline, which was the first TB drug approved by USFDA after 40 years.

However, there are stringent restrictions which make the drugs out of reach of ordinary patients. For one, it will be available only at the six TB centres of Delhi, Chennai, Mumbai, Guwahati and Gujarat. Government guidelines indicate that patients who do not belong to these cities cannot access the drug. "After making several visits to LRS hospital, my daughter was refused treatment because she is not from Delhi," Kaushal Kumar told ET. Tripathi has filed a writ petition against the health ministry, asking it to ensure easier access to these drugs. The petition, which will come up for hearing at the Delhi High Court on Monday, has also made the LRS hospital a party to this case. Tripathi is represented by Anand Grover of Lawyers Collective.

5. **Hospitals dealing in radiopharma products to comply with all provisions in Act: Govt – Daily News and Analysis**

Vexed over the noncompliance of Drugs & Cosmetics Act 1940 while importing radiopharmaceutical diagnostic products, the Centre has issued notices to several hospitals across the country, asking them to immediately fulfil all provisions under the Act. Radiopharmaceutical and radioimmunoassay diagnostic products for therapeutic and diagnostic use are required in hospitals for the treatment of cancer and many other diseases. These products are regulated under the provisions of Drugs & Cosmetics Act 1940 and Rules, 1945.

Concerned over the ignorance at the end of importers, the Central Drugs Standard Control Organisation (CDSCO) under the Ministry of Health and Family Welfare convened a meeting in November 2016 with stakeholders along with experts to discuss the issues related to regulations for import of radiopharmaceutical products.

6. **Merck gets demand notice from NPPA over pricing syrup – The Hindu Business Line**

Pharmaceutical major Merck has informed the exchanges that it has received a demand notice from the National Pharmaceutical Pricing Authority (NPPA) for a sum of ₹11.68 crore plus interest of ₹15.78 crore for alleged overcharging of the formulation Polybion L 100 ML syrup, during the

period January 2006 to June 2009. The communiqué adds that the government has issued the demand notice despite the company neither being the manufacturer nor marketer of the drug. Merck said it will challenge the order and will defend itself vigorously.

7. **Lupin gets USFDA nod for pitavastatin – The Economic Times**
Drug firm Lupin has received tentative approval from the US health regulator to market its cholesterol lowering Pitavastatin tablets in the American market. The firm has received tentative approval from United States Food and Drug Administration to market its Pitavastatin tablets in the strength of 1mg, 2 mg and 4 mg, Lupin said in a filing to BSE. The tablets are generic versions of Kowa's Livalo tablets in the same strengths, it added.

As per IMS MAT September 2016 data Livalo tablets had US sales of $245.3 million, Lupin said. "Pitavastatin tablets are indicated as an adjunctive therapy to diet to reduce elevated total cholesterol, low-density lipoprotein cholesterol, apolipoprotein B, triglycerides and to increase HDL-C in adult patients with primary hyperlipidemia or mixed dyslipidemia," it added.

8. **Duterte urges Filipinos to support war on drugs, corruption – Business Standard**
Philippines President Rodrigo Duterte on Saturday urged Filipinos to support his war on drugs and corruption to attain peace in the country of more than 100 million. "I invite everyone to be our government's partners in our fight against illegal drugs, criminality and corruption, and in attaining peace and development in our country," Xinhua news agency quoted Duterte as saying in his New Year message.
"The achievement of these goals will reclaim order and safety in our communities and will enable us to restore the public's trust in government and in our people's capacity to serve," Duterte said. Nearly 6,000 suspected drug addicts and pushers have been killed since Duterte took office, prompting many Western countries like the US and the European Union to criticise the new administration. However, Duterte was unfazed by the mounting criticism, vowing to continue his bloody war on drugs until the last addict is dead.

9. **Indian medical association's annual agenda begins with autonomy for Medical Council of India – The Times of India**
The national Indian Medical Association (IMA) has listed the issue of protecting the autonomy of Medical Council of India (MCI) at the top of its agenda for the year. Among other academic, research and ethical issues related to the medical profession, it has listed capping compensation, insulation against violence by way of central Act, amendments in Clinical Establishment Act (CEA) and PCPNDT Act, and a ban on non-MBBS and non-BDS doctors prescribing modern medicines. The new agenda includes a lot of new initiatives to be taken up pan India to make health care 'available, accessible, affordable and accountable'. New IMA president Dr KK Aggarwal told TOI that the new IMA policies will be based on collaboration rather than cooperation, good plans instead of quick plans, and good governance and financial stability. The theme for this year is 'IMA 1 Voice'.

IMA will be instituting two additional constitutional awards this year. These are Dr Kishor Taori (former Maharashtra Medical Council chairman) Memorial Oration to be delivered by an eminent expert on July 1 every year on Doctors' Day, and IMA Dr Ketan Desai Medical Statesman of the Highest Order Award also to be conferred on Doctors' Day to a person for his/her consistent contribution to the cause of medical education and health profession.

10. **5 trends to watch out for in the pharma sector in 2017 – Moneycontrol.com**
It was a tough year for the pharma sector, which normally has a reputation for delivering credible returns even in tough market conditions. Pharma companies finished among the worst performers

of 2016, alongside sectors like IT, power, real estate and capital goods. From the look of it 2017 is unlikely to be any easier. Pricing pressures in US – the world's largest market for generic drugs — tighter regulatory scrutiny by the US FDA and thereby higher compliance costs, global macro-economic uncertainty and price controls back home are expected to continue in the 2017. Seen another way, 2017 could perhaps provide opportunities for investors who have been looking to buy pharma shares, but found valuations prohibitive.

11. **DoP rejects Sun Pharma's review petition against fixation of ceiling price on ondansetron tablet – Pharmabiz.com**

    The Department of Pharmaceuticals (DoP) has rejected the Sun Pharmaceutical Industries' review petition against fixing of ceiling price for the formulation 'Ondansetron 8mg tablet. Earlier, the National Pharmaceutical Pricing Authority (NPPA) had fixed the ceiling price of ondansetron 8 mg tablet vide its notification S.O. No. 2193(E)[corrected SO No.2195(E)] dated 23.06.2016 issued under Drugs (Prices Control) Order, 2013 (DPCO, 2013). Aggrieved by the notification, the Sun Pharmaceutical Industries filed a review petition against the NPPA notification.

    In the review petition, the petitioner stated that he price calculation shown in working sheet captures our 3 formulations – 2 plain tablets (zofer 8 mg tablet 4, zofer 8 mg tablet 10) and 1 mouth dissolving (MD) tablet (zofer md 8 mg tablet MD 10). As mouth dissolving tablets have added benefits over plain tablets like rapid onset of action, improved bioavailability, lesser side effects, these should not have been clubbed with plain formulation of ondansetron tablets while calculating the revised ceiling price. Hereby, we submit that we are aggrieved with this notification and, we therefore seek a review of the same under paragraph 31 of DPCO 2013.

12. **Pharma & healthcare sectors see R&D, manufacture & predictive analytics as growth drivers in 2017 – Pharmabiz.com**

    Indian pharma companies will prove its mettle in R&D and manufacture in 2017. The sector's capability holds immense potential in contract research and clinical trial segments. In the healthcare space, IoT (Internet of Things), wearable technology and remote healthcare programmes, besides predictive analytics can be used to devise a plan for personalized care where the patients can choose to customize all aspects of their healthcare. From a government perspective, there is need for a slew of initiatives like dedicated medical device regulation, Goods and Services Tax (GST), handling the issue of Fixed Dose Combinations (FDCs) at a faster pace, and the release the Uniform Code of Pharmaceutical Marketing Practices (UCPMP) guidelines and the much anticipated Drugs & Cosmetics Act 2016. The industry is also looking at new regulations and technology which transform the operations at production plants and research laboratories.