OPPI

Daily News Monitor

December 6, 2016

1. **Bid for bulk drug parks gets government's in-principle nod – Mint**

A proposal by the department of pharmaceuticals (DoP) to build multiple bulk drug parks in order to reduce dependence on raw material imports has received in-principle approval from the department of expenditure. "The availability of funds is going to be taken up with the finance ministry now," said an official, requesting anonymity.

Bulk drugs, also known as active pharmaceutical ingredients (API), are used as raw materials by the pharmaceuticals industry. Close to 80% of India's requirement is met through imports, a major chunk of it from China. APIs are the ingredients that produce the intended therapeutic effect on a patient.

The government plans to establish three bulk drugs and three medical devices parks through the public-private partnership (PPP) mode. These parks would require a combined investment of about Rs60,000 crore, chemicals and fertilizers minister Ananth Kumar said in June.

2. **Indian Medical Association may collate list of combination drugs that are 'irrational' & 'unsafe' – The Economic Times**

Now that the Delhi High Court has quashed a government ban on over 300 combination medicines, a body of doctors has asked the central drug regulator whether these medicines are unsafe and shouldn't be prescribed despite the judgment. The body says it may also collate its own list of combination drugs that are 'irrational' and 'unsafe' so that its members can avoid prescribing them. The Indian Medical Association (IMA), which represents over two lakh doctors in India, wrote to Drug Controller General of India (DCGI) GN Singh after the Delhi court's verdict, sources aware of the development told ET.

IMA's letter suggests that the ban notifications were mainly quashed over issues related to the procedure followed—that the government exercised power under the Drugs & Cosmetics Act without consulting the Drugs Technical Advisory Board and Drugs Consultative Committee.

3. **Use of antibiotic needs to be brought down – The Times of India**

There is an overall decline in antibiotic effectiveness across the world. While the US Center for Disease Control and Prevention (CDC) estimates that antibiotic resistance is responsible for more than 2 million infections and 23,000 deaths each year in the US, the `State of the

World's Antibiotics2015' estimates that 58,000 neonatal sepsis deaths are attributable to drug resistant infections in India alone. Director of the Antibiotic Resistance Action Center at the George Washington University's Milken Institute School of Public Health, Lance Price, says we need aggressive global reduction targets for antibiotic use in people and animals.

A recent study suggests contaminated meat may be spreading superbugs through the food chain and the environment, potentially causing hard-to-treat infections in people. Farms supplying India's biggest poultrymeat companies routinely use antibiotics classified by the World Health Organisation as "critically important" as a way of staving off disease. You have advised Americans to stop buying animals that are being fed antibiotics to get rid of the `superbug' syndrome.

4. **Panel suggests one-time licensing for drugs – Business Standard**

The drugs technical advisory board recently recommended one-time licensing for manufacture and sales of drugs, with a rider that there be at least one annual inspection and in cases where risk is high, more. At present, the renewal of licences for each formulation rests with state regulators and is around three years.

"It will help in 'ease of doing business' and the government's 'Make in India' initiative at a time when the country is slipping in the competitiveness index. It will give a boost to industry and give comfort to our customers," Dinesh Dua, vice-chairman of the Pharmaceuticals Export Promotion Council, told this newspaper. The board has also asked for separate rules for manufacturing, import, sale and distribution of cosmetics. It has suggested the European Union's model.

5. **MoU signed for academic exchange in global healthcare research – The Hindu**

The National Institute of Pharmaceutical Education and Research (NIPER), Kolkota, has signed a Memorandum of Understanding (MoU) with Alagappa University here to establish collaboration for research and academic exchange in 'Global healthcare research'. The MoU between Department of Biotechnology, Alagappa University, and NIPER was signed in the presence of Prof S. Subbiah, Vice-Chancellor of the university and V. Ravichandran, Director, NIPER, here on Monday, a release from the university said.

The two institutions would initially concentrate on research activities in the area of active principle testing using model system available in the department. NIPER, an autonomous body, established under the aegis of department of pharmaceuticals, Government of India, is known for promoting academic excellence and research in the areas pharmaceuticals and consumer healthcare products for the past few years, the release said.

6. **Boston Scientific's India tour showcases latest medical devices – Business Standard**

Global medical devices company Boston Scientific's 'Navigation Express' -- a mobile van showcasing ground-breaking medical innovations -- on Monday completed a tour of 130 hospitals in 52 cities in India to demonstrate the latest medical technologies to nearly 2,690 medical professionals. The Navigation Express began its tour on July 15 and covered more than 14,834 kilometres through 12 states in the past 21 weeks. "We are delighted with the successful completion of the journey of the Navigation Express," Prabal Chakraborty, Vice President and Managing Director, Boston Scientific India, said in a statement.

7. **Government lifts curbs on stocking of Tami Flu – Asian Age**

In a significant move, the government has decided to lift restrictions on stocking and selling of Osteltamivir or Tami Flu (antiviral medicine for treatment of flu/swine flu) and Zanamivir, a medication used to treat and prevent influenza caused by influenza A and B viruses, allowing lakhs of chemists across the country to sell the drug instead of a few limited ones. In a recent Drug Technical Advisory Board (DTAB) meeting, the government's chief advisory body on drugs, it was

decided to shift both drugs from Schedule X to Schedule H1, enabling the chemists to sell the drug on prescription. Earlier, the drugs were sold under Schedule X, which means to stock these medicines the chemists would have to procure a special licence besides maintaining records of every unit sold for two years.

However, the DTAB in their recent meeting, proposed amendments in Drugs and Cosmetics rules, 1945 for the inclusion of both the drugs under the appropriate schedule other than schedule X subject to the condition that "details of the manufacture and sale of the drugs should be submitted by the manufacturers to the DCGI at regular intervals and the DCGI should direct his enforcement officials to keep a strong vigil on manufacture, sale of these drugs," pointed the DTAB.

8. **Pfizer blood cancer drug tops standard therapy for untreated patients – Reuters.com**
   Pfizer Inc said on Monday its cancer drug, Bosulif, was found superior to Novartis AG's Gleevec in a late-stage study on untreated patients with a form of blood and bone marrow cancer characterized by abnormal white blood cells production. Most people with chronic myeloid leukemia (CML) have a genetic mutation, called the Philadelphia chromosome, which causes the bone marrow to make an enzyme that triggers the development of abnormal and unhealthy white blood cells. Gleevec is considered a standard-of-care therapy for these patients. Bosulif is already approved to treat adults with Philadelphia chromosome positive (Ph+) CML who are resistant or intolerant to prior therapies, including Gleevec.

9. **Advantage Health Care India 2016 – Business Standard**
   The successful launch of the inaugural edition last year, Department of Commerce, Government of India organized the second edition of Advantage Health Care India 2016 (AHCI 2016), an International Summit on Medical Value Travel with the aim of Promoting Healthcare Services Exports from India, from 3 - 5 October, 2016 at India Expo Centre & Mart, Greater Noida, NCR India.

   The objective of this international summit was to promote India as a Premier Global Healthcare Destination and to enable streamlined medical services exports from India. This underlying objective is a unique conglomeration of 5Ts, namely Tradition, Technology, Tourism, Talent and Trade.

10. **DCGI sets up advisory committee for engagement of community pharmacists in PvPI – Pharmabiz.com**
    Taking serious note of rising incidence of adverse drug reactions (ADRs) involved in over the counter (OTC) drugs, Drugs Controller General of India (DCGI) has constituted a national level advisory committee for engagement of community pharmacists in Pharmacovigilance Programme of India (PvPI).

    Pharmacists play a crucial role in healthcare system of India by assisting patients and by giving needful advise on OTC drugs. The newly constituted committee will help in framing guidelines & training modules, to identify trainer /institute for imparting training to community pharmacists, and to bridge the existing lacunae in the system.