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IPR & Innovation

Anti-microbial resistance: India wants access, resources, tech transfer spelt out in global action plan, The Times of India
The World Health Organization's draft Global Action Plan to tackle Anti-Microbial Resistance (AMR) is being criticized by the developing countries for not taking their concerns on board such as access to new antibiotics and the source of finance needed to put the plan into action. India's heath minister being the president of the 68th World Health Assembly that kicked off on Monday, there is pressure from various quarters on India to support the Global Action Plan (GAP) in its current form. Developed countries including UK and Sweden and the European Union are among those trying to push the GAP through.

Access to Healthcare

Campaign for a healthy India, Business Standard
With support from the Indian Medical Association, Alkem Chronic, a strategic business unit of Alkem Laboratories, is all set to roll out a national movement by Indian doctors with the message "A Clean India will deliver a Healthy India." The campaign will witness participation of over 20,000 doctors, 3 lakh citizens and 900 Alkem employees across 135 cities in India on May 23. The rally will be initiated at Bhagwan Mahavir Hospital and the Guru Tej Bahadur Hospital, the company said in a press release. "Improper sanitation, unhygienic habits, unclean surroundings, improper disposal of waste and open defecation drastically increase the prevalence of diseases. Over 3 lakh children die before the age of 3 every year of diarrheal illnesses. This situation is preventable and medical fraternity can play a great role in educating masses about the relationship between sanitation and health," said Mahesh Kavathekar, Vice President of Alkem Laboratories Ltd.

Medical & Regulatory

FDA writes to National Pharmaceutical Pricing Authority to regulate prices of stents, The Economic Times
The Maharashtra FDA has written to the National Pharmaceutical Pricing Authority (NPPA) to bring the cardiac stents under the Essential Commodities Act after it busted a major scam involving the import of cardiac stents. Maharashtra FDA Commissioner Harshadeep Kamble has written to the NPPA after its officers have found during investigation that cardiac stents are being sold at more than 300 to 700 % of the actual cost of the import of the cardiac stents. The Maharashtra FDA has found that the companies that import cardiac stents inflate the Maximum Retail Price (MRP) of the stents during import. The domestic distributors of these medical stents then sell the stents to hospitals at a profit margin of 125 % more than what they brought it from the importers. The hospital then again charges the patients who have to have these stents placed in them 25% more than what they paid to the distributors.

Similar reports have appeared in:
Business Standard
The Hindu Business Line
Asian Age
Mumbai Mirror
India Today
MoneyControl

Indian pharma eyes skill-based experts in regulatory affairs, occupational therapists & product marketing, Pharmabiz.com
Indian pharma industry is indicating a huge demand for experts in regulatory affairs, research & development, occupational therapists and product marketing. The sector is also showing that the salary paid is largely differentiated and is increasingly based on skills. The demand is driven by the frequent new guidelines from global and Indian regulatory authorities. The R&D personnel now need to be equipped to innovate. Occupational therapists are being hired to ensure workforce are not tied down by job-related hazards. There is new realm in product marketing with the onset of Big Data and Analytics providing ease in data volume and velocity. “There is a huge dearth of experts armed with this proficiency and skill-sets which are difficult to find, Rituparna Chakraborty, senior vice president and co-founder, TeamLease told Pharmabiz.

Lack of rules making India lose out on drug trials, The Times of India
With a huge disease burden and an emergent pharma industry, India was slated to be the world's favourite destination for outsourcing drug trials. However, today less that 2% of the world's clinical trials are taking place in the country. Considering the huge benefits of such trials for the country's healthcare, experts believe it is time the government and some home grown companies give greater importance to medical research.
Several factors including trials not being seen in a good light by people and multi-national companies not finding the methods of research efficient are responsible for fewer clinical trials in India. Researchers say that, like in several western countries, people in India need to understand the importance of these trials and demand that the government to work towards it.

CPCB directs drug units to install online system to monitor effluents, industry upset, Pharmabiz.com
Earlier in February last year, the CPCB had directed the industries to install an online monitoring system in every unit for air emissions and liquid effluents discharged. The CPCB had expressed the need to inculcate the habit of self- monitoring mechanism within the industrial units for complying the prescribed standards by the methods of installing online effluent and emission monitoring devices. Industries under 17 categories of highly polluting industries, common hazardous waste incinerators, biomedical waste incinerators and common effluents treatment plants (CETPs) operating in the state/UT are directed to install the online monitoring system for strengthening the monitoring and compliance through self-regulatory mechanism.

Health ministry to harmonise Indian Pharmacopoeia with top global pharmaceutical standards, Pharmabiz.com
In a move to strength the Indian Pharmacopoeia (IP) further, the health ministry in association with the Indian Pharmacopoeia Commission (IPC) is closely working with other key global pharmaceuticals standard setting bodies to harmonise the IP standards. It is understood that currently the authorities are identifying select monographs that are most similar to the other globally accepted ones to harmonise the same. The main agenda behind this move is to harmonise with the international pharmacopoeias in few monographs in the initial stage through bilateral dialogue between the respective governments. This will not only place IP as globally accepted standards but also will ease the business opportunities for the manufacturers.

Need to review pet ban, Pharmabiz.com
In September 2014, the union health ministry issued a notification banning the use of PET bottles for packaging of drug formulations for paediatric use, geriatric use and for use in pregnant and women of reproductive age group. The pharma companies, then, were been given a transition period of 6 months for switching over to alternate packaging medium. The health ministry’s decision to ban PET bottles is based on the recommendations of the Drugs Technical Advisory Board in line

with the concerns expressed by an expert panel headed by Dr Y K Gupta. The expert panel felt that the use of PET bottles for packaging medicines will have serious adverse effects on humans due to presence of endocrine disruptors and leaching which takes place under varying storage and temperature conditions and the age of packaging. Now more than six months have passed after the issue of the notification. No fresh direction has come from the ministry in furtherance of the September notification.

OPPI in News

NPPA asks drug firms to register with online database, Business Standard
With 32 of top 100 pharma firms not responding to its direction to register for online database, national drug price regulator, NPPA has asked pharma associations to ask their members to register immediately. National Pharmaceutical Pricing Authority (NPPA) had asked all pharma firms to register themselves with Integrated Pharmaceutical Database Management System (IPDMS) in September last year and had warned early this month to take action against the companies that had not complied with its order. "32 companies have not yet registered with the Integrated Pharmaceutical Database Management System (IPDMS)," NPPA said in a letter to pharma industry bodies. There are various bodies which represent pharmaceutical companies in India, including Indian Pharmaceutical Alliance (IPA), **Organisation of Pharmaceutical Producers of India** and Indian Drug Manufacturers' Association (IDMA).