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â€œFlashback 2013-Policy Push: Hits and Misses!â€?

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â€œFlashback 2013-Policy Push: Hits and Misses!â€?

The policymaking determines the fate of any industry in a nation as in the longer run it cannot expand and thrive without favourable and timely policies. As far as bioscience industry in India is concerned, there has been major push for research activities in pharma, agriculture and energy. However, at the same time, the lack of clear regulatory policies has almost stunted the growth of agribiotech and bioservices industry. Among the guidelines that have been developed are the prevention, management and control of reproductive tract infections including sexually transmitted infections, management of diabetes, management of three type of cancers (oral, buccal and stomach), revised nutritional guidelines.

Also the guidelines on genetically modified foods and probiotics were released. The policies in pipeline include the bill on assisted reproductive technology, a bill on recognition of alternate systems of medicine, bill on biomedical research on human participants, knowledge management policy and e-governance, national health research policy and accreditation of health research institutes.

The Positives

â—? Health research gets a major push in 12th for the department of health research (DHR) and Indian Council for Medical Research (ICMR) during
12th five year plan (2012-17). Spearheading the key initiatives in health research, the DHR and ICMR have been boosted with doubled budget allocation for the implementation of various schemes and research initiatives in the next five years. These premier medical research agencies have played a significant role in development of indigenous reagents for H1N1, indigenous vaccines for H1N1, reagents/tests for Japanese Encephalitis, dengue etc. During the last five years, altogether 20 virology laboratories have been upgraded and 16 new laboratories including 14 bio safety laboratory II level and 2 bio safety III level established for working on viral diseases and TB.

â™¦ The health ministry to relook at education regulation: In order to set standards in pharmacy education and to bring about an ethics code in pharmacy practice, the health ministry will soon review the draft on M Pharm and pharmacy practice

regulations framed by the Pharmacy Council of India (PCI). Once made functional, M Pharm regulations would help the pharmacy institutes address gaps in the delivery of education in a qualitative manner. Plan: An amount of Rs 10, 000 crore has been earmarked

â™¦ Open Source Drug Discovery crosses 7000 members mark: The OSDD community under the Council for Scientific and Industrial Research (CSIR) has reached 7074 members from 130 countries. The increasing numbers as per the team heading the initiative shows wide acceptance
of OSDD across nations.

â—? Anti-microbial resistance policy: Under the 12th initiating steps for the containment of anti-microbial resistance in the country through thirty lab networks and awareness activity for rational use of antibiotics. The government has already framed a comprehensive policy, namely, the National Policy for Containment of Antimicrobial Resistance, to address the problem of multi-drug resistance due to widespread and indiscriminate use of antimicrobial/antibiotic drugs in the country. The policy was developed by a Task Force constituted under the chairmanship of director general of health services (DGHS) to address the problem. The policy is available on the website of the ministry of health and family welfare as revealed by its minister, Ghulam Nabi Azad in the parliament on August 20, 2013. Recommend the design for creation of a national surveillance system for antibiotic resistance and to initiate studies documenting prescriptions patterns and establish a monitoring system for the same.

â—? India evolves roadmap for biological attacks: With the growing fears of biological warfare due to possible use of bio agents by terrorists, India is trying to create strong defense to handle it well in advance. While health is a state subject, National Disaster Management Authority (NDMA) has published guidelines on biological disasters including bio warfare and bio-terrorism in consultation with the ministry of home affairs and health. The guidelines have identified the bio warfare/bio terrorism agents, characteristics of these agents, epidemiological clues to identify outbreak of disease caused by them.

â—? CDSCO order on drug launch within six months: In January 2013, taking a strong stand, the Central Drugs Standard Control Organization (CDSCO) asked the drug manufacturers to either launch the particular product within a period of six months of obtaining the permission or face cancellation of licence. The drug controller general of India (DCGI), Dr GN Singh sent a notice dated January 11, 2013 o all state licensing authorities to implement the order which puts a time limit for the manufacturers or applicants to launch their products after securing permission.

â—? IP protection bill on anvil: The Science and Technology Minister, Mr Jaipal Reddy has revealed in March, 2013 that a new bill concerning the protection and utilization of public funded intellectual property is in draft stage and it contains better royalty arrangement for inventors.

â—? India publishes formula for clinical death compensation: The Central Drug Standard Organization has released the formula to determine quantum of compensation in cases of serious adverse events (SAEs) of deaths occurring during clinical trials. Compensation= B*F*R/99.37. The compensation amount for an adverse event or death would vary from a minimum of Rs 70 lakh depending on the age of the trial subject and the risk factors. The formula was developed by three Independent Expert Committees convened by the CDSCO according to the provisions of the 1 January 2013, amendment to the Drugs and Cosmetics Rules to determine the amount of compensation, if any, to be paid by the sponsor or his
representative.

The Negatives

â™¦ BRAI bill remains a dream in 2013: The introduction of the biotechnology regulatory authority of India bill was introduced in the lower house of the parliament on April 22, 2013, was witnessed curiously by the industry.But the bill continues to test the patience as it could not move further.

â™¦ NIH suspends clinical trials in India: America's top medical research center, the National Institute of Health (NIH), has suspended its clinical trials in India in the wake of the country toughening its regulatory norms.

â™¦ Standing Committee's adverse comments on PATH's project: On August 30, 2013, the Indian Parliament's Standing Committee on Health and Family Welfare released a report critical of a cervical cancer vaccine demonstration project conducted in India from 2009 to 2010 through
a collaboration among PATH, the Indian Council of Medical Research (ICMR), and the state governments of Andhra Pradesh

and Gujarat.

â™¦ Video Consent made mandatory for trials: The Union health ministry in November 2013, has made audio-visual recording of the informed consent of each subject mandatory in a clinical trial. This is in addition to obtaining his/her written consent. The order came after the Supreme Court passed an order on ensuring that audio-visual recording of the informed consent process was done and the documentation preserved, adhering to confidentiality principles.

â™¦ GEAC met after a year, only: After being unresponsive for more than one year, the Genetic Engineering Appraisal Committee met in June, 2013 and gave clearances for the field trials of several genetically modified (GM) crops.

â™¦ Supreme Court keeps the GM trials pending:

Outsider's perspective:

A report prepared for the Boston-based USA India Chamber of Commerce had identified India's clinical trial policies as one of the biggest hurdles to the country's booming pharma sector, which as per current projections is expected to grow to USD 45 billion by 2020 from the USD 18 billion today.

"While both global and Indian industry leaders opine that India's intellectual property (IP) situation needs to be addressed and clarified, they have highlighted that in fact clinical trials infrastructure and policy are the biggest obstacle for India to meet its potential of driving R&D innovation at scale," Similar views were expressed, by the industry experts at a recently held US-India Bio-Pharma and Health Care Summit 2013 in Boston organised by the USA India Chamber of Commerce, wherein they said that the current policy and is not conducive to clinical trials in India.