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Strides subsidiaries get FDA approvals

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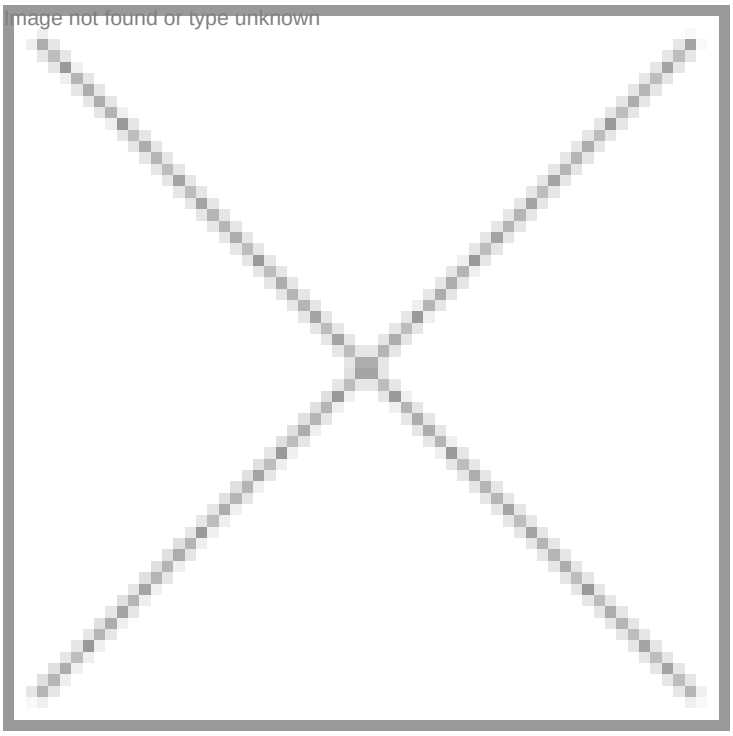

The sterile products manufacturing facility (SPD 1) of Agila in Bangalore, which was recently inspected by the US FDA as part of the routine GMP compliance audit, has been classified as acceptable. Agila Specialties is the specialties unit of Strides Arcolab, which was spun off as a separate division following the company's restructuring in 2009. It is focused on key domains such as oncolytics, penems, pencillins, cephalosporins, ophthalmics, peptides and biosimilars and operates from eight world class global manufacturing facilities, including one of the largest sterile capacity in India and amongst the largest lyophilization capacities in the world.

Another subsidiary of Strides Arcolab, Onco Therapies, received an approval for fludarabine phosphate. It is a part of the oncology portfolio licensed to Pfizer in January 2010 for the US market. Fludarabine injection is used to treat chronic lymphocytic leukemia in adults who have already been treated with at least one other medication and have not gotten better.

Transparent regulatory system soon

The Ministry of Science and Technology (S&T), India, besides working on a fresh S&T policy, is also looking at increasingthe R&D spending from the current one percent to two percent of the gross domestic product (GDP). This was revealed by Science and Technology Minister Mr Vilasrao Deshmukh at the 99th Session of Indian Science Congress.

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Mr Deshmukh further highlighted that India needed big ideas in science, new methods in governance of R&D systems, right investment of resources, aspiration to emerge as world leader in science and dedication to serve the people of India through the tools of technology and affordable innovations. He is hopeful that India will emerge as a major player in science before the end of 2017. The minister called for paradigm shift in the mindsets from 'developing policy for science' to 'developing science policy for people'.

Curb on stem cell transplants

The National Apex Committee for Stem Cell Research and Therapy (NACSCRT) has made it mandatory for stem cell transplants to be registered on clinical trials registry. The commitee has determined that only hematopoietic stem cell transplants for blood diseases and limbal stem cell transplants for corneal diseases can be performed as standard therapy outside of clinical trials in India. The committee also made it mandatory that all other forms of stem cell transplants, including those with blood or marrow derived stem cells, cord blood stem cells, mesenchymal stem cells and any embryonic stem cell derived tissue should only be used within an appropriately reviewed and monitored clinical trial that has been registered on the ICMR clinical registry. Indian institutions will have to send the information pertaining to their Institutional Committee for Stem Cell Research and Therapy as per format to the member secretary, NACSCRT.

GEAC rethinks NOC on GM trials

In view of the constraints in getting clearance from the state governments for conducting GM crops field trials, the Genetic Engineering Appraisal Committee (GEAC) may reconsider its earlier decision on the requirement of no objection certificate (NOC) from states for these research trials. On the basis of detailed deliberations, the committee concluded that the issue of non-issuance of NOC by state governments is mainly due to lack of awareness on highly technical issues associated with biotechnology and biosafety measures. However, the committee reiterated that the role of the state government is very critical for compliance monitoring and, therefore, it is important to have a dialogue with the state government to provide necessary clarification.

TDR-TB to be investigated

The Ministry of Health and Family Welfare sent a central team of doctors to Mumbai to ascertain facts about the reported cases of drug resistant tuberculosis cases. The ministry pointed out that Hinduja Hospital's lab is not accredited by the Revised National Tuberculosis Control Programme (RNTCP), for culture and sensitivity of second line drugs to diagnose extensively drug-resistant (XDR) or total drug resistant (TDR) cases. It is only accredited for conducting drug susceptibility testing (DST) by liquid culture and sensitivity for first line drug. Preliminary results of second-line DST for MDR-TB patients from DOTS plus sites and also isolates collected from Gujarat and Maharashtra drug resistance surveys show that there is not yet any XDR-TB amongst new cases and around 0.5 percent amongst re-treatment cases.