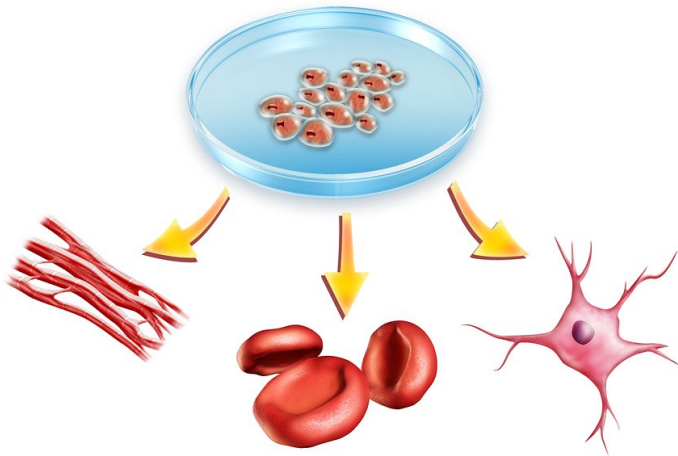


DCGI warns hospital against false stem cell treatment promises

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DCGI warns hospital against false stem cell treatment promises



In a letter dated December 11 and signed by the DCGI, Dr G N Singh the premier regulatory agency of India while issuing warning to the Pune based hospital has asked it to stop all the treatments.

The DCGI had earlier issued a notice on November 21, 2014 seeking a reply within ten days from the hospital on the issue. But the respondent failed to give any reply during the stipulated timeline. The action came after a complaint had been filed against the hospital that various stem cell treatments with high costs for Cerebral Palsy, Stroke, Wilson's Disease and Spinal cord injury were being offered to the patients.

The processing of bone marrow derived mono nuclear cells was claimed to fall under minimum manipulation category as per ICMR guidelines but it was reported that the hospital had no instrument provided which ensures aseptic processing and no documents were maintained as required in the Good Clinical Practices. Moreover, the patients were charged heavily for the treatment for period 2013 to September 2014.

Keeping that in view, the DCGI had initiated an enquiry in the matter and the team investigating the same had reported that required permission was not obtained for the clinical trials of the disease conditions. It concluded that the hospital had violated the Drugs and Cosmetics Act 1940 and Drugs and Cosmetics Rule 1945 which has a bearing on the patient safety.