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Directorate General of Health Services
Central Drugs Standard Control Organization
Biological Division

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NOTICE

Taking note of the increasing use of stem cells and other cell based therapies in recent years by clinicians in India and internationally for treatment of human diseases, the Ministry of Health and Family Welfare, Government of India had set up a Committee in June 2013 under the Chairmanship of Prof. Lalji Singh, Vice Chancellor of Banaras Hindu University, to suggest a roadmap for how the Ministry can guide and regulate the usage of stem cell and other cell based therapies in India. The Committee, after several deliberations, recently submitted its report to the Ministry. It has given detailed comments on all issues raised in its "Terms of Reference" by the Ministry and has prepared a draft Guidance Document that provides the technical and organizational details of how a regulatory framework can be setup and operated for this purpose.

The Committee has recommended three main action points: (a) amend the relevant rules in the Drugs and Cosmetics Act of 1940 so as to include stem cells and other cell based products (SCCPs) as New Drugs; (b) set up a system through specially appointed technical evaluation committees and trained examiners for examining and licensing facilities where work related to SCCP usage is being done or proposed to be done; (c) invite, evaluate and approve specific applications from companies, hospitals, research institutes and universities that propose to use SCCPs in clinical trials.

The Secretary Health and AS&DG, Ministry of Health & Family Welfare have asked DCG(I) to take urgent steps to ensure that the recommendations of the Committee are implemented at the earliest and instruments for starting the regulatory process is put in place.

The draft Guidance Document is now placed in the website of CDSCO for inviting comments from all the stakeholders within 45 days. The comments from stakeholders may be send through e-mail at dcg@nic.in


(Dr. G.N. Singh)
Drugs Controller General (India)