SRI DEVARAJ URS ACADEMY OF HIGHER EDUCATION & RESEARCH
SRI DEVARAJ URS MEDICAL COLLEGE
Tamaka, Kolar
UNIVERSITY LIBRARY & LEARNING RESOURCE CENTRE

Online Newspaper Clipping Service
Dtd- Tuesday, 01st, April- 2018

DECCAN HERALD

Page No. 08

Stem cell therapy: Health ministry wings divided

DCGI's draft notification has loopholes, claims ICMR

Kalyan Ray

NEW DELHI, DHNS: A proposal to regulate stem cell-based therapies offered by a large number of clinics across the country has split the Union Health Ministry with its two wings– DCGI and ICMR– having a sharp difference of opinion on the plan.

Earlier this month, the Drugs Controller General of India (DCGI) issued a draft notification with an objective of amending the Drugs and Cosmetics rules, 1945 to regulate stem-cell based drugs.

Homologous treatment

The draft notification excludes "homologous stem cell treatment," in which patient's own stem cells are extracted from the bone marrow and used as a drug to treat a diseases for which treatments are currently not available.

"Nearly 80-90% of the stem cell treatment offered by Indian hospitals and clinics are based on homologous (patient's own) stem cells." said Mumbai-based neurosurgeon Alok Sharma, who is the president of Stem Cell Society of India.

The DCGI notification was published without any consultation with the Indian Council of Medical Research (ICMR) that brought four national guidelines on stem-cell research and therapy since 2002, updating the scientific content each time. The last one came in October 2017.

"The draft notification has many loopholes. For instance, if it recognises stem-cell based products as drugs, then why it is silent on the dosage and modes of administration. To prove if a drug works for an indication, one has to carry out a clinical trial," said an ICMR official.

The DCGI notification excludes any regulation on the use of "minimally-manipulated cells" even for unapproved indications.

But ICMR sources said it was important to include such usages in the official notification to prevent rampant unscientific and unethical practices found in the country. The medical research agency had received several complaints in the past.

"ICMR is a research agency. It has no role in regulation. The draft notification is intended for regulating those stem-cell products that were manipulated for therapeutic purposes," S Eswara Reddy, Drugs Controller General of India, told *DH*.

Reddy claims in case of patient's own stem cells being used for treatment, there is no need for a regulation as there is "no manipulation."

ICMR officials, on the other hand, doubted the scientific veracity of such claim.

After consultations with the Department of Biotechnology, ICMR submitted its objections to the draft notifications last Saturday.

In its December 2017 guidelines, US Food and Drug Administration proposed a more relaxed regulatory approach for "minimally manipulated" human cells and tissues including stem cells.

But there are still several aspects of regulations that a clinic or doctor has to adhere to before offering such treatments.