Centre to Enact Law to Regulate Medical Devices after Consultation with States; Bill Likely In Winter Session: Dinesh Trivedi

NEW DELHI, June 11, 2010. The Centre proposes to enact a comprehensive legislation to ensure standards, safety, quality and effectiveness of medical devices. The Bill, which will be finalized after receiving the concurrence of the states, is likely to be introduced in Parliament during the monsoon session, **Mr. Dinesh Trivedi, Minister of State for Health and Family Welfare,** announced here today.

Inaugurating the **National Workshop on Medical Device Regulations in India, organised jointly by FICCI and Central Drugs Standard Control Organisation (CDSCO),** Mr. Trivedi said, "The increasing population with greater awareness and transforming disease profile of the country has resulted in an increased demand for healthcare services. Medical devices provide the means for complex diagnosis and life support systems. In view of their extensive use, it is necessary to have a proper regulatory control over medical devices so that the patients are provided with safe, affordable and effective tools of healthcare."

Mr. Trivedi also announced that the Health Ministry was venturing into setting up a National Health Portal to share information in the public domain on standardization and protocols. "Our effort would also be to ensure that the medical records of all citizens are electronically stored for ease of access by pathologists and doctors for diagnosis and treatment of patients", he declared.

He said that the Ministry had signed a MoU with the Railway Ministry for acquiring railway land for setting up diagnostic centres and hospitals at or near railway stations.

The Minister said that India had a large scientific talent and medical expertise for the manufacture and use of medical devices in the country. However, the high cost of medical devices raises healthcare costs and the objective of providing healthcare to the poor and needy patients by the government through government hospitals gets retarded. It was therefore necessary, he said, that the medical device industry grows at a faster rate and medical devices are developed indigenously at affordable costs.

Mr. Trivedi underlined the need to address basic issues of healthcare and education if GDP was to grow at a sustainable 9 per cent per annum. In this context, he said that the right to safe drinking water should be legislated upon and the mandate for ensuring this right should be given to the Health Ministry.

Dr. Surinder Singh, Drugs Controller General of India, said that the proposed law to regulate medical devices would be specific to India to cater to the country's socio-economic conditions. The role of the government would be to enforce the law and facilitate the growth of the indigenous industry.

Earlier, welcoming the participants, **Mr. V K Topa, Adivsor, FICCI,** said that both industry and regulators wanted a safe, reliable and dependable system and for this both were in sync. Industry and the government, he said, will have to team up to work out a practical implementation approach.

FICCI has suggested the development of a roadmap for training of regulators for Medical Devices. It has called for the creation of an Institutional Development Plan for Medical Devices, involving and allowing participation for the regulators to the global & regional harmonization forums such as GHTF & AHWP, to foster best practices on medical device regulations from various economies and placing dedicated manpower & develop specific and systematic training modules for CDSCO staff handling medical devices.

MEDIA DIVISION