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DCGI to come out with vaccine specific regulatory policy

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The Drugs Controller General of India, S. Eswara Reddy has announced that he plans to come out with vaccine specific regulatory policy and a manual for regulatory requirements for commercialization of new drug and how to conduct clinical trials in India.

Speaking at a symposium on ‘research and development of vaccines: issues, challenges and opportunities organized by PC2 Scientific Services, a strategic and technical consulting company in association with Federation of Asian Biotech Associations (FABA) and CR RAO AIMSCS at University of Hyderabad, he said that since pneumococcal is one of the majority vaccines, they would first come out with a policy to facilitate introducing indigenously-produced vaccines. He further listed out the steps being taken by his organization to promote innovation through transparent system and regulatory changes.

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Reddy underlined the need to communicate to media the facts about the deaths due to clinical trials. He told the gathering that media gives a wrong projection about the number of deaths.

He said that although media reports that during last 7-8 years, 25,000 patients died during clinical trials in India, the fact is that only 5 percent of these deaths are actually due to clinical trials. "For example, during clinical trials related to cancer, patients who are already in terminal stage die. The death of such patients is not due to clinical trials," he said.

With the drug developers and researchers raising concern about the restrictions on import of animal models, the Drug Controller General hoped that the Union Environment and Forests Ministry would look into the issue.

He said the import of animals was restricted by the Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA) guidelines and suggested that the innovators, industry and regulator make a joint representation on the issue.

Some participants spoke how the researchers were forced to go abroad because of non-availability of such animals in the country for studies and the restrictions on the import. Reddy said the issues was relating in the country losing its credibility and the forex reserves.

Manuel Elkin Patarroyo, the malaria vaccine scientist from Columbia, was the keynote speaker. The symposium was attended by delegates from scientific research & academic and industry both from India and abroad.

Dr. Dasari V Ravi Kumar, Director of PC2 Scientific Services, pointed out that Hyderabad is producing about 33 per cent of global vaccines dosages and 35 per cent to the pharmaceutical production in the country.