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Govt to spend Rs 1750 crore on modernizing regulator, industry welcomes move

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On August 12, 2015, the cabinet committee on economic affairs (CCEA), chaired by the Prime Minister, Mr Narendra Modi, approved the proposal for strengthening the drug regulatory system both at the central and the state levels at a total cost of Rs 1750 crore.

The note from Press Information Bureau stated that the strengthening or up-gradation of the system will be spread over a period of three years. Out of the total amount of Rs 1750 crore, an amount of Rs 900 crore will be spent on strengthening central structures that mainly includes the Central Drug Standards Organization (CDSCO). The rest of Rs 850 crore will be made available to the state governments, after signing a Memorandum of Understanding.

During his exclusive chat with BioSpectrum a few months back, Dr G N Singh, drug controller general of India (DGCI) had hinted at a revamp in offing. "2015 is going to be a year of streamlined regulations. The industry is upgrading its capacity and skills. Capacity building is a major thrust of the government of India when we are going to have the regulatory frameworks, tools, setups in place. We intend to graduate to the next level and in 2-3 years, we would be better placed. The government has taken proactive steps. We had the strength of 40 inspectors in 2008 and now it has gone upto 347. There will be the addition of 200 more in next 2 years. The basic issue is to train them as per current national and international expectations. Government is supporting us the regulations stringent yet streamlined"' he had commented.

Industry terms it positive step

In his first reaction, Dr P M Murali, president, Association of Biotechnology Led Enterprises (ABLE) expressed utmost pleasure at this decision. "ABLE is delighted to understand that the Prime Minister has decided to allocate 1750 crores for regulatory matters. This is the most forward looking activity done by any government in the past two decades. A much needed investment and the Industry is thankful," he told BioSpectrum.

Responding to BioSpectrum's Rahul Koul on Twitter, Dr Kiran Mazumdar Shaw, CMD, Biocon too was upbeat over the government's decision. On being asked whether it is enough for revamp, she mentioned, "Yes. Infact a lot has improved

within the regulatory structure and has been made more transparent and simplified."

India is one of the largest manufacturers of drugs and exports pharmaceutical products to over 200 countries or economies. The implementation of the scheme will facilitate domestic manufacture of quality medical products and help establish a robust industry in the field of medical devices, biologicals and other areas. The common training programmes for regulatory and laboratory staff will also help in evolving uniform practices throughout the country.

Where will the funds go?

The funds are expected to be strategically used to help the centre and state drug regulatory departments in their capacity building measures, like construction of new drug and food testing laboratories, expansion of the existing facilities and hiring manpower.

"The planned provision of additional funding to strengthen the drug regulatory system at both the central and state level is welcome, opined Dr Anant Bhan, researcher, Global Health and Bioethics and adjunct professor, Yenepoya University. "It's good to see that these funds will be spent on enhancing the regulatory infrastructure (labs, equipment etc) and also to hire new personnel as well as enhance training facilities," he added further.

Assistance will be provided to the states for strengthening their drug regulatory structures. The measure will help enhance quality, safety and efficacy of drugs and other medical products manufactured in the country, and thereby help mitigate the disease burden as also increase export of pharmaceutical products from India. Besides, it will also help trigger growth of the domestic medical devices sector.

Dr Jitendra Verma, managing director, Lifecare Innovations suggested the ways in which funds could be used appropriately. "There is need to identify at least five universities or academic centers for M. Pharm with curricular contents including testing/analysis, quality control, quality assurance, regulatory affairs, and pharmacovigilence, said Dr Verma. He added further, "Training centers must be created in different parts of the country for training and refresher programs of the regulatory officials and MSME personnel. Cold chain infrastructure may be strengthened to ensure uninterested cold chain from Production to consumption. Infrastructure should be strengthened to ensure un-interrupted power supply at the time of granting manufacturing licences. This authority and responsibility with accountability may be given to state drugs controllers."

The CDSCO is expected to bear the 75 per cent of total expenditure of the projects undertaken by the state drug regulatory departments will be borne by the centre, whereas 25 will have to be borne by the state governments.

Funds will help in:

âˆ?Up-gradation including provision of additional equipment and manpower in existing drug testing laboratories;
âˆ?Setting up of new laboratories for testing drugs, medical devices and cosmetics;
âˆ? Making mobile drug testing laboratories available;
âˆ? Creation of additional manpower for regulatory structures, including for new and emerging areas such as stem cell, regenerative medicine, biologicals and medical devices in addition to drugs.
âˆ? E-governance and information technology enabled online services.
âˆ? Training academy for regulatory and drug testing officials, of both the central and state governments.