



PHARMACEUTICALS EXPORT PROMOTION COUNCIL

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DoP plans state-of-the-art greenfield medical device & equipment parks to boost sector

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<http://www.pharmabiz.com/article/detnews.asp?articleid=55782§ionid=>

In order to assist the fledgling medical devices industry in the country, which is handicapped by factors like poor access to high end-technology, lack of adequate infrastructure and limited availability of skilled manpower, the Department of Pharmaceuticals (DoP) has come out with a proposal to develop Cluster Based Projects in select parts of the country.

Under the scheme, which is at the concept stage, the DoP would collaborate with state governments (or its designated agency) to set up greenfield medical device and equipment parks having state-of-the-art infrastructure and facilities. The state government is expected to provide land during phase-I of the development, expandable in a phased manner for setting up the Greenfield Medical Devices Park including the common facilities centre (CFC) at reasonable cost. The state government would provide the land for CFC (approx 5 acres) free of cost to DoP or the agency appointed by it.

Under the proposal, the DoP and the state government or its designated agencies would jointly do the screening of the entrepreneurs willing to set up units in the Park. The CFC would preferably be set up on a Public Private Partnership mode in an appropriate manner with the predetermined revenue sharing mechanism and the members of the Park would use the same on 'use and pay' basis.

The proposed Medical Devices Cluster would benefit more than 100 industries situated in the region. The outer limit of the grant to be sanctioned by the central government will be 70 per cent of the cost of the project subject to the maximum of Rs 15 crore.

The DoP's initiative on the medical devices sector comes in the wake of a Gap Analysis study conducted by the department which has found that the sector is faced with a lot of problems like lack of access to business development services (BDS) and information on quality related requirements. To attain quality certifications like ISO, CE Mark, WHO-GMP, the SMEs often lack the required information, appropriate technical training, knowledge of desired plant layout/machinery requirements, and are not able to locate affordable BDS providers to organize such activities.

Most of the SMEs are scattered in the country and these units operate either in small rented/owned premises with minimum facilities like testing laboratory, training centres for skilled manpower, etc. There is also lack of focus on R&D and innovation. Medical devices sector in general, and SMEs within the sector in particular, have no focus on R&D and new product development. Hence, the industry continues to be at a nascent stage and is dominated by imports. Due to several reasons, most of the SMEs find it convenient to import and supply to the consumers rather than getting into manufacturing.

In view of the impediments to growth, the DoP has proposed that the medical devices/medical equipments may be added as an independent definition instead of being included in the overall definition of drugs and

there is a need for separate provisions for the regulation of medical devices, instrument, apparatus, appliance, material, etc.

The DoP has issued a detailed Concept Paper on the scheme asking the industry to make suggestions and comments.