GOVERNMENT OF INDIA
CHEMICALS AND FERTILIZERS
LOK SABHA

UNSTARRED QUESTION NO:6302
ANSWERED ON:05.05.2015
PRODUCTION OF MEDICAL DEVICES
Antony Shri Anto ;Mahendran Shri C.;Mullappally Shri Ramachandran;Panda Shri Baijayant "Jay";Pradhan Shri Nagendra Kumar;Rai Shri Prem Das;Raut Shri Vinayak Bhaurao;Senguttuvan Shri Balasubramaniam;Shinde Dr. Shrikant Eknath

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:

(a) the percentage requirement of medical devices being met through indigenous production;

(b) whether the task force set up by the Government to promote/boost domestic production of high end medical devices and pharmaceutical manufacturing equipment, has submitted its reports to the Government;

(c) if so, the findings thereof and the major recommendations made by the task force and the time by which these recommendations are likely to be implemented;

(d) whether the Government proposes to create a National List of Essential Devices (NLED) on the line of National List of Essential Medicines (NLEM) and if so, the salient features and the purpose thereof along with the details of medical devices likely to be covered under the NLED; and

(e) whether the Government also proposes to set up medical devices parks in the country and if so, the details thereof and the locations identified for the purpose along with the time by which these parks are likely to be set up?

Answer

MINISTER OF STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS (SHRI HANSRAJ GANGARAM AHIR)

(a): As per the recommendation of the Task Force on the Medical Device Sector in India - 2015, about 70% of the domestic sales was met through imports.

(b) and (c): Yes, Madam. The Task Force on Medical Devices constituted by Department of Pharmaceuticals has inter-alia recommended the following:

Create necessary bodies to drive the policies.

Preferential treatment in government procurement.

Set up manufacturing hubs/ clusters in PPP mode.

Set up Medical device parks.

Financing support.

Medical device testing centers should be set up preferably in the PPP mode.

Designate `Centers of Excellence` (CoE) for supporting product development and validation.

Strengthen a made in India marking (BIS) specific to Medical devices in line with international standards like CE and FDA.

#Set up a system for IP exchange.

Set up/ promote Incubation centers.

Provide requisite financing support.

Promote industry specific `independent software vendor` by extending similar benefits.

Separate price control order for medical devices.

Discounts on import duties.

Restrictions on import of second hand diagnostic equipment/ toots.

Incentivize and promote exports in the medical devices sector..

No time frame has yet been earmark to implement the above recommendations.

(d): Central Drug Standard Control Organization (CDSCO) has set up a Core Committee for preparation of National List of Essential Medical Devices (NLEMD).

The following criteria was considered suitable for identifying medical devices for inclusion into the essential list of medical devices:

Consideration of requirement of particular medical devices in market.

Cost of treatment.

Available health delivery infrastructure (e.g. treatment facilities, training & experience of the available personnel, environment factor etc.)

Safety of Medical device.

Risk-to-benefit ratio.

Additionally medical devices required for emergency care, or use in life threatening situation was also to be considered.

(e): The Task Force on Medical Devices Sector in India-2015 had inter-alia recommended setting up of medical device parks. To begin with one such park was recommended to be promoted near Chennai.