GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:4009
ANSWERED ON:09.04.2003
BIO-TECH REGULATORY POLICY
RAJO SINGH

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) the problems being faced by the Government in the regulation of Medical bio-tech products;

(b) the problems projected before the Government by the Pharmaceutical Industries in this regard;

(c) whether the Government propose to evolve any `Regulatory System` for effective regulation of Bio-tech and Genomic Research;

(d) if so, the time by which the said system is likely to be evolved; and

(e) if not, the reasons therefor and the reasons for delay in formulating a clear bio-tech regulatory policy in the interest of our country?

Answer

MINISTER OF HEALTH AND FAMILY WELFARE AND PARLIAMENTARY AFFAIRS (SMT. SUSHMA SWARAJ)

(a) to (e) The Ministry of Environment and Forest, vide Gazette Notification No.G.S.R. 1039 dated 5th December 1989, has prescribed norms for permitting import, manufacture and marketing of DNA based bio-tech products including drugs. Under these norms, there is a multi-disciplinary procedure for evaluation of applications for medical bio-tech products.

The local manufacturers of Bio-tech drugs are initially required to seek clearance from Review Committee on Genetic Manipulation (RCGM) under Deptt. of Bio-technology, for carrying out pre-clinical animal experimentation with their products, based on examination of molecular characterization, gene manipulation techniques, impurity profile, and immuno chemical properties etc.

After RCGM clearance, and based on the pre-clinical data generated with the drug, permission to conduct human clinical trial is granted by the office of Drugs Controller General of India.

The clinical data generated by the applicant and molecular characterization etc. are then examined by an expert panel which is coordinated by DCG (I) for granting market authorisation of the drugs under the provisions of Drugs and Cosmetics Rules.

Clearance of Genetic Engineering Approval Committee (GEAC) under Ministry of Environment and Forest, is further required for manufacturing and marketing of such bio-tech products.

Keeping in view the complexity of medical bio-tech products and environmental issues, an expert panel has been set up, to advise DCG(I) for clearance of locally manufactured bio-tech drugs.