GOVERNMENT OF INDIA
ENVIRONMENT AND FORESTS
LOK SABHA

UNSTARRED QUESTION NO:3731
ANSWERED ON:23.08.2004
CLINICAL TRIALS OF PRODUCTS BY BIO-TECH COMPANIES
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Will the Minister of ENVIRONMENT AND FORESTS be pleased to state:

(a) whether the Government are aware that certain bio-tech companies are conducting Clinical trials of their products and drugs on human being without obtaining permission of Genetic Approval Engineering Committee (GAEC) which leads to the deaths in many cases;

(b) if so, the action taken by the Government against such companies; and

(c) The concrete measures taken by the Government to ensure the compliance of the provisions of Environment Protection Act by the bio-tech companies?

Answer

MINISTER OF STATE IN THE MINISTRY OF ENVIRONMENT AND F0RESTS (SHRI NAMO NARAIN MEENA)

(a & b) Some such cases were brought to the notice of the Genetic Engineering Approval Committee (GEAC). In such cases the policy of the GEAC is to look at them on a case-to-case basis on merit. If there is any evidence of a deliberate attempt on the part of the company to short circuit the GEAC clearance and derive some undue benefits thereby, the matter is viewed very seriously and punitive action under EPA initiated. However, if there is no such evidence, the procedural lapse may be condoned by the GEAC. It may be mentioned that clinical trials are essential for determining the safety and efficacy of the product before their market authorization and these are required to be conducted in accordance with the safety Protocols prescribed by the Drugs Controller General of India (DCGI) under the Drugs & Cosmetic Rules, 1945 and with the due approval of the DCGI and Human Ethics Committee. All these aspects are taken into account by the GEAC before taking a final view.

(c) The recombinant pharma products are regulated under the Rules for the Manufacture, Use/ Import/ Export and Storage of Hazardous Microorganisms/ Genetically Engineered Organisms or Cells of 1989 under the Environment (Protection) Act, 1986 (EPA) as well as the Drugs & Cosmetic Rules, 1945. These Rules cover the areas of research, development, clinical trials and the commercial usage of the product. These Rules also define the competent authorities and composition of such authorities for handling of various aspects of the rules. Detailed norms for conducting pre-clinical trials have been provided under Schedule `Y` of Drugs and Cosmetics Rules 1945. The Department of Biotechnology (DBT) has also published exhaustive guidelines on good clinical practices.