

**GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA**

UNSTARRED QUESTION NO:3615
ANSWERED ON:22.12.2004
NEW NORMS FOR PHARMACEUTICAL RESEARCH
Harsha Kumar Shri G.V.

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

(a) whether the Government is working out new norms for pharmaceutical research as reported in the Pioneer dated September 14, 2004; and

(b) if so, the details thereof?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH & FAMILY WELFARE (SMT. PANABAKA LAKSHMI)

(a) & (b) The new item published in Pioneer dated September 14, 2004 pertains to drugs produced using recombinant technology (biotech drugs) and the role of Generic Engineering Approval Committee (GEAC) concerning these products. GEAC has been set up under the provisions of Environment Protection Act and rules framed thereunder.

Ministry of Environment and Forest has set up a Task Force under Dr. R.A. Mashelkar, D.G. CSIR with a view to streamlining the regulatory process for recombinant pharma sector under the `Rules for Manufacture, Use Import, Export and Storage of hazardous micro organisms/Genetically Engineered Organisms or Cells, 1989`. The final report of the Task Force is yet to be submitted.