GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:2698
ANSWERED ON:12.03.2010
SCHEDULE Y REQUIREMENTS FOR BIOTECH DRUGS
Bali Ram Dr.

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

(a) the details of the requirements and guidelines for approval of new drugs in the country;

(b) whether the office of Drugs Controller General (India) is adhering to Schedule Y requirements while granting marketing permissions for new biotech drugs;

(c) if so, the details thereof and if not, the reasons therefor;

(d) whether Insulin formulation of Multinational Generics Biotechnology Corporation was approved without any clinical trials in the country; and

(e) if so, the reasons therefor and the action taken in this regard?

Answer

MINISTER OF THE STATE IN THE MINISTRY OF HEALTH & FAMILY WELFARE (SHRI DINESH TRIVEDI)

(a): As per the Drugs and Cosmetics Act, the applicants for the new drugs under Rule 122E are required to apply to the Drugs Controller General India as per requirements given under rule 122A, i.e. application for the permission to import new drug and 122B, i.e. application to manufacture new drugs other than the drugs classified under C and C1 wherein the applicants are required to submit the data as per Schedule Y including on clinical trials and results thereof .

(b) & (c): Yes, as per Drugs and Cosmetics Act and rules there under.

(d) & (e): The insulin formulation of M/s generics Biotechnology was approved with the condition to conduct their Post marketing Surveillance studies, by the Licensing authority , under rule 21(b) of Drugs and Cosmetics Act. There after due to the news report raising concern about the phase of clinical trial, the import permission of the said formulation was put on 'hold' for review. Permission to evaluate safety and efficacy of the said formulation was granted to M/s Shreya Life Sciences, the authorized agent of M/s Generics Biotechnology in India.