GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:3400
ANSWERED ON:29.07.2009
APPROVALS FOR CLINICAL TRIALS AND NEW DRUGS
Thamaraiselvan Shri R.

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

(a) the detailed procedure for granting approval for clinical trials and new drugs;

(b) whether there is a huge backlog/ pending applications for clinical trial approvals and new drug approval under various categories for more than ten months to two years;

(c) if so, the details thereof alongwith the reasons therefor;

(d) whether even after upgrading the systems the exact date of filing and approvals are not displayed on the official websites;

(e) if so, the details thereof and the reasons therefor; and

(f) the remedial measures being taken by the Government to rectify the system?

Answer

MINISTER OF THE STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABI AZAD)

(a): Guidelines and requirements for approval for clinical trial and new drugs are specified in Schedule Y and Rule 122A, 122B, 122D, 122DA, 122DAA & 122E of Drugs and Cosmetics Rules. The evaluation of clinical trial and new drug applications, wherein establishing safety and efficacy of the drug in human is of paramount importance, is a complex process which varies according to the nature of molecule/drug, published data and information furnished by the applicants. It involve examination of chemical & pharmaceutical information, animal pharmacological & toxicological data, clinical data of safety & efficacy, laboratory test report etc. Depending upon the nature of the application, it may take on an average 3 to 5 years for an applicant to complete all phases of trials required for approval of investigational New Drug (i.e. a drug molecule not tested on human being anywhere in the world); about 1-3 years for the first time approval of the drug already approved elsewhere but requiring confirmatory clinical trial, and about 2-3 months for subsequent applications for already approved new drugs. This is, however, subject to submission of all required data as per provisions of Schedule-Y of Drugs & Cosmetics Rules.

(b)&(c): No. During last two years, office of Drugs Controller General (India) has received about 4000 applications for approval of clinical trials and new drugs which includes investigational new drugs, new drug molecules, vaccines, biotech products, fixed dose combinations, subsequent approvals, new dosage forms, new indications, etc. During the said period about 2700 approvals for various categories of new drugs and clinical trials have been issued. Rest of the applications are at various stages of evaluation viz clinical trials, bio equivalence study, stability study, laboratory testing, seeking further information from the applicants etc.

(d) to (f): Since time required for approval of new drugs and clinical trials varies according to categories, nature of drug/diseases etc. as mentioned above, displaying of exact date of filing the application and approval does not serve any purpose.