GOVERNMENT OF INDIA
CHEMICALS AND FERTILIZERS
LOK SABHA

UNSTARRED QUESTION NO:3454
ANSWERED ON:06.08.2002
REVISION OF REGULATORY CODE FOR ANTI TB DRUG COMBINATION
NARESH KUMAR PUGLIA

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:

(a)whether the Government have revised the regulatory code for the fixed doseanti-T.B. drug combination (FDC) of refampicin, isonizzid, pyrazinamide and ethambutol;

(b)if so, the details thereof;

(c) whether any time limit has been allowed to the drug manufacturing companies to dry out their existing stock;

(d) if so, the details thereof;

(e) whether a new drug or a new FDC requires the prior approval of Central Drug Authority before licensing by States;

(f) if so, whether cases of violations of this principle by drug manufacturing companies have come to the notice of the Government; and
(g) if so, the details thereof and the action taken in case of such violations?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS (SHRI TAPAN SIKDAR)

(a)& (b):The matter of fixed dose combination of four anti-T.B. drugs, viz., Rifampicin+Isoniazid+Pyrazinamide+Ethambutol was discussed and deliberated in Drug Technical Advisory Board meeting and principally DTAB agreed for introduction of FDC of four anti T.B. drugs, as per formula recommended by the WHO and the formula included in WHO Model List of Essential Drugs.

(c) &(d): Issue of time limit will be considered at the time of notification.

(e): Yes, Sir. Under rule 122 A to E of Drugs and Cosmetics Act and Rules thereunder, new drug or new FDC require prior approval of Central Drug Authority before licensing by the States.

(f)& (g): Certain cases of violation of the above provisions made under Drugs and Cosmetics Rules were noticed and concerned State Licensing Authorities were directed to withdraw the permissions. Further the Government of India has amended the rule 69 vide notification No.GSR 311 (E) dated 1st May 2002 to restrain the StateLicensing Authority from granting the license for new drugs at their level.