GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:128
ANSWERED ON:22.02.2013
DRUG RESISTANCE
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Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether the Government had set up a Committee to make drug regulations more stringent in the light of increasing incidence of drug resistance in the country;

(b) if so, the details of the recommendations made by the Committee along with the follow up action taken/proposed by the Government thereon; and

(c) the other measures taken/proposed by the Government to arrest the rising incidence of resistance to drugs/antibiotics in the country?

Answer

MINISTER OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABI AZAD)

(a) to (c) On account of the growing public health concern regarding antimicrobial resistance in pathogens a Task Force was constituted by the Government to recommend measures to address the problem of multi drugs resistance arising out of widespread and indiscriminate use of antimicrobial drugs in the country and to assess, review and suggest measures on anti-microbial resistance. The Task Force recommended various steps to rationalize the use of antibiotics in the country. The recommendations included inter alia insertion of a separate Schedule under the Drugs and Cosmetics Rules to regulate the sale of antibiotics, curtail the availability of Fixed Dose Combinations, start colour coding of third generation of antibiotics and restrict their access only to tertiary care hospitals. It also recommended to develop standardized Antimicrobial Susceptibility Testing methodology, develop detailed Standard Operating Procedure for microbial identification and for reporting and training of doctors, etc. Based on the recommendations of the Task Force, a draft notification GSR 228 (E) dated 20.03.2012 has been published in the Gazette of India for inviting public comments on the draft amendments to the Drugs & Cosmetics Rules, 1945 for taking out all antibiotics, TB drugs and certain habit forming drugs from the existing Schedule `H` of the said Rules and putting them in a separate new Schedule `H1` stipulating that the container of the substance specified in such Schedule `H1` will be labelled with a symbol `Rx` which shall be in red colour and conspicuously displayed on the left corner of the label with the warning - `It is dangerous to take this prescription except in accordance with medical advice and not to be sold by retail without the prescription of the Registered Medical Practitioner.`