

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

UNSTARRED QUESTION NO:1188

ANSWERED ON:17.08.2012

USE OF ANTIBIOTICS

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

- (a) whether use of antibiotics has increased manifold over the last few years in the country;
- (b) if so, the details thereof;
- (c) whether the Central Drug Standard Control Organisation (CDSCO) has drawn/ proposed any plan to restrict access to certain drugs including antibiotics in the country;
- (d) if so, the details thereof along with the reasons therefor;
- (e) the fresh guidelines issued by the CDSCO for approval of bio-similar drugs;and
- (f) the number of complaints received against the Drugs Controller General of India during the last three years and the current year along with the action taken thereon?

Answer

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

(a) to (d): On account of the growing public health concern regarding antimicrobial resistance in pathogens on account of increased availability and use of antibiotics across the country meant for human, animal and industrial consumption, a Task Force was constituted by the Government to recommend measures to attend to 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 include inter alia 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 notification GSR 228 (E) dated 20.03.2012 has been published in the Gazette of India containing 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.'

(e): Fresh comprehensive guidelines on bio-similars have been uploaded on the web-site of CDSCO www.cdsc.nic.in.

(f): Some complaints have been received from various sources, including some Hon'ble Members of Parliament and an organisation, namely, 1 Citizens Awareness Council. The allegations contained in these complaints have been examined and not found to be true.