GOVERNMENT OF INDIA MINISTRY OF HEALTH AND FAMILY WELFARE DEPARTMENT OF HEALTH RESEARCH

LOK SABHA UNSTARRED QUESTION NO. 2575 TO BE ANSWERED ON 17TH MARCH, 2017

DRUG RESISTANCE

2575. SHRIMATI DARSHANA VIKRAM JARDOSH:

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

- (a) the details of bacteria/viruses found in the country that have shown signs of drug resistance in various studies carried out by ICMR or other agencies during the last three years along with the reasons therefor;
- (b) the action taken by the Government in consultation with the State Governments and other entities to contain this rising trend;
- (c) whether the Government proposes to send advisory to MCI, IMA, State Governments to curb the tendency of advising unnecessary strong antibiotics to patients thereby making them drug resistant; and
- (d) if so, the details thereof and if not, the reasons therefor?

ANSWER THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SMT. ANUPRIYA PATEL)

(a): Indian Council of Medical Research (ICMR) in 2013, set up an Anti-Microbial Resistance (AMR) surveillance network which is currently networking the tertiary care hospitals in the country.

Data obtained from across the country shows that, more than 70% Enterobacteriaceae is resistant to 3rd-generation cephalosporins. Among the Enterobacteriaceae species, Klebsiella and Escherichia coli have been found to be resistant to 3rd-generation cephalosporins (80%). A bulk of hospital-acquired infections is caused by Acinetobacter baumannii and Pseudomonas aeruginosa showing 50% resistance to carbapenems. Salmonella Typhi multidrug resistance (MDR) to ampicillin, chloramphenicol and trimethoprim – sulfamethoxazole is showing a downward trend and resistance to fluoroquinolones is increasing. The list of the pathogens covered under ICMR network covers 90% of the World Health Organisation (WHO) priority

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pathogens. The aims of establishing this network are (i) To collect nationally representative data on drug resistance and monitor trends across the country, (ii) To generate evidence on mechanisms of resistance in different pathogenic groups, (iii) To guide antimicrobial policies for both treatment and prophylaxis; and (iv) To direct hospital infection control efforts that facilitate prevention of the spread of resistant organisms.

(b): As informed by Central Drugs Standard Control Organisation (CDSCO), in order to have focused regulation on manufacture and sale of antibiotics and habit forming drugs, the Drugs & Cosmetics Rule, 1945 were amended vide Gazette Notification No GSR 588 (E) dated 30-08-2013 w.e.f. 01.03.2014 incorporating a new Schedule H1 containing 46 drugs which include 24 IIIrd & IVth generation antibiotics, 11 Anti TB drugs and 11 habit forming drugs.

The drugs falling under Schedule H1 are required to be sold in the country under the following conditions:

(1) To be labelled with the symbol Rx which shall be in red and conspicuously displayed on the left top corner of the label. It shall also be labelled with the following words in a box with a red border:

"Schedule H1 Drug-Warning:

- -It is dangerous to take this preparation except in accordance with the medical advice.
- -Not to be sold by retail without the prescription of a Registered Medical Practitioner".
- (2) The supply of a drug specified in Schedule H1 shall be recorded in a separate register at the time of the supply giving the name and address of the prescriber, the name of the patient, the name of the drug and the quantity supplied and such records shall be maintained for three years and be open for inspection.
- (c) & (d): Ministry of Health and Family Welfare (MoHFW) has identified National Center for Disease Control, New Delhi (NCDC) as a nodal agency for managing the burden of AMR in the country. NCDC developed and published National Policy for Containment of AMR in 2011. With the aim to establish a national laboratory based surveillance system by strengthening laboratories for AMR, to generate quality data on AMR for pathogens of public health relevance, and to generate awareness about rational use of antibiotics in the community and healthcare providers and to strengthen infection control guidelines and practices.

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