

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

UNSTARRED QUESTION NO:3328
ANSWERED ON:01.08.2014
STORAGE AND DISTRIBUTION OF DRUGS
Nimmala Shri Kristappa

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

- (a) whether the Central Drugs Standard Control Organisation (CDSCO) has formulated any guidelines for proper storage and distribution practices for retail chemists in the country and if so, the details thereof;
- (b) the mechanism put in place by the Government to ensure compliance of the above guidelines;
- (c) whether the Government has taken note of improper storage and distribution of drugs in violation of the prescribed guidelines by a number of retail chemists in the country and if so, the details thereof;
- (d) the number of retail chemists found guilty and penalised for the same during each of the last three years and the current year, State/UT-wise; and
- (e) the other steps being taken by the Government for compliance of good/ proper storage and distribution practices by retail chemists in the country?

Answer

THE MINISTER OF HEALTH AND FAMILY WELFARE (DR. HARSH VARDHAN)

- (a) & (b): (i) CDSCO has prepared guidelines for Good Distribution Practices for biological products which is uploaded on its website. CDSCO has also prepared draft "Guidelines on Good Distribution Practices for Pharmaceutical Products" for all entities responsible for storage, distribution of drugs in the supply chain which were uploaded on its website for comments from public/ stakeholders.
 - (ii) The objective of these guidelines is to ensure the safety, identity, strength, purity and quality of pharmaceutical products during all aspects of the distribution process. These aspects include, but are not limited to procurement, storage, distribution, transportation, documentation and record-keeping practices.
 - (iii) These guidelines are intended to be applicable to all persons and outlets involved in any aspect of the storage and distribution of pharmaceutical products from the premises of the manufacturer of the product to the person dispensing or providing pharmaceutical products directly to a patient or his or her agent.
- (c) to (e): Under the provisions of Drugs & Cosmetics Act, 1940 & Rules thereunder, the State Licensing Authorities appointed by State Governments are empowered to monitor and take action for non-compliance with respect to storage and distribution practices by retail chemists in the country. The details regarding retail chemists found guilty and having been penalised is not maintained centrally.