

- (d) whether Government will put this information in public domain;
- (e) whether Government will make it mandatory to print these OTC medicine labels with drug information such as Do's and Don'ts since OTCs can be purchased without prescription; and
- (f) whether Government will consider the international norms to print the required information on medicines with prescribed fonts and readability and the details thereof?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI ASHWINI KUMAR CHOUBEY): (a) to (f) Schedule K of the Drugs and Cosmetics Rules, 1945 already provides the list of certain medicines which are exempted from the requirements of obtaining sale license under the Drugs and Cosmetics Act and Rules made thereunder subject to the conditions as mentioned therein.

State Licensing Authorities (SCAs) appointed by respective State Governments are empowered to monitor/track the sale of drugs including the drugs allowed to be sold without prescription and take action in case of non-compliance.

Policy for disposal of expired and unused unwanted medicines

1359. SHRI KUMAR KETKAR: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

- (a) whether Government has framed any rules for disposal of date expired and unused drugs;
- (b) whether there is a Drug Take Back programme or guidelines;
- (c) whether Government has any plan to develop policy and implement it with adequate funding support; and
- (d) whether Government is considering creating awareness on issues like medicines thrown in dustbin, toilets, sinks etc. are polluting environments and are coming back to us through some or other way despite knowing very well that one of the reasons for antibiotic resistance is improper disposal of antibiotics?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI ASHWINI KUMAR CHOUBEY): (a) to (d) The manufacture, sale and distribution of drugs in the country is regulated under the provisions of Drugs and

Cosmetics Act, 1940 and Rules, 1945 thereunder through a system of licensing and inspection. Licenses for manufacture, sale and distribution of drugs are granted by the State Licensing Authorities (SLAs) appointed by respective State Governments. SLAs are legally empowered to take stringent action against violation of provisions of the Act and Rules.

Licensee is required to comply with all the conditions of licence. One of the conditions of licence states that no drug shall be sold or stocked by the licensee after the date of expiration of potency recorded on its container, label or wrapper, or in violation of any statement or direction recorded on such container, label or wrapper.

Provided that any such drug in respect of which the licensee has taken steps with the manufacturer or his representative for the withdrawal, reimbursement or disposal of the same, may be stocked after the date of expiration of pending such withdrawal, reimbursement or disposal, as the case may be, subject to the condition that the same shall be stored separately from the trade stocks and all such drugs shall be kept in packages or cartons, the top of which shall display prominently, the words - Not for sale.

One of the conditions of manufacturing license is that the manufacturing site is required to comply with the requirements of Good Manufacturing Practices prescribed in Schedule M of the Drugs and Cosmetics Rules, 1945. As per Schedule M, the disposal of sewage and effluents (Solid, liquid and gas) from manufacturing factory shall be in conformity with the requirements of Environment Pollution Control Board.

As per the Bio-Medical Waste Management Rules, 2016, discarded medicines shall be either sent back to manufacturer or disposed by incineration. Pollution control boards in States and UTs are implementing the Biomedical Waste management Rules 2016.

Extending the age of superannuation of Central Government doctors

1360. SHRI VIVEK K. TANKHA: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it is a fact that India suffers an 82 per cent shortage of specialist doctors in its community and primary health centres and has just one allopathic doctor for every 11,082 people amounting to shortage of an estimated 6,00,000 doctors and 2 million nurses;