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

LOK SABHA
UNSTARRED QUESTION NO. 3835
TO BE ANSWERED ON 25th MARCH, 2022

USE OF EXPIRED MEDICINES

3835: KUNWAR DANISH ALI:

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

(a) whether the Government is aware that expired medicines are re-used by erasing original manufacturing details and re-stamping them by the pharmaceutical companies;
(b) if so, the details thereof and the threat posed to people's health due to use of expired medicines; and
(c) the measures taken by the Government to curb such practice?

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE
(DR. BHARATI PRAVIN PAWAR)

(a) to (c): The manufacturing, sale and distribution of drugs in the country are regulated under the provisions of Drugs & Cosmetics Act, 1940 and Rules, 1945. The regulatory control over the manufacture, sale and distribution of drugs in the country is exercised through a system of licensing and inspection by the State Licensing Authorities (SLAs) appointed by the respective State Governments. Manufacturers are required to comply with the conditions of Licence granted under the said Act and Rules to manufacture any drugs for sale and distribution in the country.

One of the conditions for licensing is regarding withdrawal/recall/take back of drugs which is reproduced below:

"*the licensee shall on being informed by the Licensing Authority or the Controlling Authority that any part of any batch of the drug has been found by the Licensing Authority or the Controlling Authority not to conform with the standards of strength, quality or purity specified in these rules and on being directed so to do, withdraw the remainder of the batch from sale, and, so far as may in the particular circumstances of the case be practicable, recall all issues already made from that batch*."

The SLAs are empowered to take action on violations of any of the conditions of Licence including directing the concerned manufacturer to take back expired drugs.

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