

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

STARRED QUESTION NO:253

ANSWERED ON:13.03.2015

PET BOTTLES FOR PACKAGING OF MEDICINES

Kashyap Shri Virender;Maragatham Smt. K.

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

- (a) whether plastic or polyethylene terephthalate (PET) bottles used for storing/ packaging liquid medicines are health hazards and if so, the details thereof;
- (b) whether a number of health experts have urged the Government to impose a ban on plastic/PET bottles as primary packaging material for pharmaceutical products;
- (c) if so, the details thereof along with the action taken/proposed to be taken by the Government thereon;
- (d) whether the Government has also received representations against the ban on use of plastic/PET bottles; and
- (e) if so, the details thereof?

Answer

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI JAGAT PRAKASH NADDA)

(a) to (e): A statement is laid on the Table of the House

STATEMENT REFERRED TO IN REPLY TO LOK SABHA STARRED QUESTION NO. 253 FOR 13TH MARCH, 2015

(a) to (c): In May, 2013 and August, 2013, a Dehradun based Non-Governmental Organisation (NGO) requested that a ban be imposed on the use of Polyethylene Terephthalate (PET) bottles as primary packaging material in Pharmaceutical liquid orals, suspensions and dry syrups. The NGO claimed that use of PET bottles had severe adverse effects on human health due to presence of endocrine disruptors and leaching which takes place under varying storage and temperature conditions and the age of packaging.

The representation was considered by Drugs Technical Advisory Board (DTAB) and an Expert Committee under the Head of the Department (HOD), Department of Pharmacology, All India Institute of Medical Sciences (AIIMS), New Delhi, was constituted to examine the issues raised in the representation. In the light of the information provided by the NGO and that available in the existing literature, the Expert Committee suggested that sufficient evidence to establish a definite correlation of causality of plastic container for pharmaceutical products and adverse health effects is not established and that this was an important health concern and needed detailed investigation. It also added that the 'absence of evidence' may not be considered as 'evidence of absence' of the potential harmful effects of packaging pharmaceutical products in plastic containers.

Thereafter, a draft notification was published in the Gazette of India dated 29th September, 2014, inviting objections and suggestions from the public including all the stakeholders. The Expert Committee had also stated that scientific evidence needs to be generated over a period of time.

(d) & (e): In response to the draft notification, a large number of representations were received from various stakeholders against the proposed ban. Around 292 representations inter alia opposed the ban and stated that sufficient scientific evidence is not available about the alleged ill-effects of the use of PET bottles for packaging medicines. Some of these representations also cited studies by various agencies to claim that use of such bottles is safe and is widely used across the world. Four representations supported imposition of ban.