

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

**LOK SABHA
UNSTARRED QUESTION NO. 3396
TO BE ANSWERED ON 5TH AUGUST, 2016**

MEDICINE IN PET BOTTLES

3396. SHRI VENKATESH BABU T.G.:

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

- (a) whether the Government is aware that storing of medicines in Polyethylene Terephthalate (PET) bottles may pose threat to children and pregnant women;
- (b) if so, the details thereof;
- (c) whether the Government proposes ban on storage of medicines in the PET bottles; and
- (d) if so, the details thereof and the steps taken by the Government for any alternative arrangements in storing of medicines in the unbreakable quality and hygiene bottles?

ANSWER

**THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND
FAMILY WELFARE
(SHRI FAGGAN SINGH KULASTE)**

(a) to (d): A representation received from an NGO requesting to impose a complete ban on usage of PET bottles as primary packaging material in pharmaceutical liquid orals, suspensions and dry syrups was considered by Drugs Technical Advisory Board (DTAB). After consideration, the DTAB recommended that in the first phase, the use of plastic/PET containers in liquid oral formulations for primary packaging of paediatric formulations as well as formulations for geriatrics, women in reproductive age group and pregnant women should be phased out and banned.

The Government, accordingly, published draft Rules vide Gazette notification No. G.S.R 701 (E) dated 29.09.2014 inviting objections and suggestions of the public thereon. In response, a large number of representations were received, most of which opposed the proposed Rules. Keeping in view the fact that the issue involved a number of Ministries/Departments and there could be concerns about public health, the matter was referred to a Committee of eminent scientists, with representatives of different Ministries, to assess the health and environment impact of the use of Polyethylene Terephthalate (PET) or plastic containers for primary packaging of drug formulation and to arrive at a considered decision based on scientific evidence. The Committee in its report has, inter alia, recommended that there is no conclusive, reproducible evidence to suggest that use of PET or the additive used with it such as antimony, for pharmaceutical packaging may leach substance(s) beyond limits that pose threat to human health; there is also no conclusive, reproducible evidence that such use has ill effects on human health; and, within a robust regulatory system and process with clearly defined standards and requirements, the use of PET as packaging material for pharmaceuticals can be practiced with assurance of safety.

An application, seeking prohibition of use of plastics in consumables and pharmaceuticals, has also been filed before the National Green Tribunal (NGT) and the matter is currently sub-judice.