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

RAJYA SABHA
UNSTARRED QUESTION NO. 4144
TO BE ANSWERED ON 3RD APRIL, 2018

BANNING OF PLASTIC BOTTLED MEDICINES

4144. DR. PRADEEP KUMAR BALMUCHU:

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

(a) whether it is a fact that Statutory Authority on standard for medicines, the Drugs Technical Advisory Board which conducted laboratory tests, has recommended banning the bottling of medicines in plastic and PET bottles;

(b) if so, the details thereof; and

(c) the remedial measures being taken by Government in this regard?

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE
(SHRI ASHWINI KUMAR CHOUBEY)

(a) to (c): 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 Adivisory 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 that 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.

A study was conducted at the All India Institute of Hygiene and Public Health in which samples of five different pharmaceutical preparations packaged in PET bottles were subjected to testing at National Test House, Kolkata. It was found that Antimony, Chromium, Lead and DEHP were present at room temperature in all five samples. The concentration increased on exposure to higher temperature in the laboratory.

The matter was again deliberated in 72nd DTAB meeting held on 13.05.2016 and after deliberations; DTAB reiterated its earlier recommendations.

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.