

■ Govt gives firms 6 months to switch over **Medical firms to stop plastic container use**

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Indian pharmaceutical companies will have to stop using plastic or PET containers in liquid oral formulations meant for paediatric formulations, geriatrics, women in reproductive age group and pregnant women.

Viewing adverse effects on drug formulations packed in plastic bottles, the government has decided to ban use of plastic/PET containers in liquid oral formulations and has given six months to the companies to switch over.

The decision has been taken after concerns were raised about the safety of the plastic/pet containers used in the packing of pharmaceuticals, food and water. "The HIM JAGRITI, Uttaranchal Welfare Society, Dehradun had forwarded a representation to the secretary, ministry of health & family welfare, directorate general health service and

drug controller (I), wherein it was requested to impose a ban on polyethylene terephthalate (PET) bottles (both colour and non-colour) as primary

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packaging material in pharmaceutical liquid orals, suspensions and dry syrups with immediate effect as it has severe adverse effects on human health due to the presence of endocrine disrupters," said a senior official.

It was stated that leaching takes place under varying storage-temperature conditions and the age of the packaging (leaching becomes faster in hot/warm conditions, and also as the packaging becomes old). The leached elements can cause several diseases including cancer and physical infirmities.

The pharma industry was earlier using glass bottles only as primary packaging material for pharmaceuticals.

While, the switch over to packing in plastic / PET bottles by the industry is not based on any scientific studies to show that packing of drug formulations in

plastic/PET bottles does not have any harmful effect on the drug formulations and there are no releases of endocrine disrupters due to leaching. "India has large variation in temperatures. In summer days temperature rises to 40-45 degree centigrade and exposure of plastic bottles to such a high temperature may result in adverse effect on the drug formulations packed plastic bottles and the high temperature may result in increased leachability. The harmful effects because of the packaging and leachability may be further magnified in the case of drug formulations," said the government's chief advisory body on drugs-Drug Technical Advisory Board (DTAB).

The members therefore suggested that in first phase, the use of plastic / PET containers in liquid oral formulations for primary packaging of paediatric formulations as well as formulations meant for geriatrics, women in reproductive age group and pregnant women should be phased out and banned. The pharmaceutical industry has been given six months for smooth switch over.

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