



Regn. No. 370

Plastic Manufacturers' Association Rajasthan

(Registered Under Rajasthan Non Trading Companies Act. 1960)

F-9, Ashirwad Complex, 3-Central Spine, Vidhyadhar Nagar, Jaipur-302 039 #Ph. : 0141-2337393

E-mail : pmarjaipur@gmail.com, info@pmar.in

Website : www.pmar.in

No.PMAR/JPR/2014-15/

Dated: 15.10. 2014

To,
The Under Secretary (Drugs)
Room No 523 – A, Ministry of Health & Family Welfare,
Government of India,
NirmanBhavan, New Delhi 110011.

SUB: **Draft Rules GSR 701(E). Prohibition of Use of Polyethylene Terephthalate or Plastic containers for primary packaging of drug formulations for use in certain cases Rules, 2014.**
F. No. X.11014/10/2013-DFQC

Respected Sir,

We, the Plastic Manufacturers' Association of Rajasthan, would like bring on record our strong objection to this draft rule mentioned above.

Polyethylene Terephthalate, normally called PET, has been approved for primary packaging of Foods, Beverages and Pharmaceuticals globally. In Rajasthan, a large number of Small Scale Industries are involved in the manufacturing of PET packaging for drug formulations. In fact, in the Indian industry PET packaging is widely used for exports of pharmaceuticals since it has so many inherent advantages.

As far as health reasons are concerned, the use of PET in the pharmaceuticals industry has never been the cause of any ill effect and no adverse case has been known to be reported anywhere to the contrary. Usage of PET packaging is approved in several continents and countries as below

- In USA is governed by **USFDA CFR 21**, of US Food & Drug Administration
- In Europe by **EU regulation 10/2011** of the European Union, and
- In India by **BIS IS: 12252-1987**, Bureau of Indian Standards who have done approved the same after rigorous testing and protocol, as per the following standards:
 - i. **IS 12252-1987**: Specification for Polyethylene Terephthalate (PET & PBT) for their safe use in contact with **Foodstuffs, Pharmaceuticals** and **Drinking Water**.
 - ii. **IS 14537-1998** :PET bottles for Packaging of Alcoholic Liquors.
 - iii. **IS 9845-1998** : Determination of Overall Migration of constituents of Plastics Materials and Articles intended to come in contact with Foodstuffs – Method of Analysis.
 - iv. **IS : 101711-1999** : Guide on Suitability of Plastics for Food Packaging including Alcohol.



Plastic Manufacturers' Association Rajasthan

(Registered Under Rajasthan Non Trading Companies Act. 1960)

F-9, Ashirwad Complex, 3-Central Spine, Vidhyadhar Nagar, Jaipur-302 039 #Ph. : 0141-2337393

E-mail : pmarjaipur@gmail.com, info@pmar.in

Website : www.pmar.in

In addition PET containers are also permitted by other regulatory regimes under Food and Safety Standards Act, 2006 and the Regulations made thereunder as well as the Rules made under

Bombay Prohibition Act. Thus the use of PET bottles has been statutorily permitted and regulated after thorough evaluation and testing. The Food and Drug Administration (FDA) of USA has certified after diligent research that the PET bottles are not harmful for use, sale and storage of food, pharmaceutical & alcoholic products.

Various Government Laboratories have also certified PET for suitability as a packaging material specifically viz;

- Central Food Technological Research Institute, Mysore;
- Indian Institute of Packaging, Mumbai;
- ITALAB, Mumbai; and
- Industrial Toxicology Research Center, Lucknow.

The overall migration standards are well within the permissible limits and therefore different products can safely be packed and stored in PET bottles.

PET packaging for pharma products is covered by different pharmacopeia standards / testing procedures like USP, IP and EP. Food Safety Management System (FSMS) certificate is also available for PET material confirming to the requirements of ISO 22000:2005.

Studies made by the International Life Sciences Institute (ILSI), an international non-profit science organization based in Washington, DC, USA since 1978, conclusively state that PET has intrinsic properties that do not rely on additives and pose no threat to human health being chemically inert and non-toxic. There is also a report by EFBW (European Federation of Bottled Water), which negates the presence of endocrine disruptors in PET packaging.

PET is the eco-friendly packaging material. It has lower 'Green House Gases' (GHG) emission. PET cuts Transportation energy used in global food supply chain by half- 13.7 MJ per kg of PET as against 25.4 MJ of Glass. Also, as per a study specific to Pharma industry, 1.50 Lac of PET bottles can be transported in a container vs 90 K Glass Bottles (100 ml). Weight of PET Bottle case is ~10 times lower than Glass Bottles case. So fuel quantity goes down for transportation in PET.

Also, we would like to bring to your knowledge that interests in glass bottle trade tried to get a ban imposed on PET by misrepresenting facts through Public Interest Litigations (PIL) in the High Courts of Madhya Pradesh, Uttar Pradesh and Karnataka through different NGOs recently. We wish to inform you that all the Honorable High Courts dismissed the PIL in all the three states on grounds that PET has been tested and approved for such use.



Plastic Manufacturers' Association Rajasthan

(Registered Under Rajasthan Non Trading Companies Act. 1960)

F-9, Ashirwad Complex, 3-Central Spine, Vidhyadhar Nagar, Jaipur-302 039 #Ph. : 0141-2337393

E-mail : pmarjaipur@gmail.com, info@pmar.in

Website : www.pmar.in

To conclude, it is submitted that:

- PET with its inherent strengths such as product safety, eco-friendliness and recyclability is ideal product to be used in food, beverage and pharmaceuticals packaging.
- Consumer's preference is for hygienic, clean, comfortable, convenient & light packaging.
- PET is a universally safe and environment friendly packaging material and its use should be encouraged rather than the retrograde step envisaged by these draft rules.

Keeping in mind the "Make in India" development campaign introduced by our Honourable Prime Minister, Shri Narendra Modi, this proposed notification is a step that will take us in the wrong direction – maybe due to wrong information provided by vested interests. Innumerable Small-Medium Scale Industries would be impaired if these rules are not withdrawn.

This is an appeal on the behalf of the plastic manufacturers' of Rajasthan to bring to light the harm this rule can cause to our industry if not withdrawn.

We would be grateful if we are given an opportunity to present the facts and merits of our case in person before you.

Thanking You,

For Plastic Manufacturers' Association Rajasthan,

(SHARWAN SHARMA)
PRESIDENT