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Under Secretary (Drugs), Room No. 523-A  
Ministry of Health and Family Welfare, Government of India  
Nirman Bhavan, New Delhi – 110011  
India

Brussels, 29 October 2014

Dear Secretary of the Indian Government,

**The Gazette of India – New Delhi, the 29<sup>th</sup> September, 2014.**

**Notification of draft rules on the prohibition of Polyethylene Terephthalate (PET) or Plastics containers for primary packaging of drug formulations for use in certain cases Rules, 2014.**

Our association Petcore Europe represents the entire value chain of PET manufacturers, converters and recyclers in Europe, and we closely work together with all users of PET in the packaging sector, including pharmaceutical packaging.

The notification refers to “the prohibition of Polyethylene Terephthalate (PET) or Plastic containers”. PET is indeed one type of plastic, which we are qualified to comment on, but we cannot comment on other plastic materials, so will limit our comments to PET.

We understand fully that your mission and first duty is to protect the health of the Indian people, including the most vulnerable ones such as pregnant women and their foetus.

We recognise that you might consider that as we are not based in India and this might detract from our legitimacy in expressing views to a public consultation in your country.

We do believe, however, that you will realise, by receiving a letter from a trade Association in Europe, the considerable debate that your proposal to prohibit PET for drug formulations has started globally.

A large number of scientific studies and other information have been provided to your ministry by credible organisations, both from India and from other sources. In particular refer to the Indian Drug Manufacturer’s Association<sup>1</sup> which sent The Ministry of Health & Family Welfare very detailed and reliable scientific information on every aspect of potential concerns that your ministry may have such as high temperature exposure, endocrine disruptors, phthalates, migration and leaching etc.

We would respectfully point out that

- To the best of our information, your draft proposal is not supported by any accredited scientific evidence
- PET is approved as safe for use in food and drugs packaging worldwide including Europe, USA and Japan for instance.

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<sup>1</sup> Indian Drug Manufacturers Association dated 20th December 2013 to Dr Jagdish Prasad and cc'd to The Honorable Minister of Health & Family Welfare and the Secretary, Ministry of Family health & Welfare, Nirman Bhavan, New Delhi.



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We therefore believe that this proposed prohibition is unreliable. We also believe that it would create considerable, unnecessary and unjustified damage to the reputation of PET as a safe and essential packaging material.

We do hope that our plea will be considered with attention, and remain at your entire disposal for any further information you may wish to receive from us.

Patrick Peuch

Executive Director, Petcore Europe