

## Medical experts demand ban on PET medicinal bottles

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Medical experts from various medical institutions in Delhi on February 19, 2015, joined hands to press upon the ban on polyethylene terephthalate (PET) usage for certain medical formulations as notified by the Ministry of Health and Family Welfare within the stipulated timeframe in the wake of recent studies emanating on the various side effects. They condemned the latest move by the pharma industry to justify the use of PET bottle as safe and economical.

Research has shown that medicines packed in PET bottles are a health hazard and can have adverse effect on children, women in their reproductive age and the geriatric population. The latest evidence suggests endocrine-disrupting chemicals found in PET bottles can cause early menopause in women. As per study published in PLoS ONE journal, women with the highest levels of these chemicals in their bodies went through menopause anywhere between two and four years earlier than women with the lowest levels. The study adds to a growing body of evidence linking so-called endocrine-disrupting chemicals to a range of effects in people such as cancer, recurrent abortions, and infertility.

In a recent study published in a peer reviewed journal Carcinogenesis, it was found that terephthalic acid (TPA), a major chemical precursor of polyethylene terephthalate (PET) containers used for the storage of food and beverages, because of hormonal action increases the chances of breast cancer and also alters the response to breast cancer drugs. The study concluded that due to DNA damage the importance of human exposure to TPA, particularly at vulnerable life stages cannot be neglected.

The matter has become so grave that the European Society for Paediatric Endocrinology and the Pediatric Endocrine Society alerted physicians to the possible dangers of endocrine-disrupting chemicals and encouraged them to participate in research on their effects. Experimental animal and wildlife studies have shown that such chemicals can function as disrupters of the endocrine systems, either by interaction with hormone receptors or with hormone production and metabolism.

As per Dr Seema Singhal, Assistant Professor, Department of Obstetrics and Gynaecology, AIIMS, "PET bottles may have long term medical consequences for women, especially in the reproductive age group and children. The release of bisphenol A (BPA) and additives like di-ethylhexyl phthalate can blend with the contents and lead to health issues like impaired immune development, increased miscarriage rates, pre- term birth, low birth weight. BPA acts as a faux-estrogen, and can cause chromosomal abnormalities, birth defects and developmental disabilities in utero and childhood. Exposure to these faux-estrogens in uterus can cause early onset of puberty and increase the infant's risk of prostate or breast cancer as an adult. It may also affect the future fertility potential of a female fetus. BPA exposure is also linked with hyperactivity disorders and aggressive behaviors in young girls."

In India, PET bottles are used in 70 percent pediatric and liquid geriatric formulations. And a great majority of pregnant women are unknowingly getting exposed by use of tonics or other medicines. In a recent study conducted by Texas university published in Environmental Health Perspectives, wherein it was found that even safest BPA free PET bottles leached and it showed that more than 70 percent of the products released chemicals that acted like estrogen. And that was before they exposed the stuff to real-world conditions: simulated sunlight, dishwashing and microwaving,

Dr AP Dubey, professor and HoD Pediatrics, Maulana Azad Medical College said, "Women especially in the reproductive age group consuming medicine out of such bottles could have impaired immune development, loss of pregnancy, pre- term birth while children can suffer from low birth weight and congenital defects which could manifest in later stages of life. While the potential harmful effects of such toxins and chemicals is manifold, it is time our pharmaceutical and ancillary industry took the right cue from this government ordinance and minimized usage of plastics packaging for various liquid formulations. The new resolution by Government is really commendable as it keeps patient safety first."

Indian Medical Association's former secretary, Dr Narendra Saini said that medical effects of plastic on human health cannot be ignored. As per Dr Saini, "The pharma industry uses amber colored glass bottles in certain instances to protect medicine from being exposed to UV light. However their usage is minimal. Also, many patients tend to ignore the shelf-life mentioned on PET containers and the temperature at which drugs need to be stored which could be harmful."

PET bottles have been tested for permissible levels of phthalates, antimony, acetaldehyde etc., for storage at temperatures of around 20 degrees centigrade. This potential endocrine disruptor leaching, increases to as high as 4 times the permissible limit, at higher temperatures which are prevalent in our country. Prolonged storage beyond 120 days also results in toxic loading of the medication. A point to note is that prolonged storage also results (beyond 120 days) in toxic loading of the medication. Thus unnecessarily prolonging shelf life should also be discouraged.

As per Prof. Dr Sanjeev Bagai, Padma Shree, senior consultant Paediatrician, vice chairman and director Dwarka Manipal Hospital, "A well-functioning endocrine system is necessary to regulate the release of certain hormones essential for functions such as metabolism, growth and development, sleep and mood. External agents can alter the function(s) of this hormonal system impacting the quality of life. Because most of the symptoms come on gradually, it is difficult to figure out initially, until the problems become more pronounced and the hormones become even more imbalanced."

He added that exposure to endocrine disruptors found in PET containers can negatively impact the nervous system and lead to attention deficit or hyperactivity in children. Chemicals such as DHEP-plthalate are reasons for higher incidence of precocious puberty among young girls and genital abnormality among newborn babies."

Mr Ajay Jugran, president, Him Jagriti said, "The plastic manufacturers and some of the pharmaceutical companies do not want the act to be passed and have written to the health ministry requesting them to reconsider their decision. This is very unfortunate."

In September 2014, the government had proposed a ban on plastic (PET) containers as primary packaging in liquid oral formulations for paediatric, geriatric and reproductive healthcare use. The decision followed a PIL by HIM Jagriti, an NGO in public interest. The Government's directive to Pharmaceutical Industry also called for total ban on use of Plastic in medicines and medical equipment of all age groups as well as in all food and non-food items consumed by human beings. It also sought labeling of food & non-food items of human use as "SAFE FOR HUMAN USE."

The doctors also said that studies in India should be started immediately to collect more data.

Dr Kiran Agarwal, president, Indian Academy of Paediatrics, Delhi said, "The impact of such exposure may not be evident now but could manifest in the future, hence it is important to adopt safety measures as soon as early as possible. While we

are hopeful that the government will go ahead and implement the ban, a lot could happen before then. Until then the health of a large section of the population remains compromised."

Dr Prakash Trivedi, president, Federation of Obstetricians and Gynaecologists of India, "We urge upon the government to pass the Gazette & abolish use of Polyethylene Terephthalate or Plastic containers for primary packaging of drug formulations especially for pregnant women and in larger interest of general health of all."

Allying the fears of some pharma companies of not having to have sufficient glass bottles in the event of the ban, the glass packaging industry have assured they are completely geared up to meet the demand of the pharma industry both in terms of quality and quantity.