(2014) 11 GUJ CK 0009

In the Gujarat High Court

Case No : Special Civil Application Nos. 16639 and 16640 of 2014

Gujarat State Plastic Manufacturers Association — APPELLANT

Vs

Union of India — RESPONDENT

Date of Decision : 17-11-2014

Acts Referred:

Citation : (2014) 11 GUJ CK 0009

Hon'ble Judges : V.M. Sahai, Acting C.J.;R.P. Dholaria, J

Bench : Division Bench

Advocate : Mihir Joshi and Mihir Thakore, Sr. Advocates, Megha Jani, Advocate and Amrita Thakore, Advocate for the Appellant

Judgement

V.M. Sahai, Actg. C.J.

1. These two writ-petitions have been filed by Gujarat State Plastic Manufacturers Associations and various PET container manufacturers as well as other manufacturers challenging the decision of Drugs Technical Advisory Board dated 25.11.2013 to recommend ban of PET/plastic containers in liquid oral formulations for primary packaging of pediatric formulation as well as formulation meant for use of geriatric, women of reproductive age group and pregnant women as well as the Notification dated 29th September, 2014 issued by the Central Government of accepting recommendations of Drugs Technical Advisory Board.

2. As common issue is involved in both these petitions, both the petitions are taken up and heard together.

3. For the sake of brevity, facts are taken from the Special Civil Application No. 16639 of 2014.

4. Brief facts leading to filing of the present petitions are that a letter/ representation dated 6th May, 2013 was written by Him Jagriti Uttaranchal Welfare Society, an NGO, addressed to the Department of Health and Family

Welfare and others, objecting to use of PET/plastic bottles in packaging of pharmaceutical liquids on the ground that the same is hazardous to the public health as well as to the environment. The said letter was examined by the Drugs Technical Advisory Board in its meeting held on 16th May, 2013, wherein, a decision was taken to constitute an expert committee for examination and generation of scientific opinion on the issues raised in the representation made by the said NGO. Accordingly, Expert Committee was appointed and the Expert Committee, in its meeting held on 12th July, 2013 took a decision, relevant part of its discussion is extracted hereunder:

"It was therefore recommended that a well planned study need to be conducted in a time bound manner[may be in six months] involving accredited laboratories to assess the leachability of randomly collected samples. The sample should be drawn of drug formulation from different part of the country. The study plan should be worked out in consultation with the concerned laboratories/institutions by the Government.

The committee finally concluded that the information provided in the representation of HIM JAGRITI and according to the available literature, is not sufficient enough to establish a definite correlation of casualty of plastic container for pharmaceutical products and adverse health effects. However, this is an important public health concern and needs detailed investigation. Also, the ''absence of evidence'' may not be considered as ''evidence of absence'' of the potential harmful effects of packaging of pharmaceutical products in plastic containers. This issue also needs to be viewed from environmental hazard being posed by the use of plastic containers.

A scientific evidence needs to be generated in a time bound manner through systematic studies as elaborated above, to arrive at answers to the following questions a] The extent of leachability from plastic container used for packing different drugs formulations, b] The type of toxicants leached, c] Health hazard due to exposure of the leached toxicant.

On the basis of the evidence so generated and keeping in view the risk assessment and also environmental hazards, a phasing out plan may then be considered.

Meeting ended with the vote of thanks to the Chair."

5. Thereafter, the Drugs Technical Advisory Board, again in its 65th meeting held on 25th November, 2013, after considering the report of the Expert Committee, took a decision, relevant part of the minutes of the said meeting is extracted hereunder:

"In order to generate scientific evidence on leachability in common drugs available in plastic bottles samples were sent to Central Institute of Plastic Engineering and Technology [CIPT] Guindy, Chennai and Laboratory for Advanced Research in Polymeric Materials [LARPM], Bhubaneswar. However, these labs

have shown their inability to carry ut the assessment of leachability of PET Bottles. CISR has now been requested to provide information about the laboratories in the country having facility to test the extent of leachability from plastic containers used for packing different drug formulations.

The PET Container Manufacturers Associations also represented to the Director General Health Services stating that PET packaging with its inherent strength such as product safety, eco-friendliness and recyclability will continue to be used in food, beverage and pharmaceuticals packaging. The PET is universally safe and environment friendly packaging material. The literature attacked to the representation, however, did not address the issues raised by HIM Jagriti.

The pharma industry was earlier using glass bottles only as primary packaging material for pharmaceuticals. 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 endoctrine disruptors due to leaching. India has large variation in temperatures. In summer days temperature rises to 40-45 degree centigrade and exposure of plastic bottlesto 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.

The members opined that the reports of environmental/health hazards because of increasing exposure to endocrine disrupter chemicals known as phthalates etc. are increasing. Therefore, it would be in the public interest specially considering the precautionary principle that the children, geriatrics, women in reproductive age group and pregnant women are not exposed to the hazards involved in the packaging of drugs in plastic/PET containers.

The DTAB after deliberations 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 meant for geriatrics, women in reproductive age group and pregnant women should be phased out and banned. However, the pharmaceutical industry may be given an adequate time of six months for smooth switch over."

6. In pursuance of the recommendations made by the Drug Technical Advisory Board in its meeting held on 25th November, 2013, the Central Government, by its letter annexed as Annexure: K to Special Civil Application No. 16639 of 2014, referred the matter to the Indian Council of Medical Research ["ICMR" for short]. Accordingly, the expert group of the ICMR made recommendations on PET/plastic bottles for Pharmaceutical Applications, which have been filed by the petitioners as Annexure-E along with the Special Civil Application No. 16639 of 2014. The recommendation made by the ICMR in the above recommendations was as under:

"Thus, scientific prudence calls for avoidance of use of PET material for

pharmaceuticals to be used during pregnancy and by growing children.

6. The committee recommends that to resolve the issue of continued use of PET bottles for uses other than pharmaceuticals as discussed above, a nationwide, multi-institutional, long term surveillance mechanism will need to be put in place. Appreciating the difficulties in devising a robust sampling plan due to the large number of confounding factors [the varying agro-climatic zones which affect the leaching process on account of the temp., humidity, sun exposure, etc.], the ground realities and practices of using these containers would need to be studied prior to taking up such a surveillance study. This study would need to be planned as a holistic chemical analysis investigation aimed at identifying various other chemicals that might have detrimental effect[s] on health."

It further appears that in paragraph-4, the ICMR has opined that the nation wide one time study as proposed by the Drug Controller General of India would not be meaningful due to the large number of confounding factors which cannot be controlled.

7. After receiving the report of the ICMR, it appears that the Central Government has published draft rules vide notification dated 29th September, 2014. The said notification is challenged in these two petitions along with the decision taken by the Drugs Technical Advisory Board and the expert committee which would come into effect after 180 days from the date of its final publication in the Official Gazette.

8. Mr. Devang Bhatt, the learned Assistant Solicitor General has informed the Court that the final publication of the said draft rules has not yet been made.

9. Mr. Mihir Joshi, learned Sr. Advocate assisted by Ms. Megha Jani, learned counsel for the petitioner in Special Civil Application No. 16639 of 2014 and Mr. Mihir Thakore, learned Sr. Advocate assisted by Ms. Amrita Thakore, learned counsel appearing on behalf of the petitioner in Special Civil Application No. 16640 of 2014 have submitted that the Central Government has mechanically accepted the recommendations made by the ICMR without considering the representations made by the petitioners from time to time and without considering the standards prescribed by Indian Pharmacopoeia Commission, Bureau of Indian Standards etc. It is submitted that the use of PET in packaging of pharmaceutical products is an accepted phenomenon, that its quality is duly regulated under a strict regulatory regime and that parameters for maintenance of quality have been laid down by specialized bodies. The drugs like expectorants etc. provide for specifications and they have to be accepted and the drugs sold in plastic bottles are not hazardous to the public health either of adult persons or of pregnant women and children. But all these aspects have not been considered by the respondent authorities. During the course of the arguments, the learned counsel for the petitioners have emphasized that even the blood is being stored in plastic bottles. Apart from this, various other contentions are raised by the learned counsel appearing on behalf of the petitioners, which we do not think it

fit to look into at this stage.

10. It appears that various representations have been made by the petitioners from time to time, but the same have not been considered by the respondent authorities prior to issuance of the draft rules vide notification dated 29th September, 2014.

11. Even in the draft rules published vide above notification dated 29th September, 2014, and annexed as Annexure: A, it is provided that the persons who are likely to be affected by the said draft rules framed by the Central Government can file their objections to the said draft rules within 45 days from the date on which the copies of the Gazette of India containing the said notification are made available to the public and the objections and suggestions, if any, received from any person with respect to the said draft notification within the period so specified shall be taken into consideration by the Central Government and the objections and suggestions, if any, are to be sent to the Under Secretary [Drugs], Room No. 523-A, Ministry of Health & Family Welfare, Government of India, Nirman Bhavan, New Delhi-110011.

12. Thus, it appears that representations have been made by the petitioners, but the same do not appear to have been taken into consideration by the respondent authorities.

13. Learned counsel for the petitioners state that the petitioners have already filed their representations within the period prescribed in the Notification. The petitioners are permitted to file additional representation in support of their contentions made in the earlier representations within a period of one week from today which shall be considered by the respondent authorities by treating that since the main representations/objections were made within 45 days from the date of the notification dated 29th September, 2014, additional representation will be treated to be within the time of 45 days and the said representations made earlier as also the additional representations that may be made by the petitioners, shall be decided by the respondents by a reasoned and speaking order expeditiously.

14. We make it clear that once the final decision is taken by the respondent authorities upon the representations made by the petitioners earlier as well as the additional representations that may be made by them hereafter and is communicated to the petitioners, the final notification, if any, shall be issued by the Central Government only after 15 days pursuant to communication of such final decision to the petitioners.

15. With the aforesaid direction, both these petitions are finally disposed of.

16. We, however, make it clear that we have not entered into the merits of the case and it will be open to the petitioners, if they are so advised, to challenge the decision/order that may be passed by the Central Government on the representations made by the petitioners, and also to pray for the reliefs which

are claimed in these petitions.

