

FOPE

Federation
Of
Pharma
Entrepreneurs

The Under Secretary (Drugs)
Ministry of Health & Family Welfare
Room No. 414 A, D Wing,
Nirman Bhawan
New Delhi - 110011

15th May, 2017

Subject: Comments on G.S.R. 302 (E) dated 30.03.2017

Sir,

Federation of Pharmaceutical Entrepreneurs (FOPE) is an all India association of small and medium scale pharmaceutical manufacturers.

We introduce ourselves as Federation of Pharma Entrepreneurs (FOPE). FOPE was formed in the year 2006 representing the likeminded entrepreneurs who migrated from different parts of the Country to central excise free zones established by the Government of India in the States of Himachal Pradesh and Uttarakhand for promoting industrial development in these States. The objective of FOPE was to take up the issues relating to pharmaceutical industry, particularly concerning small and medium scale manufacturers, with the Government. Due to laborious efforts of its office bearers, FOPE is now having reorganization across the Country and have more than 400 individual manufacturers as its members in the States of Karnataka, Gujarat, Maharashtra, Rajasthan, Haryana, Punjab etc.

The proposed amendment to rule 96 of the Drugs and Cosmetics Rules, 1945 will affect the members of this association economically as well as it will be very difficult to comply with proposed amendment for the following reasons:

The proposed amendment requires that the proper name of the drug shall be printed in a conspicuous manner which shall be in the same font but at least, two font size larger than the brand or trade name. It may be done in secondary packing but in primary packing the proportion of length and breadth is variable depending on the packing material and size of container. For example, in strip packing, length is smaller than breadth (breadth is in continuous strip). In the secondary packing, carton's length is more while breadth is less. So, when the matter composed for either primary packing or secondary packing when either enlarged or reduced, the font size of proper name may not be exactly two font size larger. Thus, there will be practical difficulty to comply with this amendment.

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2. Many a time, some design is embedded in the trade/brand name which may have variation in font size in a letter or two, then the question will be which font size will be taken into consideration for complying with the provision.
3. Normally industrial practice is to store 3-8 months' requirement of packing material for different products. For fast running items the inventory may be even for 9-12 months.
4. For printing the strips rollers are made specifically for each product and each roller cost the manufacturer Rs. 5,000 to 10,000. When the changes are to be made, economic loss would be heavy depending on the number of products.
5. Last time when rules were amended to make generic name more prominent, the industry had to incur huge losses in term of inventory of packaging material going waste and also for making new printing rollers. This repetitive exercise will again result into huge losses due to inventory going waste and expenses for new printing cylinders. The purpose of showing the generic name in prominent manner was served by the previous amendment which has been complied. We feel no further change is warranted.

We understand the purpose of the proposed amendment is to give more visibility to the proper name than the trade/brand name. This object can be achieved with the current provision also by issuing an explanation of conspicuous manner. It may be stated that the proper name shall be in the font size larger than the trade/ brand name. If shade effect has been used, the shade of proper name will be darker than trade/ brand name.

This will allow the industry time to consume printed packaging material already lying with it. Where needed, manufacturer will modify the printing.

However, for any reason, if this amendment is to be incorporated in rule 96 of the Drugs & Cosmetics Rules, it may be modified as under,

"For this purpose, the proper name of the drug or fixed dose combination of drug other than fixed dose combinations of vitamins and other fixed dose combinations containing three or more drugs, shall be printed or written in a conspicuous manner which shall be in the same font but in larger font size than the trade/ brand name, if any, in other cases the brand name or the trade name, if any, shall be written in brackets below or after the proper name and shall be"

Pharmaceutical manufacturers may be given sufficient time to consume old printed packaging materials by making the amendment effective from a prospective date.

We request you to give us suitable time and date to explain the matter in person through our delegation. Our submission at paragraph (1) and (2) above will also be explained by samples of packaging material /art work at the time of personal meeting.

Thanking you,



(Sudesh Kumar)
Executive Secretary (II)
Federation of Pharma Entrepreneurs (FOPE)

Cc: Shri K.L. Sharma, Jt. Secretary (Drugs), Ministry of Health & Family Welfare, Nirman Bhawan, New Delhi-110 011
(ii). Dr. G.N. Singh, Drugs Controller General, FDA Bhawan, New Delhi-110 002

