

DRAFT RULES GSR 302(E)

| Point | Rules | Existing Rule 96 | Proposed Amendment | Our Suggestion |
|-------------|---|---|--|--|
| Point No. 2 | Rule 96, Sub Rule 1, Clause (i), Sub Clause (A) | <p>Manner of Labelling.- (A) For this purpose, [the proper name of the drug shall be printed or written in a more conspicuous manner than the trade name. if any, which shall be shown immediately after or under the proper name and shall be]</p> | <p>“For this purpose “, the proper name of the drug or fixed dose combination drug other than fixed dose combinations of vitamin 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 at least two font size larger than the brand name or trade name, if any , and 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 “ shall be substituted.</p> | <p>There is no much difference between the existing rule and the proposed rule. Because the proper name of the drug is already in conspicuous manner from the trade name, the only difference between the both is that trade name and proper name should be of the same font.</p> <p>2. This has to be understood that there are about 8000 existing pharmaceutical industries. Obviously, every company has to change their design/artwork and Printing Rollers and other machinery parts to print Labels, Stickers, cartons etc. To change strips for Blister packing, alu alu packing and strip packing, Rollers of all the products are needed to be changed and one Roller costs around Rs. 4000 per colour. There are about more than 50000 formulations which are available in the country and to change the pattern of Labelling and printing etc. for these 50000 formulations, heavy amount has to be spent by the Pharmaceutical industry. It is also true that investment made by the Pharma companies ultimately be recovered from the patients.</p> <p>On one side, we are trying to supply drugs on reasonable prices and on the other side, such type of amendments are increasing the cost of Drugs. We disagree with this amendment, therefore, Small scale Pharma Industry humbly requests not to modify the present Rule 96.</p> |