INDIAN DRUG MANUFACTURERS' ASSOCIATION

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PARTNERS IN GLOBAL HEALTHCARE 28 May 2013

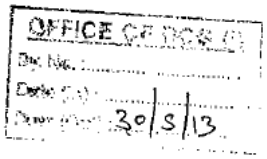
Dr. G.N. Singh
The Drugs Controller General India
Central Drugs Control Standard Organization
FDA Bhawan, CHEB campus,
Kotla road, (Adjacent to Mata Sundri Girls College)
New Delhi-110002.

Sub: Drugs and Cosmetics Act, 1940 and Rules, 1945 / Request for issue of clarification on proper interpretation of labeling requirement under Rule 96(1)(i)(A) of the Drugs and Cosmetics Rules, 1945.

Dear Sir,

It has been brought to our notice by some of our members that the Government Analyst in some states are declaring samples of drugs [Multi Ingredient Formulations] as misbranded on account of proper name of all ingredients not being displayed more conspicuously on such drugs. Some of the Drugs Inspectors are also raising similar objections and are issuing prohibitory order in form 15 directing the Distributors / dealers not to distribute stock of drugs and in some cases, oral instructions are issued not to stock and sell such drugs alleged to be not labeled in prescribed manner.

(1) In this regard, we wish to submit that such inference is erroneous and appears to have been drawn on the basis of wrong interpretation of the provisions of Rule 96(1)(i)(A) of the Drugs and Cosmetics Rules, 1945. Such trend has become more pronounced after your directions to State Licensing Authorities not to approve any product under trade / brand name and approve the product only under generic name / proper name. These directives also state that multi ingredient formulations should be approved as category such as multivitamin, cough syrup etc. Your office also issued clarification that manufacturers are free to affix brand name. However, inspite of clear intent of directives, Government Analyst and Drugs Inspectors are misinterpreting provision of Rule 96(1)(i)(A). The said Rule 96 is reproduced below for your ready reference:-



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[**96**. *Manner of Labelling* .— *(1)* Subject to the other provisions of these Rules, the following particulars shall be either printed or written in indelible ink and shall appear in a conspicuous manner on the label of the innermost container of any drug and on every other covering in which the container is packed, namely :—
(*i*) the name of the drug–
[3][(*A*) for this purpose, [5][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]—
(*a*) for drugs included in the Schedule F or Schedule F (1), the name given therein;
(*b*) for drugs included in the Indian Pharmacopoeia or the official pharmacopoeias and official compendia of drug standards prescribed in Rule 124, the name or synonym specified in the respective official pharmacopoeias and official compendia of drug standards followed by the letters 'I.P., or, as the case may be, by the recognized abbreviations of the respective official pharmacopoeias and official compendia of drug standards;
(*c*) for drugs included in the National Formulary of India, the name or synonym specified therein followed by the letters 'N.F.I.';
(*d*) for other drugs, the international non-proprietary name, if any, published by the World Health Organisation or where an international non-proprietary name is not published, **the name descriptive of the true nature or origin of the substance;**

(2) We submit that the inference of misbranding drawn by the Government Analyst or by the Drugs Inspector is erroneous and is based on misinterpretation of the provisions of Rule 96(1)(i)(A). In support of our contentions, we submit following points for your consideration:-

(i) For multi ingredient formulations, the provisions of Rule 96(1)(i)(A) are not applicable and it is extremely difficult to write name of every ingredient in more conspicuous manner on the label. In any case no purpose is served by writing proper names of all ingredients above the brand name / trade name as this cannot lead to promotion of generic drugs as envisaged in Drug Policy, based on Hathi Committee recommendations.

(ii) The industry has been following practice of displaying proper name / generic name in more conspicuous manner in case of single ingredient formulations or pharmacopoeial formulations. In case of multi ingredient formulations the

category of the product e.g. cough syrup, multi vitamin – multi mineral products etc. is declared on the label. Such practice has not been objected to for last 50-60 years.

(iii) The provisions of Rule 96(1)(i)(A) have been incorporated in the rules with a view to promote manufacturing, marketing and use of generic drugs on the basis of Hathi Committee recommendations.

(iv) Hathi Committee, in its report, had recommended manufacturing and marketing of single ingredient formulations only in generic drug and it had recommended that in the first instance, formulations of 13 drugs should be allowed to be sold only in generic / proper name.

(v) Hathi Committee recommendations were given effect in the Drug Policy, 1978 and in policy statement, it was decided to abolish brand names in the first instance in respect of five drugs.

(vi) From the Drug Policy Statement 1978, it is clear that single ingredient drugs and drug included in IP were required to be labeled with proper / generic name. The para 99 of the policy statement is reproduced below:-

> *"All single ingredient drugs and drugs included in the Indian Pharmacopoeia other than those in respect of which brand names have been abolished shall bear labels displaying prominently the generic names. Brand names may be shown on labels in a less conspicuous manner."*

(vii) The policy statement also envisaged amendments to Drugs and Cosmetics Act and Rules.

(viii) Based on this policy statement, Drugs and Cosmetics Rules, 1945 were amended and Schedule W containing those five drugs was included in the Drugs and Cosmetics Rules, 1945. Clause B was also inserted in Rule 96 wherein it was provided that preparations containing any drug specified in Schedule W as single active ingredient shall be labeled only with proper name of drug and not with any trade name. [Schedule W is omitted after Delhi High Court Judgment.]

(ix) By the same GSR Clause A of Rule 96(1)(i) was amended and it was provided that the proper name of drug shall be printed or written in more conspicuous manner than the trade name.

(x) From the above said background, it is clear that the provisions of Rule 96(1)(i)(A) are applicable to only single

ingredient drugs and drugs included in the Indian Pharmacopoeia. The said provisions are not applicable to multi ingredient formulations.

(xi) In view of above, it is clear multi-ingredient products should not be considered as misbranded and the Government Analyst Report should not declare such products as misbranded on the basis of misinterpretation of Rule 96(1)(i)(A).

We submit that the rigid misinterpretation of the provision of Rule 96(i)(A) will require large number of formulations to be recalled from the market causing great hardship to the manufacturers and revenue loss of the companies. This may also create unnecessary shortage of drugs in the market.

Hence, we request you to kindly examine our submission in the light of legislative background leading to amendment to Rule 96 and issue clarification / guidelines to the State Licensing Authorities in clear terms about the applicability of Rule 96(1)(i)(A) only to the single ingredient and pharmacopoeial formulations.

Thanking you.

Yours sincerely,

M U Doshi
President