INDIAN DRUG MANUFACTURERS' ASSOCIATION

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PARTNERS IN GLOBAL HEALTHCARE

9th January 2013

The Secretary,
Ministry of Health & Family Welfare,
Government of India,
Nirman Bhavan,
New Delhi.

Sub.:- Draft notification GSR 748(E) dated 05.10.2012 regarding proposed amendment of the Drugs and Cosmetics Rules for making a provision for approval of drug formulation containing single active ingredient only in generic name – regarding.

Ref.: Draft Rules published via Gazette notification GSR 748(E) dated 05.10.2012

Dear Sir,

In continuation of our submission dated 12-11-2012 (copy enclosed) to the draft notification as above, we hereby submit further suggestions/objections on proposed amendments for approval of single active ingredient formulations in generic name only for the reasons stated below:-

1. **Form no. 45 – Permission to import Finished Formulation of a New Drug:** The condition no. (2) Stated in Form no. 45 describe labeling manners for the "proper name" of the drug and the "Trade name". Thus, it allows importing any finished formulation including formulation containing a single ingredient with trade name but the draft rules restrict domestic manufacturers with respect to trade name. There cannot be two different yard sticks for the formulations imported and manufactured indigenously.

2. **Form no. 45 – Permission / Approval for manufacture of a New Drug Formulation**: The condition no. (2) stated in Form no. 46 describe labeling manners for the "proper name" of the drug and the "Trade name". Thus, it allows permitting / approving any new drug formulation including formulation containing single ingredient with trade name. There cannot be two different yard sticks for the formulations that fall under category of new drug and formulation that do not fall under category of new drug.

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Further, the draft notification also restricts the applicant for applying single ingredient formulation with trade name during application for renewal of license. Therefore, it implies that the applicant can apply with Trade Name when the formulation is a "New Drug" but after completion of four years from the date of approval of "New Drug" or its inclusion in Indian Pharmacopeia, the applicant has to apply for said formulation with generic name / proper name only at the time of next application for the renewal of license. These are very much contradictory provisions and create lot of confusion for the regulators, applicants, marketers, medical practitioners and patients.

3. **Rule no. 96** also describes labeling manners for the "proper name" of the drug and the "Trade name". The draft rules or any other rule of the Act do not restrict the applicant to market single ingredient formulation with trade name. Therefore, after obtaining a product license with generic name / proper name, the manufacturer may market the formulation with one or more than one different brand names as per labeling provision of Rule no. 96 and the State Licensing Authority shall not have any information regarding the trade names and its manufacturers. Under such circumstances, it would be extremely difficult for State Licensing authority to initiate actions against the manufacturer and meet the preamble of the Act.

4. At present, at the time of grant of product licenses, due care is taken to ensure that the trade name of a product do not contravene provisions of Drugs & Magic Remedies (Objectionable Advertisements) Act 1954 and its Rules. As stated in above point no. 3, when the manufacturer gets liberty to market a product with trade mane without getting it endorsed by State Licensing Authority / CLAA, there would be no control in the matter what so ever.

5. Single Ingredient Formulations are available with several variants in the formulation & they may be used for different ailments too. E.g. A single Ingredient Formulation of Aspirin.
   i. Aspirin Tablet (e.g. Trade Name : ASPRO)
   ii. Effervescent Aspirin Tablet (e.g. Trade Name : DISPRIN)
   iii. Enteric Coated Aspirin Tablet (e.g. Trade Name : ECOSPRIN)

   Though above single ingredient formulation (tablet) contains same API, the characteristics of the formulations &/or strength differ with each other and hence they are used for different ailments. Enteric Coated Aspirin Tablet like Ecosprin is widely used as one of the important component of treatment for patients with cardiac problems. It is practically impossible to expect lay man of any country to differentiate above formulations if sold with generic names only.

6. Trade name is always associated with the quality, trust and reputation of the manufacturer. Now a day, almost all commodities including food items like milk, ghee, butter (e.g. AMUL), edible oils (e.g. Saffola, Fortune) etc. are available with trade names and all consumers prefers such branded commodities over loose or unbranded commodities. It is very unusual to take U-turn for pharmaceutical products through the draft notification.

7. If all single ingredient formulations are available with generic name only, then it empowers the Chemist to sell formulation of any manufacturer on the prescription of Registered Medical Practitioner and it would be difficult to implement Rule no. 65(9)(a) of the Act by any state licensing authority in trade.

We sincerely request you once again to consider our suggestions and objections as above, as also our earlier submission dated 12 November 2012, and in view of the same, not to finalise the proposed draft Rules and not to amend the Drugs and Cosmetics Rules as proposed.

Thanking you,

Yours sincerely,

M U Doshi
President

Encl: Submission dated 12 November 2012

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Date: 12/11/2012.

The Secretary
Ministry of Health and Family Welfare
Government of India
Department of Health,
Nirman Bhawan,
New Delhi.

Sub: Comments on amendment to Drugs and Cosmetics Rules, 1945 proposed under GSR 748(E) dated 05/10/2012.

Dear Sir,

We have gone through the draft rules issued under GSR 748(E) dated 05/10/2012 under which amendment to Rule 71, 71A, 71B, 76 and 76A are proposed. In this regard, we submit our comments as under:-

1. Section 2 of the Drugs and Cosmetics Act, 1940 provides that the provisions of this Act shall be in addition to and not in derogation of any other law for the time being in force. The proposed amendments are inconsistent with the provisions of Section 28 of the Trade Mark Act which gives exclusive right to the registered proprietors of the trade mark to the use of the trade mark in relation to the goods or services in respect of which the trade mark is registered.

2. It is not clear as to whether the proposed amendment is intended to take away the right of the registered proprietor of trade mark under Section 28 referred above. We respectfully submit that any amendment to Drugs and Cosmetics Rules, 1945 cannot take away the rights under the Trade Mark Act, 1999 which is a valid law and is in force.

3. The background of the proposed amendment is not clear. However, from the minutes of Drugs Consultative Committee meeting, it appears that the Government has taken a view that grant of product permission under brand

name is not in line with the scheme and object of the Drugs and Cosmetics Act, 1940. However, such view is inconsistent with the provisions of Rule 96(1)(i)(A) which recognizes right of the manufacturer to label the drug with the brand name. The said view is also inconsistent with the provisions of Rule 65(11-A) which prohibits substitution. The said provisions of Rule 65(11-A) are reproduced below for ready reference:-

> "No person dispensing a prescription containing substances specified in [Schedule H or X] may supply any other preparation, whether containing the same substances or not in lieu thereof."

4. The proposed amendment will require all single ingredient formulations to be manufactured and sold under proper / generic name. However, even Hathi Committee had suggested that beginning should be made with 13 drugs changing over to generic name.

5. Drugs manufactured by different manufacturers defer both in their therapeutic equivalence and also in the standard of production and a brand name enable a doctor to make the choice of the precise drugs that he wants to prescribe for his patient. However, we apprehend that if this amendment is effected this choice may get transferred from a doctor to the chemist and his decision might be influenced by the business considerations such as discount and schemes offered by a particular manufacturer. We believe that this situation is not in the best interest of the consumer.

In view of above, we request you not to finalize the proposed draft rules and the Drugs and Cosmetics Rules, 1945 should not be amended as proposed.

Thanking you.

Yours sincerely,

M.U. Doshi
President