The Indian Pharmaceutical Association (IPA)

(Society Regn No. Bom. 10 of 1960 GBBSD • Public Trust Regn. No. F- 746 (Bom) dt. 4.4.1960)

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MISSION

The Indian Pharmaceutical Association (IPA) founded in 1939, is the national professional body of pharmacists engaged in various facets of the profession of pharmacy. The IPA is committed to promote the highest professional and ethical standards of pharmacy, focus the image of pharmacists as competent healthcare professional, sensitize the community, government and others on vital professional issues and support pharmaceutical education and sciences in all aspects

IPA/110/252 June 5, 2019

Dr. S. Eswara Reddy
The Drugs Controller General of India
FDA Bhavan, Kotla Road,
New Delhi -110002.

Ref. File No. : 12-01/18-DC(Pt. 396) dated 16.05.2019

Sir,

We appreciate your concern expressed in the above-referred letter and your request to discourage the manufacturers from using the same brand name when the composition is changed. Presently, the state drug control departments issue license to products for manufacture by the generic name/composition and not by the Brand name. However, experts believe that it is difficult to implement this request made by the DCGI as there is no suitable legislative provision at this moment to support it and so requires a suitable amendment of the relevant rules and regulations.

Several memorandums have been sent to the concerned authorities for a quick resolution of the problem to protect the health of the people. This issue has been discussed in several meetings of DCC during 2008 to 2011 where DCC unanimously resolved that "the change of formulation composition without changing the brand name is not only misleading but may also result in undesirable pharmacological effects as the consumer would take the formulation assuming that it has the earlier composition". DCC further recommended that such type of practice needs to be discouraged and the state drugs controllers should ensure that the same brand name should not be permitted to retain by the manufacturers, if the composition of the API(s) in the new formulation changed, and as a result your good office has requested Drugs Controllers of all states and UTs to take steps in this matter.

Nevertheless, we at IPA share the concern that it is also highly essential to amend the relevant rules and regulations first to bring about an effective resolution to this problem. We, therefore, would like to request you to take immediate measures to amend the rules and regulations in the interest of patient safety so that manufacturers will not continue with the same brand name after changing the composition of the formulation.

It is also important that the DCGI maintain a full database of the present brand names in the country along with their composition. This needs to be done on top priority since such a database would help the state licensing authorities to ensure that a license is not issued to any product bearing a brand name that has already been issued for another similar product in our country.

Thank you,

With best regards.

Suresh Khanna
Hon. Gen. Secretary