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INDIAN DRUG MANUFACTURERS' ASSOCIATION

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26 March 2014

PARTNERS IN GLOBAL HEALTHCARE

Dr. G. N. SINGH,
Drugs Controller General (India)
Central Drugs Standard Control Organization,
FDA Bhavan, Kotla Road
New Delhi 110 002

Sub: Evaluation of Fixed Dose Combinations

Dear Sir,

We thank you for your circular dated 03rd February 2014 to All State Drug Controllers advising the manufacturers to provide additional documents if any to substantiate their safety and efficacy data.

We also understand that a committee has been formed under the Chairmanship of Dr. B. Suresh to review the applications, and to support him 10 Expert Committees have been constituted.

In the mean time, we understand that the first meeting of Expert Committee was held on 6th March 2014 at FDA Bhawan, New Delhi to evaluate a set of formulations and the concerned Manufacturers had been invited to make a presentation on their FDCs.

It will indeed be helpful if the Office of Drugs Controller General (India) could clarify on the methodology that will be adopted in evaluating the safety and efficacy data submitted by the Manufacturers. This will provide clarity to the Manufacturers to get ready with the details. This will also help us in explaining to our Members who are anxiously awaiting the outcome.

With regards,

S V Veerramani
President, IDMA

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