INDIAN DRUG MANUFACTURERS' ASSOCIATION

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Letter Submitted to JS on 3/2/2015

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INDIAN PHARMACEUTICALS FOR GLOBAL HEALTH

3rd February 2015

Shri. K L Sharma
Joint Secretary (R)
MINISTRY OF HEALTH AND FAMILY WELFARE
Nirman Bhawan
New Delhi 110 108

Dear Sir,

Subject: SLA-Approved Fixed Dose Combinations (FDCs)

This is with reference to our delegation meeting with yourself on several occasions on behalf of various Healthcare Associations primarily represented by Indian Drug Manufacturers' Association (**IDMA)** on formulating guidance issues pertaining to scrutinizing of SLA-Approved FDCs.

In this context, we understand that Prof Kokate's Expert Panel who is responsible for segregating FDCs into 3 categories: Rational, Doubtful & Irrational has submitted the final verdict for those products whose dossiers were submitted. It is indeed commendable that under the new Govt such a herculean task has been accomplished in such a short spell of time; however, the industry is waiting with baited breath on the outcome so as to chart a suitable road map for the future. You have assured us that the irrational FDCs may not exceed 10-15% and these would those products that are medically grossly unacceptable. We do remember the words of Dr Venkateshwarlu, the former DCGI that even if there is a slight rationality to the combination it should not be weeded out since there has been an acceptance by the Medical Profession and established history of safe use.

Our purpose of this communication is to strongly request you to provide us with the list – exclusive to IDMA, before it is put up in public domain. In this methodology we could revert with our concerns, if any rather than having to battle it out. Also the pressing urgency is how the so-categorized 'doubtful' FDCs would be *further* scrutinized? We here request you strongly that the same should not be evaluated by the erstwhile experts who had earlier expressed denial of go-ahead with almost all the FDCs they had deliberated with the industry – any move in this direction would lead us back to square A. Our suggestion, which could be considered, is that the doubtful FDCs must solely be scrutinized on the basis of safety of ingredients and existing history of safe use of the product as such since its existence. Since it is categorized as doubtful evidently it is not grossly irrational and safety-based analysis would be fully justifiable from the patient's perspective as well.

Even, if there is any deliberation needed, the same should be bilateral between industry and regulators and no unilateral decision should be taken. If deliberation is required then members of the Prof Kokate's Expert Panel must be involved since it was these panelists who have so-categorized the concerned FDCs.

Lastly, it is also our sincere request that those FDCs which are classified as irrational, there could be debate with concerned associations' personnel before they are surgically weeded out. Our Medical Subcommittee has enough experience since they have been involved in deliberations of the 294 SLA-Approved FDCs issue, which has seen a logical conclusion on a mutually acceptable scientific basis. It needs to be emphasized here that the Medical Subcommittee had during this exercise voluntarily submitted a list of irrational FDCs thatwere scientifically unjustifiable.

We at IDMA believe in Medical Ethics and we wish to assure you of our full support in putting an end to uncertainty prevailing with respect to FDCs, albeit scientifically.

Thanking You,

Yours Sincerely

S V VEERAMANI
President, IDMA

DR R K SANGHAVI
Chairman, Medical Subcommittee (IDMA)