Delivered on 13/2/2014 at the office of DCGI

INDIAN DRUG MANUFACTURERS' ASSOCIATION

102-B, POONAM CHAMBERS, 'A-WING', DR. A.B. ROAD, WORLI, MUMBAI-400 018, INDIA

Phone : 91- 22 - 24974308
91- 22 - 24944624
Fax : 91- 22 - 24950723

E-mail : idma@vsnl.com
idma1@idmaindia.com
Website : www.idma-assn.org

PARTNERS IN GLOBAL HEALTHCARE

10th February 2014

Dr G N Singh
Drugs Controller General (India)
Directorate General of Health Services
FDA Bhavan; Kotla Road
New Delhi

Subject: SLA-Approved Fixed Dose Combinations (FDCs) – our appeal

Dear Sir,

We refer to the 294 FDCs (currently under review by the Expert Committee) and also the SLA-approved FDCs, for which the industry has applied with 'efficacy and safety' data.

294 FDCs

This is with reference to the meeting on rationality of 38 FDCs (+ 11 more imposed by the Nagpur High Court) held on 4th Jan 2014 at DCGI Office. During this meeting the panelists discussed almost 30 FDCs but **none** were considered to be as NOT IRRATIONAL. This is inspite of presenting scientific reasons to combine the ingredients present, more so in 2 Drug FDCs (setting aside the inherent reservation of panelists for 3 or more drug FDC).

In this regard, we submit the following for your kind consideration.

The very purpose of discussing the FDCs was to rationalize scientifically. It is but a foregone conclusion that the 294 FDCs under consideration would not have a history of prevalence in most cases; in view of the FDC not being marketed as such in any other country naturally clinical evidence of the combination cannot be made available. Also all the FDCs' ingredients can always be given separately by those clinicians who wish to do so. The FDC is intended to replace such cumbersome intake of multiple pill syndrome, and the same has been always preferred by many medical professionals and welcomed by patients.

Whether the FDC is required only for a minority group of patients or not is a commercial consideration and need not be taken into account when products need for evaluating the FDCs.

Registered under the Societies Reg. Act XXI of 1860 Reg. No. Bom. 111/1961 G.B.B.S.D.
Registered under the Bombay Public Trust Act, 1950 (Bom. XXIX of 1950) Reg. No. F-1514 (Bom.) Dt. 11-4-67

Having a FDC only does not foster drug (unnecessary) overuse – even single ingredient agents can be overused / abused in view of the prevailing dispensing practices.

The disease profile and drugs' pharmacology can also be considered and not clinical evidence alone. Ultimately the Indian clinicians take pride in their clinical acumen and do not make patients suffer a whole battery of tests to diagnose; the same can be the principle in deciding the FDC's rationality.

We humbly request you to permit us to re-discuss the FDCs already debated on 4th January 2014 with a fresh panel of doctors and also request you to kindly include privately practicing clinicians as well in the group.

SLA-Approved FDCs (applied for those permitted upto 30th Sept 2013)

The DCGI is facing the prospect of having to (with the industry awaiting the outcome) scrutinize thousands of FDCs that have been applied for by the manufacturers. We are sure that similar principles in determining rationality would be the underlying guideline. However, we take this opportunity to request that the Experts to scrutinize the same need to include privately practicing clinicians to provide more practical inputs and make the exercise a balanced effort by the DCGI office. Ideally, relevant medical personnel from the industry should also be incorporated – at least before deciding on weeding out the 'not so rational' FDCs.

India is the world leader in FDCs and today even regulated markets are seeing more combination products. Hence the bias against FDCs, if any, would be a retrograde step and negate the achievements of the Indian Pharma manufacturers / marketers.

We are confident that you would consider our suggestions favorably so as to ensure that the consumers are not denied the convenience provided by FDCs and patient compliance is fostered for ultimate superior healthcare benefits.

Thanking you,

DR R K SANGHAVI
Chairman, Medical Subcommittee

S V VEERRAMANI
President