F. No. 04-01/2013-DC (Misc. 13-PSC)
Directorate General of Health Services
Office of Drugs Controller General (India)
(FDC Division)

FDA Bhawan, Kotla Road,
New Delhi-110002

Dated: 05 JUN 2017

NOTICE

Subject: Examination for Safety and Efficacy of Fixed Dose Combinations (FDCs) licensed for manufacture for sale in the country without due approval from office of DCG (I)-regarding.

Reference: 1. This Directorate letter no. 4-01/2013-DC (Misc.-PSC) dated: 15.01.2013.
2. This Directorate Notices dated: 17.06.2016 and 01.09.2016 and 01.03.2017.

This is in continuation to this office earlier letters addressed to individual firms as well as notices dated: 17.06.2016, 01.09.2016 and 01.03.2017 whereby all concerned stakeholders were requested to submit phase IV trial protocol based on recommendations of Expert Committee. In this regard, it has been observed that most of the companies are yet to submit Phase IV trial protocols. In order to facilitate the stakeholders for submission of these protocols, the matter was also taken up with the Expert Committee.

The Committee opined that the FDCs for which the post marketing trials have been asked are those FDCs which appear to be rational, however safety in such FDCs is yet to be further ascertained, therefore the Committee recommended that:-

1. Main focus and primary objective for conducting such trials in these FDCs could be safety and efficacy could be secondary objective.
2. The study could be Open label /Double Blind/Comparative/Single arm/Crossover multi-centric trial depending upon the concerned FDC and its therapeutic indication and the number of subjects should be statistically significant.
3. Scientific evaluation by validated parameters/methods should be included for assessing the safety and efficacy.
4. During the study, anticipated safety parameter should be defined clearly alongwith its monitoring mechanism.
5. The study sites should be geographically distributed.

It is therefore again requested that all the applicants who have not yet submitted post marketing Phase IV trial protocols shall submit the same in line with Schedule Y of Drugs and Cosmetics Rules, 1945 taking into consideration all the points as mentioned above.

This may be treated as regulatory reminder for further necessary action.

Yours faithfully,

(Dr. G. N. Singh)
Drugs Controller General (India)

Copy to:-

1. JS (R), Ministry of Health and Family Welfare, Nirman Bhawan, New Delhi.
2. All State/UT Drugs Controllers
3. All Zonal/Sub Zonal offices of CDSCO
4. Manufacturing Associations: IDMA/OPPI/IPA/CIPI/FOPE etc.