Nil

File No. 4-01/2019-DC (Misc. 53)
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(FDC Division)

Tele. No.: 011-23236965
Fax No. : 011-23236973

To,
All State/UTs Drugs Controller

19 SEP 2019

Subject: Manufacturing and marketing of FDC of Aceclofenac 100mg + Drotaverine Hydrochloride 80mg tablet-regarding.

Sir,

The FDC of Aceclofenac 100mg + Drotaverine Hydrochloride 80mg tablet was initially approved by this office on 15.09.2008 in favour of M/s Themis Medicare. Based on the 59th report of Parliamentary Standing Committee (PSC) dated 08.05.2012, it was decided that FDC of Aceclofenac 100mg + Drotaverine Hydrochloride 80mg tablet would be referred to New Drug Advisory Committee (NDAC)/Subject Expert Committee (SEC) for examination and review related to its continued marketing and updation of product monograph in light of recent knowledge and regulatory changes in overseas.

Accordingly, the matter was discussed in a series of meetings of the NDAC/SEC. Based on the recommendations of Subject Expert Committee, it was decided that the FDC of Aceclofenac 100mg + Drotaverine Hydrochloride 80mg tablet shall be indicated for treatment of "colicky pain due to smooth muscle spasm" for its continued marketing. However, manufacturers of this product shall conduct clinical trial.

As per the recommendations of Subject Expert Committee, M/s. Themis Medicare was asked to revise the indication and submit the clinical trial protocol for conducting the study. However, after a series of communications, M/s. Themis Medicare finally surrendered the product license.

Recently, the proposal was again re-deliberated in 60th SEC (Reproductive & Urology) dated 29.08.2019 with current status. The committee reviewed its earlier decision for conducting the Phase-IV clinical trial on the FDC. After detailed deliberation, the committee recommended that the firm(s) may be directed to conduct Active Post Marketing Surveillance in minimum 200 patients and the study should include patients of Primary dysmenorrhea, biliary colic and ureteric colic. The study should be completed within one year and results of study should placed before the committee for further review.

In view of above, facts and circumstances, you are requested to direct all the manufacturers of said FDC under your jurisdiction to conduct Active Post Marketing Surveillance on minimum 200 patients for the treatment of **colicky pain due to smooth muscle spasm** as per Drugs and Cosmetics Rules. The study should include patients of Primary dysmenorrhea, biliary colic, ureteric colic and report of the same shall be submitted to this Directorate within one year for further review by the Subject Expert Committee.

Yours faithfully,

(Dr. V. G. Somani)
Drugs Controller General (India)

Copy to:-

1. All Zonal/Sub Zonal offices of CDSCO.
2. Indian Drug/Pharmaceuticals Association Forum
3. Website of CDSCO