Nil

File No. 4-213/2008-DC
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(FDC Division)

Tele. No.: 011-23236965
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To,
All State/UTs Drugs Controller

Dated 01 SEP 2021

Subject: Manufacturing and marketing of FDC of Tolperisone HCl 150mg + Paracetamol IP 500mg tablet-regarding.

Sir,

The FDC of Tolperisone HCl 150mg + Paracetamol IP 500mg tablet was initially approved by this office on 21.10.2010. Based on the 59th report of Parliamentary Standing Committee (PSC) dated 08.05.2012, it was decided that FDC of Tolperisone HCl 150mg + Paracetamol IP 500mg 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 26th SEC (Analgesic & Rheumatology) meeting held on 08.09.2016 wherein the Committee noted that FDC of Tolperisone HCl 150mg + Paracetamol IP 500mg tablet was approved by this office on 21.10.2010 for the treatment of patients with acute painful musculoskeletal conditions. The committee reviewed the FDC in light of the recommendation of the PSC regarding its continued manufacturing and updation of product monograph in light of recent knowledge and regulatory changes overseas.

After detailed deliberation, the committee recommended that the FDC should be marketed only for symptomatic treatment of post stroke spasticity associated with pain in adults. Further the firm should conduct a Phase IV study on the recommended revised indication. Accordingly, the protocol shall be submitted for further review. The firm is advised to revise their package insert accordingly.

Accordingly, the initial applicant was asked to conduct the phase IV clinical trial. However, the firm surrendered the original product permission on 10.10.2017. As FDC of Tolperisone HCl 150mg + Paracetamol IP 500mg tablet is no more a new drug, you might have issued the product license for the same FDC to other manufacturers.

In view of above facts and circumstances, you are therefore requested to direct all the manufacturers of said FDC under your jurisdiction to market the subject FDC only for **"symptomatic treatment of post stroke spasticity associated with pain in adults"**. Further the manufacturers of this FDC should also be directed to submit the Phase IV clinical trial protocol on the revised indication to this office at the earliest for further review.

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