Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
Office of Drugs Controller General (India)
(New Drugs Division)

FDA Bhawan, Kotla Road,
New Delhi-110002
Date: 21/12/2020

NOTICE

Subject: Approval of FDCs containing new drugs – reg.

CDSCO receives and process application for approval of FDCs in accordance with the provisions of New Drugs and Clinical Trials Rules 2019.

Concerns have been raised that FDCs containing new drugs are approved only after approval of individual new drugs.

In this regard, it is clarified that there is no such requirement that approval process of new drug and FDC containing that particular new drug are sequential and first approval of new drug needs to be obtained followed by approval of FDC containing that particular new drug.

As per the requirements of Paragraph 4 of Second Schedule of the New Drugs and Clinical Trials Rules, 2019, the first group of Fixed Dose Combinations (FDCs) includes those in which one or more of the active ingredients are a new drug. For such Fixed Dose Combinations (FDCs) to be approved for marketing data to be submitted will be similar to data required for any new drug (including clinical trials). However, such issues are examined as case-by case basis depending of nature of the products, indication, etc in consultation with the SEC to ensure safety and efficacy of the FDC.

Yours faithfully,

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

To,

1. **All Stakeholders.**