File No. 15-35/2019-DC
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(DTAB-DCC Division)

FDA Bhawan, Kotla Road,
New Delhi-110002
Date: 09.08.2019

To
All State/ UT Drugs Controllers

Subject: Advisory on labeling requirements for combi kit of Misoprostol and Mifepristone tablets for Medical Termination of Pregnancy (MTP) -Reg.

Sir/ Madam,

Combi kit of Misoprostol and Mifepristone tablets (1 uncoated mifepristone 200 mg tablet + 4 uncoated misoprostol 200 mcg tablets) for MTP was approved on 24.12.2008 by CDSCO with following warning:

"Warning: product is to be used only under the supervision of a service provider and in a medical facility as specified under MTP Act 2002 & MTP Rules 2003"

The issue of labeling requirements for combi kit of Misoprostol and Mifepristone was deliberated in 56th Drugs Consultative Committee (DCC) meeting held on 01.06.2019. In meeting, the DCC suggested that a letter should be issued by CDSCO to all State Drugs Controllers about the labeling requirements and also to ensure the effective implementation of labeling requirements as per MTP provisions.

You are therefore, requested to ensure the effective implementation of labeling requirements for Combi kit of Misoprostol and Mifepristone tablets as per the provisions of Drugs and Cosmetics Act, 1940 & Rules, 1945 and MTP Act, 2002 & MTP Rules, 2003.

Yours Faithfully

(Dr.S.Eswara Reddy)
Drugs Controller General (I)

Copy to:

1. Joint Secretary (R), Ministry of Health and Family Welfare, Government of India, Nirman Bhawan, New Delhi.
2. All Zonal/ Sub-Zonal/ Port Offices of CDSCO.
3. CDSCO Website.