Dy. No. 1-3/2024-DD (RRR)
Government of Pakistan
Ministry of National Health Services, Regulations & Coordination
Drug Regulatory Authority of Pakistan
(Division of Pharmaceutical Evaluation & Registration)
****

Islamabad the 24th April 2024

(ADVISORY)

Subject: **IMPLEMENTATION OF POST REGISTRATION VARIATION GUIDELINES (2ND EDITION)**

Reference to the subject cited above. The Post Registration Variation Guidelines (2nd Edition) for pharmaceutical and biological drug products were posted on official website of DRAP on 01.10.2023. In the aforesaid guidelines the pharmaceutical companies (manufacturers & importers) were advised to submit the application of variations of their registered drugs on the given "Form" along with the documentation requirements as laid down in these guidelines. However, it has been observed that variation applications are not being submitted on the prescribed "Form" and as per documentation requirement provided against each variation.

2. It is therefore requested to advise your member companies to comply with requirements and procedures laid down in the Post Registration Variation Guidelines (2nd Edition). The variation applications submitted without filled Form and in complete documentation shall not be entertained in future.

24.4.24

(Muneeb Ahmed Cheema)
Deputy Director (PE&R)
051-9107311

1. Pakistan Pharmaceutical Manufacturers Association,
   House No. 474, Street No. 34, Sector I-8/2,
   Islamabad.

2. Pharma Bureau,
   Chamber of Commerce Building Talpur Road,
   Karachi.

3. Pakistan Chemist & Druggist Association,
   504, 5th Floor Mashriq Center Near Civic Centre,
   Gulshan e Iqbal Block 14,
   Karachi.

4. All Pakistan Pharmaceutical Manufacturers & Importers.

Through E-Office:

1. Director MIS, DRAP, Islamabad with the request to upload on DRAP website.