No.F.1-12/2017-Add:Dir.(PE&R)
Government of Pakistan
Drug Regulatory Authority of Pakistan
Division of Pharmaceutical Evaluation & Registration
*****

**"SAY NO TO CORRUPTION"**

Islamabad, the 27th January, 2021

# CIRCULAR

All Pharmaceutical Manufacturers

Subject: **SUBMISSION OF FORM 5-F WITH 03 MONTHS PRODUCT DEVELOPMENT AND STABILITY STUDY DATA.**

I am directed to refer to the subject captioned above. Rule 26 of Drugs (Licensing, Registering & Advertising) Rules, 1976 was amended by incorporating Common Technical Document (CTD) as Form 5-F (notified vide S.R.O.713(I)/2018 dated 09.06.2018). Aforementioned amendment was done in compliance to Section 7(c)(ix) of DRAP Act, 2012 and also to adopt internationally recognized standards and guidelines for evaluation and registration of pharmaceutical and biological drug products. The core structure of form 5-F is based upon the CTD format from International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). In this regard, DRAP has also notified guidance document for submission of application on Form 5-F (CTD) for registration of pharmaceutical drug products for human use (https://dra.gov.pk/docs/Guidance%20Document%20on%20CTD-Doc%20No.%20PE&R-GL-AF-004.pdf).

2. Product development and stability studies are integral requirements of Form 5-F. Initially 6 months accelerated and long-term / real time stability studies data was mandated for submission of registration application. Lately, Registration Board decided that firm may submit registration application with product development and stability study data (along with related documents) after completion of aforementioned studies after 3 months' time. Application will be scrutinized/evaluated and shortcomings (if any) will be communicated to the applicant. However, registration application will be presented before the Board upon the submission of 6 months stability study data and rectification of earlier communicated shortcomings (if any) and requisite evaluation.

**(ABDULLAH)** 27/01/2021
Additional Director (PE&R)/
Secretary Registration Board

**Distribution: -**

1. Chairman, Pakistan Pharmaceutical Manufacturers Association, Islamabad.
2. Executive Director, Pharma Bureau, Karachi.
3. Executive Director/Chairman, Pakistan Chemist & Druggists Association (PCDA), Karachi.
4. Director, MIS Division, with the request to upload on DRAP's website.

**Copy for information to: -**

1. PS to Chief Executive Officer, DRAP.
2. APS to Director, PE&R, DRAP.