



Drug Regulatory Authority Of Pakistan
Division of Health & OTC Products
T.F. Complex, Sector G-9/4, Islamabad

"SAy NO TO CORRUPTION"

Islamabad, the 21st April, 2020

NOTIFICATION

F.No.4-2/2017 - DD(H&OTC).- In exercise of the powers conferred by the clause (c) of section 7 of the Drug Regulatory Authority of Pakistan Act, 2012 (XXI of 2012), read with condition "e" of the Provisional Enlistment Certificate as Manufacturer (Form-6) prescribed under the Alternative Medicines & Health Products (Enlistment) Rules, 2014, the Drug Regulatory Authority of Pakistan, is pleased to issue the following guidelines for holders of Provisional Enlistment Certificate as local manufacturer (Form-6) for provisional enlistment of Homoeopathic Combinations, under the provisions of the aforesaid rules, namely:-

- (1) The combinations having evidence of Free Sale (CoPP on WHO format or Free Sale Certificate) along with proof of marketing in any of regulatory authorities of reference countries, namely; USA, Canada, Australia, Japan, United Kingdom, Germany, France, Switzerland, Netherlands, Austria, Denmark, Sweden, Norway, Belgium, Finland, Italy, Ireland, Iceland, Spain or combinations having evidence of Free Sale in, at least, three European Union countries, shall be considered for enlistment under the Alternative Medicines & Health Products (Enlistment) Rules, 2014.
- (2) If the information under paragraph (1), is not available, the combination may be enlisted if the following evidences are provided in support of the claim of availability of the proposed combination in local market for last 10 years;
 - i. Company/Firm Establishment Documents;
 - ii. Sales Invoices including distribution record; and
 - iii. Undertaking for the correctness of information duly signed by CEO/Managing partner/Managing Director.
- (3) The above requirements shall be in addition to other codal formalities as defined under the Alternative Medicines & Health Products (Enlistment) Rules, 2014.
- (4) The evidence of enlisted combinations shall be sufficient for consideration of the application for enlistment of the same combination by any new applicant.

(MUHAMMAD ABDUL GHAFFAR)
Additional Director/Secretary EEC