



**F. No. 9-11/2018-DD(PS)**  
Government of Pakistan  
Drug Regulatory Authority of Pakistan  
Ministry of National Health Services, Regulations & Coordination  
Division of Pharmacy Services  
دوائی تنظیم و تنظیم و تنظیم

Islamabad, the 16<sup>th</sup> of August, 2023.

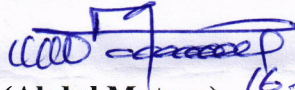
1. The Chairman, Pakistan Pharmaceutical Manufacturer Association, Islamabad.
2. The Executive Director, Pharma Bureau, Karachi.
3. The Chairman, Pakistan Chemist & Druggist Association, Karachi.

Subject: **NOMINATION OF QUALIFIED PERSON FOR PHARMACOVIGILANCE/ LOCAL SAFETY OFFICER.**

Dear Sir/Madam,

Please refer to this office communication of even number dated, 11<sup>th</sup> of July, 2023 on the subject cited above (copy enclosed). It is again informed that submission of nomination of Qualified Person for Pharmacovigilance (QPPV)/ Local Safety Officer (LSO) is the legal responsibility of each registration holder as per Rule 11 (2) of Pharmacovigilance Rules, 2022. Further guidelines regarding the detail of submission is provided in guidelines on Good Pharmacovigilance Practices (GVP) for Registration Holders available on DRAP website. <https://www.dra.gov.pk/wp-content/uploads/2022/04/Good-Pharmacovigilance-Guidelines-for-Registration-Holders.pdf>.

2. However, it is to inform with great concern that a few pharmaceutical companies have submitted their nomination of QPPV/LSO to the National Pharmacovigilance Centre (NPC) in spite of the above mentioned communication. Therefore, all registration holders are hereby once again advised to submit the nomination of QPPV/ LSO to the email address: [pv@dra.gov.pk](mailto:pv@dra.gov.pk) with the title of QPPV/LSO and name of the company in the subject within 30 days along with documents as per Module 1 of GVP guidelines.
3. For any assistance, queries can be sent to [abdul.mateen@dra.gov.pk](mailto:abdul.mateen@dra.gov.pk).

  
(Abdul Mateen) 16-08-2023

Deputy Director (Pharmacovigilance)

Copy to:

1. Additional Directors/Officer Incharge, DRAP field offices Islamabad, Karachi, Lahore, Peshawar and Quetta with a request for circulation to all licensed units/importers.
2. Director (Pharmacy Services), DRAP.
- ✓ 3. Director (MIS), DRAP for uploading on the DRAP website.
4. P.S. to CEO, DRAP, Islamabad.
5. Office copy.