Through UMS

F. No.9-13/2019-DD(PS)
Government of Pakistan
Drug Regulatory Authority of Pakistan
Ministry of National Health Services, Regulations & Coordination
Division of Pharmacy Services

Islamabad, the 30th of October, 2024.

1. The Chairman, Pakistan Pharmaceutical Manufacturer Association (PPMA), House No.474, Street No.34, Sector 1-8/2, Islamabad.
2. The Executive Director, Pharma Bureau, Chamber of Commerce Building, Talpur Road, Karachi.
3. The Chairman, Pakistan Chemist & Druggist Association (PCDA), Suite No.504, 5th Floor, Mashriq Centre, Near Civic Centre, Gulshan Iqbal Block 14, Karachi.

Subject: - **IMPLEMENTATION OF INDUSTRY E-REPORTING SYSTEM FOR REPORTING OF ADVERSE DRUG REACTIONS BY REGISTRATION HOLDERS.**

I am directed to refer to the subject cited above. The Drug Regulatory Authority of Pakistan (DRAP) established the National Pharmacovigilance Centre (NPC) under the Division of Pharmacy Services to ensure the safety of therapeutic goods. Subsequently, the DRAP notified Pharmacovigilance Rules, 2022 which outline the roles and responsibilities of pharmacovigilance stakeholders, including registration holders of therapeutic goods.

2. Since its inception, the DRAP has been committed to promote transparency and facilitation in document submission by registration holders (manufacturers or importers) through different tools i.e. email and/or hard format submission on the mailing address. In collaboration with the Uppsala Monitoring Centre (UMC), the DRAP has now launched an Industry e-reporting system for reporting individual case safety reports (ICSRs) to the NPC-DRAP by registration holders. The purpose of this system is to ease the submission of data by registration holders within the defined timelines. This system is a one-way submission tool, where the pharmaceutical companies will directly submit the reports to the NPC-DRAP through two modules namely: E2B XML submission; and manual data entry for non-E2B pharmaceutical companies. Access to this system is through a secure username and two accounts per registration holders will be provided. Further details on the Industry e-reporting system are provided in the "***Industry e-reporting manual for registration holders***" which is available on the DRAP website.

3. The DRAP has successfully conducted a pilot project for this Industry e-reporting system among a selected number of registration holders and has decided to extend its scope to all registration holders. **Therefore, all registration holders are hereby directed to submit all**

future ICSRs (E2B XML files or manual data entry reports) only through the Industry e-reporting system with effect from 8th of November, 2024. For further guidelines, *the Industry e-reporting manual for registration holders* should be consulted.

4. In this regard, registration holders are advised to submit the details of two persons preferably the Qualified Person for Pharmacovigilance (QPPV)/ Local Safety Officer (LSO) and his/her backup on the attached form **(Annex-A)** to this office within thirty calendar days through the mailing address and email pv@dra.gov.pk to get their users names/accounts and subsequently start submission of their data through Industry e-reporting system to the DRAP.

5. This issue with the approval of the CEO-DRAP.

30-10-2024

(Abdul Mateen)
Deputy Director (PV-I)
Division of Pharmacy Services
Phone # 051-9255981
abdul.mateen@dra.gov.pk

Copy to:

1) Director MIS, DRAP, Islamabad with request to upload this letter on official website of DRAP.
2) Office copy.

Pharmaceutical companies: organisations and user accounts for Industry eReporting

Country:	**Pakistan**
Country ISO Code:	**PK**

Pharmaceutical company		1	
Short name (*populates WWUID*) :			(max 60 characters)
Long name (legal name):			(max 100 characters)
Sender organisation (in E2B XML)			(max 100 characters)
Sender identifier (in E2B XML)			(max 60 characters)
Receiver identifier (in E2B XML):		DRAP	(max 60 characters)
User 1	Given name:		
	Family name:		
	Email:		
	Mobile No		
User 2	Given name:		
	Family name:		
	Email:		
	Mobile No		