F. No. 1-2/2021- CEO DRAP
Government of Pakistan
Drug Regulatory Authority of Pakistan
Ministry of National Health Services, Regulations & Coordination

Office of the
Chief Executive Officer

Islamabad, the 26th April 2021

1. *Chairman,*
Pakistan Pharmaceutical
Manufacturer Association, PPMA,
Islamabad.

2. *Executive Director,*
Pharma Bureau, Chamber
of Commerce Building,
Karachi.

Subject: **DEPLOYMENT OF PAKISTAN INTEGRATED REGULATORY INFORMATION MANAGEMENT SYSETM AT DRAP.**

I am directed to refer to the subject cited above. Drug Regulatory Authority of Pakistan (DRAP) has deployed Pakistan Integrated Regulatory Information Management System (PIRIMS) for optimization of its operations. PIRIMS allows pharmaceutical and biological manufacturers/ importers to submit fee and various regulatory applications to DRAP through a secured online management system by using their registered accounts.

2. In this context, it is hereby informed that all applications for grant of **new Drug Manufacturing Licenses (DML) for Pharmaceutical & Biologicals** will only be accepted and processed through PIRIMS w.e.f. **03rd May 2021**. The direct submission of applications for new DML to R&I of DRAP will not be entertained after the cut-off date. Furthermore, QA&LT Division of DRAP will schedule and conduct regulatory inspections through their respective module in PIRIMS.

3. You are, therefore, requested to disburse this information to your member companies for compliance, please.

4. This issues on the directions of CEO, DRAP.

26/04/21

(Sayyad Hussain Khan)
Deputy Director to CEO

Distribution:

1. PS to CEO, DRAP
2. Additional Director, MIS with the request to upload the letter on DRAP's website for information of stakeholders along with **guidance documents** on "**How to Apply**".
3. All Additional Directors/ Office Incharge of field office, DRAP with the advice to plan and conduct all type of inspection of pharmaceutical firms through PIRIMS from today onwards.
4. Additional Director (QA&LT), Islamabad with the request to constitute new panels for inspections of pharmaceutical firms through PIRIMS.
5. Office copy