F.No.4-3/2023-DMC
Government of Pakistan
Drug Regulatory Authority of Pakistan
(Division of Pharmaceutical Evaluation & Registration)
Data Management Cell (DMC)

Islamabad the 29th March,2023

Attention: **All Market Authorization / Registration Holders**

Subject: COMPLIANCE TO THE NOTICE DATED 13-03-2023 WITH REGARD TO SPECIFICATIONS AND DATA RELATED ACTIVITY IN PIRIMS

DRAP has deployed an online application management system namely *"Pakistan Integrated Regulatory Information Management System (PIRIMS)"*, for processing of regulatory information related to licensing, registration, and inspections of pharmaceutical and biological drugs.

2. Accordingly a notice was uploaded on the website of DRAP on 13th March, 2023 (copy enclosed) with the direction to all Registration Holders of pharmaceutical and Biological drug products to update finished products specifications and validated method of testing i.e. Pharmacopoeial or in case of non-availability in any pharmacopeia, Innovator / Manufacturer's Specification, in the corresponding product profile / details in the PIRIMS at **http://pirims.dra.gov.pk**. It was stated that the portal to perform the above-said activity will remain accessible for thirty days after publication of aforesaid notice and afterwards, no request shall be entertained. It was further clarified that after the lapse of the due time for above-said activity, necessary regulatory fee may apply.

3. It is therefore, advised to comply with the directions as per Notice dated 13-03-2023 and the stakeholder may approach Data Management Cell (DMC) of PE&R Division through email dmc@dra.gov.pk for guidance.

4. This is issued with the approval of CEO DRAP.

(Muneeb Ahmed Cheema)
Deputy Director (PE&R)

Circulation via website www.dra.gov.pk

IMPORTANT

>>> ANNOUNCEMENT <<<

NOTICE TO PHARMACEUTICAL / BIOLOGICAL MANUFACTURERS AND IMPORTERS

Pharmaceutical Industry is hereby informed through this notice that Drug Regulatory Authority of Pakistan (DRAP) has deployed an online application management system namely Pakistan Integrated Regulatory Information Management System (PIRIMS) for performance of various regulatory functions.

All the Registration Holders are hereby directed to update the finished product specifications and validated testing procedures i.e. Pharmacopoeial or in case of non-availability in any pharmacopeia, Innovator / Manufacturer Specification, in the corresponding product details in PIRIMS portal http://pirims.dra.gov.pk.
The portal to perform the above-said activity will remain accessible for THIRTY DAYS after publication of this notice and afterwards, no request shall be entertained. It is further clarified that after the lapse of the due time for above-said activity, necessary regulatory fee may apply.

Registration holders may approach Data Management Cell (DMC) of Pharmaceutical Evaluation & Registration Division through email (dmc@dra.gov.pk) with regards to guidance for procedures and requirements etc.

For more information:
Drug Regulatory Authority of Pakistan
Data Management Cell,
PE&R Division
dmc@dra.gov.pk