



No.F.296-DRB/2020(PE&R) (Pt.)  
Government of Pakistan  
Ministry of National Health Services, Regulations and Coordination  
Drug Regulatory Authority of Pakistan  
(PE&R Division)

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**"SAY NO TO CORRUPTION"**

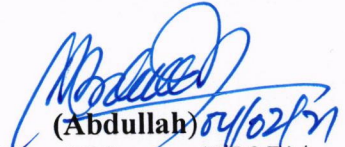
Islamabad, the 04<sup>th</sup> February, 2021.

**ADVISORY**

**SUBJECT: - DISCLOSURE OF EXCIPIENTS ON LABELING AND LEAFLETS FOR INFORMATION OF PATIENTS AND PRESCRIBERS.**

I am directed to refer to the subject cited above. Registration Board in its 296<sup>th</sup> meeting held on 8<sup>th</sup>-10<sup>th</sup> September, 2020 considered the case with reference to various complaints received through Pakistan Citizen's Portal from patients suffering from Celiac disease for the availability of gluten-free medicines. The matter was deliberated considering practices and guidance documents of Reference Regulatory Authorities and it was decided that label (primary or secondary packing) and patient information leaflet should mention words that "Product contains gluten/lactose" in order to avoid any possibilities of untoward reaction for patients with Celiac disease relating to the use of such excipients (containing gluten, lactose etc.)

2. All Pharmaceutical Manufacturers/Importers are hereby advised to comply with the above decision of Registration Board.

  
(Abdullah) 04/02/21  
Additional Director (PE&R)/  
Secretary Registration Board  
051-9107322

**Distribution:**

1. Chairman, Pakistan Pharmaceutical Manufacturing Association (PPMA), Islamabad.
2. Executive Director, Pharma Bureau, Karachi.
3. Executive Director, Pakistan Chemist & Druggists Association (PCDA), Karachi.
4. Director, Quality Assurance & Lab Testing, DRAP
5. Additional Director (E&M), DRAP, Islamabad, Lahore, Karachi, Quetta, Peshawar.
- ✓ 6. Director MIS, with the request to upload on DRAP's website.

**Copy for Information to:**

- i. PS to CEO, DRAP
- ii. PA to Director (PE&R)/Chairman, Registration Board.