

F. No. 01-02/2025-CPS(DRAP)

Government of Pakistan

Ministry of National Health Services, Regulation & Coordination

Drug Regulatory Authority of Pakistan

Prime Minister Health Complex, Park Road, Islamabad

Islamabad, the 3rd June 2025.

NOTIFICATION

Subject: PRIORITY PROCESSING OF CYSTEAMINE REGISTRATION APPLICATIONS

In light of the current non-registration status of Cysteamine and to ensure its earliest possible availability, the Drug Regulatory Authority of Pakistan (DRAP) in its 205th meeting held on 29th May 2025 has designated Cysteamine as priority drug. All registration applications for Cysteamine will be processed on priority basis, out of queue, for a period of one (1) year from the date of issuance of this notification.

 All relevant stakeholders are requested to acknowledge this decision of DRAP and proceed accordingly to facilitate the expedited processing and availability of Cysteamine in the market.

(Ahsan Ul Haq Athar)

Deputy Director

Communication, Publication & Stakeholder Engagement

CEO-Secretriate

Distribution: -

PS to CEO-DRAP, Islamabad

2. Director (PE&R), DRAP, Islamabad.

3. Director (MIS), DRAP with request to upload on DRAP official website.

- Chairman, Pakistan Pharmaceutical Manufacturer Assosciation (PPMA), H.No.474, St.34
 I-8/2 Islamabad
- 5. Executive Director, Pharma Bureau, Chamber of Commerce, Talpur Road, Karachi.
- Pakistan Chemist and Druggist Association (PCDA), Suit No.504, 5th Floor, Mashriq Center, Block 14, Gulshan e Iqbal, Karachi.
- 7. Office File



F. No. 01-02/2025-CPS(DRAP)

Government of Pakistan

Ministry of National Health Services, Regulation & Coordination

Drug Regulatory Authority of Pakistan

Prime Minister Health Complex, Park Road, Islamabad

Islamabad, the 5th June 2025.

CORRIGENDUM

Subject: PRIORITY PROCESSING OF MEXILETINE REGISTRATION APPLICATIONS

In partial modification of Authority's Notification of even number dated 27th May 2025, it is hereby informed that the Drug Regulatory Authority of Pakistan (DRAP) has extended the period for priority processing of registration applications for Mexiletine from six (6) months to one (1) year from the date of the original notification.

(Ahsan Ul Haq Athar)

Deputy Director

CEO-Secretariat

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