Clozapine – Updated labeling and elimination of REMS

- On June 13, 2025, the FDA approved updating labeling for clozapine products (Clozaril®, Versacloz®) and **officially eliminated the Clozapine Risk Evaluation and Mitigation Strategies (REMS) program for these products**.

- This approval follows the February 24, 2025 announcement that the FDA did not expect prescribers, pharmacies, and patients to participate in the REMS program for clozapine or to report results of absolute neutrophil count (ANC) blood tests before pharmacies dispense clozapine.

- Although the risk of severe neutropenia with clozapine still exists, FDA has determined that the Clozapine REMS is no longer necessary to ensure the benefits of the medicine outweigh that risk.

    — Eliminating the REMS is expected to decrease the burden on the health care delivery system and improve access to clozapine.

- FDA still recommends that prescribers monitor patients' ANC according to the monitoring frequencies described in the prescribing information. **Information about severe neutropenia remains in the prescribing information for all clozapine medicines, including in the existing *Boxed Warnings*, and ANC monitoring frequencies are unchanged**.

- Clozapine products are approved for treatment-resistant schizophrenia and reduction in the risk of recurrent suicidal behavior in schizophrenia or schizoaffective disorder.