

D. Statement of Affiliated Treatment Pair (Health Care Practitioner/Pharmacist) OBLIGATIONS:

- We and all pharmacists with dispensing privileges in the pharmacy have reviewed the FazaClo package insert and agree to participate in prescribing and monitoring only according to product labeling and only with a health care practitioner enrolled in the FazaClo Patient Registry.
 - We understand the risk of death associated with agranulocytosis and granulocytopenia when prescribing FazaClo and agree to register all applicable patients in the FazaClo Patient Registry to support early detection of WBC and ANC suppression and ensure that no patient is inappropriately rechallenged with a clozapine product.
 - We agree to prescribe FazaClo only after verifying patient rechallenge status and an acceptable baseline WBC count ($\geq 3500/\text{mm}^3$) and ANC ($\geq 2000/\text{mm}^3$) test results and only after receiving a Patient Registration Number (PRN) from the FazaClo Patient Registry.*
 - We agree to provide the FazaClo Patient Registry with all WBC count and ANC test results for all registered patients within:
 - 7 days of blood draw for patients on weekly monitoring schedule*
 - 14 days of blood draw for patients on an every-2-weeks monitoring schedule*
 - 28 days of blood draw for patients on an every-4-weeks monitoring schedule*
 - We agree to notify the FazaClo Patient Registry of all patients discontinued on FazaClo and submit required WBC count and ANC test results until they return to normal and for at least 4 weeks from day of discontinuation of therapy.
 - We understand the FazaClo Patient Registry will verify rechallenge status against the Clozapine National Non-Rechallenge Masterfile and will update this list with all patients discontinued on FazaClo due to an abnormal blood event as defined by product labeling.
 - We understand the FazaClo Patient Registry will be internally audited and will monitor adherence to prescribing, monitoring, and timeliness requirements and will promptly notify enrolled health care practitioners and pharmacies of any discrepancies or missing information.
- * If the patient is being switched to FazaClo from another formulation of clozapine, FazaClo may be dispensed before a PRN is obtained. In this case, the PRN will be issued when the pharmacist reports the WBC count and ANC test results to the FPR.

*The blood work draw date may not be more than 7 days old in order for the pharmacist to dispense the drug, regardless of the patients' monitoring schedule