



MIKE DEWINE
GOVERNOR
STATE OF OHIO

Executive Order 2022-17D

The Emergency Adoption of Rule 4729:9-1-01.3 of the Ohio Administrative Code
by the State of Ohio Board of Pharmacy

WHEREAS, tianeptine is an atypical tricyclic antidepressant that is not approved for use by the U.S. Food and Drug Administration (FDA) and is not subject to the same regulatory or medical oversight as other tricyclic antidepressants approved for use in the United States; and

WHEREAS, the FDA issued a consumer update on tianeptine products in February 2022 noting that it has identified cases in which people experienced harmful effects from abusing or misusing tianeptine by itself or with other drugs, including antidepressants and anti-anxiety medicines. These effects included agitation, drowsiness, confusion, sweating, rapid heartbeat, high blood pressure, nausea, vomiting, slowed or stopped breathing, coma, and death; and

WHEREAS, peer reviewed literature and case reports documented by the Centers for Disease Control and Prevention demonstrate that tianeptine toxicity mimicked opioid toxicity and withdrawal due to its strong affinity at the mu-opioid receptors and that naloxone was an effective therapy; and

WHEREAS, tianeptine has a high potential for abuse and can lead to emergency department visits, hospitalizations, and fatal overdoses; and

WHEREAS, case reports have documented neonatal abstinence syndrome mimicking opioid neonatal abstinence syndrome occurring after tianeptine dependence during pregnancy; and

WHEREAS, tianeptine is currently prohibited for use in Michigan, Alabama, Minnesota, Tennessee, Georgia, and Indiana; and

WHEREAS, Section 3719.45 of the Ohio Revised Code authorizes the State of Ohio Board of Pharmacy (State Board of Pharmacy) to add a previously unscheduled compound, mixture, preparation, or substance to schedule I by emergency rule if the Board determines the compound has no accepted medical use in treatment in this state and poses an imminent hazard to the public health, safety, or welfare; and

WHEREAS, the State Board of Pharmacy found that tianeptine has no accepted medical use in treatment in this state, has a high potential for abuse, and poses an imminent hazard to the public health, safety, or welfare; and

WHEREAS, Section 119.03(G) of the Ohio Revised Code authorizes the Governor, on the request of a State agency, to suspend the normal rule making procedures with respect to specific rules when an emergency exists necessitating the immediate adoption, amendment, or rescission of such rules. When such a determination is made, the agency may immediately adopt, amend, or rescind such rules, but the rules are only valid for one hundred and eighty (180) days; and

WHEREAS, the State Board of Pharmacy has requested a determination whether an emergency exists that requires rule 4729:9-1-01.3 of the Ohio Administrative Code on an emergency basis and that would therefore permit the State Board of Pharmacy, pursuant to Section 3719.45 of the Ohio Revised Code, to immediately adopt this rule.

NOW THEREFORE, I, Mike DeWine, Governor of the State of Ohio, have determined, upon the request of the State Board of Pharmacy, that an emergency exists requiring the immediate adoption of rule 4729:9-1-01.3 of the Ohio Administrative Code.

Further, I hereby order that the procedures prescribed by Section 119.03 of the Ohio Revised Code with respect to the adoption or amendment of the specified rule be suspended and that the State Board of Pharmacy be permitted to adopt the rule immediately by filing it electronically with the Secretary of State, the Director of the Legislative Service Commission, and the Joint Committee on Agency Rule Review (JCARR).

Furthermore, I hereby order that this Executive Order be filed in electronic form with the State Board of Pharmacy, the Secretary of State, the Director of the Legislative Service Commission, and JCARR.

I signed this Executive Order on December 22, 2022, in Columbus, Ohio, and it will expire one hundred and eighty (180) days from the effective date of the emergency rule, or upon the adoption of the rule through the normal JCARR process, whichever is sooner.


Mike DeWine, Governor

ATTEST:

Frank LaRose, Secretary of State

