FDA Announces Safety Labeling Changes and Postmarket Study Requirements for Opioids

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Last month, the U.S. Food and Drug Administration (FDA) issued a press release about class-wide safety labeling changes and new postmarket study requirements for all extended-release and long-acting (ER/LA) opioid analgesics intended to treat pain.

Given the serious risks of using ER/LA opioids, the class-wide labeling changes, when final, will include important new language to help health care professionals tailor their prescribing decisions based on a patient’s individual needs.

The updated indication states that ER/LA opioids are indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

The updated indication further clarifies that, because of the risks of addiction, abuse, and misuse, even at recommended doses, and because of the greater risks of overdose and death, these drugs should be reserved for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain; ER/LA opioid analgesics are not indicated for as-needed pain relief.

“The FDA’s primary tool for informing prescribers about the approved uses of medications is the product labeling,” said Douglas Throckmorton, M.D., deputy director for regulatory programs in the FDA’s Center for Drug Evaluation
and Research. “These labeling changes describe more clearly the risks and safety concerns associated with ER/LA opioids and will encourage better, more appropriate, prescribing, monitoring and patient counseling practices involving these drugs.”

Recognizing that more information is needed to assess the serious risks associated with long-term use of ER/LA opioids, the FDA is requiring the drug companies that make these products to conduct further studies and clinical trials. The goals of these postmarket requirements are to further assess the known serious risks of misuse, abuse, increased sensitivity to pain (hyperalgesia), addiction, overdose, and death.

The FDA is also requiring a new boxed warning on ER/LA opioid analgesics to caution that chronic maternal use of these products during pregnancy can result in neonatal opioid withdrawal syndrome (NOWS), which may be life-threatening and require management according to protocols developed by neonatology experts. NOWS can occur in a newborn exposed to opioid drugs while in the mother’s womb. Symptoms may include poor feeding, rapid breathing, trembling, and excessive or high-pitched crying.

In addition, the FDA is notifying ER/LA opioid analgesic application holders of the need for changes to the following sections of drug labeling: Dosage and Administration; Warnings and Precautions; Drug Interactions; Use in Specific Populations; Patient Counseling Information, and the Medication Guide.

Once the safety labeling changes are finalized, modifications will also be made to the ER/LA Opioid Analgesics Risk Evaluation and Mitigation Strategy (REMS), to reflect the updated information. Originally approved in 2012, the ER/LA Opioid Analgesics REMS requires companies to make available to health care professionals educational programs on how to safely prescribe ER/LA opioid analgesics and to provide Medication Guides and patient counseling documents containing information on the safe use, storage, and disposal of ER/LA opioids. For more information: http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm363722.htm. [1]

Addressing Opioid Abuse Numerous organizations, including the Centers for Disease Control and Prevention, the FDA, state medical societies and more are focusing on strategies to reduce the prevalence of misuse of prescription medications, most notably opioids. In previous newsletters, we have reinforced the importance of physicians educating themselves on this issue and listed several notable resources such as:

- American Medical Association
  - —EPoCH CME: Prevention of Prescription Drug Misuse and Diversion
- Agency Medical Directors Group (A “Quality Tool Topic” by the Agency For Healthcare Research and Quality)
  - —Interagency Guideline on Opioid Dosing for Chronic Non-Cancer Pain (2010 Update)

The information provided in this resource does not constitute legal, medical or any other professional advice, nor does it establish a standard of care. This resource has been created as an aid to you in your practice. The ultimate decision on how to use the information provided rests solely with you, the PolicyOwner.

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