Immediate-release opioids – Safety update

- On September 18, 2018, the FDA announced the approval of the Opioid Analgesic Risk Evaluation and Mitigation Strategy (REMS).

- The expanded Opioid REMS now applies to immediate-release (IR) opioid analgesics intended for use in an outpatient setting application, in addition to extended-release and long-acting (ER/LA) opioid analgesics, which have been subject to a REMS since 2012.

    — Previously, the ER/LA Opioid Analgesic REMS included 62 products. The modified REMS now requires that 347 opioid analgesics intended for outpatient use be subject to these requirements.

- The Opioid REMS program also requires that training be made available to prescribing and non-prescribing healthcare providers (eg, nurses and pharmacists) who are involved in the management of patients with pain.

- The REMS requires that the education cover broader information about appropriate pain management, including alternatives to opioids for the treatment of pain.

- The agency has also approved the new FDA Opioid Analgesic REMS Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain (Blueprint), which includes updated educational content.

- The FDA believes that all healthcare providers involved in the management of patients with pain should be educated about the safe use of opioids so that when they write or dispense a prescription for an opioid analgesic, or monitor patients receiving these medications, they can help ensure the proper product is selected for the patient and used with appropriate clinical oversight.

    — It is expected that continuing education training under the REMS will be available to healthcare providers by March 2019.
    — There is no mandatory federal requirement that prescribers or other healthcare providers take the training provided through the REMS and completion of the training is not a precondition to prescribing opioid analgesics to patients.
    — However, the FDA's Opioid Policy Steering Committee continues to consider whether there are circumstances when the FDA should require some form of mandatory education for healthcare providers and how the FDA would pursue such a goal.

- The FDA is also approving new safety labeling changes for all opioid analgesic products intended for use in an outpatient setting. The opioid drug labels will include information about the availability of education through the REMS for prescribers and other healthcare providers who are involved in the treatment and monitoring of patients with pain.

- REMS-compliant education will be added to the *Boxed Warning* and *Warnings and Precautions* sections of opioid labeling and strongly encourage providers to complete a REMS-compliant education program; counsel patients and caregivers on the safe use, risks, and appropriate storage and disposal of these products; emphasize to patients and their caregivers the importance of reading the Medication Guide every time it is provided by their pharmacist; and to consider other tools to improve patient, household and community safety.

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- The REMS program continues to include Medication Guides for patients and caregivers to read, new Patient Counseling Guides to assist health care providers with important discussions with patients, and plans for assessing the program's effectiveness.

- The FDA recently awarded a contract to the National Academies of Sciences, Engineering, and Medicine to help develop a framework to assist medical professional societies in creating evidence-based guidelines on appropriate opioid analgesic prescribing to treat acute pain resulting from specific medical conditions and common surgical procedures for which these drugs are prescribed.

    — The agency's aim is to reduce unnecessary and/or inappropriate exposure to opioids by making certain that prescribers are properly informed about appropriate prescribing recommendations, that providers understand how to identify abuse by individual patients, and know how to get patients with opioid use disorder into treatment.

- As part of the U.S. Department of Health and Human Services' Five-Point Strategy to Combat the Opioid Crisis, the FDA remains committed to addressing the national crisis of opioid addiction on all fronts, with a significant focus on decreasing unnecessary and/or inappropriate exposure to opioids and preventing new addiction; supporting the treatment of those with opioid use disorder; fostering the development of novel pain treatment therapies and opioids more resistant to abuse and misuse; and taking action against those who contribute to the illegal importation and sale of opioid products.

- The FDA will continue to evaluate how drugs currently on the market are used, in both medical and illicit settings, and take regulatory action where needed.