Immediate-release opioids – Safety update

- On September 28, 2017, the FDA announced that a Risk Evaluation and Mitigation Strategy (REMS) is necessary for immediate-release (IR) opioid analgesics to ensure that the benefits of these drugs continue to outweigh the risks, and the IR opioid analgesics that are intended to be used in the outpatient setting will be subject to the same REMS requirements as the extended-release/long-acting (ER/LA) opioid analgesics.

- The FDA sent letters, detailing the new requirements, to IR opioid analgesic manufacturers. The ER/LA opioid analgesic manufacturers also received letters detailing additional modifications to the approved REMS.

- The modified REMS will include revisions to the Blueprint for healthcare provider training to require additional educational content in pain management, including the principles of acute and chronic pain management; and non-pharmacologic and pharmacologic treatments for pain (both non-opioid and opioid analgesics). Additional information will also be included about the safe use of opioids as well as some basic information about addiction medicine and opioid use disorders.

- Training will also be made available to other healthcare providers (eg, nurses and pharmacists) involved in the management of patients with pain. Training will be aimed at making sure providers who write prescriptions for any opioids are doing so for properly indicated patients and under appropriate clinical circumstances.

- The FDA believes that all healthcare providers involved in the management of pain should be educated about the safe use of opioids. The FDA's Opioid Policy Steering Committee is currently considering if there are circumstances under which the FDA should require some form of mandatory education for healthcare providers to make certain that prescribing doctors are properly informed about appropriate prescribing recommendations, understand how to identify the risk of abuse in individual patients, and know how to get addicted patients into treatment.

- In 2016, the FDA announced class-wide safety labeling changes for IR opioids and announced additional safety label changes about several issues with the entire class of opioids.

- Over the past several years, the FDA has announced several safety updates for the ER/LA opioids, including post-marketing requirements and safety-related label updates.