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REMS-Required Drug Monitoring During the COVID-19 Pandemic

Announcer:
You're listening to *The Drug Report* on ReachMD, hosted by Linda Bernstein, Pharm.D., Clinical Professor on the Volunteer Faculty of the School of Pharmacy, University of California, San Francisco.

Dr. Bernstein:
Welcome to *The Drug Report*, with a special focus on the COVID-19 pandemic.

Due to the pandemic, the Food and Drug Administration has received a number of queries concerning certain risk evaluation and mitigation strategies (REMS) requirements that include laboratory monitoring and imaging and the impact of these requirements on patient access to certain REMS drugs when patients self-isolate or are subject to quarantine.

In response, the FDA issued a guidance this week to communicate its temporary policy for (REMS) requirements for the duration of the public health emergency. The guidance is being implemented immediately but remains subject to comment in accordance with the Agency's good guidance practices.

FDA Principal Deputy Commissioner, Amy Abernethy, MD, PhD stated in a press release, "The FDA recognizes that during the COVID-19 public health emergency, the completion of some REMS-required laboratory testing or imaging studies may be difficult because patients suspected of having COVID-19 may be self-isolating and/or subject to quarantine. Under these circumstances, undergoing testing or imaging studies in order to obtain a drug that is subject to a REMS can put patients and others at risk for transmission of the coronavirus. We will continue to work with sponsors to ensure that patients have appropriate access to the medications they need."

As background, the FDA may utilize for a drug certain "elements to assure safe use" (ETASU) as part of REMS which may include one or any combination of the following requirements:

- Health care providers who prescribe the drug have particular training or experience, or are specially certified;
- Pharmacies, practitioners, or health care settings that dispense the drug are specially certified;
- The drug be dispensed to patients only in certain health care settings, such as hospitals;
- The drug be dispensed to patients with evidence or other documentation of safe use conditions, such as laboratory test results;
- Each patient using the drug be subject to monitoring; or
- Each patient using the drug be enrolled in a registry

ETASU may include medical interventions or other actions healthcare professionals are required to do before prescribing or dispensing the drug to the patients, such as monthly laboratory testing (e.g., liver enzyme testing) or imaging studies such as magnetic resonance imaging. Similar actions may be required for medication continuation.

Clinicians are urged to use their best medical judgment in weighing the benefits and risks of continuing treatment without the usually required laboratory testing and imaging studies to monitor use of some medications. This decision, along with potential benefits and risks, should also be discussed with their patients.

The FDA will not take action against sponsors and others during the pandemic for failing to follow REMS requirements for certain laboratory testing or imaging studies. Other REMS components may still be in place such as a medication guide, patient package insert, communication plan and certain packaging and safe disposal technologies for drugs with serious abuse or overdose potential.

For *The Drug Report*, I'm pharmacist, Dr. Linda Bernstein.

Announcer:
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