WINSTON & STRAWN LLP

CLIENT ALERT

FDA Identifies Essential Medicines, Medical Countermeasures, and Critical Inputs Required by Executive Order 13944

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On October 30, 2020, the U.S. Food and Drug Administration (FDA or the Agency) published a list of essential medicines, medical countermeasures, and critical inputs required by President Trump's August 6, 2020 Executive Order 13944. The order directed the FDA to work with federal partners to identify a list of essential medicines, medical countermeasures, and critical inputs that are medically necessary to have available at all times in amounts adequate to serve patient needs and in the appropriate dosage forms.

The stated goal of the work is to ensure the American public is protected against outbreaks of emerging infectious diseases, such as COVID-19, as well as chemical, biological, radiological, and nuclear threats. To accomplish this goal, the executive order seeks to ensure sufficient and reliable, long-term domestic production of these products, and to minimize potential shortages by reducing U.S. dependence on foreign manufacturers of these products.

See Winston & Strawn's August 11, 2020 briefing on the Executive Order, *available here*.

The list published by FDA includes 223 drug and biological product essential medicines and medical countermeasures and 96 device medical countermeasures. The device countermeasures include diagnostic testing kits and supplies for rapid test development and processing, personal protective equipment, active vital sign monitoring devices, devices for vaccine delivery, and devices for management of acute illnesses such as ventilators, among others. The complete list is available on FDA's website here.

The FDA has also published the criteria used for identifying essential medicines, medical countermeasures, and critical inputs that are on the list. The general criteria for identifying essential medicines include approved medicines that are necessary to address immediately life-threatening medical conditions that are encountered in U.S. acute care facilities and those used to stabilize patients for discharge for continued outpatient care. Medicines, however, for longer-term chronic pain management, including those needed to cure a condition through weeks or months of outpatient treatment, are not included.

For medical countermeasures, the general criteria include agents the FDA anticipates needing to respond to future pandemics and other threats and which align with national medical countermeasures stockpile planning. General criteria for critical inputs track the purpose and language of the executive order, and include all APIs, all active ingredients or starting materials for biological and natural source products, and ingredients or constituent parts that possess unique attributes essential to the approved uses of the product.

A device qualifies as a medical countermeasure if it:

1. Fits within the definition of one of four elements of the medical countermeasures definition provided in the order:
    a. “qualified countermeasure” (as defined in 42 U.S.C. § 247d–6a(a)(2)(A);
    b. “qualified pandemic or epidemic product” (as defined in 42 U.S.C. § 247d–6d(i)(7));
    c. “security countermeasure” (as defined in 42 U.S.C. § 247d–6b(c)(1)(B)); or
    d. “personal protective equipment” (PPE, as described in 29 C.F.R. part 1910);
2. Is always medically necessary to have available in adequate supply;
3. Is not able to be substituted by another device on the list; and
4. Meets one or more of the following:
    a. Diagnostic testing and supplies generally applicable to PCR testing to enable rapid test development and processing;
    b. PPE needed to protect healthcare workers from airborne, bloodborne, waterborne, chemical, biological, radiological, or nuclear events;
    c. Devices that are not permanently implanted that are intended to provide acute mechanical support in treating an acute event or condition in a healthcare setting for vital physiologic functions and are not intended solely for the treatment of chronic conditions;
        i. Devices that provide adequate vital signs monitoring in a healthcare setting to enable the use of the mechanical support MCM devices;
    d. Devices used for the delivery of a vaccine that are intended to prevent or mitigate the spread of an epidemic or pandemic; or
    e. Devices used for the acute management of injury or illness caused by chemical, biological, radiological, or nuclear events.

Critical device inputs include 1) a component of a device identified on the list; 2) a component that is always medically necessary to have in adequate supply; 3) a component that is critical to assessing the safety and effectiveness of a listed device; 4) components expected to be a part of most of the listed devices for a specific device type; and don’t include 5) components for which identification could potentially disclose confidential commercial information and trade secrets information.

FDA is seeking comments to the public docket concerning: 1) feedback on the criteria developed by FDA for inclusion of essential medicines, medical countermeasures, or their critical inputs; 2) whether there are any additional essential medicines, medical countermeasures, or critical inputs that should be included on the list and which ones, if any, should be removed; and 3) feedback on how frequently, and by what type of process, the list should be evaluated for additions and removals.

We note that government orders on the local, state, and federal level are changing every day, and the information contained herein is accurate only as of the date set forth above.

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For further information or questions on the list or on providing comments, please contact Amandeep S. Sidhu, T. Reed Stephens, Christopher Parker, or your Winston relationship attorney.

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