Essential Medicines Executive Order – FDA List

NASEM Workshop

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AGENDA

- Executive Order (EO) 13944
- The FDA Executive Order List
  - Essential Medicines (EM)
  - Medical Countermeasures (MCM)
  - Critical Inputs (CI)
- Next Steps
- Questions

EXECUTIVE ORDER 13944

- On August 6, 2020, President Trump signed an Executive Order on Ensuring Essential Medicines, Medical Countermeasures, and Critical Inputs are Made in the United States.
- Under the order, the FDA is directed to identify the list of essential medicines, medical countermeasures, and their critical inputs that are medically necessary to have available at all times in an amount adequate to serve patient needs and in the appropriate dosage forms (the FDA Executive Order List).

THE FDA EXECUTIVE ORDER LIST (SECTION 3(c))

"Within 90 days of the date of this order, and periodically updated as appropriate, the FDA Commissioner, in consultation with the Director of OMB, the Assistant Secretary for Preparedness and Response in the Department of Health and Human Services, the Assistant to the President for Economic Policy, and the Director of the Office of Trade and Manufacturing Policy, shall identify the list of Essential Medicines, Medical Countermeasures, and their Critical Inputs that are medically necessary to have available at all times in an amount adequate to serve patient needs and in the appropriate dosage forms."

CREATION OF THE THREE PARTS OF THE FDA EXECUTIVE ORDER LIST

CREATION OF THE FDA LIST

- Development
  - Work involved personnel from across FDA to ensure consistency in interpretation of the Executive Order and associated deliverables
  - Subject matter experts developed and applied public-health focused criteria
  - Development of the list involved consultation with multiple Federal agencies and partners
- Publication
  - FDA's list was published on October 30, 2020
    - https://www.fda.gov/about-fda/reports/executive-order-13944-list-essential-medicines-medical-countermeasures-and-critical-inputs
  - A docket is open for public comment
    - https://beta.regulations.gov/docket/FDA-2020-N-2123

THE FDA LIST

U.S. FOOD & DRUG ADMINISTRATION

Criteria For Identifying Human Drug and Biologic Essential Medicines, Medical Countermeasures, and Critical Inputs for the List Described in

c) of the Executive Order (EO) 13944

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Drug and Biologic Essential Medicines, Medical Countermeasures, and Critical Inputs for the List Described in Section 3(c) of the Executive Order 13944

Device Medical Countermeasures and Critical Inputs for the List Described in Section 3(c) of the Executive Order 13944

CRITERIA FOR ESSENTIAL MEDICINES

- Approved* medicines that are necessary to address immediately life-threatening medical conditions** that are encountered in US acute care medical facilities, and that are used to stabilize patients with those medical conditions so that patients can be discharged for continued outpatient care.

  * Although we focused generally on approved drug and biological products, we identified a few drug products that are marketed without an approved NDA or ANDA because they met these general criteria but for the existence of an approved NDA or ANDA

  ** Rare conditions are included if they are fatal within hours to days, and this outcome is preventable with a specific medicine

- Medicines that would be used for longer-term chronic management, including those needed to cure a condition through weeks or months of outpatient treatment, are not included. While these medicines are important and medically necessary for many patients, the list is focused on addressing more immediate medical needs that are likely to occur in a public health emergency.

CRITERIA FOR ESSENTIAL MEDICINES (cont.)

- The selection of these medicines, including the dosage form and presentation (including drug-device combination products where applicable), will be determined by identifying those most commonly needed for patients in US acute care medical facilities, with a focus on the dosage forms and presentations that can be used for the widest populations encountered. Specifically:
  - Where multiple drugs (or drug classes) treat the same condition, include the drug (or drug class) that can treat the widest population with the condition and if possible, treat more than one condition, taking into account the needs of special patient populations that may need a particular drug in a class, for example, pediatric and pregnant women.
  - If there is more than one drug in a class as identified in the bullet above, consider whether there are unique safety profiles that might warrant one rather than the other.
  - If multiple drugs in the class have different safety profiles such that it is likely that one or more drugs will be necessary to cover the entire population, consider including additional drugs.

ABBREVIATED CRITERIA FOR DRUG & BIOLOGIC MEDICAL COUNTERMEASURES

- Consistent with the definition of "Medical Countermeasures" set forth in Section 7(j) of the EO, the selection of drug and biologic MCMs was primarily based on the statutory definitions of "Qualified Countermeasure," "Qualified Pandemic or Epidemic Product," and "Security Countermeasure." This selection included those agents we anticipate needing to respond to future pandemics, epidemics, and chemical, biological, and radiological/nuclear (CBRN) threats.
- The selection of medicines, including dosage forms and presentations (including drug-device combination products), was informed by available lists of MCMs developed by FDA and other Agencies. It also aligns with national MCM stockpile planning.

ABBREV. CRITERIA FOR DRUG & BIOLOGIC MEDICAL COUNTERMEASURE (cont.)

- MCMs are limited to medicines that are approved or otherwise legally marketed in the US.
  - This category may in some cases include medicines that are approved or otherwise legally marketed, but for which the MCM use is not included in the product's labeling.
  - However, FDA will exclude such medicines if FDA has information to suggest they are unsafe or ineffective for use as an MCM (e.g. those for which we've rejected an EUA).
  - This category will not include medicines that are only available pursuant to an EUA or IND, even if they otherwise fall within one of these statutory definitions.

CRITERIA FOR DRUG & BIOLOGIC CRITICAL INPUTS

- API (Active Pharmaceutical Ingredients)
- All active ingredients or starting materials for biological and natural source products (e.g., cell lines, master cell bank, human plasma, crude heparin). FDA has not identified starting materials for small molecule APIs that meet the criteria of the EO.
- Ingredients or constituent parts that possess unique attributes essential to the approved uses of the product, which may include:
  - Excipients and other ingredients that have unique properties that are directly related to one or more of the critical uses of the drug or biologic.
  - Device constituent parts of Essential Medicines or Medical Countermeasures that are single-entity drug-device or biological product-device combination products approved under a single BLA, NDA, or ANDA.

CRITERIA FOR DEVICE MEDICAL COUNTERMEASURES

A device [as defined in section 201(h) of the FD&C Act] qualifies as an MCM, as defined in Section 7(j) of the EO, if the device meets the following criteria:

- Fits within the definition of one of four elements of the MCM definition provided in the EO;
- Is always medically necessary to have available in adequate supply;
- Is not able to be substituted by another device on the list; and
- Meets one or more of the following:
  - Diagnostic testing and supplies generally applicable to PCR testing to enable rapid test development and processing;
  - PPE needed to protect healthcare workers from airborne, blood-borne, water-borne, chemical, biological, radiological or nuclear events;
  - 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;
    - Devices that provide adequate vital signs monitoring in a healthcare setting to enable the use of the mechanical support MCM devices;
  - Devices used for the delivery of a vaccine that are intended to prevent or mitigate the spread of an epidemic or pandemic; or
  - Devices used for the acute management of injury or illness caused by chemical, biological, radiological or nuclear events.

CRITERIA FOR DEVICE CRITICAL INPUTS

A device component [as defined 21 CFR 820.3(c)] qualifies as a CI, as defined in Section 7(d) of the EO, on the basis that it is:

- A component of a medical device identified on the list;
- Always medically necessary to have available in adequate supply;
- Critical to assessing the safety and effectiveness of a device identified on the list, as established by meeting the following criteria:
  - Be critical for the use/manufacture of a device identified on the list;
  - Reasonable substitutes are not easily available:
    - Inputs are so unique that there are no or limited substitutes; or
    - Inputs are widely used in multiple devices identified on the list; and
  - Substitutions (or modifications or omissions) generally would require a reassessment of safety and effectiveness of the identified device;
- Expected to be part of most devices identified on the list for a specific device type (i.e., not a unique component specific to a proprietary device); and
- Not components for which their identification could potentially disclose confidential commercial information.

EXECUTIVE ORDER LIST BY THE NUMBERS

227 Products on the Drug & Biologic Executive Order List

- **174** Essential Medicine products
- **53** MCM only products

96 Medical Device MCM procodes on the Executive Order List

NEXT STEPS

- The Executive Order List (3(c) of the EO)
  - Further consultation with agencies under the EO
  - Consider public comments
  - Develop process for updates and update periodically

NEXT STEPS, cont.

- Other provisions of the EO
  - Deliverables under 3(a)
    - Includes directives to take necessary and appropriate action to identify and mitigate vulnerabilities in the supply chain
    - Due in February 2021
  - Deliverables under 3(b)
    - Includes directives to accelerate approval or clearance, as appropriate, for domestic producers of items on the Executive Order List and provisions related to inspections
    - No due date

QUESTIONS